Rad-57™

Masimo Rainbow™ SET®
Pulse CO-Oximeter

OPERATOR'S MANUAL

Masimo SET®
Rainbow™

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

General knowledge of pulse oximetry and an understanding of the features and functions of the Rad-57 Pulse CO-Oximeter are prerequisites for proper use.

Do not operate the Rad-57 Pulse CO-Oximeter without completely reading and understanding these instructions.

NOTICE

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

CAUTION:

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

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Manufactured in USA

The Rad-57 Pulse CO-Oximeter is designed to minimize the possibility of hazards from errors in the software program by following sound engineering design processes, Risk Analysis and Software Validation.

- Explosion hazard. Do not use the Pulse CO-Oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- The Pulse CO-Oximeter is NOT intended for use as an apnea monitor.
- A Pulse CO-Oximeter should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.
- The Pulse CO-Oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Electric shock hazard. Do not open the Pulse CO-Oximeter cover except to replace the batteries. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the Pulse CO-Oximeter or accessories in any position that might cause it to fall on the patient. Do not lift the Pulse CO-Oximeter by the patient cable.
- Interfering Substances: Carboxyhemoglobin may erroneously increase SpO_2 readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Severe anemia may cause erroneous SpO_2 readings.
- Do not use the Pulse CO-Oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pulse CO-Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- If using pulse CO-oximetry during full body irradiation, keep the sensor out of the irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.
- Always remove the sensor from the patient and completely disconnect the patient from the Pulse CO-Oximeter before bathing the patient.
- Do not place the Pulse CO-Oximeter where the controls can be changed by the patient.
- Do not place the Pulse CO-Oximeter face against a surface. This will cause the alarm to be muffled.
- Do not place the Pulse CO-Oximeter on electrical equipment that may affect the Pulse CO-Oximeter, preventing it from working properly.

- Do not expose the Pulse CO-Oximeter to excessive moisture such as direct exposure to rain. Excessive moisture can cause the Pulse CO-Oximeter to perform inaccurately or fail.
- Do not place containers containing liquids on or near the Pulse CO-Oximeter. Liquids spilled on the Pulse CO-Oximeter may cause it to perform inaccurately or fail.
- Failure of Operation - If the Pulse CO-Oximeter fails any part of the setup procedures remove the Pulse CO-Oximeter from operation until qualified service personnel have corrected the situation.
- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- The Pulse CO-Oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.
- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving device.
  - Increase the separation between the equipment.
  - Consult the manufacturer for help.

About this Manual

This manual explains how to set up and use the Rad-57 Pulse CO-Oximeter (Rad-57). 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 oximetry.

SECTION 2 SYSTEM DESCRIPTION describes the Rad-57 Handheld Pulse CO-Oximeter system and its 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 Pulse CO-Oximetry system.

SECTION 5 ALARMS AND MESSAGES describes the alarm system messages.

SECTION 6 TROUBLESHOOTING gives troubleshooting information.

SECTION 7 SPECIFICATIONS gives the detailed specifications of the Rad-57 Handheld Pulse CO-Oximeter.

SECTION 8 SENSORS AND PATIENT CABLES outlines how to use and care for the Rainbow, LNOP, LNOPv and LNCS sensors and Masimo SET 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 device or damage to other property.

Sample of Caution:

CAUTION: THIS IS A SAMPLE OF A CAUTION STATEMENT.

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

Sample of Note:

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

Product Description

The Rad-57 Rainbow SET Pulse CO-Oximeter 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 and pulse rate, a Low Signal IQ Indicator (Low SIQ) indicator, LED indicator bars for Perfusion Index (PI), Carboxyhemoglobin saturation (%SpCO), alarm status, alarm silence, battery life and SpCO sensor connected.

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

FEATURES AND BENEFITS

- Clinically proven Masimo SET™ technology performance
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, Perfusion Index and % SpCO displays
- Low Signal IQ (SIQ) indicator
- Lightweight, convenient handheld design
- Up to 8 hours of continuous use on 4 "AA" alkaline batteries
- Visual battery life indicator
- Audible Alarm for sensor-off and low battery
- Alarms for high/low SpO_2, high/low pulse rate and SpCO
- 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

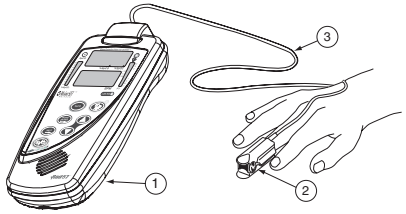
INDICATIONS FOR USE

The Rad-57 Pulse CO-Oximeter and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate and carboxyhemoglobin saturation (measured by an SpCO sensor). The Rad-57 and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile and home environments.

Pulse 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), and 2) as a pulse rate (PR). The following figure shows the general monitoring setup.



1. Instrument
2. Sensor
3. Patient Cable

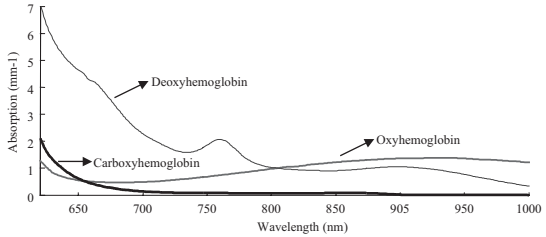
SpCO GENERAL DESCRIPTION

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 principles of pulse oximetry to make its SpCO measurement. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults. The sensor connects directly to the pulse CO-Oximetry instrument or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO. The Rad-57 is a combined SpO_2 and SpCO monitor with the same setup as that of a pulse oximeter, shown above, and can display a percentage value for SpCO as well as SpO_2.

PRINCIPLE OF OPERATION

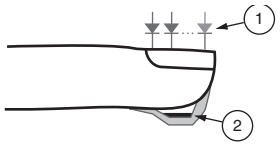
Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood) and carboxyhemoglobin (blood with carbon monoxide content) species differ in their absorption of visible and infrared light (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, and blood with carbon monoxide content. Signal data is obtained by passing various visible and infrared lights (LED's, 400 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. See figure below. The photodetector receives the light, converts it into an electronic signal and sends it to the Rad-57 for calculation.



1. Light Emitting Diodes (LEDs)
2. Recessed Photo 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, fractional concentration of carboxyhemoglobin, and pulse rate. The SpCO measurement relies on a multiwavelength calibration equation to estimate the percentage of carbon-monoxide in arterial blood.

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 can transport oxygen. The Rad-57 does not measure fractional saturation: oxygenated hemoglobin expressed as a percentage of the four main hemoglobin species, i.e., oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin. To convert fractional saturation to functional saturation, the fractional saturation measurements must be converted according to:

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

MEASURED VS. CALCULATED VALUES

SpO_2 and SpCO measurements obtained from the Rad-57 are commonly compared to invasive measurements obtained from blood gas samples. When comparing invasive and noninvasive measurements and interpreting values, caution should be used, as the calculated values obtained from the blood gas sample may differ from the SpO_2 and SpCO measurements of the 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, in addition to the effects of temperature and pH, different results are also expected if the oxygen saturation and/or concentration of methemoglobin in the blood gas sample

are abnormal (less than 90% for arterial oxygen saturation, and greater than 1% for methemoglobin concentration). As blood gas 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 core oxygen saturation and carboxyhemoglobin concentration of the patient are stable and not changing over the period of time that the blood gas sample is taken.

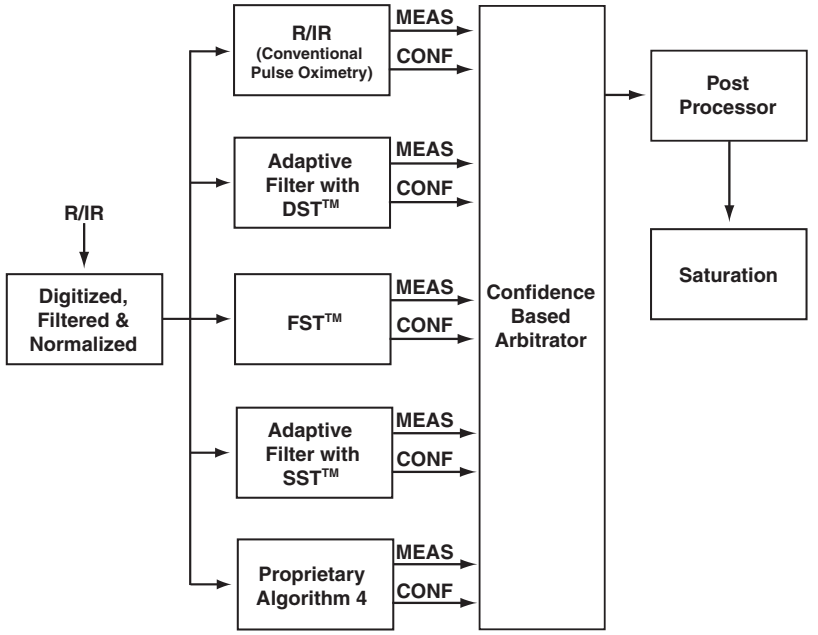
MASIMO SET SIGNAL EXTRACTION TECHNOLOGY FOR SpO_2 MEASUREMENTS

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.

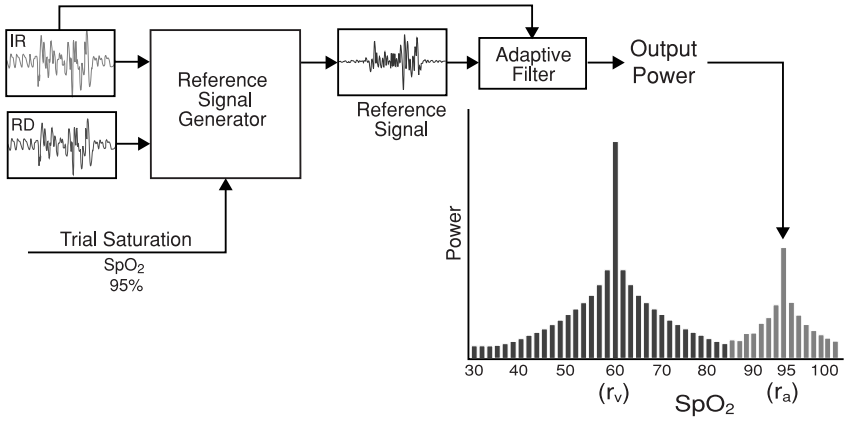
SpCO MEASUREMENTS DURING PATIENT MOTION

Rad-57 displays measurements of SpCO 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 is not reliable.

MASIMO SET PARALLEL ENGINES



MASIMO SET DST



Introduction

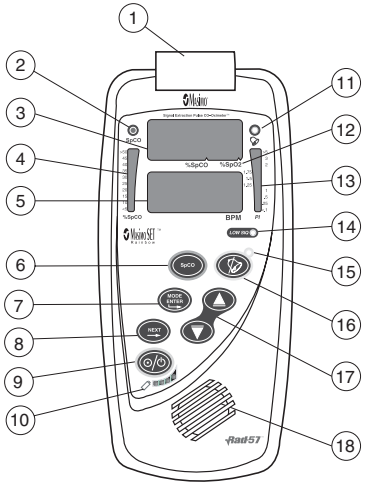
The Rad-57 is a full featured Pulse CO-Oximeter designed for ease of operation. All pulse oximetry measurement information, as well as device status data, is displayed on the front panel of the device. All user input is handled by control buttons on the front panel and the sensor cable connection is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

The Rad-57 is powered by 4 “AA” alkaline batteries, which provide over 8 hours of battery life.

- Rad-57 offers full Masimo Rainbow SET technology in a small, hand held device
- Rad-57 supports the full line of Masimo sensors (see Section 8, *sensors and patient cables*).
- Rad-57 provides 72 hours of trending memory

A Rainbow DC-I-DC Sensor or Rainbow Patient Cable and Masimo sensor attach to the connector on the top of the Rad-57 unit. 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

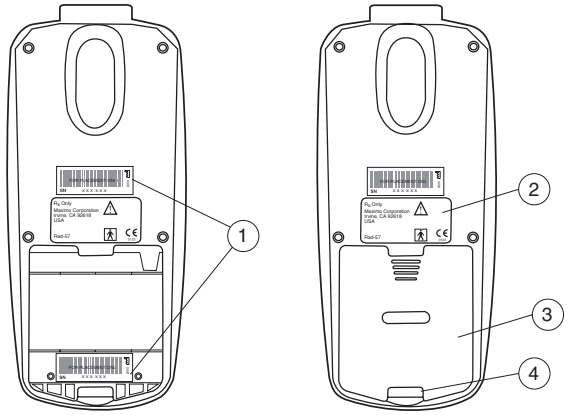


Rad-57

CONTROL / INDICATOR		DESCRIPTION
①	**Patient Cable Connector**	Connects to Rainbow sensor or Rainbow Patient Cable
②	**SpCO indicator**	**Slow flashing indicator**: The confidence in the SpCO value obtained is low. **Fast flashing indicator**: Flashes when an SpCO alarm condition exists.
③	**Saturation (%SpO_2) and Carboxyhemoglobin (%SpCO) Displays**	The functional arterial hemoglobin oxygen saturation is displayed in units of SpO_2. When searching for a saturation and pulse, it will flash dashed lines. See *SpCO Button* description, below.
④	**%SpCO Bar**	Illuminates when SpCO capable sensor is attached. Bar will flash for SpCO alarm conditions.Continuously indicates the concentration of carboxyhemoglobin in 5% increments.
⑤	**Pulse Rate Display**	The pulse rate in beats per minute (bpm). When searching for a saturation and pulse, it will flash dashed lines.

CONTROL / INDICATOR		DESCRIPTION
⑥	**SpCO Button**	Pressing this button will display the numeric SpCO value for 10 seconds in place of the SpO_2 numeric value. Pressing the Mode/Enter or Next button during this 10-second period will return to the SpO_2 numeric value.
⑦	**Mode / Enter Button**	Used to enter the setup menus and to select/activate certain entries within the menu/setup system.
⑧	**Next Button**	Used within the menu/setup system to move through setup options. Not active during normal patient monitoring.
⑨	**Power On / Off**	Press to turn the unit on. Press-and-hold for 2 seconds to turn the unit off.
⑩	**Battery Level Indicator**	Four LED's indicate the status of the battery. When the final indicator begins flashing, replace the batteries.
⑪	**Visual Alarm Indicator**	Illuminates when any alarm condition exists. This indicator may not be turned-off or otherwise over-ridden.
⑫	**%SpO_2 / %SpCO Indicator**	Indicator above label will illuminate to provide an additional visual indication of the value currently being displayed.
⑬	**PI**	Perfusion Index, or PI, is a relative assessment of the perfusion at the monitoring site. PI is displayed on a 10 segment LED bar, ranging from <1% (very weak perfusion) to >5% (strong perfusion). The highest LED will remain lit continuously to allow a PI level to be viewed. The Perfusion Index is the ratio of the AC (pulsitile) to DC (non-pulsatile) components of the IR (Infrared) signal where the AC and DC components correspond to the pulsatile and non-pulsatile amounts of blood, respectively.
⑭	**Low SIQ**	Flashes to indicate low SpO_2 Signal IQ. Refer to Section 4, *Low Signal IQ*.
⑮	**Alarm Silenced Indicator**	Flashes to indicate the alarm is temporarily silenced.
⑯	**Alarm Silence Button**	Push once to temporarily silence the alarm for 120 seconds. Push a second time to return the unit to standard alarm monitoring.
⑰	**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.
⑱	**Speaker**	Provides audible indication of alarm conditions, pulse tone and feedback for key-presses. Ensure the speaker is not covered or the unit is placed face-down on bedding or other sound absorbing surface.

Rad-57 rear panel



CONTROL / INDICATOR		DESCRIPTION
①	Serial Number Label	One label located inside battery compartment, one on outside of case
②	Agency Approvals Label	
③	Battery Cover	
④	Battery Cover Release	Press down and slide the battery cover off the bottom of the oximeter

SYMBOLS

SYMBOL	DESCRIPTION
	Caution, consult accompanying documents
	Type BF applied part complying with IEC 60601-1
	WEEE Compliant

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 Repair*.

Preparation for monitoring

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

POWER REQUIREMENTS

The Rad-57 is powered by 4 "AA" alkaline batteries. Do not use any other type of batteries or power source to run the device. The battery compartment is accessed from the back of the device. To install the batteries first remove the battery cover by depressing the small rectangular button at the bottom of the cover, and sliding the cover down off the bottom of the device. Install the batteries in the directions indicated by the battery icons inside the battery compartment. Replace the battery cover by sliding it back up from the bottom of the device until the rectangular locking button snaps back into position.

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

WARNING: USE OF BATTERIES WITH A CELL VOLTAGE OF MORE THAN 1.5V COULD CAUSE DAMAGE TO THE 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 less than ten (10) percent battery life remains, the final battery indicator will begin to flash and an audible alarm will sound.

Monitor setup

INITIAL SETUP

1. Inspect the oximeter case for damage.
2. Install 4 (four) new AA alkaline batteries.
3. Turn the unit 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 unit 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 UNIT 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 unit.

Introduction

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

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

Basic operation

GENERAL SETUP AND USE

1. Inspect the oximeter case for damage.

2. Ensure that the batteries are correctly installed.

3. Connect a Rainbow Sensor or Rainbow patient cable to the Patient Cable connector of the oximeter. Make sure it is a secure connection and the cable is not twisted, sliced or frayed. See Section 5, *messages*, to view messages that may be displayed pertaining to sensors and cables.

4. Select a sensor that is compatible with the oximeter before connecting it to the patient cable. See Section 8, *Sensors and Patient Cables*. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the photodetector are properly aligned. If using a reusable sensor, make sure it opens and closes smoothly. Remove any substances that may interfere with the transmission of light between the sensor's light source and photodetector.

5. Attach the sensor to the patient. Refer to the Directions for Use of the sensor.

6. Connect the sensor to the unit (or patient cable) with the logos lining up; make sure it is a secure connection.

7. Press the Power button to turn the oximeter on.

8. Verify all front-panel indicators momentarily illuminate and a one-second tone is heard.

9. Verify the 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*)

10. On the display, verify the readings for SpO_2, SpCO and pulse rate.

NOTE: *"- - - " will flash on the numeric display until the SpO_2, SpCO and pulse rate readings have stabilized (less than 15 seconds for SpO_2 and up to 25 seconds for SpCO).*

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 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 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.

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

DEFAULT SETTINGS

The Rad-57 stores two types of default values: those that the device automatically reverts to after a power cycle, and those that can be changed by the user and will be remembered after a power cycle.

The following table outlines the default values that the Rad-57 reverts to after a power cycle:

OPTION	DEFAULT SETTING
SpO_2 high alarm limit	Set to Off
SpO_2 low alarm limit	Set to 90%
Pulse rate high alarm limit	Set to 140 BPM
Pulse rate low alarm limit	Set to 50 BPM
SpCO high alarm limit	Set to pre-power down setting (Factory Default is 10%)
SpCO low alarm limit	Set to pre-power down setting (Factory Default is off)
Averaging Time	Set to pre-power down setting
FastSat	Set to pre-power down setting
Sensitivity	Set to pre-power down setting
Display brightness	Set to pre-power down setting
Pulse tone volume	Set to pre-power down setting
Alarm Volume	Set to pre-power down setting
Line Frequency	Set to pre-power down setting
Trend Active	Set to pre-power down setting
Alarm Silence	Set to all alarms active

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 constrict the monitoring site when securing a sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor Directions for Use for proper sensor application.

NUMERIC DISPLAY - 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.

CAUTIONS

- Unless indicated otherwise in the directions for use, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.
- Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site at least every two (2) hours with poorly perfused patients.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.
- Sensors applied too tightly may cause erroneously low readings.
- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.
- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.

- The sensor should be free of visible defects. Never use a damaged sensor or one with exposed electrical circuitry.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Intravascular dyes or externally applied coloring (such as nail polish) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 and SpCO measurements.
- Failure to apply the sensor properly may cause incorrect measurements.
- Do not use the sensor during MRI scanning.
- If using pulse CO-oximetry during full body irradiation, keep the sensor out of the irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.
- Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should be not below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor)
- Venous pulsations may cause erroneous low readings (e.g. tricuspid value regurgitation).
- Circulation distal to the sensor site should be checked routinely.

NUMERIC DISPLAY - SpCO

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

Inaccurate measurements may be caused by:

- Significant levels of methemoglobin.
- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal hemoglobin levels.
- Abnormally low arterial perfusion.

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 instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can be additive to the pulse rate displayed on the Pulse CO-Oximeter .

LOW SIGNAL IQ (LOW SIQ)

The Rad-57 display provides a visual indicator Signal IQ and an alert when the displayed SpO_2 values are not based on adequate Signal IQ. The Signal IQ indicator displayed on the Rad-57 as “Low SIQ”.

The Low SIQ indicator flashes when the SpO_2 measurement 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 is not interrupted. For example, as may occur while lifting or crossing their legs, during a diaper change.

After performing the above, if the “Low 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 / PERFUSION INDEX (PI)

Perfusion Index, or PI, is a relative assessment of the perfusion at the monitoring site. PI is displayed on a 10 segment LED bar, ranging from <1% (very weak perfusion) to >5% (strong perfusion). The lower two segments of the bar will turn red when the amplitude of the arterial pulsations are very low (weak perfusion). The highest LED will remain lit continuously to allow a PI level to be viewed.

The PI is shown as a "bouncing bar" indicator, where the peak of the bar coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Rad-57 locates the arterial pulsation. The pulse tone (when enabled) coincides with the peak of the PI bar.

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

ACTIONS TO BE TAKEN

If the 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) 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

BATTERY LEVEL INDICATOR

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

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

LOW BATTERY AUDIBLE ALARM

If a low battery condition occurs during patient monitoring, a low priority alarm will sound, and can be silenced for 120 seconds by pressing the Alarm Silence Button.

If a low battery condition occurs while not monitoring a patient, pressing the Alarm Silence Button will suspend the 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 unit for prolonged periods to enhance battery life.*

WARNING: FAILURE TO REPLACE BATTERIES PROMPLTY AFTER A LOW BATTERY ALARM MAY RESULT IN THE OXIMETER SHUTTING DOWN 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.

Normal patient monitoring

During normal operation, the Rad-57 Display shows oxygen saturation (as % $Sp0_2$) on the upper number and Pulse Rate (in beats per minute) on the lower number.

The carboxyhemoglobin saturation (%SpCO) and Perfusion Index (PI) are displayed on 10-LED bar displays.

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 display the numeric SpCO value for 10 seconds in place of the SpO_2 numeric value. Pressing the "Mode/Enter" or "Next" button during this 10-second period will return to the SpO_2 numeric value.
	Enters the Rad-57 setup/menu system. See Section 4, *Operation*.
	No function during normal patient monitoring.
	Push once to temporarily silence the alarm for 120 seconds. Push a second time to return the unit 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 opitons for each setting
	Power "on/off" button. Press this button to turn the unit on. Press-and-hold for 2 seconds to turn the unit off.

Setup menu

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

MENU NAVIGATION

The Rad-57 set-up and configuration options are accessed through the menu system. The *Mode/Enter* key is used to enter the menu system and to move through the different menu levels. Within each level of the system, the *Next* key is used to move from one option to the next. The *Up* and *Down* arrow keys are used to select values within each option. The parameter is set/selected when either the *Mode/Enter* or *Next* keys are pressed.

SETUP MENU LEVEL 1 – ALARM VOLUME

Push the Mode/Enter button to enter menu level 1.

	SETTING	
MODE 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 Mode/Enter button again to enter menu level 2.

	SETTING	
	SpO_2 Low Alarm Limit	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting.
NEXT	SpO_2 High Alarm Limit	
NEXT	Pulse Rate Low Alarm Limit	
NEXT	Pulse Rate High Alarm Limit	
NEXT	SpCO Low Alarm Limit	
NEXT	SpCO High Alarm Limit	

MODE ENTER 2X

SETUP MENU LEVEL 3 – AVERAGING AND SENSITIVITY

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

	SETTING	
	Sensitivity. **Hi** = Maximum **Nor** = Normal **APO** = APOD	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting. ***Note:*** *These changes affect SpO_2 monitoring only.*
NEXT	Averaging. The signal averaging time of this device can be set to: 2*, 4*, 8, 10, 12, 14 or 16 seconds	
NEXT	FastSat* On, Off	

MODE ENTER 3X

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

SETUP MENU LEVEL 4 - TREND SETTINGS

Push the Mode/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
MODE ENTER	Set Month	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting.
MODE ENTER	Set Day	
MODE ENTER	Set Year	
MODE ENTER	Set Hour	
MODE ENTER	Set Minute	

MODE ENTER 4X

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 fo the Trend Settings menu, the trend will <u>not</u> 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 Mode/Enter button again to enter menu level 5.

	SETTING	
	LED Display Brightness (4 levels) ***Note:*** *All LED indicators are illuminated while adjusting this setting.*	Use *Up* or *Down* Arrow Keys to adjust parameter to desired setting.
NEXT	Restore Factory Defaults	

MODE ENTER 5X

Pressing MODE ENTER a sixth time returns the Rad-57 to patient monitoring display in the Saturation/Pulse Rate Mode.

MENU TIMEOUT

Additionally, the Rad-57 will automatically return to patient monitoring display from any menu level/setting after a 10 seconds with no key presses.

POWER OFF

OFF – Press and hold 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

1. Turn the Rad-57 off.
2. Hold the Down  arrow key while turning the Rad-57 back on.
3. 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.
4. Push the Up  arrow to set the line frequency to 60 Hz and the Down  arrow to set it to 50 Hz.
5. Turn the unit off.

BUTTON	SETTING		
Hold  + press 	 5X	Enter Line Frequencey Menu	Use *Up or Down* Arrow Keys to adjust parameter to desired setting. ***Note:*** *The parameter is set/selected when the unit is turned off.*
	LF	Set Line Frequency	

Trend Setup and Use

INTRODUCTION

The Rad-57 can store 72 hours of SpO_2, Pulse Rate, SpCO 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 unit is shut off or when the batteries are replaced.

A special serial cable is required to connect the sensor connector of the Rad-57 to the PC. Patient monitoring is not possible while trend memory is being transferred to a PC.

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

TRENDCOM UTILITY INSTALLATION

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

TRENDCOM UTILITY OPERATION

1. Disconnect patient cable from the Rad-57.
2. Connect the mini-D end of the Rad-57 PRONTO serial cable to the Rad-57 patient cable connector (See Section 2, *Rad-57 front panel controls*) and connect the DB-9 end to a COM port on the PC.
3. Turn the Rad-57 on
4. Start the TrendCom Utility
5. Select the appropriate COM port number, if necessary.
6. Push the **RETRIEVE TREND** button on the TrendCom utility.
   Select the desired location and assign a filename for the trend file. Press **Save**.
7. The Rad-57 will display "dat out" while trend data is being transferred.
   A progress bar will advance to indicate the status of the download.
   Larger trend files will take longer to download. Transfer time is approximatly 20 seconds per hour of trend data.

   Note: *During download of trend information, all normal Rad-57 functions are unavailable and the keypad is locked, except for the power button.*
8. When trend data transfer is complete, close TrendCom and disconnect the Rad-57 from the Rad-57 PRONTO serial cable.
9. Turn the Rad-57 off to exit the trend download mode.

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

Note: *Enabling trend (setting Trend to "ON") will erase all trend information in the Rad-57.*

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 unit 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
SpO_2	001 to 100, or "---" meaning parameter not available
SpCO	001 to 099, or "---" meaning parameter not available
Pulse Rate	001 to 240, or "---" meaning parameter not available
Perfusion Index	00.00 to 20.00
Exception Messages	The exceptions are displayed as a 3 digit, ASCII encoded, hexadecimal value. The binary bits of the hexadecimal value are encoded as follows: 000 = Normal operation; no exceptions 001 = No Sensor 002 = Defective Sensor 004 = Low Perfusion 008 = Pulse Search 010 = Interference 020 = Sensor Off 040 = Ambient Light 080 = Unrecognized Sensor 100 = reserved 200 = reserved 400 = Low Signal IQ 800 = Masimo SET. This flag means the algorithm is running is full SET mode. It requires a SET sensor and needs to acquire some clean data for this flag to be set

SAMPLE TREND OUTPUT

```
07/21/04 09:56:08 SpO2=000 SpCO=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/04 09:56:10 SpO2=000 SpCO=000 PR=000 PI=00.00 EXC=828:Search,OffPat,SET
07/21/04 09:56:12 SpO2=097 SpCO=001 PR=069 PI=04.69 EXC=800:SET
07/21/04 09:56:14 SpO2=096 SpCO=001 PR=074 PI=02.28 EXC=C00:LowSigIQ,SET
07/21/04 09:56:16 SpO2=098 SpCO=001 PR=078 PI=03.64 EXC=800:SET
07/21/04 09:56:18 SpO2=000 SpCO=000 PR=000 PI=00.00 EXC=800:SET
07/21/04 09:56:20 SpO2=000 SpCO=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/04 09:56:22 SpO2=096 SpCO=001 PR=078 PI=02.68 EXC=800: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 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.

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

SETTING	RANGE
SpO_2 High Limit	The SpO_2 high alarm limit can be set anywhere between 2% and 100%, with a 1% step size. In the "----" (off) setting, the SpO_2 High Limit alarm is disabled.
SpO_2 Low Limit	The SpO_2 low alarm limit can be set anywhere between 1% and 100%, with a 1% step size. ***Note:** 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.*
Pulse Rate High Limit (BPM)	The pulse rate high alarm limit can be set anywhere between 30 BPM and 240 BPM, with a 5 BPM step size.
Pulse Rate Low Limit (BPM)	The pulse rate low alarm limit can be set anywhere between 25 BPM and 235 BPM, with a 5 BPM step size. ***Note:** The low alarm limit must always be 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 anywhere between 5% and 50%, with a 5% step size. In the "----" (off) setting, the SpCO High Limit Alarm is disabled. Factory default setting is 10%.
SpCO Low Limit	The SpCO low alarm limit can be set anywhere between 5% and 45%, with a 5% 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.*

ALARM SILENCE

Audible alarms may be suspended, while visual alarms may not. There are three audible alarm suspension settings, all controlled by the Alarm Silence Button. Repeated pressing the Alarm Silence Button will cycle though all three Alarm Silence options.

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.

ALARM SILENCED INDICATOR

The Alarm Silenced Indicator provides visual feedback regarding the audible alarm status. The audible alarms are muted when the indicator is 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 alarm indicator is off.

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

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

MESSAGES

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

Message conditions for the Rad-57 follow:

DISPLAY	TYPE	SOLUTION
SpO_2 NUMBER FLASHES	Saturation limit alarm	Assess /address patient condition. Re-set alarm limits if indicated.
PULSE RATE NUMBER FLASHES	Pulse Rate limit alarm	Assess /address patient condition. Re-set alarm limits if indicated.
	No Sensor Connected	Connect sensor to cable.
	Sensor off patient	1. Reattach sensor to patient. 2. Verify proper sensor placement.
LEDS FLASH HORIZONTAL BARS	Pulse Search	Wait for pulse detection. (This Search should occur whenever a sensor is first applied to a patient).
LOW SIQ INDICATOR FLASHES	Low SpO_2 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.*
% SpCO BAR GRAPH	Alarm Condition	Contunuously indicates the concentration of Carboxyhemoglobin in 5% increments. When an SpCO alarm is violated, the bargraph will flash the color of the SpCO level being violated along with an audible alarm. ***Note:*** *For a more accurate reading press the SpCO button.*
SINGLE BATTERY LEVEL INDICATOR FLASHES (WITH AUDIBLE ALARM)	Battery level too low	Replace batteries immediatly.

MESSAGES CONTINUED

DISPLAY	TYPE	SOLUTION
	No Cable Connected	Connect appropriate cable to unit.
	System Fault	Return for service. There are several error codes. All error codes require return of the unit to an authorized service center for repair. See Section 9, *Service and Repair*.
	Defective cable	Replace cable
 (Blinking)	Incompatible cable	Connect appropriate cable
	Defective sensor	Replace sensor
 (Blinking)	Unrecognized sensor	Connect appropriate cable

Troubleshooting

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

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
DIFFICULTY OR NO SpCO READING	Interference from line-frequency induced noise.	Minimize or eliminate interference from surgical or flourscent lighting. Verify/set 50/60hz menu setting. Refer to Section 3, *Initial Setup* for details.
	Inappropriate sensor	Verify use of an SpCO capable sensor. LNOP or LNCS or LNOPv sensors can not provide SpCO measurements.
	Excessive motion	Minimize or eliminate motion at the monitoring site. Also, see Section 4, *Successful Monitoring* for additional information.
UNIT DOES NOT POWER ON	Low battery	Check / replace battery
CONTINUOUS SPEAKER TONE	Internal Failure	Unit requires service. Press the Alarm Silence button. If alarm continues to sound, power down unit and remove batteries.
NO SPEAKER TONE	Pulse tone set to "mute" Alarm Silence Enabled	Press Up Arrow. Inspect Alarm Silence Indicator. See Section 4, *Alarm Silence*. Press Alarm Silence Button until Alarm Silence Indicator is no longer illuminated or flashing.
BUTTONS DON'T WORK WHEN PRESSED	Internal Failure	Return for service.

Rad-57 family specifications

PERFORMANCE

measurement range

Oxygen Saturation (%SpO_2):	1-100%
Carboxyhemoglobin Saturation (%SpCO)	1 - 99%
Pulse Rate (bpm):	25-240 beats per minute
Perfusion Index:	0.02 - 20%

ACCURACY

Oxygen Saturation Accuracy (%SpO_2) **during no motion conditions**[1]	
Adults, Pediatrics	70% - 100% ±2 digits
	1% - 69% unspecified
Neonate	70% - 100% ±3 digits
	1% - 69% unspecified
Oxygen Saturation Accuracy (%SpO_2) **during motion conditions**[2]	
Adults, Pediatrics[2]	70% - 100% ±2 digits
	1% - 69% unspecified
Neonate	70% - 100% ±3 digits
	1% - 69% unspecified
Carboxyhemoglobin Saturation Accuracy (%SpCO)[3,7]	1% - 40% ±3 digits
Pulse Rate (bpm) during no motion conditions[1]	
Adults, Pediatrics, Neonate	25 to 240 ±3 digits
Pulse Rate (bpm) during motion conditions[2]	
Adults, Pediatrics, Neonate	25 to 240 ±5 digits
Low Perfusion Performance[3]	
>0.02% Pulse Amplitude and	Oxygen Saturation (%SpO_2) ±2 digits
% transmission > 5%	Pulse Rate ±3 digits
Resolution	
Oxygen Saturation (%SpO_2)	1%
Carboxyhemoglobin saturation (%SpCO), digital display	1%
Carboxyhemoglobin saturation(%SpCO), continuous bar display	5%
Pulse Rate (bpm)	1 bpm

Interfering Substances

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

ELECTRICAL

Batteries

Type:	4 "AA" Alkaline[5]
Capacity:	over 8 hours[4]
Isolation:	No external power or ground connection, internally powered only.

ENVIRONMENTAL

Operating Temperature:	41°F to 104°F (5°C to 40°C)
Storage Temperature:	-40°F to 158s°F (-40°C to +70°C)[5]
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. (0.32 kg)

SpO_2 Modes

Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[6]
Sensitivity:	Normal, Maximum and APOD

Alarms

Audible and visual alarms for high low saturation and pulse rate
(SpO_2 range 1-100%, pulse rate range 25-240 bpm and SpCO %5 - %50)
Sensor condition, system failure and low battery alarms

High Priority:	571 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
Low Priority:	500Hz tone, 1 pulse, repeat time: 5s

Display/Indicators

Data display: %SpO_2, %SpCO, SpCO bar, pulse rate, alarm status, alarm silenced status, Perfusion Index (PI) / pleth bar, Low Signal IQ, battery status and SpCO connected.

Type:	LED
Display update rate	1 second

Compliance

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

1 Masimo Rainbow SET technology with LNOP, LNOPv and LNCS sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. 1% was added to account for the properties of fetal hemoglobin. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

2 Masimo Rainbow SET technology with LNOP, LNOPv and LNCS sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

3 Masimo Rainbow SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

4 This represents approximate run time at lowest indicator brightness, using a new, fully charged battery.

5 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.

6 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.

7 SpCO accuracy has been validated on healthy adult volunteers against a laboratory co-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpCO accuracy has not been validated under motion conditions.

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 for SpO_2 and SpCO 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. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO SENSORS.
- DO NOT REPROCESS ANY MASIMO SET PATIENT CABLES OR SINGLE USE SENSORS.
- 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 light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

SENSOR APPLICATION SITE

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). Rainbow sensors will only function with oximeter devices equipped with Masimo Rainbow SET Technology.

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

RAINBOW REUSABLE SENSORS

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

SENSOR	Weight Range	Saturation Accuracy No Motion	Saturation Accuracy Motion	Pulse Rate Accuracy No Motion	Pulse Rate Accuracy Motion	Low Perfusion Accuracy Saturation	Low Perfusion Accuracy Pulse Rate
Rainbow DC-I-DC	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3%

SpCO accuracy is specifed as ±3% under no motion conditions.

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 Cabels respectively. This will allow the Rad-57 to work as a Masimo SET pulse oximeter without the Carboxyhemoglobin measurement. When using one of these sensors, the front panel SpCO indicator will not be illuminated. See Section 2, *Rad-57 Front Panel Controls*.

Select the appropriate patient cable to attach the LNOP or LNCS sensor to the device.

RED REUSABLE SENSORS

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

SENSOR	Weight Range	Saturation Accuracy No Motion	Saturation Accuracy Motion	Pulse Rate Accuracy No Motion	Pulse Rate Accuracy Motion	Low Perfusion Accuracy Saturation	Low Perfusion Accuracy Pulse Rate
Red DC-I-DC	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3%

LNOP® REUSABLE SENSORS (LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy No Motion	Saturation Accuracy Motion	Pulse Rate Accuracy No Motion	Pulse Rate Accuracy Motion	Low Perfusion Accuracy Saturation	Low Perfusion Accuracy Pulse Rate
LNOP DC-I	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP DC-IP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Y-I	> 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 DCSC	> 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 No Motion	Saturation Accuracy Motion	Pulse Rate Accuracy No Motion	Pulse Rate Accuracy Motion	Low Perfusion Accuracy Saturation	Low Perfusion Accuracy 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	< 10 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP NeoPt	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Neo-L	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 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	± 3%	± 3 bpm

LNOP® SPECIALTY SENSORS (LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy No Motion	Saturation Accuracy Motion	Pulse Rate Accuracy No Motion	Pulse Rate Accuracy Motion	Low Perfusion Accuracy Saturation	Low Perfusion Accuracy Pulse Rate
LNOP Blue	3-20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Hi Fi Inf/Ped	3-10 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	10-30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Hi Fi Neo/Adult	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNCS™ REUSABLE SENSORS (LNCS sensors must be used in conjunction with Red LNC cables)

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

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

LNCS™ ADHESIVE SENSORS (LNCS sensors must be used in conjunction with Red LNC cables)

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

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

	Weight	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
SENSOR	Range	No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOPv In	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOPv Ne	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOPv Ad	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOPv Ne	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOPv Pd-L	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

SENSOR ACCURACY

Refer to Section 7, *Specifications* for SpO_2, SpCO 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%.

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

- LNOP single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.
- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

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

CAUTION: DO NOT REPROCESS ANY MASIMO SINGLE USE SENSORS.

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 DEVICE'S MATERIALS AND DEVICE FAILURE CAN RESULT.

Refer to Section 8, *Cleaning and Reuse of Masimo Reusable Sensors and Cables* for cleaning instructions of the sensor 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 device. The battery compartment is accessed from the back of the device. To replace the batteries first remove the battery cover by depressing the small rectangular button at the bottom of the cover, and sliding the cover down off the bottom of

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

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

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

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.

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 unit 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. 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 Mode/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 unit repaired.

Please clean contaminated/dirty equipment before returning, following the cleaning procedure described in Section 9, *Cleaning*. Make sure it is fully dry before packing the equipment.

To return the Rad-57 unit 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 include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the oximeter is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the oximeter has been decontaminated for bloodborne pathogens.

Return Rad-57 Pulse CO-Oximeter to the following shipping address:

Masimo Corporation
40 Parker
Irvine, California 92618
Tel.: 949-297-7000
Fax.: 949-297-7001

Warranty

Masimo warrants to the initial purchaser that each new Pulse CO-Oximeter will be free from defects in workmanship or materials for a period of one (1) year from the date of purchase. Masimo's sole obligation under this warranty is to repair or replace any product that Masimo deems to be covered under warranty with a repaired or a replacement Pulse CO-Oximeter.

Batteries are not warrantied.

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

Exclusions

This warranty does not extend to any product that has been subject to misuse, neglect or accident; that has been damaged by causes external to the Product; that has been used in violation of the operating instructions supplied with the product. The warranty does not extend to any product that has been connected to an unlicensed instrument system, modified accessories or any unit that has been disassembled or reassembled by anyone but an authorized Masimo agent.

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Accessories

PART NUMBER	DESCRIPTION
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
1842	Rubber protective boot, Grey
13158	Nylon protective carrying case.
13279	Rad-57 Operator's Manual, English
31002	Rad-57 Operator's Manual, French
31003	Rad-57 Operator's Manual, German
31004	Rad-57 Operator's Manual, Italian
31005	Rad-57 Operator's Manual, Spanish
31006	Rad-57 Operator's Manual, Swedish
31007	Rad-57 Operator's Manual, Dutch
31008	Rad-57 Operator's Manual, Danish
31009	Rad-57 Operator's Manual, Portuguese
31010	Rad-57 Operator's Manual, Chinese
31011	Rad-57 Operator's Manual, Japanese
13027	4-Pack, AA alkaline batteries

13279/3564C-1005

Masimo SET® Rainbow™

www.masimo.com

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