Operator's Manual

Rad-5®/5v® Pulse Oximeter

Masimo

These operating instructions provide the necessary information for proper operation of all models of the Rad®-5/5v. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Rad-5/5v are prerequisites for its proper use. Do not operate Rad-5/5v without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

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. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings and precautions.

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

CE 0123

EU authorized representative for Masimo Corporation:

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany
Tel.: +49-511-62 62 86 30
Fax.: +49-511-62 62 86 33

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

3149433

MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005+A1:2012, CAN/CSA C22.2 No. 60601-1:2014, and applicable Particular (EN/ISO 80601-2-61:2011) and related Collateral (IEC 60601-1-8:2006+A1:2012) Standards for which the product has been found to comply by Intertek.

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

Contents

About This Manual

This manual explains how to set up and use Rad-5®/5v® Pulse Oximeter. Important safety information relating to general use of Rad-5/5v appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example 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.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features and Indications for Use

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 SpO_2 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

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

Rad-5

The Masimo SET® Rad-5 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 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.

Rad-5v

The Masimo SET® Rad-5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 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.

Contraindications

None

Safety Information, Warnings and Cautions

The Rad-5®/5v® Pulse Oximeter software program is designed to minimize the possibility of hazards from errors by following sound engineering design processes, Risk Analysis and Software Validation.

Safety Warnings and Cautions

WARNING: Electric shock hazard. Do not open the Rad-5/5v 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.

WARNING: Do not use Rad-5/5v if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.

WARNING: Do not adjust, repair, open, disassemble, or modify the Rad-5/5v. Damage to the device may result in degraded performance and/or patient injury.

WARNING: Do not start or operate the Rad-5/5v unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.

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

WARNING: Do not place the Rad-5/5v or accessories in any position that might cause it to fall on the patient. Do not lift the Rad-5/5v by the patient cable.

WARNING: Explosion hazard. Do not use the Rad-5/5v in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING: Only use Masimo authorized devices with Rad-5/5v. Using unauthorized devices with Rad-5/5v may result in damage to the device and/or patient injury.

WARNING: All sensors and cables are designed for use with specific devices. Verify the compatibility of the device, cable, and sensor before use; otherwise degraded performance and/or patient injury can result.

WARNING: Do not use the Rad-5/5v or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Rad-5/5v may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

WARNING: Rad-5/5v may be used during defibrillation. However, to reduce the risk of electric shock, the operator should not touch the Rad-5/5v during defibrillation.

WARNING: To protect against electrical shock injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this Operator's Manual.
- Do not attempt to clean the Rad-5/5v while monitoring patient.

WARNING: To ensure safety, avoid placing anything on the device during operation.

WARNING: If a sensor is damaged in any way, discontinue use immediately.

CAUTION: Do not place the Rad-5/5v where the controls can be changed by the patient.

CAUTION: Do not expose the Rad-5/5v to excessive moisture such as direct exposure to rain. Excessive moisture can cause the Rad-5/5v to perform inaccurately or fail.

CAUTION: Do not place containers containing liquids on or near the Rad-5/5v. Liquids spilled on the Rad-5/5v may cause it to perform inaccurately or fail.

CAUTION: To ensure patient electrical isolation, all external device connections to the output interface port must be done using only authorized data cables.

Note: Use and store the Rad-5/5v in accordance with specifications. See Specifications.

Performance Warnings and Cautions

WARNING: Rad-5/5v should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Rad-5/5v 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.

WARNING: The Rad-5/5v is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.

WARNING: The Rad-5 is intended for continuous patient monitoring.

WARNING: The Rad-5v is intended for spot-check monitoring only, no physiological alarms are provided.

WARNING: The Rad-5/5v is NOT intended for use as an apnea monitor.

WARNING: 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.

WARNING: Rad-5/5v can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

WARNING: Do not place the Rad-5/5v face against a surface. This will cause the alarm to be muffled.

WARNING: Severe anemia may cause erroneous SpO_2 readings.

WARNING: Always remove the sensor from the patient and completely disconnect the patient from the Rad-5/5v before bathing the patient.

WARNING: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Rad-5/5v for proper functioning.

WARNING: Rad-5/5v may be used during electrocautery. This may affect the accuracy or availability of the parameters and measurements.

WARNING: Properly apply sensors according to sensor's directions for use. Misapplied sensor or sensors that become partially dislodged may cause no or incorrect readings.

WARNING: Select a well perfused site for monitoring, very low perfusion at the monitored site may result in no or incorrect readings.

WARNING: Do not use Rad-5/5v on patients that have been injected with dyes or any substance containing dyes, the change in usual blood pigmentation may cause no or incorrect readings.

WARNING: If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

WARNING: Optical, pleth-based measurements (e.g. SpO_2) can be affected by the following:

- Improper sensor application or use of use of incorrect sensor.
- Blood pressure cuff applied to the same arm as the sensor site.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.
- Abnormal venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- A physiological condition that may effect vasomotor tone or changes in vasomotor tone.

WARNING: Inaccurate SpO_2 readings may be caused by:

- Elevated levels of COHb and/or MetHb.
- Severe anemia.
- Extremely low arterial perfusion.
- Excessive induced motion.
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (quantitative defects such as Thalassemias).

CAUTION: Do not place the Rad-5/5v on electrical equipment that may affect the Rad-5/5v, preventing it from working properly.

CAUTION: 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.

CAUTION: Failure of Operation - If the Rad-5/5v fails any part of the setup procedures remove the Rad-5/5v from operation until qualified service personnel have corrected the situation.

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

CAUTION: High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.

CAUTION: 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.

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

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to Rad-5/5v.

Note: Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor Directions for Use for the specified duration of patient monitoring time.

Note: Physiological conditions that result in loss of pulsatile signal may result in no SpO_2 readings.

Note: A functional tester cannot be used to assess the accuracy of Rad-5/5v.

Note: Additional information specific to the Masimo sensors compatible with Rad-5/5v, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

Cleaning and Service Warnings and Cautions

WARNING: Do not attempt to remanufacture, recondition or recycle the Rad-5/5v as these processes may damage the electrical components, potentially leading to patient harm.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Rad-5/5v for servicing.

CAUTION: Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the display.

CAUTION: Do not use petroleum-based or acetone solutions, undiluted bleach (5% - 5.25% sodium hypochlorite solution), or other harsh solvents. These substances affect the device's materials and instrument failure can result.

CAUTION: Do not use different cleaning solutions to clean the same instrument. Unpredictable chemical reactions that may damage the instrument may occur.

CAUTION: Do not immerse the instrument in any liquid solution.

CAUTION: Do not sterilize by irradiation, steam autoclave, or ethylene oxide.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

WARNING: Per RSS-Gen, Section 8.4 This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. Per RSS-Gen, Radio apparatus shall comply with the requirements to include required notices or statements to the user of equipment with each unit of equipment model offered for sale.

CAUTION: Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.

Note: Use Rad-5/5v in accordance with the Environmental Specifications section in the Operator's Manual.

Note: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for 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.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2: 2007, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

Note: To satisfy RF exposure requirements, this device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

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

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Chapter 1: Technology Overview

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

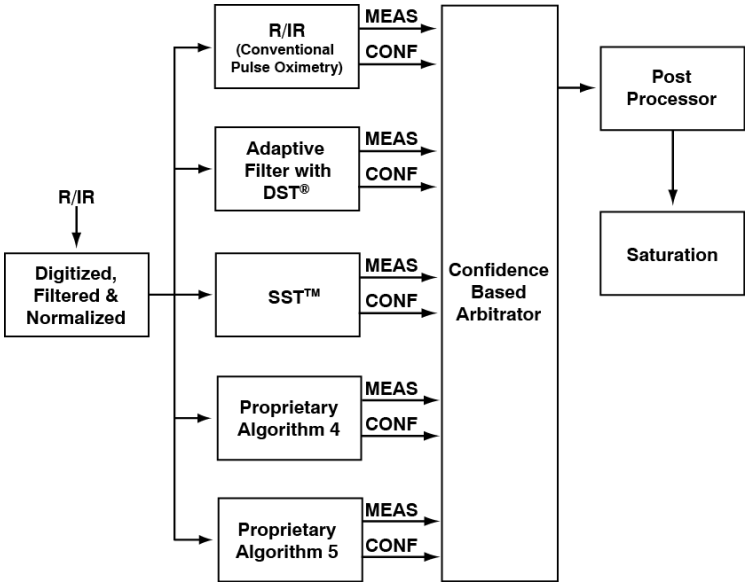
Signal Extraction Technology® (SET®)

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

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

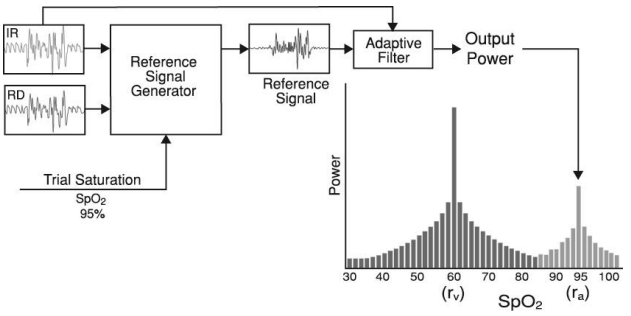
Masimo SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

Pulse oximetry is governed by the following principles:

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

Successful Monitoring for SpO2 and PR

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

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

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.

Functional Oxygen Saturation (SpO2)

The Rad-5/5v is calibrated to measure and display functional oxygen saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

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

General Description for Pulse Rate (PR)

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

Signal IQ

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

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

The height of the vertical line of the SpO_2 SIQ provides an assessment of the confidence in the measurement displayed. A high vertical bar indicates higher confidence in the measurement. A small vertical bar indicates lower confidence in the displayed measurement. When the Signal IQ is very low, this suggests that the accuracy of the displayed measurement may be compromised. See ***Signal SIQ and Pulse Bar*** on page 25.

Chapter 2: Description

This chapter contains the description of the Rad-5/5v physical features.

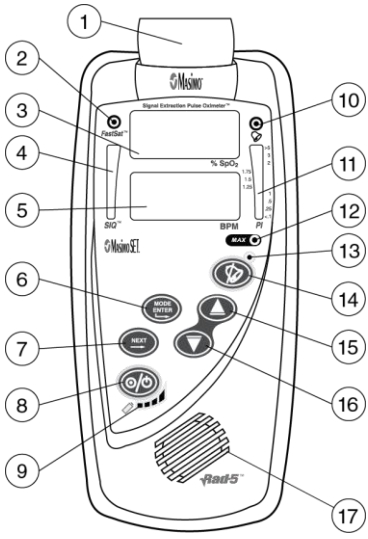
General System Description

The Rad®-5/5v includes the following:

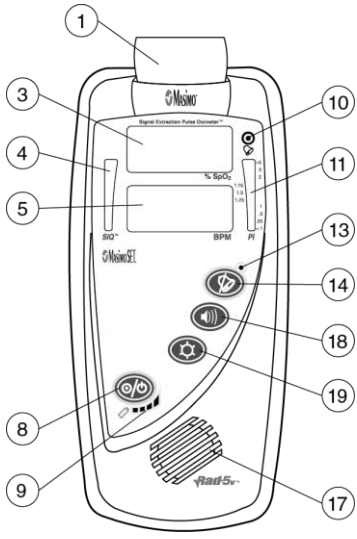
- Rad-5/5v Device.

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

Front View



Rad-5



Rad-5v

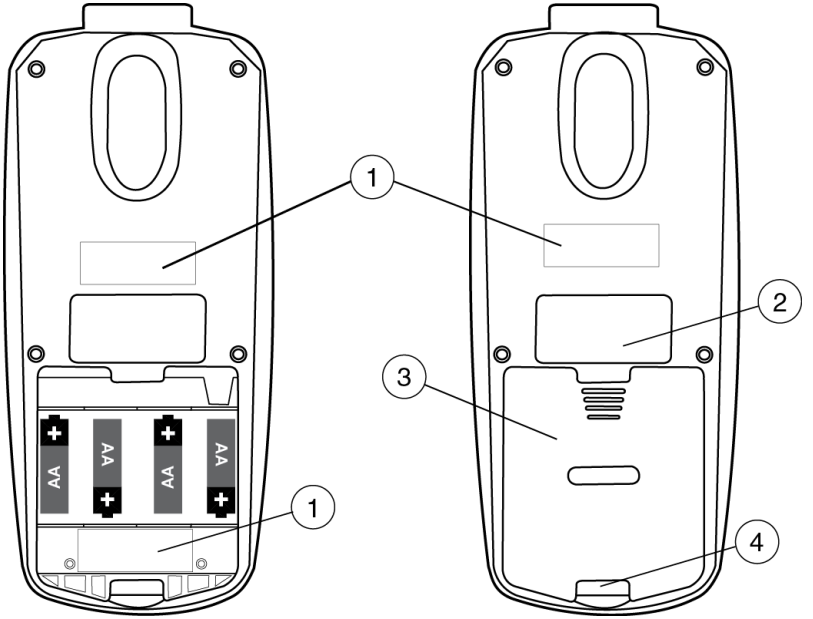
No.	Control / Indicator	Description
1	Patient Cable Connector	Connects to Red Direct Connect Series Spot Check sensor or Masimo Patient Cable.
2*	FastSat indicator	Illuminates when FastSat mode is enabled.

3	Saturation Display	Displays functional arterial hemoglobin oxygen saturation in units of SpO_2. When searching for saturation, it will flash dashed lines.
4	Signal IQ / Pulse Bar	Displays the timing of the pulse. The height indicates the quality of the signal.
5	Pulse Rate Display	Displays pulse rate in beats per minute (bpm). When searching for a 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 patient monitoring.
8	Power On / Off	Used to turn the unit on and off.
9	Battery Level Indicator	Indicates the status of batteries. See ***Battery Level Indicator*** on page 26.
10	Visual Alarm Indicator	Illuminates when any alarm condition exists. This indicator may not be turned-off or over-ridden.
11	Perfusion Index	Displays the percentage of pulsatile signal to non-pulsatile signal. Bar is highest when signal quality is best.
12*	MAX Sensitivity Indicator	On when MAX Sensitivity mode is enabled. See ***Sensitivity (Rad-5)*** on page 29.
13	Alarm Silenced Indicator	Displays current alarm silence status. See ***Alarm Silenced Indicator*** on page 40.
14	Alarm Silence Button	Press to silence alarms. See ***Alarm Silence*** on page 40.
15*	Up Button	During monitoring, use to adjust volume of the pulse tone. Within the menu/setup system, use to select values within each menu option.
16*	Down Button	

17	Speaker	Provides audible indication of alarm conditions, pulse tone and key-presses.
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.

* Available on Rad-5 only.

Back View



No.	Control / Indicator	Description
1	Serial Number Label	Located inside battery compartment and on back of device.
2	Agency Approvals Label	Agency Approvals Label
3	Battery Cover	Covers the batteries.
4	Battery Cover Release	Press down and slide the battery cover off the bottom of the Rad-5/5v.

Chapter 3: Basic Setup and Use

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. This chapter contains information about setting up Rad-5/5v before use.

Unpacking and Inspection

Remove the device from the package and check for signs of damage. Check all items against the packing list. Save all packing materials, invoice and shipping labels. These items may be required to process a claim with the carrier.

If anything is missing or damaged, contact the Technical Service Department. See ***Contacting Masimo*** on page 61.

Initial Setup

The following information describes the preparation and set-up of the Rad-5/5v.

1. Inspect the device case for damage.
2. Install four new AA alkaline batteries. See ***Battery Installation and Replacement*** on page 57.
3. Verify the device powers-up when the batteries are installed.
4. Press and hold the Power On/Off Button for 2-seconds to turn the oximeter off. See ***Front View*** on page 19.
5. Press the Power On/Off Button to turn the device on again. Verify all LEDs light up and that the speaker makes a brief sound.
6. Connect the cable and/or sensor to the Rad-5/5v.

   Refer to ***Basic Use*** on page 23 for steps to verify proper operation of the device.

Basic Use

These steps are to be performed after performing the initial setup steps.

1. Connect a Red Direct Connect Spot Check Sensor or patient cable to the Patient Cable connector of the device. See ***Front View*** on page 19. Check that the cable is secure, and not twisted or damaged.

   Note: Select a sensor that is compatible with the device before attaching it to the patient or connecting it to the patient cable. See the *Directions for Use* for the sensor.
2. Attach the sensor to the patient. Refer to the *Directions for Use* for the sensor to properly apply the sensor.
3. Connect the sensor to the patient cable.
4. Press the Power button to turn the device on. All front-panel LEDs momentarily illuminate and a one-second tone is heard. See ***Front View*** on page 19.

5. Check that the display shows mode, SpO_2 Low Alarm Limit, SpO_2 High Alarm Limit, Pulse Rate Low Alarm Limit, Pulse Rate High ---- Alarm Limit, Sensitivity and Averaging Time.
6. Check that the front panel display is free of alarm and system failure messages (see ***Chapter 5: Alarms and Messages*** on page 39) and the battery indicator shows a good charge (see ***Battery Level Indicator*** on page 26.)
7. On the display, verify the readings for SpO_2 and pulse rate.

   Note: "- - - " will flash on the numeric display until the SpO_2 and pulse rate readings from the sensor have stabilized (approximately 10-seconds).
8. **Rad-5 only:** Check that the patient alarms are functional by setting the high and low SpO_2 and pulse rate alarm limits above and below the patient readings. See ***Menu Level 1 - Alarm Limit and Alarm Volume*** on page 33.
   - An alarm tone sounds.
   - The alarm limit and reading flash on the display.
9. Check the sensor alarms are functional by removing the sensor from the patient.
   - "SEn OFF" message appears on the display.
   - The alarm tone sounds.
   - The Visual Alarm Indicator flashes.
10. Disconnect the sensor from the patient cable or device.
    - Confirm that "NO SEn" message now appears on the display with the alarm tone.

    NOTE: "NO SEn" and "SEn OFF" will only generate an alarm if the Rad-5/5v is actively monitoring a patient when the sensor is disconnected.
11. **Rad-5 only:** Check the parameter-violation alarm silence operation.
    - Create an alarm condition by lowering the SpO_2 or pulse rate high alarm limits below the patient readings.
    - Press the Alarm Silence button.
    - The alarm tone silences for 120-seconds.
12. To begin patient monitoring:
    - Set the alarm limits (**Rad-5 only**).
    - Set the alarm volume (**Rad-5 only**).
    - Set the pulse beep volume.
13. Check that the measured data is appropriate. See ***Successful Monitoring for SpO2 and PR*** on page 16.
14. Monitor the patient. See ***Normal Patient Monitoring*** on page 26.
15. After monitoring is complete, remove the sensor from the patient. If trending is enabled, turn it off.
16. Press and hold the Power On/Off Button for 2-seconds to turn the device off.

    NOTE: Turn the device off between uses to conserve battery life.

Chapter 4: Operation

The information in this chapter assumes that Rad-5/5v is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate Rad-5/5v without completely reading and understanding these instructions.

Basic Operation

The following information covers basic operation of the Rad-5 and Rad-5v.

Power Rad-5/5v On and Off

To Power ON Rad-5/5v

1. Press the Power On/Off Button.
2. The LEDs illuminate briefly, the speaker beeps and the device powers on.

To Power OFF Rad-5/5v

1. Press and hold the Power On/Off Button.
2. The Rad-5/5v will power down and turn off.

LED Indicators

For LED indicator descriptions and locations, see ***Front View*** on page 19. To modify the brightness of the LEDs, see ***Menu Level 4 - LED Brightness and Factory Defaults*** on page 36.

Signal SIQ and Pulse Bar

The Rad-5/5v indicates signal quality and pulse on a 10-bar LED indicator. See ***Front View*** on page 19. The height of the indicator provides an assessment of the confidence in the SpO_2 measurement displayed (signal quality) and the rhythm of the indicator displays the timing of the pulse.

Perfusion Index

The Rad-5/5v indicates perfusion on a 10-bar LED Perfusion Index indicator. See ***Front View*** page 19. The lower two segments of the bar turn red when the amplitude of the arterial pulsations are very low (low perfusion).

Battery Level Indicator

Four LED indicators provide information on the remaining battery capacity. See ***Front View*** on page 19. 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%

Normal Patient Monitoring

During normal operation, the Rad-5/5v Display shows oxygen saturation (as % SpO_2) 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-5 Front Panel Control Operation

Button	Function
	Power On/Off • Press to turn On. • Press and Hold for 2 seconds to turn off.
	Press to enter the setup/menu system. See ***Menu Navigation*** on page 33.

Button	Function
	No function during normal patient monitoring.
	Alarm Silence Press this button one time to temporarily silence the audible alarm for 120 seconds. A second press permanently silences all audible alarms. If a low battery alarm occurs during patient monitoring, press this button to silence the audible alarm for 120 seconds. Pressing this button also permanently silences 'sensor-off' or 'no-sensor' audible alarms as well as a low battery audible alarm (if the Rad-5 is not monitoring a patient).
	Up and Down Arrow keys During 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.

Rad-5v Front panel Control Operation

Button	Function
	Power On/Off • Press to turn On. • Press and Hold for 2 seconds to turn off.
	Front panel indicator brightness Press this button repeatedly to cycle through the full brightness range.
	Alarm Silence If a low battery alarm occurs during patient monitoring, press this button to silence the audible alarm for 120 seconds. Pressing this button also permanently silences 'sensor-off' or 'no-sensor' audible alarms as well as a low battery audible alarm (if the Rad-5 is not monitoring a patient).
	Pulse Tone Volume Press this button repeatedly to cycle through the pulse tone volume range, and back to the 'silence' setting.

Advanced Operation

The following information is designed for advanced users of the Rad-5/5v.

Default Settings

The Rad-5/5v store two types of default values: those that the device automatically resets to after a power cycle, and those that can be changed by the user and are saved after a power cycle.

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

Option	Default Setting
Brightness display	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 reverts 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	

Option	Default Setting*
Alarm Volume	
Trending on/off	Set to pre-power down setting (Strongly recommend turning trending off prior to turning device off)
Sleep Study Mode	Set to pre-power down setting

* To manual revert Rad-5 to the default values, see ***Menu Level 4 - LED Brightness and Factory Defaults*** on page 36.

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

Rad-5 Device Settings

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.

Sensitivity (Rad-5)

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. See ***Menu Level 2 - Averaging, Sensitivity, FastSat, and SmartTone*** on page 34. 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. In

addition, 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.

Alarm Limits

WARNING: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.

On Rad-5, 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. To modify the alarm limits, see ***Menu Level 2 - Averaging, Sensitivity, FastSat, and SmartTone*** on page 34.

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:** 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.
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. 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.

Trend Settings

The Rad-5 can store 72 hours of SpO_2 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. The Data Transfer Download Cable (PN 2063) 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.

To modify the Trend Settings, see ***Menu Level 3 - Trend Settings*** on page 34.

TrendCom Utility

Installation

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

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 ***Front View*** on page 19) 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.
7. Select the desired location and assign a filename for the trend file. Press Save.
8. 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.
9. When trend data transfer is complete, close TrendCom and disconnect the Rad-5 from the Data Transfer Download cable.
10. 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, an ".out" file is 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	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 09:56:08 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

Menu Navigation

The Rad-5 settings 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.

Menu Level 1 - Alarm Limit and Alarm Volume

Button	Setting		
		Alarm Volume	Use Up or Down Arrow Keys to adjust parameter to desired setting. **Note:** The parameter is set/selected when the Mode/Enter and Next buttons are pressed. For alarm limit information, see ***Alarm Limits*** on page 30.
		SpO_2 Low Alarm Limit	
		SpO_2 High Alarm Limit	
		PR Low Alarm Limit	
		PR High Alarm Limit	

Menu Level 2 - Averaging, Sensitivity, FastSat, and SmartTone

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

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

[1] FastSat is automatically enabled in 2 and 4 second averaging.

[2] Defaults to APOD and Normal only. High sensitivity will default to normal.

[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 an averaged pulse rate measurement from the proprietary algorithm and may not identify irregular heart beat patterns when there is excessive artifact present.

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 ***Trend Settings*** on page 31. 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	Use Up key to turn Trend ON. Use Down key to turn Trend OFF
		Set Year	Use Up or Down Arrow Keys to adjust parameter to desired setting.
		Set month	
		Set Day	
		Set Hour	
		Set Minute	

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.

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 the Mode/Enter button 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.

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.

Sleep Mode Operation

The Rad-5 Sleep Mode allows the device to capture normal and abnormal data without triggering alarms. This mode blanks out the device display and disables the alarms with the exception of the Battery Level Indicator and Alarm Silenced Indicator, even after a power cycle. The keypad is locked except for the power button. However, any single key press brings the display back for 10-seconds. Upon power up, SLP mode is displayed along with a 10-second display of parameters. Pressing and holding both the Mode Enter and Next keys for 3 seconds (select next (STD), Mode Enter) will put Rad-5 back into the special menu to exit.

CAUTION: Alarms are disabled in this mode.

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.

<table>
<tr><th>Buttons</th><th colspan="3">Settings</th><th></th></tr>
<tr><td rowspan="2"> 

+

</td><td colspan="3">Standard Mode</td><td rowspan="2">Use Up or Down Arrow Keys to adjust parameter to desired setting.

Note: The parameter is set/selected when the Mode/Enter and Next buttons are pressed.</td></tr>
<tr><td> 

Sleep Mode (SLP)</td><td> 
</td><td>LED Display Brightness (4 levels)

Note: Only available indicators illuminate while adjusting setting.</td></tr>
</table>

Chapter 5: Alarms and Messages

The following chapter contains information about alarms and messages.

Alarm Indication

An alarm condition is indicated by an audible alarm tone and visual alarm indicator.

- Sensor condition, system failure and low battery alarms.
- "SEn OFF" and "nO SEn" will only generate an alarm condition after a pulse has been found.
- Rad-5 only: Audible and visual alarms for high low saturation and pulse rate (SpO_2 range 1-100%, pulse rate range 25-240 bpm).

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

Alarm Priority	Need of Response	Result of Failure	Description
High	Immediate	Death or irreversible 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.

Low Battery Audible Alarm

All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge. See ***Battery Level Indicator*** on page 26. When less than ten (10) percent battery life remains, the final battery indicator will begin to flash and an audible alarm will sound.

- 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.

Alarm Silence

Audible alarms may be suspended. There are three audible alarm suspension settings. All three settings are controlled by the Alarm Suspend Button. See ***Front View*** on page 19. 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 audible alarms on Rad-5/5v are muted. See ***Front View*** on page 19.

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 data or system errors.

Rad-5 Messages

The following messages display on Rad-5:

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	• Reattach sensor to patient. • 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	• Rule out occlusion of blood flow. • Verify proper sensor placement.
Perfusion bar turns red (Bottom two LEDs only)	Low Perfusion	• Rule out occlusion of blood flow. • Attempt to warm patient. • 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 ***Service and Maintenance*** on page 57.

Display	Type	Solution
bAd SEn	Defective sensor	Replace sensor
SEn *blinking*	Unrecognized sensor	Connect appropriate cable
I nt dEt Blinking	Interference detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.

Rad-5v Messages

The following messages display on Rad-5v:

Display Message	Type	Solution
no CbL	No cable connected	Connect cable
I nC CbL	Incompatible cable	Replace cable
rPL CbL	Defective or unrecognized cable	Replace cable
rPL CbL *blinking*	Cable life expired	Replace cable as soon as possible
no SEn	No sensor connected	Connect sensor
I nC SEn	Incompatible sensor	Replace sensor

Display Message	Type	Solution
rPL SEN	Unrecognized or defective sensor	Replace sensor
rPL SEN *blinking*	Sensor life expired	Replace sensor as soon as possible
NO AdH	No adhesive sensor connected	Connect adhesive sensor
INC AdH	Incompatible adhesive sensor	Replace adhesive sensor
rPL AdH	Defective or unrecognized adhesive sensor	Replace adhesive sensor
rPL AdH *blinking*	Adhesive sensor life expired	Replace adhesive sensor as soon as possible
rPL AdH	Defective or unrecognized adhesive sensor	Replace adhesive sensor

Chapter 6: Troubleshooting

Troubleshooting Chart

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

Problem	Possible Cause	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). • Press Alarm Suspend button until Alarm Suspend Indicator is no longer illuminated or flashing. See ***Alarm Silence*** on page 40.
Buttons Do Not Work When Pressed	Internal Failure	• Return for service. See ***Return Procedure*** on page 60.

Chapter 7: Specifications

The following chapter contains specifications for the Rad-5/5v.

Display Range

Measurement	Display Range
SpO_2 (Functional Oxygen Saturation)	1% to 100%
PR (Pulse Rate)	25 bpm to 240 bpm
Pi (Perfusion Index)	0.02% to 20%

Accuracy (ARMS*)

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

* The ARMS Accuracy is calculated based upon measurement values that are statistically distributed; approximately 68% of the measured values fell within +/- the ARMS value when compared to the reference device under a controlled study.

Resolution

Parameter	Resolution
SpO_2	1%
PR	1 bpm

Electrical

Battery	
Type	4 "AA" Alkaline [5]
Capacity	> 30 hours [6]

Environmental

Environmental Conditions	
Operating Temperature	2°C to 43°C (36°F to 109°F)
Storage Temperature	-50°C to 70°C [5] (-58°F to 158°F)
Storage Humidity	15% to 95%, non-condensing
Operating Atmospheric Pressure	500 mbar to 1,060 mbar (500 hPa to 1060 hPa)

Physical Characteristics

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

Modes

Modes	
Rad-5	
Averaging Mode	2, 4, 8, 10, 12, or 16 seconds [7]
Sensitivity	Normal, Maximum and APOD
Rad-5v	
Averaging Mode	8 seconds
Sensitivity	Normal

Alarms

Alarm	Details
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

Display/Indicator	Description
Data Display	
Rad5/Rad5v	%SpO_2, pulse rate, alarm status, alarm silenced status, Signal IQ/pleth bar, perfusion index bar, battery status
Rad-5 Only	MAX, FastSat
Indicator Type	LED

Compliance

EMC Compliance
IEC 60601-1 2, Class B

Safety Standards Compliance
ANSI/AAMI ES 60601-1:2005+A1:2012
CAN/CSA C22.2 No. 60601-1:2014
IEC 60601-1:2005+A1:2012
EN/ISO 80601-2-61:2011
IEC 60601-1-8:2006+A1:2012 (Rad-5 only)

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (Battery power)

Equipment Classification per IEC 60601-1	
Degree of Protection of Electrical Shock	Type BF-Applied Part
Protection against harm from liquid ingress	IP22, Protection from ingress of particulates > than 12.5 mm and protection against vertically falling water drops when enclosure is tilted at 15 degrees.
Mode of Operation	
Rad-5	Continuous Operation
Rad-5v	Not Continuous (Spot Check)

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions	N/A	

IEC 61000-3-3		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	---	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	---	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	---	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-3	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 150 kHz to 80MHz	3 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
ISO 80601-2-61, Clause 202	20 V/m 80 MHz to 2.5 GHz	20 V/m	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
---	---	---	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.			

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

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.018	0.035
0.1	0.37	0.057	0.11
1	1.17	0.18	0.35
10	3.7	0.57	1.1

100	11.7	1.8	3.5
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbols

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

Symbols	Definition	Symbols	Definition
	Follow Instructions for Use		Consult instructions for use
CE 0123	Mark of Conformity to European Medical Device Directive 93/42/EEC		ETL Intertek certification.See ***Declarations on page 1*** for certifications
IP22	Protection from ingress of particulates > than 12.5 mm and protection against vertically falling water drops when enclosure is tilted at 15 degrees.	Segurança 	UL-BR product complies with the Brazilian standards; INMETRO Mark of the National Institute of Metrology, Standardization and Industrial Quality in Brazil
Rx ONLY	Federal (USA) Law Restricts this Device to Sale by Or on the Order of a Physician		Not for continuous monitoring (No alarm) Rad-5v only
	Separate Collection for Electronic Waste		Defibrillation Proof Type BF
	Date of Manufacture		Manufacturer

Symbols	Definition	Symbols	Definition
	Storage Temperature Range		Authorized representative in the European community
	Atmospheric Pressure Limitation		Keep Dry
	Storage/transport relative humidity range		Fragile/Breakable, Handle with Care
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] The Masimo rainbow SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor.

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

[3] 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%.

[4] Masimo rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator.

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

[6] 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.

[7] 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.

Chapter 8: Service and Maintenance

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

Cleaning

To clean the device:

1. Disconnect the AC Power Supply and ensure the sensor is not applied to the patient.
2. Turn off the device and remove the batteries. See ***Battery Installation and Replacement*** on page 57.
3. Wipe the outer surfaces using a dampened soft cloth with a mild detergent and warm water solution or one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue.

   CAUTION: Do not allow liquids to enter the interior of the device.
4. Dry the device thoroughly prior to using on a patient.

The surfaces of the Rad-5/5v may be cleaned with the following solvents or cleaning agents:

- 70% Isopropyl Alcohol (IPA)
- 10% bleach/water solution (˜0.5% sodium hypochlorite solution)
- Up to 55% alcohol/0.5% quaternary ammonium chloride solution, such as Ecolab Asepti-Wipe® II Germicidal Wipes or PDI Super Sani-Cloth® Germicidal Wipes
- Accelerated Hydrogen Peroxide® Oxivir® Tb
- Cidex® Plus (3.4% glutaraldehyde)

CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the device may occur.

CAUTION: To prevent damage, do not soak or immerse the device in any liquid solution.

CAUTION: Do not sterilize by irradiation, steam, and autoclave or ethylene oxide.

Battery Installation and Replacement

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.

1. Remove the battery cover by depressing the small rectangular button at the bottom of the cover. See ***Back View*** on page 21.
2. Slide the cover down off the bottom of the device.

3. Install the batteries in the directions indicated by the battery icons inside the battery compartment.
4. Replace the battery cover by sliding it back up from the bottom of the device until the rectangular locking button snaps back into position.

Performance Verification

To test the performance of the Rad-5/5v following repairs or during routine maintenance, follow the procedures 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. 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

With the monitor turned on, 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)

1. With the monitor turned on, select the Menu Access key and enter the Alarm menu. See ***Menu Level 1 - Alarm Limit and Alarm Volume*** on page 33.
2. Change the High Saturation Alarm parameter to a value two points below the currently selected value, and accept the change.
3. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display, next to the SpO_2 or pulse rate measurement display.
4. Return the High Saturation Alarm parameter to its original setting.
5. Repeat steps 1 to 3 with the Low Saturation Alarm parameter.
6. Repeat steps 1 to 3 with the High Pulse Rate Alarm parameter.
7. Repeat steps 1 to 3 with the Low Pulse Rate Alarm parameter.
8. Reset the alarm limits again to the original settings.

LED Brightness

Rad-5

1. With the monitor turned on, select menu level 3 (see ***Menu Level 4 - LED Brightness and Factory Defaults*** on page 36) 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.

Rad-5v

1. With the monitor turned on, push the Display Brightness key several times to cycle through all four brightness levels. See ***Front View*** on page 19.
2. Exit the Menu system by pressing the Mode/Enter key or waiting for the normal time-out.

Testing Rad-5/5v with Masimo SET Tester

Rad-5

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 ***Menu Level 1 - Alarm Limit and Alarm Volume*** on page 33).
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.

Rad-5v

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 SEn” 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.

Repair Policy

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

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

To return the device for service, refer to ***Return Procedure*** on page 60.

Return Procedure

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

- RMA number
- A letter describing in detail any difficulties experienced with the Rad-5/5v
- Warranty information, a copy of the invoice, or other applicable documentation
- Purchase order number to cover repair if the Rad-5/5v is not under warranty, or for tracking purposes if it is
- Ship-to and bill-to information
- Contact person (name, telephone/Telex/fax number, and country) for any questions about the repairs
- A certificate stating the Rad-5/5v has been decontaminated for bloodborne pathogens

Return the Rad-5/5v to the shipping address listed in ***Contacting Masimo*** on page 61 below.

Restrictions

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

modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.

3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. U.S. Government Rights: If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

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

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Rad-5®/5v® Pulse Oximeter) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, Masimo will not be liable for any incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Index

I

K

L

M

N

O

P

R

S

T

U

www.masimo.com

33606/LAB-5724H-0920