Rad-57™

OPERATOR'S MANUAL

Masimo Rainbow® SET®

Signal Extraction Pulse CO-Oximeter™

The Rad-57 Signal Extraction Pulse CO-Oximeter Operating Instructions intend to provide the necessary information for proper operation of all Rad-57 Pulse CO-Oximeter models.

General knowledge of Pulse CO-Oximetry and an understanding of the features and functions of the Rad-57 Signal Extraction Pulse CO-Oximeter models are prerequisites for proper use.

Do not operate any of the Rad-57 Signal Extraction Pulse CO-Oximeter models 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.

For further information contact:
Masimo Corporation
40 Parker
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

CONTRAINDICATIONS: The Rad-57 is contraindicated for use as an apnea monitor.

Safety Information, Warnings and Cautions

The Rad-57™ is designed to minimize the possibility of hazards from errors in the software program by following Sound Engineering Design Processes, Risk Analysis and Software Validation.

- The Rad-57 is to be operated by qualified personnel only. This manual, accessories, *Directions for Use*, all precautionary information, and specifications should be read before use.
- Explosion hazard. Do not use the Rad-57 in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Electric shock hazard. Do not open the Rad-57 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.
- High intensity extreme lights (such as pulsating strobe lights and direct sunlight) directed on the sensor, may not allow the Rad-57 to obtain readings.
- EMI radiation interference such as computer displays and/or LCD/plasma TVs can cause errors or incorrect measurements on the Rad-57.
- If patient hypoxemia is indicated, blood samples should be analyzed by laboratory devices 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 Rad-57 should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the Rad-57 or accessories in any position that might cause it to fall on the patient.
- Do not lift the Rad-57 by the patient cable or sensor.
- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- Rad-57 should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- Always remove the sensor from the patient and completely disconnect the patient from the Rad-57 before bathing the patient.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Do not use the Rad-57 or sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Rad-57 may affect the MRI image, and the MRI device may affect the accuracy of the Pulse CO-Oximetry parameters and measurements.
- Do not use the Rad-57 during electrocautery.
- Do not use the Rad-57 or sensor during defibrillation.
- If using the Rad-57 during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read f the active irradiation period.

Safety Information, Warnings and Cautions, continued

- Do not place the Rad-57 where the controls can be changed by the patient.
- Do not place the Rad-57 on electrical equipment that may affect the instrument, preventing it from working properly.
- Do not expose the Rad-57 to excessive moisture such as direct exposure to rain. Excessive moisture can cause the instrument to perform inaccurately or fail.
- Do not place containers containing liquids on or near the Rad-57. Liquids spilled on the instrument may cause it to perform inaccurately or fail.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment
- SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). The Rad-57 cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.
- Inaccurate SpO_2 readings can be caused by:
  - Improper sensor placement
  - Elevated levels of COHb and MetHb
  - For increased COHb: COHb levels above normal tend to increase the level of SpO2. The level of increase is approximately equal to the amount of COHb that is present.
  - ***NOTE:*** High levels of COHb may occur with a seemingly normal SpO2. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s.

  When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Inaccurate SpCO and SpMet readings can be caused by:
  - Improper sensor application
  - Intravascular dyes such as indocyanine green or methylene blue
  - Abnormal hemoglobin levels
  - Low arterial perfusion
  - Low arterial oxygen saturation levels including altitude induced hypoxemia
  - Elevated total bilirubin levels
  - Motion artifact
  - SpCO readings may not be provided if SpO2 readings are less than 90%
  - SpCO readings may not be provided if SpMet readings are greater than 2%
  - Intravascular dyes such as indocyanine green or methylene blue

- Externally applied coloring (such as nail polish)
- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

- Do not place the Rad-57 against a surface or cover the speaker. This can cause the system or battery (non clinical) alarm to be muffled.
- If the Rad-57 fails any part of the setup procedures remove the instrument from operation until qualified service personnel have corrected the situation.
- Use the Rad-57 in accordance with *Section 7, Environmental Specifications* in of this manual.
- Do not incinerate batteries.
- To protect against injury from electric shock, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Use cleanings solutions sparingly.
- 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.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential 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 radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, 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 antenna.

  Increase the separation between the equipment and receiver.

  Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

  Consult the dealer or an experienced radio/TV technician for help.
- In accordance with international telecommunication requirements, the frequency band of 5,150 MHz to 5,250 MHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

Safety Information, Warnings and Cautions, continued

- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC and Class B.
- A functional tester cannot be utilized to assess the accuracy of the Rad-57 or any sensors.
- Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) for noninvasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or cleared by the FDA, or in any manner inconsistent with the instructions for use or labeling. The device and related accessories are not intended for use in combination with other medical devices or in high-risk applications.
- Disposal of product - Comply with local laws in the disposal of the instrument and/or its accessories.
- This Class B digital apparatus complies with Canadian ICES-003.

Table of Contents

Table of Contents

About this Manual

This manual explains how to set up and use the Rad-57 Instrument Signal Extraction Pulse CO-Oximeter. Important safety information relating to general use of the Rad-57 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 CO-Oximetry.

SECTION 2 **System Description** describes the Rad-57 system, functions and features.

SECTION 3 **Setup** describes how to setup the Rad-57 for use.

SECTION 4 **Operation** describes the operation of the Rad-57.

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-57.

SECTION 8 **Sensors and Patient Cables** outlines how to use and care for Masimo sensors and patient cables.

SECTION 9 **Service And Maintenance** describes how to maintain, service and obtain repair for the Rad-57.

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 are as follows:

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

Sample of Warning:

WARNING: THIS IS A SAMPLE OF A WARNING STATEMENT.

A **CAUTION** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this instrument or damage to other property.

Sample of Caution:

CAUTION: THIS IS A SAMPLE OF A CAUTION STATEMENT.

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

Sample of Note:

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

Product Description

The Rad-57 Handheld Pulse CO-Oximeter with Masimo Rainbow® SET® Technology is a noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-57 features a multicolored LED display that continuously displays numeric values for SpO_2, Perfusion Index (PI) and pulse rate (PR), a Low Signal IQ Indicator (Low SIQ) indicator, alarm status, alarm silence and battery life.

After upgrading, Carboxyhemoglobin saturation (%SpCO), Methemoglobin percentage (%SpMet), and Pleth Variability Index (PVI™) can display if the corresponding sensors are attached.

When upgrading the Instrument, follow the upgrade procedures as described in the *"Field Upgrader Tool" Directions for Use*, part number 31650.

The following list outlines the key features and benefits of the Rad-57 Handheld Pulse CO-Oximeter.

Features and Benefits

- Clinically proven Masimo SET® technology performance
- Proven for accurate SpO_2 and pulse rate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, Perfusion Index, Pleth Variability Index (PVI)*, carboxyhemoglobin (% SpCO)* and methemoglobin (SpMet)* displays
- Low Signal IQ (SIQ™) indicator
- Lightweight, convenient handheld design
- Over 8 hours of continuous use on 4 AA alkaline batteries
- Visual battery life indicator
- Audible Alarm for sensor-off and low battery
- Alarms for SpO_2, PR, SpCO* and SpMet*, PVI*
- FastSat® (for SpO_2 measurement)
- Three sensitivity levels - Max, Normal and APOD™ (for SpO_2 measurement)
- 72 hours of trending memory
- Adjustable alarm volume
- Adjustable averaging 2 to 16 seconds

* available in upgraded Instrument

Indications for Use

The Masimo SET® Rad-57 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) and carboxyhemoglobin and methemoglobin saturation or methemoglobin (measured by an SpCO/SpMet sensor). The Masimo SET® Rad-57 Pulse CO-Oximeter and accessories are 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.

* available in upgraded Instrument

Pulse CO-Oximetry

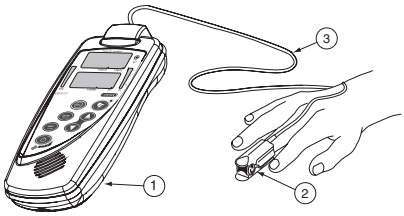
SpO_2 General Description

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 instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two ways:

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

2) As a pulse rate (PR)

The following figure shows the general monitoring setup.



1. Instrument
2. Sensor
3. Patient Cable

SpCO General Description

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of carbon monoxide concentration (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through an instrument patient cable. The sensor collects signal data from the patient and sends it to the instrument. The Rad-57 displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

SpMet General Description

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpMet measurement. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through an instrument patient cable. The sensor collects signal data from the patient and sends it to the instrument. The Rad-57 displays the calculated data as percentage value for the SpMet.

Pleth Variability Index - (PVI) General Description

The Pleth Variability Index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

Low Perfusion

It has been suggested that at extremely low perfusion levels, Pulse CO-Oximeters can measure peripheral saturation, which may differ from central arterial saturation. This “localized hypoxemia” may result from the metabolic demands of other tissues extracting oxygen proximal to the measurement site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

CAUTION:
IF LOW PERFUSION IS FREQUENTLY INDICATED, FIND A BETTER-PERFUSED MONITORING SITE. IN THE INTERIM, ASSESS THE PATIENT AND, IF INDICATED, VERIFY OXYGENATION STATUS THROUGH OTHER MEANS.

FastSat

FastSat enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend. When the Rad-57 is set to FastSat "On", the averaging algorithm evaluates all the saturation values providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat, the averaging time is dependent on the input signal.

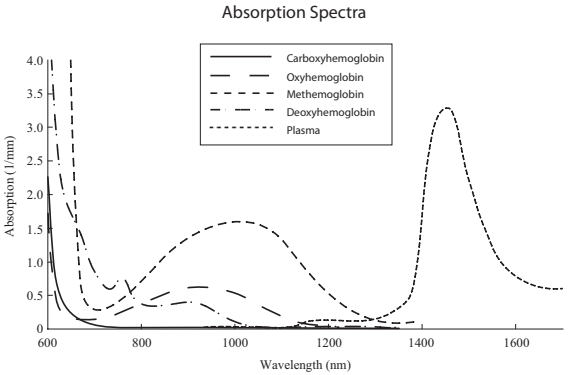
SmartTone

The SmartTone feature uses a proprietary algorithm that will provide pulse tones during excessive motion and low perfusion conditions. The pulse tone is based on an averaged pulse rate measurement from the proprietary algorithm and may not identify irregular heart beat patterns when there is excessive artifact present. The Normal Tone feature uses a proprietary algorithm that will provide pulse tones during non motion and adequate perfusion conditions. In this mode, the pulse tone may not sound if excessive artifact is present.

Principles of Operation

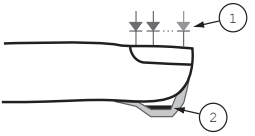
Pulse oximetry is governed by the following principles:

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



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

The Rad-57 Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma. The Rad-57 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a photodiode (detector). See figure below. Signal data is obtained by passing various visible and infrared lights (LED's, 500 to 1000nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25mW. The detector receives the light, converts it into an electronic signal and sends it to the Rad-57 for calculation.



1. Light Emitting Diodes (LEDs) (7 + wavelengths)
2. Detector

Once the Rad-57 receives the signal from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation ($\%SpO_2$), blood levels of carboxyhemoglobin (SpCO*), methemoglobin (SpMet*) and pulse rate. The SpCO and SpMet measurements rely on a multiwavelength calibration equation to quantify the percentage of: carbon monoxide or methemoglobin in arterial blood. The maximum of the skin surface temperature is measured at an ambient temperature of less than 106° F (41° C). This is verified by Masimo sensor skin temperature test procedures.

*available in upgraded Instrument

Functional vs. Fractional Saturation

The Rad-57 is calibrated to measure and display functional saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen. Note that carboxyhemoglobin is not capable of transporting oxygen, but is recognized as oxygenated hemoglobin by conventional pulse oximetry.

Rad-57 vs. Drawn Whole Blood Measurements

When SpO_2, SpCO, and SpMet measurements obtained from the Rad-57 (noninvasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory CO-Oximetry methods, caution should be taken when evaluating and interpreting the results. The blood gas and/or laboratory CO-Oximetry measurements may differ from the SpO_2, SpCO, and SpMet measurements of the Rad-57 Pulse CO-Oximeter. In the case of SpO_2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (PO_2) and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. In the case of SpCO, different results are also expected if concentration of methemoglobin in the blood gas sample is elevated. High levels of bilirubin may cause erroneous SpO_2, SpMet, and SpCO readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation, carboxyhemoglobin and methemoglobin concentration of the patient are stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory CO-Oximetry measurements of SpO_2, SpCO, and SpMet may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn, whole-blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

Masimo SET Signal Extraction Technology For SpO_2 Measurements

Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the non-arterial blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform® (DST)®, reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

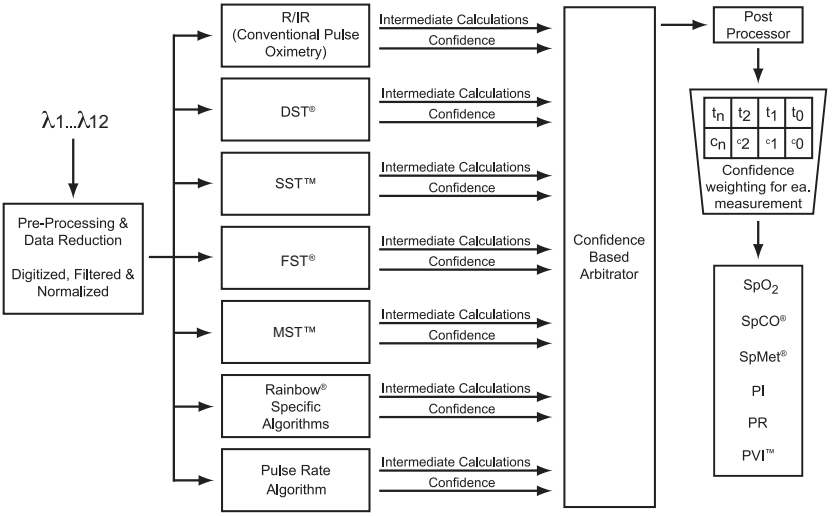
SpMet, and SpCO Measurements During Patient Motion

The Rad-57 displays measurements of SpCO* and SpMet* during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive motion. When the Rad-57 does not have confidence in the value of a parameter due to poor signal quality caused by excessive motion or other signal interference, the Low Signal IQ (Low SIQ) LED will flash.

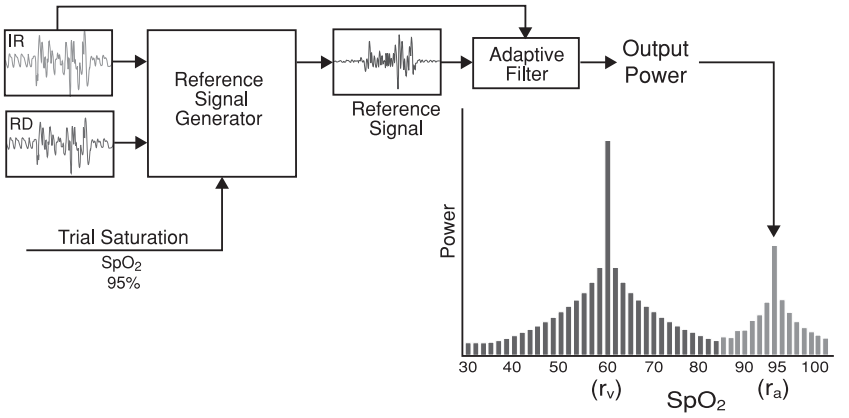
*available in upgraded Instrument

Masimo Rainbow SET Parallel Engines

This figure is for conceptual purposes only.



Masimo SET DST®



Introduction

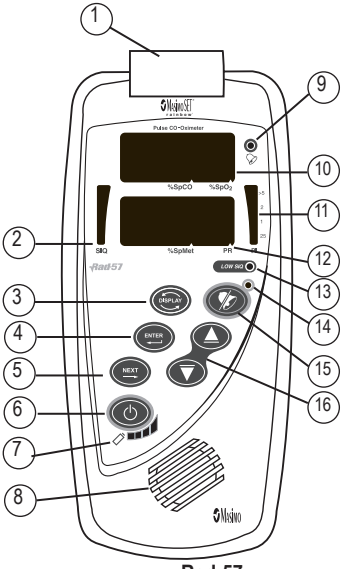
The Rad-57 is a full featured Pulse CO-Oximeter designed for ease of operation. All pulse oximetry measurement information, as well as instrument status data, is displayed on the front panel of the instrument. All user input is handled by control buttons on the front panel and the sensor cable connection is located at the top edge of the instrument.

The Rad-57 is powered by 4 AA alkaline batteries, which provides a minimum of 8 hours of battery life.

- Rad-57 offers full Masimo Rainbow SET Technology in a small, hand held instrument.
- Rad-57 supports the full line of Masimo sensors (see Section 8, *Sensors and Patient Cables*).
- Provides 72 hours of trending memory.

A Direct Connect Rainbow reusable sensor or patient cable or a Direct Connect Red reusable sensor or patient cable attaches to the patient cable connector on the top of the Rad-57 Instrument. The Rad-57 can be used either as a transport monitor or as a handheld Pulse CO-Oximeter for spot checks.

Rad-57 Front Panel Controls

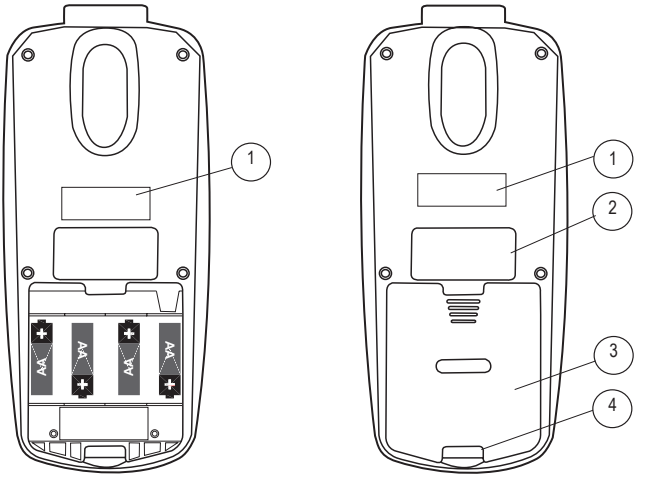


Rad-57

CONTROL / INDICATOR		DESCRIPTION
1	**Patient Cable Connector**	Connects to an appropriate Masimo Sensor or Patient Cable. Refer to *Section 8* for details.
2	**SIQ 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.
3	**Display Button**	Press to display the parameters/measurements selected in the Setup Menu screens. Refer to *Chapter 4, Setup Menu Level 5* for the options.
4	**Enter Button**	Used to enter the setup menus and to select/activate certain entries within the menu/setup system.
5	**Next Button**	Used within the menu/setup system to move through setup options. Not active when default screen displays.
6	**Power On / Off**	Press to turn the Instrument on. Press-and-hold for 2 seconds to turn the Instrument off.
7	**Battery Level**	. Four LED's indicate the status of the battery. When the final indicator begins flashing, replace the batteries

8	**Speaker**	Provides audible indication of alarm conditions, pulse tone and feedback for key-presses. Ensure the speaker is not covered or the Instrument is placed face-down on bedding or other sound absorbing surface.
9	**Visual Alarm Indicator**	Illuminates when any alrm condition exists. This indicator may not be turned off or otherwise over-ridden.
10	**Parameter/ Measurement Value Display and Indicator**	Displays parameter/measurement numeric values and indicates parameter/measurement label.
11	**PI Bar**	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	**Parameter/ Measurement Value Display and Indicator**	Displays parameter/measurement numeric values and indicates parameter/measurement label.
13	**Low SIQ**	Flashes to indicate low Signal IQ. Refer to *Section 4*, *Low Signal IQ* for details.
14	**Alarm Silenced Indicator**	The indicator can flash or be solidly illuminated. Refer to *Alarm Silenced Indicator* in *Section 5* for details.
15	**Alarm Silence Button**	Push once to temporarily silence the alarm for 120 seconds. Push a second time to return the Instrument to standard alarm monitoring
16	**Up button** **Down button**	During saturation monitoring, use these buttons to adjust the volume of the pulse beep tone. Within the menu/setup system, these buttons are used to select values within each menu option.

Rad-57 Rear Panel



CONTROL / INDICATOR		DESCRIPTION
1	Serial Number Label	Located on outside of case
2	Agency Approvals Label	Located on outside of case
3	Battery Cover	Located on back of Instrument
4	Battery Cover Release	Press down and slide the battery cover off the bottom of the oximeter

Battery Installation

The Rad-57 is powered by 4 AA alkaline batteries. Do not use any other type of batteries or power source to run the instrument. The battery compartment is accessed from the back of the instrument. 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 instrument. 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 instrument 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 RAD-57.

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 the battery life is low, the battery indicator will begin to flash and an audible alarm will sound.

Symbols

The following symbols may be found on the back of the Rad-57 Signal Pulse CO-Oximeter or packaging and are defined below:

SYMBOL	DESCRIPTION
	Caution, consult accompanying documents
 (blue background)	Follow Instructions for Use
	Type BF applied part complying with IEC 60601-1
	WEEE Compliant
CE 0123	Mark of Conformity to European Medical Device Directive 93/42/EEC
Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician
	Underwriter's Laboratories Inc. approved
	Storage humidity range
	Storage temperature range Storage altitude range
	Keep dry
	Fragile/breakable, handle with care
	Year of Manufacture
	Manufacturer

Setup

3

Introduction

Before the Rad-57 Pulse CO-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 instrument 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 Maintenance*.

Preparation for Monitoring

The following sections of the manual describe the preparation, set-up and initial installation of the Rad-57 Pulse CO-Oximeter.

Monitor Setup

Initial Setup

1. Inspect the oximeter case for damage.
2. Install 4 (four) new AA alkaline batteries.
3. Turn the Instrument on, the LEDs will scroll in the display window as the sensor calibrates, verify all indicators illuminate and speaker sounds a brief tone.
4. Configure the Instrument for your regional power line frequency (50 or 60 Hz) if needed. Default is 60 Hz (standard for the United States). See Section 4, *Special Menu, Special menu - Line Frequency Configuration*.

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

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

Introduction

To operate the Rad-57 Pulse CO-Oximeter effectively, the operator must:

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

Basic Operation

General Setup and Use

1. Inspect the Rad-57 case for damage. If damaged, refer to Section 9, **Service and Repair.**
2. Install the batteries, refer to Section 2, **Battery Installation.**
3. Connect a compatible patient cable or a direct connect sensor to the Rad-57. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
4. If utilizing a patient cable, select a sensor that is compatible with the Instrument and the patient before connecting it to the cable. See section 8, **Sensors and Patient Cables**. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the detector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
5. Follow the Indications, Instructions and Cautions in the sensor's *Direction for Use* when attaching, reattaching or disconnecting the sensor(s).
6. Press the Power button to turn the Rad-57 on.
7. Verify all front-panel indicators momentarily illuminate and an audible tone is heard
8. 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*).
9. Verify that the display shows the Instrument's enabled parameter/measurement settings in the following order:
   - SpO_2 Low Alarm Limit
   - SpO_2 High Alarm Limit
   - PR Low Alarm Limit
   - PR High Alarm Limit
   - SpCO Low Alarm Limit*
   - SpCO High Alarm Limit*
   - SpMet Low Alarm Limit*
   - SpMet High Alarm Limit*
   - PVI Low Alarm Limit*
   - PVI High Alarm Limit*
   - PI Low Alarm Limit*
   - PI High Alarm Limit*

- Sensitivity Setting
- Averaging Time
- FastSat: Setting

*available in upgraded Instrument

10. On the display, for each corresponding parameter/measurement, verify the readings (depending on the sensor used), for SpO_2, PVI*, SpCO*, SpMet* and PR.

    NOTE: *"- - - " will show on the numeric display until the SpO_2, SpCO*, PVI, SpMet* and pulse rate readings have stabilized (less than 20 seconds for SpO_2 and up to 120 seconds for PVI*,SpCO* and SpMet*).*

11. Verify that the patient alarms are functional by setting the high and low SpO_2 and pulse rate alarm limits beyond the patient readings.
    - An alarm tone sounds.
    - The violated alarm parameter/measurement flashes.
12. 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-57 was actively monitoring a patient when the sensor was disconnected.*

13. Verify parameter/measurement violation alarm silence operation.
    - Create an alarm condition by lowering the SpO_2 or pulse rate high alarm limits beyond the patient readings.
    - Press the Alarm Silence button.
    - The alarm tone ceases for 120 seconds.
14. To begin patient monitoring:
    - Adjust the alarm limits.
    - Adjust the alarm volume.
    - Adjust the pulse beep volume.
15. Verify the sensor is applied correctly and that the measured data is appropriate, see Section 4, *Successful SpO_2 Monitoring*.
16. Monitor the patient.
17. 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.
18. Press and hold the Power On/Off button for 2 seconds to turn the oximeter off.

*available in upgraded Instrument

Default Settings

The Rad-57 is shipped configured with all values set to factory default. Adjustments made by the user will be retained after a power cycle for all values except alarm silence.

NOTE: *Before use, confirm that the instrument settings are set appropriately.*

The following table outlines the default values:

OPTION	FACTORY DEFAULT SETTING	CONFIGURABLE SETTING/BEHAVIOR AT POWER-UP
SpCO* low alarm limit	(Default is Off)	Set to Pre-Power Down Setting See Section 5, *Alarm Limits* for all settings.
SpCO* high alarm limit	(Default is 10%)	
SpMet* low alarm limit	(Default is Off)	Set to Pre-Power Down Setting See Section 5, *Alarm Limits* for all settings.
SpMet* high alarm limit	(Default is 3%)	
SpO_2 low alarm limit	(Default is 90%)	Set to Pre-Power Down Setting See Section 5, *Alarm Limits* for all settings.
SpO_2 high alarm limit	(Default is OFF)	
Pulse rate low alarm limit	(Default is 50 BPM)	Set to Pre-Power Down Setting See Section 5, *Alarm Limits* for all settings.
Pulse rate high alarm limit	(Default is 140 BPM)	
PVI* low alarm limit	(Default is "---" Off)	Set to Pre-Power Down Setting See Section 5, *Alarm Limits* for all settings.
PVI* high alarm limit	(Default is "---" Off)	
PI low alarm limit	(Default is "---" Off)	Set to Pre-Power Down Setting See Section 5, *Alarm Limits* for all settings. 0.04 to 19 then "---"
PI high alarm limit	(Default is "---" Off)	
Sensitivity	(Default is Normal)	Set to Pre-Power Down Setting Normal, Maximum (HI) or APOD
Averaging Time	(Default is 8 seconds)	Set to Pre-Power Down Setting 2, 4, 8, 10, 12, 14, or 16 seconds
FastSat	(Default is Off)	Set to Pre-Power Down Setting Off/On
SmartTone	(Default is Off)	Set to Pre-Power Down Setting Off/On
Display Low SIQ Readings	(Default is No)	Set to Pre-Power Down Setting Yes/No
PVI Averaging	(Default is Long)	Set to Pre-Power Down Setting Long/Short
Display brightness	(Default is level 2)	Set to Pre-Power Down Setting Levels 1 through 4
Pulse tone volume	(Default is level 1)	Set to Pre-Power Down Setting Levels Off through 3

OPTION	FACTORY DEFAULT SETTING	CONFIGURABLE SETTING/BEHAVIOR AT POWER-UP
Alarm Volume	(Default is level 1)	Set to Pre-Power Down Setting Levels 1 through 4
Line Frequency	(Default is 60 Hz)	Set to Pre-Power Down Setting 50 Hz/ 60 Hz
Trend Active	(Default is Off)	Set to Pre-Power Down Setting Off/On
Alarm Silence	(Default is All Alarms Active)	Set to All Alarms Active Alarm on/off

*available in upgraded Instrument

Successful SpO_2 Monitoring

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

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

Masimo Sensors

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

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's *Directions for Use* to ensure skin integrity and correct positioning and adhesion of the sensor.

CAUTIONS

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

Numeric Display - SpO_2

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and PR. Inaccurate measurements may be caused by

- Elevated levels of carboxyhemoglobin
- Elevated levels of methemoglobin
- Intravascular dyes such as indocyanine green or methylene blue

- Externally applied coloring (such as nail polish)
- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

Numeric Display - Pulse Rate

The Pulse Rate displayed on the Rad-57 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 IQ 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 CO-Oximeter. Inaccurate measurements may be caused by

- Intravascular dyes such as indocyanine green or methylene blue
- Arrhythmias
- Intra-aortic balloon support

Numeric Display - SpCO (upgraded Instrument)

A stable SpCO reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

Inaccurate SpCO and SpMet readings can be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Abnormal hemoglobin levels
- Low arterial perfusion
- Low arterial oxygen saturation levels including altitude induced hypoxemia
- Elevated total bilirubin levels
- Motion artifact
- SpCO readings may not be provided if SpO2 readings are less than 90%
- SpCO readings may not be provided if SpMet readings are greater than 2%
- Elevated levels of bilirubin
- Motion artifact
- Low arterial oxygen saturation levels including altitude induced hypoxemia

Numeric Display - SpMet (upgraded Instrument)

A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

Inaccurate SpMet readings can be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Abnormal hemoglobin levels
- Low arterial perfusion
- Low arterial oxygen saturation levels including altitude induced hypoxemia
- Elevated total bilirubin levels
- Motion artifact
- SpCO readings may not be provided if SpO2 readings are less than 90%
- SpCO readings may not be provided if SpMet readings are greater than 2%
- Elevated levels of bilirubin
- Motion artifact
- Low arterial oxygen saturation levels including altitude induced hypoxemia

Numeric Display - PI

The Perfusion Index (PI) display provides a relative numeric indication of the pulse strength at the monitoring site. It is a calculated percentage between the pulsatile signal and nonpulsatile signal of arterial blood moving through the site. PI may be used to find the best perfused site and to monitor physiological changes in the patient. It displays a range of < .1% to > 5% on the bar graph display and a numerical range of 0.03% to 20.0% on the display screen. A percentage greater than 1.00% is desired. Extreme changes in the display number are due to changes in physiology and blood flow.

Pleth Variability Index - PVI (upgraded Instrument)

The Pleth Variability Index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

Low Signal IQ (Low SIQ)

The Rad-57 display provides a visual indicator Signal IQ and an alert when the displayed values are not based on adequate Signal IQ. The Low SIQ indicator flashes when the may be compromised. When the Low SIQ indicator is flashing, 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-57 to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or a spell of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site has not been interrupted. For example, as may occur while lifting or crossing their legs during a diaper change.

After performing the above, if the "Low SIQ" 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

Low Perfusion is indicated when the arterial pulsations are very low (weak perfusion). Low Perfusion is shown when the PI LED indicator bar does not exceed 0.25 on the Rad-57.

CAUTION: IF LOW PERFUSION INDICATION IS FREQUENTLY DISPLAYED, FIND A BETTER PERFUSED MONITORING SITE. IN THE INTERIM, ASSESS THE PATIENT AND, IF INDICATED, VERIFY OXYGENATION STATUS THROUGH OTHER MEANS.

Actions to be Taken

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

- Make sure the emitter and photodetector are aligned directly opposite each other.
- Select a site where the distance between the emitter and photodetector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) and allow to dry 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.

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

Sensitivity

Three sensitivity levels enables a clinician to tailor the response of the Rad-57 to the needs of the particular patient situation. They are as follows:

- Normal Sensitivity – This is the recommended mode for typical monitoring purposes. It is advisable for care areas where patients are observed frequently, such as ICU's.
- Adaptive Probe Off Detection (APOD™) – This is the recommended monitoring mode where there is a high probability of the sensor becoming detached. It is also 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 due to excessive movement.
- Maximum Sensitivity (MAX) - This mode is recommended for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. This mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings

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

Low Battery Audible Alarm

If a low battery condition occurs during patient monitoring, a medium priority alarm will sound, and can be acknowledged 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 the alarm until the power is cycled or patient monitoring begins.

If a low battery condition occurs, immediately discontinue patient monitoring and replace the batteries.

NOTE: *Remove batteries when storing Instrument for prolonged periods to maintain battery life.*

WARNING: FAILURE TO REPLACE BATTERIES PROMPTLY AFTER A LOW BATTERY ALARM MAY RESULT IN THE CO-OXIMETER SHUTTING DOWN AND LEAVING THE PATIENT IN AN UNMONITORED 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 RAD-57.

WARNING: EFFECTIVE BATTERY LIFE WILL BE REDUCED WHEN OPERATING THE INSTRUMENT BELOW 5ºF (-15º C) DUE TO ALKALINE BATTERY TECHNOLOGY.

Normal Patient Monitoring

The following sections describe the function of the Rad-57 front panel controls during normal patient monitoring.

Rad-57 Front Panel Control Operation

BUTTON	FUNCTION
	Pressing this button will cycle through the numeric values of the enabled parameters/ measurements. ***NOTE:*** *If any parameter/measurement breaches its pre-set alarm limit, the Rad-57 will automatically display the alarming parameter/measurement. Pressing* **Display** *during an alarm condition will enable the display of other parameters for 10 seconds.*
	Enters the Rad-57 setup/menu system. Refer to *Setup Menus* in this Section for details.
	Press to navigate through submenus.
	Press once to temporarily silence the alarm for 120 seconds or to acknowledge low battery or sensor off conditions. Press a second time to return the Instrument to standard alarm monitoring.
	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.
	Power "on/off" button. Press this button to turn the Instrument on. Press-and-hold for 2 seconds to turn the Instrument off.

Setup Menu

This section gives an overview of the Rad-57 menu selections available. To navigate through the menus, use the *Enter*, *Next*, *Up* and *Down* keys located on the front panel of the Pulse CO-Oximeter, below the LED display. The following sub sections describe each menu item in more detail. The Pulse CO-Oximeter has options that allow user configuration to suit specific needs.

Menu Navigation

The Rad-57 set-up and configuration options are accessed through the menu system. The *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/measurement is set/selected when either the *Enter* or *Next* keys are pressed.

Setup Menu Level 1 – Alarm Volume and Alarm Silence

Push the Enter button to enter menu level 1.

SETTING		
ENTER	Alarm Volume	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting.
NEXT	Alarm on/off	

Setup Menu Level 2 – Alarm Limits

Push the Enter button again to enter menu level 2. If the Instrument has not been upgraded, only the basic parameters will display.

SETTING		
ENTER 2X	SpCO* Low Alarm Limit	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting. *available in upgraded Instrument
	NEXT SpCO* High Alarm Limit	
	NEXT SpMet* Low Alarm Limit	
	NEXT SpMet* High Alarm Limit	
	NEXT SpO_2 Low Alarm Limit	
	NEXT SpO_2 High Alarm Limit	
	NEXT PR Low Alarm Limit	
	NEXT PR High Alarm Limit	
	NEXT PVI* Low Alarm Limit	
	NEXT PVI* High Alarm Limit	
	NEXT PI Low Alarm Limit	
	NEXT PI High Alarm Limit	

Setup Menu Level 3 – Sensitivity, Averaging, FastSat, SmartTone

Push the Enter button again to enter menu level 3.

SETTING			
ENTER 3X		Sensitivity† **HI** = Maximum **Nor** = Normal **APO** = APOD	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting. *available in upgraded Instrument †These changes affect SpO_2 monitoring only.
	NEXT	Averaging†. The signal averaging time of this instrument can be set to: 2*, 4*, 8, 10, 12, 14 or 16 seconds	
	NEXT	FastSat† ‡ On, Off	
	NEXT	SmartTone† On, Off	
	NEXT	Display SIQ Readings Yes, No	
	NEXT	PVI* Averaging† Short, Long	

‡Select "Yes" to activate the FastSat algorithm. The FastSat averaging time is dependent on the input signal. FastSat is automatically enabled in 2 and 4 second averaging.

Setup Menu Level 4 - Trend Settings
Push the Enter button again to enter menu level 4.

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".

	SETTING	
	Trend ON / OFF	Use *Up* key to turn trend ON. Use *Down* key to turn trend OFF
ENTER 4X	ENTER Set Year	Use *Up* or *Down* Arrow Keys to adjust parameter/measurement to desired setting.
	ENTER Set Month	
	ENTER Set Day	
	ENTER Set Hour	
	ENTER 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**: The date and time must be set before trending will be enabled. The Rad-57 will automatically 'time out' of the setup menu after 10 seconds with no key presses. If the Rad-57 should time-out of 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-57.*

Setup Menu Level 5 - LED Brightness and Factory Defaults

Push the Enter button again to enter menu level 5.

		SETTING	
5X		LED Display Brightness (4 levels) ***NOTE:*** *LED indicators are illuminated while adjusting this setting.*	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting.
	NEXT	OFF (automatically powers off the Rad-57 when button presses and patient monitoring are absent for a set time) 15, 10, 5 minutes, No	
	NEXT	Restore Factory Defaults	
	NEXT	PI (allows the PI value to be shown on the Display Screen) On, Off	
	NEXT	O2 (select parameter/ measurement display order) Yes (SpO2/PR, CO*/Met*, OC*, PVI*, PI) default No (CO*/Met*, OC*, SpO2/PR, PVI*, PI)	

Pressing ENTER a sixth time returns the Rad-57 to patient monitoring display.

*available in upgraded Instrument

Menu Selection

In a fully upgraded Instrument, SpCO and SpMet will be continuously displayed once the sensor is properly placed and calibration is complete. To display continuous PVI, SpCO, SpMet or PI monitoring (when available), press DISPLAY .

NOTE: *If any parameter breaches its pre-set alarm limit, the Rad-57 will automatically display the alarming parameter. Pressing* **Display** *during an alarm condition will enable the display of other parameters for 10 seconds.*

Power Off

Off – Press and hold the On/Off button for two seconds.

Special Menu

This section gives an overview of the Rad-57 special menu selection available. To navigate through the menu, use the Power, Next, Up and Down keys located on the front panel of the oximeter. The oximeter has options that allow user configuration to suit specific needs. The following sub-section describes this menu item in more detail.

Special Menu – Line Frequency Configuration

***NOTE**: The Instrument must be configured to match your local power line frequency (50 or 60 hz) to operate properly. The Instrument default is set to 60 hz (standard for the United States).*

1. Turn the Rad-57 on and wait for the displays to scroll through the current settings.
2. Simultaneously press and hold the Up Arrow key and the Enter button.
3. "*SEr* " will be displayed.
4. Press the Enter button once.
5. Push the Next button 5 times. "LF" will be diplayed in the top LED display window and the active line frequency will be displayed in the lower LED display window.
6. Push the Up arrow to set the line frequency to 60 Hz and the Down arrow to set it to 50 Hz.
7. Turn the Instrument off.

BUTTON		SETTING	
Simultaneously press and hold ▲ + ENTER	Press	ENTER	Use *Up or Down* Arrow Keys to adjust parameter to desired setting. ***NOTE:** The parameter is set/selected when the Instrument is turned off.*
	NEXT 5X	Enter Line Frequencey Menu	
	LF	Set Line Frequency	

Trend Setup and Use

Introduction

The Rad-57 can store 72 hours of SpO_2, Pulse Rate (PR), PVI*, SpCO*, SpMet* 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 Instrument is shut off or when the batteries are replaced.

A Data Transfer Download cable is required to connect the sensor connector of the Rad-57 to the PC and TrendCom software is required to download the trend data on to the PC. Refer to Section 10 - **Accessories** and contact Masimo to acquire these optional items. 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.

*available in upgraded Instrument

TrendCom Utility Installation

Copy the TrendCom utility from the CD onto a PC running MS-Windows. Refer to Trendcom *Directions for Use* for instructions.

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-57 off or replacing the batteries will not erase the trend data.

Turn trending off before storing the Instrument 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 fomat. The format is defined in the following table.

PARAMETER	SPECIFICATION
Date	MM\DD\YY
Time	HH:MM:SS
Parameter/ Measurement	Numeric value (see the display ranges in the Factory and User Configurable Default Settings table located at the beginning of this section) Non-installed parameters/measurements will display as "---" in Trendcom

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 in full SET mode. It requires a Masimo sensor and needs to acquire some clean data for this flag to be set.

Alarm Indication

An alarm condition is indicated by:

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

“SEn OFF” and “nO SEn” will only generate an alarm condition if they occur after a pulse has been found.

Alarm Limits

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

It is recommended that the operator be within a minimum of 10 feet from the Instrument. 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 Silence Mode.

SETTING	RANGE
SpCO* Low Limit	The SpCO low alarm limit can be set to “----” (Off) or anywhere between 1% and 97%, with a 1% step size. In the "----" (Off) setting, the SpCO Low Limit Alarm is disabled. Factory default setting is “off.” ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit.*
SpCO* High Limit	The SpCO high alarm limit can be set to “----” (Off) or anywhere between 2% and 98%, with a 1% step size. In the "----" (Off) setting, the SpCO High Limit Alarm is disabled. Factory default setting is 10%.
SpMet* Low Limit	The SpMet low alarm limit can be set to “----” (Off) or anywhere between 0.1% and 99%. The step size varies. When the range is 0.1 to 1.9% the step size is 0.1. When the range is from 2 to 99, the step size is .5%. In the “----“ (Off) setting, the SpMet Low Limit Alarm is disabled. Factory default setting is “Off“. ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit.*
SpMet* High Limit	The SpMet high alarm limit can be set to “----” (Off) or anywhere between 1% and 99.5% The step size varies. When the range is 1.0 to 1.9% the step size is 0.1. When the range is from 2 to 99.5, the step size is .5% In the “----“ (Off) setting, the SpMet High Alarm Limit Alarm is disabled. Factory default setting is 3%.
SpO_2 Low Limit	The SpO_2 low alarm limit can be set anywhere between 1% and 98%, with a 1% step size. ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit.*

SETTING	RANGE
SpO_2 High Limit	The SpO_2 high alarm limit can be set to "----" (Off)or anywhere between 2% and 99%, with a 1% step size. In the "----" (off) setting, the SpO_2 High Limit alarm is disabled.
PR Low Limit (BPM)	The pulse rate low alarm limit can be set anywhere between 30 BPM and 230 BPM, with a 5 BPM step size. ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit.*
PR High Limit (BPM)	The pulse rate high alarm limit can be set anywhere between 35 BPM and 235 BPM, with a 5 BPM step size.
PVI Low Limit*	The PVI low alarm limit can be set to "----" (Off) or anywhere between 1 and 98%. Adjust in increments of 1 step size. When PVI is placed in the "----" (Off) setting, the PVI Low Limit alarm is disabled.
PVI High Limit	The PVI high alarm limit can be set to "----" (Off) or anywhere between 2% and 99%. Adjust in increments of 1% step size. When PVI is placed in the "----" (Off) setting, the PVI High Limit alarm is disabled.
PI Low Limit*	The PI low alarm limit can be set to "----" (Off) or anywhere between 0.03% and 18%. Adjust in increments of 0.01% step size between 0.03% and 0.1%, 0.1% step size between 0.1% and 1% and a 1% step size between 1% and 18%. When PI is placed in the "----" (Off) setting, the PI Low Limit alarm is disabled.
PI High Limit	The PI high alarm limit can be set to "----" (Off) or anywhere between 0.04 % and 19%. Adjust in increments of 0.01% step size between 0.02% and 0.1%, 0.1% step size between 0.1% and 1% and 1% step size between 1% and 19%. When PI is placed in the "----" (Off) setting, the PI High Limit alarm is disabled.

*available in upgraded Instrument

NOTE: *See Section 4* **Operation***, Default Settings, for alarm limit behavior after a power cycle or loss of power. If the user has not adjusted the alarm limits, then they will be set back to the factory defaults.*

Alarm Silence

Audible alarms may be suspended, while visual alarms may not. The alarm suspension setting is controlled by the Alarm Silence Button. Pressing the Alarm Silence Button will suspend the alarm for 120 seconds.

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

Push Once – Alarm is silenced for 120 seconds and Alarm Silenced Indicator flashes.

Push Twice - Return to Audible Alarm Active.

To continuously silence the alarms, see Section 4 *Setup Menu Level 1.*

Alarm Silenced Indicator

The Alarm Silenced Indicator provides visual feedback regarding the audible alarm status. The audible alarms are muted when the indicator is flashing or continuously illuminated.

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 activate alarms and the alarm silence indicator will be off.

If the alarms have been silenced, per Setup Menu Level 1, then the Alarm Silence indicator will be continuously illuminated. The Alarm Silence indicator will remain illuminated until after a power cycle or until the alarms are enabled (see Section 4, **Setup Menu**).

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 or continues.

Messages

The Rad-57 will indicate other data or system errors.

Message conditions for the Rad-57 follow:

DISPLAY	REASON	SOLUTION
NUMERIC VALUE FLASHES	Parameter 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.
O2 SEN	SpO_2 sensor attached	If SpCO and/or SpMet parameters are desired, attach a Rainbow sensor to the Instrument.
LEDS FLASH HORIZONTAL BARS	Pulse Search	Wait for pulse detection. (This search should occur whenever a sensor is first applied to a patient). If necessary, shield the sensor from excessive ambient or strobing light.
CIRCULATING LEDS	Sensor is calibrating	
LOW SIQ INDICATOR FLASHES	Low Signal IQ	1. Rule out occlusion of blood flow. 2. Verify placement of sensor.
PERFUSION INDEX (PI) BAR* TURNS RED (Bottom two LEDs only.)	Low Signal Strength	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.
NO CBL	No Cable Connected	Connect appropriate cable to Instrument.

*available in upgraded Instrument

DISPLAY	REASON	SOLUTION
Err ##	System Fault	Return for service. There are several error codes. All error codes require return of the Instrument to an authorized service center for repair. See Section 9, *Service and Repair* for return procedure.
rPL CbL	Defective cable	Replace cable
rPL SEn	Sensor life expired	Replace sensor
rPL AdH	Defective adhesive sensor (resposable)	Replace adhesive sensor (resposable)
rPL rEu	Defective reusable sensor (resposable)	Replace reusable sensor (resposable)
I nt dEt (Blinking)	Interference detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.
I nC SEn	Incompatible sensor Unrecognized sensor	Insert Masimo sensor
I nC CbL	Incompatible cable Unrecognized cable	Insert Masimo cable
I nC AdH	Incompatible adhesive sensor is attached (resposable)	Attach compatible adhesive sensor (resposable)
no AdH	No adhesive sensor is attached (resposable)	Attach adhesive sensor (resposable)
SEn 000	No sensor uses remaining	Insert new Masimo sensor
CbL 000	No cable uses remaining	Insert new Masimo cable

*available in upgraded Instrument

DISPLAY	REASON	SOLUTION
Temporary blinking message: rPL CbL	Cable life expired	Replace cable as soon as possible
Temporary blinking message: rPL SEn	Sensor life expired	Replace sensor as soon as possible
Temporary blinking message: rPL AdH	Adhesive sensor life expired	Replace adhesive sensor as soon as possible
CHc SEN	Check sensor connection	Reattach sensor

Troubleshooting

The following chart describes what to do if the Rad-57 system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
INSTRUMENT DOES NOT POWER ON	Depleted battery	Check and/or replace the batteries.
CONTINUOUS SPEAKER TONE	Internal Failure	Instrument requires service. Press the Alarm Silence button to silence the alarm. If alarm continues to sound, power down Instrument and remove Handheld battery if necessary.
BUTTONS DON'T WORK WHEN PRESSED	Internal failure	Instrument requires service.

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

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

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
SpO_2 VALUES DO NOT CORRELATE WITH CLINICAL ASSESSMENT OR ABGS.	Low perfusion or sensor displacement.	Check for error messages. See section 5=*Messages* for recommended corrections. Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely on the patient. Refer to sensor Directions For Use.
UNEXPECTEDLY HIGH SpO_2, SpCO* OR SpMet READING	Low SIQ or Perfusion Index (PI) values	Reposition sensor to site with strong SIQ and PI. Average readings taken from three different sites to improve accuracy. Submit blood sample for laboratory CO-Oximetry test for comparison.
	Inappropriate sensor size or sensor measurement location.	Verify proper sensor for patient size. Verify proper sensor site.
UNEXPECTEDLY HIGH SpCO READING	Possible elevated methemoglobin level†.	Submit blood sample for laboratory CO-Oximetry test.
DIFFICULTY OR NO SpO_2/SPCO*/ SPMET* READING	Low battery/ not plugged into AC power supply.	Insert handheld into docking station, verify docking station power cord plugged in and docking station power indicator light is illuminated.
	Interference from line-frequency induced noise.	Verify/set 50/60hz menu setting. Refer to Section 3, Initial Setup for details.
	Inappropriate sensor or sensor size.	Verify proper sensor and sensor size for the patient.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.
	Also, see Section 4, Successful Monitoring for additional information.	
CIRCLING 000'S (ZERO'S)	Instrument is searching for pulse.	If Instrument fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
DIFFICULTY OR NO SpCO/SpMet READING	Excessive motion	Minimize or eliminate motion at the monitoring site.
	Inappropriate sensor or sensor size.	Verify use of an SpCO/SpMet capable sensor. Verify proper sensor size for the patient.

*available in upgraded Instrument

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

Rad-57 Specifications

PERFORMANCE

Measurement Range	
SpO_2:	0 -100%
SpMet*:	0 - 99.9%
SpCO*:	0 - 99%
Pulse Rate:	25 - 240 (bpm)
Perfusion Index:	0.02% - 20%
Pleth Variability Index (PVI*):	0 - 100%
Accuracy:	
Arterial **Oxygen Saturation Accuracy**[1]	
Saturation	60% to 80%
No Motion	
Adults, Infants, Pediatrics	±3%
Saturation	70% to 100%
No Motion[2]	
Adults, Infants, Pediatrics	± 2%
Neonates†	± 3%
Motion[3]	
Adults, Infants, Pediatrics, Neonates	± 3%
Low Perfusion[4]	
Adults, Infants, Pediatrics, Neonates	± 2%
Pulse Rate Accuracy[5]	
Pulse Rate:	25 - 240 (bpm)
No Motion	
Adults, Infants, Pediatrics, Neonates	± 3 bpm
Motion[4]	
Adults, Infants, Pediatrics, Neonates	± 5 bpm
Low Perfusion	
Adults, Infants, Pediatrics, Neonates	± 3 bpm
Carboxyhemoglobin saturation accuracy (%SpCO*)[1]	
Adults, Infants, Pediatrics	1% - 40% ± 3%
Methemoglobin saturation accuracy (%SpMet*)[1]	
Adults, Infants, Pediatrics, Neonates	1% - 15% ± 1%
Resolution	
Arterial Oxygen Saturation (%SpO_2)	1%
Carboxyhemoglobin Saturation (%SpCO*)	1%
Methemoglobin Saturation (%SpMet*)	0 .1%
Pulse Rate (bpm)	1 bpm

Interfering Substances

Carboxyhemoglobin and methemoglobin will erroneously alter oxygen saturation readings. The level of increase is approximately equal to the amount of carboxyhemoglobin and/or methemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

ELECTRICAL

Batteries

Type:	4 AA alkaline[7]
Capacity:	up to 10 hours[6]
Isolation:	No external power or ground connection, internally powered only, DC current.

ENVIRONMENTAL

Operating Temperature:	0°F to 129°F (-18°C to 54°C)
Transportation/Storage Temperature:	-40°F to 158°F (-40°C to +70°C)[8]
Operating Humidity:	5% to 95%, non-condensing
Operating Altitude:	500 mbar to 1060 mbar pressure, -1000 ft to 18,000 ft (-304 m to 5,486 m)

PHYSICAL CHARACTERISTICS

Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.37 kg)

SpO_2 Modes

Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[8]
Sensitivity:	Normal, Maximum and APOD

Alarms

Audible and visual alarms for high low saturation and pulse rate (SpO_2 range 1% - 99%, SpCO range 1% - 98%, SpMet range 1% - 99.5%, PI range 0.03% - 19%, PVI range 1% - 99%, pulse rate range 30 - 235BPM)

High Priority:	800 Hz tone, 5 pulse burst, pulse spacing: 78ms, 78ms, 320ms, 78ms, repeat time:10s
Medium Priority:	500Hz tone, 3 pulse, repeat time: 5s
Volume:	67 dB (max.)

Display/Indicators*

Data display: %SpO_2, %SpCO, ml/dl, pulse rate, %SpMet, PI, PI bar, Pleth Variability Index, alarm status, alarm silenced status, Low Signal IQ, battery status. SIQ bar

Type:	LED
Display update rate	1 second
Response time	<20 seconds

Compliance

EMC Compliance:	EN60601-1-2, Class B
Equipment Classification:	IEC 60601-1
Type of Protection:	Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type BF-Applied Part
Mode of Operation:	Continuous

1 SpO_2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range 60% - 100% SpO_2, 0% - 40% SpCO and 0% - 15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7 to 135 days old and weighting between 0.5 and 4.25 kgs. Seventy-nine (79) data samples were collected over a range of 70 - 100% SaO2 and 0.5 - 2.5% HbMet with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet. Contact Masimo for testing specifications.

2 The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

3 The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

4 The Rad-57 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 transmission of greater than 5% for saturations ranging from 70-100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

5 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

6 This represents approximate run time at lowest indicator brightness, using new, fully charged batteries.

7 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 lifetime of the batteries may be shortened.

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

Introduction

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

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

Use only Masimo oximetry sensors and cables for SpO_2, SpCO, SpMet measurements. Other oxygen transducers or sensors may cause improper Rad-57 Pulse CO-Oximeter performance.

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

CAUTIONS:

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

Selecting a Sensor

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

High ambient and strobing light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor. To prevent interference from ambient or strobing light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

Sensor Application Instructions

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

Masimo Rainbow® Sensors

Masimo Rainbow sensors must be used with the Rad-57 to enable measurement of Carboxyhemoglobin (SpCO), and/or Methemoglobin (SpMet). Rainbow sensors will only function with Instruments containing Masimo Rainbow SET Technology or licensed to use Rainbow compatible sensors.

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

Rainbow R Series Adhesive Sensors

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

Rainbow adhesive sensors must be used in conjunction with Rainbow RC cables.

Sensor	Application Site	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpMet Accuracy
			No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion
R1 25	Finger or toe	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%
R1 25L	Finger or toe	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%
R1 20	Finger or toe	10 - 50 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%
R1 20-L	Thumb or great toe	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%
	Finger or toe	10 - 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	±1%

Rainbow Adhesive Sensors

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

Rainbow adhesive sensors must be used in conjunction with Rainbow RC cables.

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

Rainbow Direct Connect Sensors

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

Rainbow Direct Connect sensors connect to the instrument directly.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpMet Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion
DC-3 DC-12	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%
DCP-3 DCP-12	10 - 50 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%

Rainbow Reusable Sensors

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

Rainbow reusable sensors must be used in conjunction with Rainbow RC cables.

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

Rainbow Resposable™ Pulse CO-Oximeter Sensor System

SpO_2, SpMet, and pulse rate accuracy for the Rainbow Resposable two piece sensor system is specified in the following table.

Sensor	Application Site	Weight Range	Saturation Accuracy	Pulse Rate Accuracy	Low Perfusion Accuracy		SpMet Accuracy
					Saturation	Pulse Rate	
R2-25a R2-25r	Middle or ring finger	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm	± 1%
R2-20a R2-20r	Middle or ring finger	10 - 50 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm	± 1%

Masimo SpO_2 Sensors

The Rad-57 may also use standard Masimo LNOP, LNOPv and LNCS SpO_2 sensors, when used with Red PC and LNCS Cables respectively. This will allow the Rad-57 to work as a Masimo SET pulse oximeter without the carboxyhemoglobin or methemoglobin measurement.

Select the appropriate patient cable to attach the LNOP, LNOPv or LNCS sensor to the instrument.

Red Reusable Sensors

SpO_2 and pulse rate accuracy for the Red sensors is specified in the following table.

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

LNOP® Reusable Sensors

LNOP sensors must be used in conjunction with Red PC cables.

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

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

LNOP® Adhesive Sensors

LNOP sensors must be used in conjunction with Red PC cables.

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

LNOP® Specialty Sensors

LNOP sensors must be used in conjunction with Red PC cables.

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP 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
LNOP Trauma	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	N/A	N/A
LNOP Newborn Neo	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Newborn Inf	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

M-LNCS™/LNCS® Reusable Sensors

M-LNCS sensors must be used in conjuction with Rainbow patient cable series. LNCS reusable sensors must be used in conjunction with Red LNC cables.

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

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

M-LNCS™/LNCS® Adhesive Sensors

M-LNCS sensors must be used in conjuction with Rainbow patient cable series.
LNCS sensors must be used in conjunction with Red LNC cables.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
M-LNCS/LNCSAdtx M-LNCS/LNCSAdtx-3	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS/LNCS Pdtx M-LNCS/LNCS Pdtx-3	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS/LNCS Inf-L M-LNCS/LNCS Inf M-LNCS/LNCS Inf-3	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS/LNCS Neo-L	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
M-LNCS/LNCS Neo M-LNCS/LNCS Neo-3	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS/LNCS NeoPt M-LNCS/LNCSNeoPt-L M-LNCS/LNCS NeoPt-3	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
M-LNCS/LNCS NeoPt-500	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm

M-LNCS™/LNCS® Specialty Sensors

M-LNCS sensors must be used in conjuction with Rainbow patient cable series.
LNCS sensors must be used in conjunction with Red LNC cables.

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

LNOPv™ Adhesive Sensors

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

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

Sensor Accuracy

Refer to Section 7, *Specifications* for SpO_2, SpCO, SpMet and pulse rate accuracy, unless otherwise specified in the tables above. Accuracy specified when used with Masimo Rainbow SET technology pulse CO-Oximetry monitors or with licensed Masimo SET pulse oximetry modules during no motion. Numbers represent ± 1 standard deviation. Plus or minus one standard deviation represents 68% of the population. SpO_2 accuracy from 70% to 100%. Pulse Rate accuracy from 25 to 240bpm. Carboxyhemoglobin accuracy (SpCO) from 1 to 40%. Methemoglobin accuracy (SpMet) from 1 to 15%.

Cleaning And Reuse Of Masimo Reusable Sensors and Cables

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

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

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

Reattachment of Single Use Adhesive Sensors

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

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

CAUTION: DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY SENSORS [illegible] MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY [illegible]ARM.

Introduction

This chapter covers how to test the operation of the Rad-57, how to properly clean the Rad-57 Pulse CO-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 Instrument.

CAUTIONS:

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THIS OXIMETER.
- DO NOT SOAK OR IMMERSE THE MONITOR IN ANY LIQUID.
- USE THE CLEANING SOLUTION SPARINGLY. EXCESSIVE SOLUTION CAN FLOW INTO THE MONITOR AND CAUSE DAMAGE TO INTERNAL COMPONENTS.
- DO NOT TOUCH, PRESS, OR RUB THE DISPLAY PANELS WITH ABRASIVE CLEANING COMPOUNDS, INSTRUMENTS, BRUSHES, ROUGH-SURFACE MATERIALS, OR BRING THEM INTO CONTACT WITH ANYTHING THAT COULD SCRATCH THE PANEL.
- DO NOT USE PETROLEUM-BASED OR ACETONE SOLUTIONS, OR OTHER HARSH SOLVENTS, TO CLEAN THE OXIMETER. THESE SUBSTANCES ATTACK THE INSTRUMENT'S MATERIALS AND INSTRUMENT FAILURE CAN RESULT.

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

Battery Replacement

The Rad-57 is powered by 4 AA alkaline batteries. Do not use any other type of batteries or power source to run the instrument. The battery compartment is accessed from the back of the intrument. 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 instrument. 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 instrument until the rectangular locking button snaps back into position.

WARNING: FAILURE TO REPLACE BATTERIES PROMPTLY AFTER A LOW BATTERY ALARM MAY RESULT IN THE CO-OXIMETER SHUTTING DOWN AND LEAVING THE PATIENT IN AN UNMONITORED 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 RAD-57.

WARNING: EFFECTIVE BATTERY LIFE WILL BE REDUCED WHEN OPERATING THE INSTRUMENT BELOW 5ºF (-15º C) DUE TO ALKALINE BATTERY TECHNOLOGY.

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.

Be sure to follow local regulations in regards to battery disposal.

Performance Verification

To test the performance of the Rad-57 Pulse CO-Oximeter following repairs or during routine maintenance, follow the procedure outlined in this section. If the Rad-57 fails any of the described tests, discontinue its use and correct the problem before returning the Instrument back to the user.

Before performing the following tests verify or install new batteries into the Rad-57 Handheld. Also disconnect any patient cables, pulse oximetry probes or serial cables from the Instrument.

Power-On Self-Test

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

Key Press Button Test

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

Alarm Limit Test

1. With the monitor turned on, select the 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 SpO_2 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. Perform the above steps for the SpCO and SpMet alarm limits.
8. Reset the alarm limits again to the original settings.

LED Brightness

1. 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. Exit the Menu system by pressing the Enter key or waiting for the normal time-out.

Service and Repair

Repair Policy

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the Instrument 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-57 Instrument 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 or include the following information and items:

- A letter describing in detail any difficulties experienced with the Pulse CO-Oximeter. Please ıber 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-57 Pulse CO-Oximeter to the following shipping address:

FOR USA, CANADA & ASIA PACIFIC (EXCEPT JAPAN):	Masimo Corporation 40 Parker Irvine, California 92618 Tel: 949-297-7000 FAX: 949-297-7001
FOR JAPAN:	Masimo Japan Corporation Kojimachi Office World Time Bldg. 4F 10-7, Ichiban-cho, Chiyoda-ku, Tokyo 102-0082 JAPAN Tel: 03 3237 3057, FAX: 03 3238 1110
FOR EUROPE:	Masimo International Sàrl Puits-Godet 10 2000 Neuchatel - Switzerland Tel: +41 32 720 1111 Fax.: +41 32 724 1448
ALL OTHER LOCATIONS:	Contact your local Masimo Representative

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Batteries are not warrantied.

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

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Accessories

PART NUMBER	DESCRIPTION
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
2208	Protective carrying case, black
2209	Protective carrying case, red
13158	Nylon protective carrying case
1908	CD, TrendCom Software
2063	Data Transfer Download Cable

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