Rad-87™

Pulse CO-Oximeter

OPERATOR'S MANUAL

Oxyhemoglobin
Carboxyhemoglobin
Methemoglobin
Pulse Rate
parameters

and

Perfusion Index
Pleth Variability Index
measurements

Masimo®

Rad-87™

Pulse CO-Oximeter

OPERATOR'S MANUAL

The Rad-87 Operating Instructions provide the necessary information for proper operation of all models of the Rad-87 device. General knowledge of pulse CO-Oximetry and an understanding of the features and functions of the Rad-87 are a prerequisite for its proper use. Do not operate the Rad-87 without completely reading and understanding the instructions in this manual.

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

CAUTION:
Federal law (U.S.) restricts this device to sale by or on the order of a physician.

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CONFORMS TO UL STD 60601-1, UL STD 763,
UL STD 963 AND NSF STD 12;
CERTIFIED TO CAN/CSA STD C22.2 NO. 601.1

3149433

CE 0123

Covered by one or more of the following U.S. Patents: RE38,492, RE38,476, 7,221,971, 7,215,986, 7,215,984, 7,186,966, 6,979,812, 6,861,639, 6,850,787, 6,826,419, 6,816,741, 6,745,060, 6,699,194, 6,684,090, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,515,273, 6,501,975, 6,463,311, 6,430,525, 6,388,240, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,157,850, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international equivalents, or one or more of the patents referenced at www.masimo.com/patents.htm. Other patents pending.

SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

The Rad-87 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 Rad-87 in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- High intensity extreme lights (including pulsating strobe lights) directed on the sensor, may not allow the Pulse CO-Oximeter to obtain readings.
- The Rad-87 is NOT intended for use as an apnea monitor.
- The 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.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- The Rad-87 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 Rad-87 device. 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 Rad-87 or accessories in any position that might cause it to fall on the patient. Do not lift the Rad-87 by the power cord or any other cable.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter can not measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.
  - For increased COHb: COHb levels above normal tend to increase the level of SpO_2. 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 SpO_2. 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.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 and SpCO measurements.
- Elevated levels of Carboxyhemoglobin (COHb) will lead to inaccurate SpO_2 measurements.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO_2, SpMet and SpCO measurements.

- Motion artifact may lead to inaccurate SpMet and SpCO measurements.
- Very low arterial Oxygen Saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements.
- Severe anemia may cause erroneous SpO_2 readings.
- Do not use the Rad-87 or sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Rad-87 may affect the MRI image and the MRI device may affect the accuracy of the Pulse CO-Oximetry parameters and measurements.
- If using Rad-87 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 device might read zero for the duration of the active radiation period.
- For home use, ensure that the Rad-87's alarm can be heard from other rooms in the house especially when noisy appliances such as vacuum cleaners, dishwashers, clothes dryers, televisions, or radios are operating.
- Always remove the sensor from the patient and completely disconnect the patient from the Rad-87 before bathing the patient.
- Additional information specific to Masimo sensors including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's Directions For Use (DFU).
- Do not place the Rad-87 where the controls can be changed by the patient.
- Do not place the Rad-87's face against a surface. This will cause the alarm to be muffled.
- Do not place the Rad-87 on electrical equipment that may affect the Pulse CO-Oximeter, preventing it from working properly.
- Do not expose the Rad-87 to excessive moisture such as direct exposure to rain. Excessive moisture can cause the device to perform inaccurately or fail.
- Do not place containers with liquids on or near the Rad-87. Liquids spilled on the device may cause it to perform inaccurately or fail.
- Failure of Operation - If the Rad-87 fails any part of the setup procedures or leakage tests, remove the device from operation until qualified service personnel have corrected the situation.
- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- The Rad-87 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 and Class B digital device, Part 15, FCC Rules/USA. 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.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer for help.

- In order to connect wirelessly to a compatible interface system like Patient SafetyNet, the Rad-87 should be placed in an environment free from RF shielding, which could hinder wireless reception.
- To minimize radio interference, other electrical equipment that emits RF transmissions should not be in close proximity to the RAD-87.
- Changes or modifications to the wireless radio feature whether intentional or unintentional are prohibited without written approval from Masimo Corporation.
- The Rad-87 (device with optional radio) transmits real-time sensor connectivity status indicating a connect and/or disconnect state. If the device is in a failure mode then the radio power is disabled and an error message is indicated on the device display. The device does not have a powered state where no information is transmitted.
- In accordance with FCC requirements, the Rad-87 (device with optional radio) must be placed greater then 20 cm from the patient's head.
- In accordance with FCC requirements, radio accessories on the Rad-87 (device with optional radio) cannot be attached directly to the patient using any accessory containing metal components.
- 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.
- The battery should be adequately charged to ensure backup power in case of AC power disruption.
- A functional tester cannot be utilized to assess the accuracy of the Pulse CO-Oximeter or any sensors.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- Ensure the speaker is not covered or the device is placed face-down on bedding or other sound absorbing surface.
- 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.
  - Always turn off and disconnect the power cord from the AC power supply before cleaning the device.
  - Use cleaning solutions sparingly.

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SECTION 4 - OPERATION - (CONTINUED)

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SECTION 10 - PART NUMBERS

About This Manual

This manual explains how to set up and use the Rad-87 Pulse CO-Oximeter containing Masimo Rainbow SET technology. Important safety information relating to general use of the Rad-87 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 Rad-87 Pulse CO-Oximeter.

SECTION 2 **SYSTEM DESCRIPTION** describes the Rad-87 Pulse CO-Oximeter system and its functions and features.

SECTION 3 **SETUP** describes how to setup the Rad-87 Pulse CO-Oximeter for use.

SECTION 4 **OPERATION** describes the operation of the Rad-87 Pulse CO-Oximeter system.

SECTION 5 **ALARMS AND MESSAGES** describes the alarm system messages.

SECTION 6 **TROUBLESHOOTING** describes troubleshooting information.

SECTION 7 **SPECIFICATIONS** gives the detailed specifications of the Rad-87 Pulse CO-Oximeter.

SECTION 8 **SENSORS AND PATIENT CABLES** outlines how to use and care for Masimo Rainbow SET technology sensors, Masimo Rainbow SET technology patient cables, Masimo Red sensors and, Masimo Red PC cables.

SECTION 9 **SERVICE AND MAINTENANCE** describes how to maintain, service and obtain repair for the Rad-87 Pulse CO-Oximeter.

SECTION 10 **PART NUMBERS** lists the available models of the Rad-87 Pulse CO-Oximeter.

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-87 Pulse CO-Oximeter Monitor is a noninvasive, arterial oxygen, carboxyhemoglobin and methemoglobin saturation, and pulse rate monitor. The Rad-87 features a multicolored LED display that continuously displays numeric values for SpO_2, SpCO®*, SpMet™*, perfusion index (PI), pleth variability index* (PVI) and pulse rate. It also provides bar graph displays for quick visual identification of Signal Identification Quality (SIQ®), perfusion index and pleth variability index.

The Rad-87 is available in four models: vertical Rad-87, horizontal Rad-87, vertical Rad-87 with radio and horizontal Rad-87 with radio.

*Optional features: SpCO, SpMet, PVI

FEATURES

These features are common to Rad-87 monitors:

- Masimo SET is clinically proven to be the highest sensitivity and specificity pulse oximeter technology in the world.
- Rainbow technology continuously and noninvasively measures arterial oxygen saturation (SpO_2) and pulse rate (BPM), as well as providing a reliable probe-off detection.
- Perfusion Index (PI) with trending capability indicates arterial pulse signal strength during low perfusion.
- Accurate on cyanotic infants with congenital heart disease when used with an LNOP® Blue Sensor.
- Signal IQ® provides signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat® tracks rapid changes in arterial O_2 saturation with high fidelity.
- Variable pitch provides tonal variance for every 1% change in saturation.
- Remote alarming interface.
- Up to 72 hours of trending. (See Section 4, *Trends Setup and Use*.)
- Allows user to customize the default settings and set the device to retain these settings through a power off/on cycle.
- The LCD Display allows the user to view a scrolling marque of (installed) parameter/measurement alarm limits, system information, and wireless radio communication (wireless radio model only).

OPTIONAL FEATURES

- Rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (SpCO), methemoglobin (SpMet), as well as providing a reliable probe-off detection.
- Pleth Variability Index (PVI) may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions. [1]
- Provides a 802.11a/b/g wireless radio which interfaces with compatible systems (wireless radio model only).
- Ability to connect to Masimo Patient SafetyNet through a wireless network (wireless radio model only).

[1] The utility of PVI is unknown at this time and requires further clinical studies. Technical factors that may affect PVI include probe malposition and patient motion.

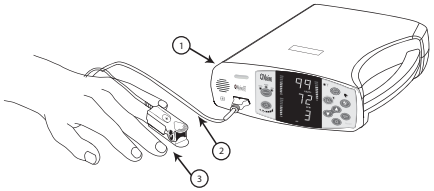
INDICATIONS FOR USE

The Rad-87 Pulse CO-Oximeter and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), carboxyhemoglobin and methemoglobin concentration expressed in percentage (SpCO and SpMet) and pulse rate (measured by an SpO_2 sensor). The Rad-87 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, who are well or poorly perfused patients in hospitals, hospital-type facilities, mobile and home environments.

Pulse CO-Oximetry

SpO_2 GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and noninvasive 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 is connected to the Pulse CO-Oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The following figure shows the general monitoring setup.



1. Instrument
2. Patient Cable
3. Sensor

SpCO GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carboxyhemoglobin (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 instrument displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

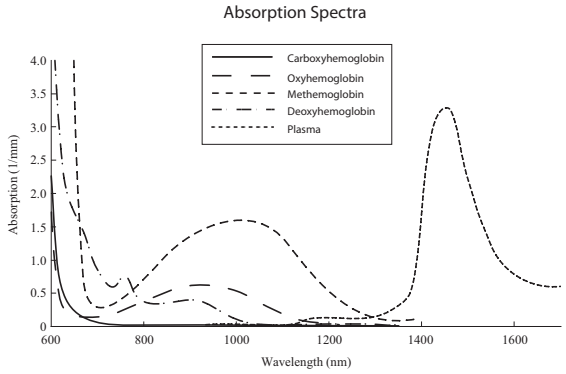
SpMet GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and noninvasive 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 instrument displays the calculated data as percentage value for the SpMet.

PRINCIPLE OF OPERATION

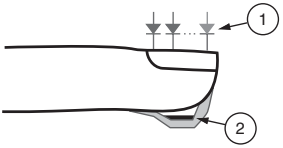
Pulse CO-Oximetry is governed by the following principles:

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-87 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-87 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 1400nm) 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-87 for calculation.



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

PRINCIPLE OF OPERATION - (CONTINUED)

Once the Rad-87 receives the signal from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional arterial oxygen saturation, 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 and methemoglobin in arterial blood. In an ambient temperature of 35º C the maximum skin surface temperature has been measured at less than 106º F (41º C), verified by Masimo sensor skin temperature test procedure.

FUNCTIONAL SATURATION

The Rad-87 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 and methemoglobin are not capable of transporting oxygen, but is recognized as oxygenated hemoglobin by conventional pulse oximetry.

RAD-87 vs. DRAWN WHOLE BLOOD MEASUREMENTS

When SpO_2, SpCO and SpMet measurements obtained from the Rad-87 (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-87 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 abnormal (greater than 2% for methemoglobin concentration). 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 SIGNAL EXTRACTION TECHNOLOGY (SET) FOR SpO_2 MEASUREMENTS

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

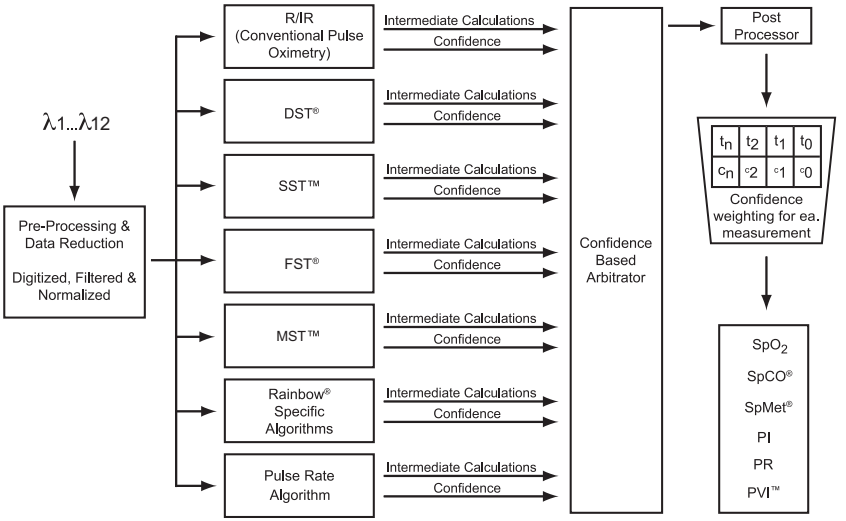
The Rad-87 displays measurements of SpCO and SpMet during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive motion. When the Rad-87 does not have confidence in the value of a parameter due to poor signal quality caused by excessive motion or other signal interference, the measurement for the parameter will alternate with "---".

FASTSAT

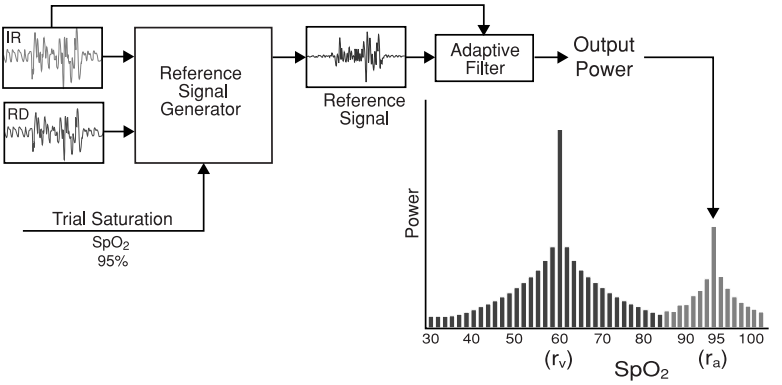
FastSat enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend. When the Rad-87 is set to FastSat "On", the averaging algorithm evaluates all the saturation values providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat, the averaging time is dependent on the input signal.

MASIMO RAINBOW SET PARALLEL ENGINES

This figure is for conceptual purposes only.



MASIMO SET DST

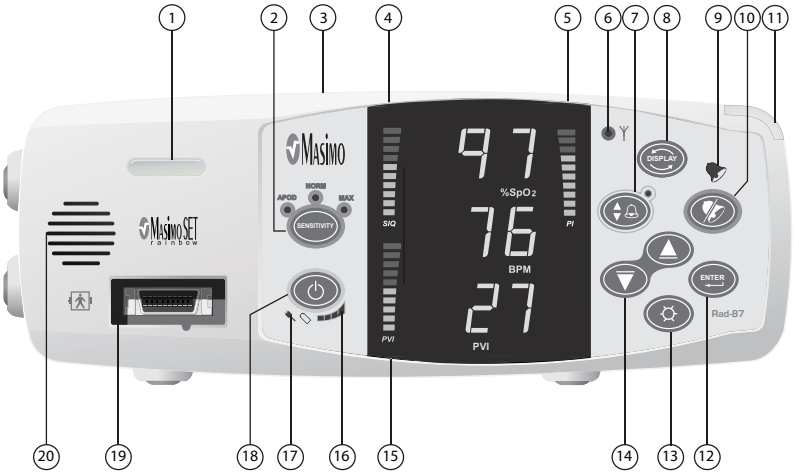


Introduction

The Rad-87 Pulse CO-Oximeters are full featured devices designed for ease of operation. All pulse CO-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. The sensor cable connections are located on the left side of the front panel for the Rad-87 horizontal device and the bottom of the front panel for the Rad-87 vertical device.

- Rad-87 offers full Masimo SET technology in a small compact device
- Rad-87 supports the full line of Masimo sensors and patient cables (see Section 8, **Sensors and Patient Cables**)
- Rad-87 supports standardization of sensors, and pulse CO-Oximetry technology throughout the hospital
- The LCD Display identifies system settings, monitoring modes, alarm limits and information from Patient SafetyNet or Philips VueLink (when connected). The LCD is located on top of the device (Horizontal) or on the left of the device (Vertical).

RAD-87 PULSE CO-OXIMETER - HORIZONTAL

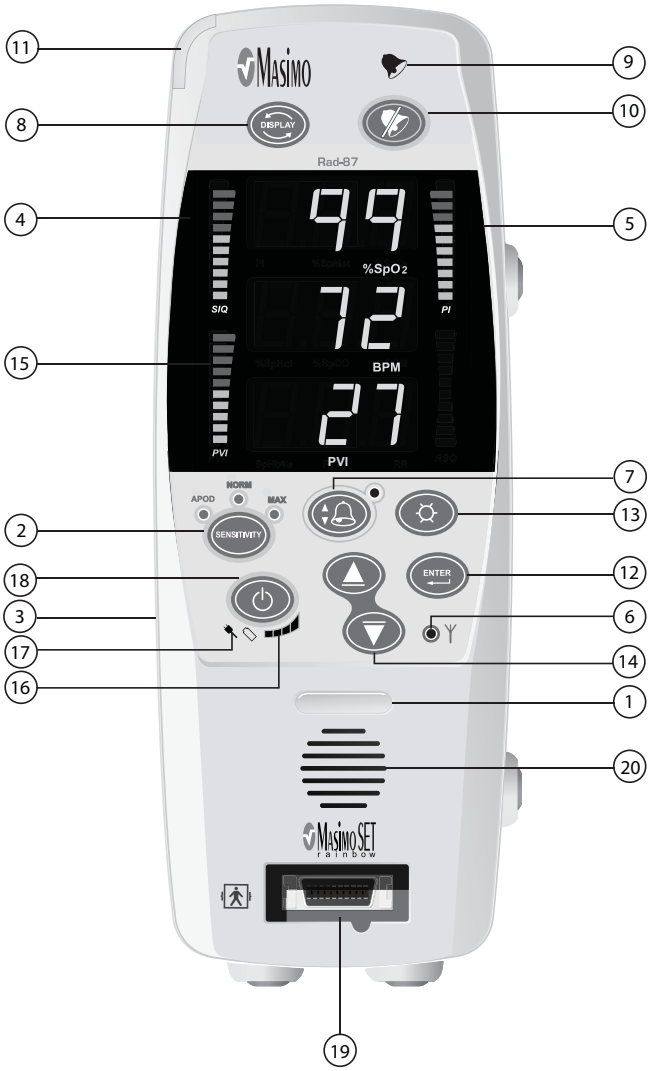


	CONTROL / INDICATOR		DESCRIPTION
1	Device Profile LED		The Device Profile LED illuminates when the device has been set to user configured "default" settings. Upon power up, the user configured default settings are retained and the Device Profile LED remain lit. When user configured default settings are active, any changes to the default settings cause the Device Profile LED to turn off until the device is returned to the user configured default settings or powered off.
2	Sensitivity Button/Indicator		Used to set the device into Maximum Sensitivity, Normal Sensitivity, or APOD Mode.
3	LCD Display		The LCD display identifies system settings, monitoring modes, alarm limits, and information from Patient SafetyNet or Philips VueLink (when connected.)
4	Signal IQ Index		The Signal IQ provides an indication of the quality of the acquired signal as well as the timing of the pulse. A green vertical LED bar rises and falls with the pulse, where the height of the bar indicates the quality of the signal.
5	Perfusion Index		The Perfusion Index provides an indication of the percentage of pulsatile signal to non pulsatile signal.

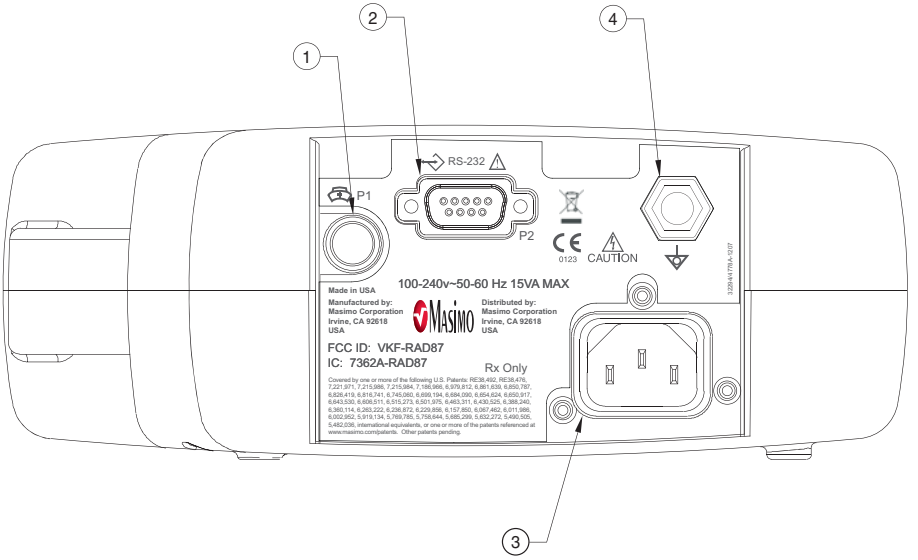
	CONTROL / INDICATOR		DESCRIPTION
6	Wireless Indicator		Off: No connection to Masimo Patient SafetyNet or other compatible interface system. Flashing Green: Rad-87 attempts to connect to Patient SafetyNet or other compatible interface system. Solid Green: Rad-87 is connected to the Patient SafetyNet or other compatible interface system.
7	Alarm Limits Button		Used to enter the alarm menu to adjust Hi/Low SpO_2, SpCO, SpMet, PI, PVI and pulse rate alarm limits. The LED indicator (located above the Alarm Limits Button) will illuminate when one or more of the factory default alarm settings is changed to alert the user to verify alarm settings.
8	Display Button		Allows movement through the 3 different display screens to view sets of parameters and measurements. Also used to exit setup menu screens and return the display to Screen 1. Press and hold the button down for 5 seconds to scroll through device settings on the LCD Display.
9	Alarm Bell		The Alarm Bell flashes red to indicate a high priority alarm.
10	Alarm Silence Button		Press the Alarm Silence Button to temporarily silence patient and low battery alarms. Press the Alarm Silence Button when the "SEN OFF" message is flashing (i.e. the sensor is removed from the patient) to acknowledge the end of monitoring. In this state, all further alarms are silenced until the Pulse CO-Oximeter starts measuring patient parameters/measurements again. ***NOTE:*** *The alarm silence time can be set for 120, 90, 60 and 30 seconds. See Section 4* - Setup Menu Level 2.
11	System Status Light		**Solid Green:** Collecting data, no alarms **Solid Yellow:** 1. Low priority alarms 2. Not monitoring and no alarms 3. Sleep Mode 4. Interface Alarms "Off" **Flashing Yellow:** 1. Low parameter/measurement confidence 2. Medium priority alarms **Flashing Red:** High priority alarms

	CONTROL / INDICATOR		DESCRIPTION
⑫	Enter Button		Used to enter the setup menus and to select/activate certain entries within the menu/setup system.
⑬	Brightness Button		Controls the level of the brightness for the LED display by providing 4 levels of brightness. Each press of the button increases the brightness one level. Once level 4 is accessed, an additional press of the button returns the brightness to level 1. Press the Enter Button to select brightness level.
⑭	Up Button Down Button		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 or the numeric value for the parameter/measurement alarm feature. *Pressing and holding down these buttons allow for the rapid scrolling of alarm limits.*
⑮	Pleth Variability Index		PVI is displayed as a percentage. The lower the height of the bar, the less variability there is in the PI over a respiratory cycle. Press the Display key to toggle to the PVI numeric measurement.
⑯	Battery Charge Level Indicator		Provides a visual representation of the battery charge status. When unplugged, bars illuminate to indicate full battery charge. As the battery discharges power, bar illumination decreases from right to left. A low battery status is indicated by a low audible beep and the first battery bar to the left flashing green.
⑰	AC Power Indicator		The AC Power Indicator is illuminated when the Rad-87 is connected to AC power and during battery charging.
⑱	Power Button		Used to turn the device on and off. Press the button once to power on the device. Press the button for 2 seconds to power off the device.
⑲	Pulse CO-Oximeter Patient Cable Connector		Connects to a Masimo Pulse CO-Oximeter sensor or Masimo Pulse CO-Oximeter Patient Cable with a sensor.
⑳	Speaker		Provides audible indication of alarm conditions, pulse tone and feedback for key-presses.

RAD-87 PULSE CO-OXIMETER - VERTICAL



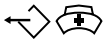
RAD-87 REAR PANEL



1	**NURSE CALL CONNECTOR**	Use the 1/4" round Connector to interface with a nurse call system. This is a stereo output and should be utilized with a stereo cable. All external device connections to the Nurse Call Connector must be IEC-60950 compliant.
2	**SERIAL OUTPUT CONNECTOR**	Use the Serial Output Connector to connect a serial device, including a serial printer, RadNet Interface Module, Patient SafetyNet or PC, to the Rad-87. See Section 7, *Output Interface Specifications*. All external device connections to the Serial Output Connector must be IEC-60950 compliant.
3	**POWER ENTRY MODULE**	The power entry module contains the input connector for AC power. The AC input provides power to the system from the AC line. Always connect the Rad-87 to the main power for continuous operation and/or battery recharging.
4	**EQUIPOTENTIAL GROUND CONNECTOR**	Use the Equipotential Ground Connector for grounding.

SYMBOLS

The following symbols are found on the Rad-87 or packaging and are defined below:

SYMBOLS	DEFINITION
 RS-232	RS-232
	Equipotential Ground Terminal
	Consult accompanying documents
	Nurse Call Interface
	WEEE compliant
CE 0123	Mark of Conformity to European Medical Device Directive 93/42/EEC
R_X Only	Federal law restricts this device to sale by or on the order of a physician (USA audiences only)
	Year of manufacture
	Storage humidity range: 5% to 95%
	Storage temperature range: +70˚C to -40˚C Storage altitude range: +1600hPa to +500hPa
	Keep dry
	Fragile/breakable, handle with care
	Indicates wireless Radio signal (wireless radio model only)
EC REP	EU authorized representative
	Defibrillation Proof Type BF
	Caution
FCC ID: VKF-RAD87	Federal Communications Commission (FCC) licensing (wireless radio model only)
IC ID: 7362A-RAD87	Industry Canada licensing (wireless radio model only)

LCD DISPLAY

The LCD Display shows radio communication information when radio communication is active (wireless radio model only). It also shows system information. All Rad-87 models are equipped with a LCD display which is located on the top panel of a horizontal model, or on the left side panel of a vertical model.

The LCD Display illuminates upon start up and displays the installed parameter's/measurement's low and high alarm limits. Once the Rad-87 completes system initiation, the display light turns off. As the front panel buttons are pressed, each menu selection is shown on the LCD Display.

When Rad-87 actively communicates with another system using the radio feature, the LCD Display shows the following:

- Patient SafetyNet: The LCD Display shows the information sent from the Patient SafetyNet to the Rad-87.
- Philips VueLink: The LCD Display shows "VueLink Conn" and "SpO_2 & PR AL On" or "SpO_2 & PR AL Off".

NOTE: *When the Rad-87 is interfaced to the Philips VueLink and the LCD Display shows "SpO_2 & PR AL On", SpO_2 and BPM audible alarms are active at the device and patient monitor. When the LCD Display shows "SpO_2 & PR AL Off", SpO_2 and BPM audible alarms are inactive at the device but active at the patient monitor.*

Additionally, if the Display Button is pressed down for 5 seconds, the LCD Display shows the following settings three times and then returns to the default screen. The display cycle can be interrupted by pressing any button except for the Sensitivity or the Alarm Silence Buttons.

- System Settings
- Monitoring Mode: Normal, Sleep or Home
- Installed parameter/measurement's low and high alarm limits
- Audible Alarm
- Alarm Volume
- Alarm Silence
- Alarm Delay
- Rapid Desat
- Sensitivity
- Averaging Time

Introduction

Before the Rad-87 Pulse CO-Oximeter can be used in a clinical setting, it needs to be inspected, properly setup and the batteries need to be fully charged.

Unpacking and inspection

Remove the instrument from the shipping carton and examine it for signs of shipping damage. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier. If anything is missing or damaged, contact the Technical Service Department. The contact address and phone numbers are listed in Section 9, *Service and Repair*.

Preparation for monitoring

The following sections of the manual describe the preparation, set-up and initial installation of the Rad-87 Pulse CO-Oximeter.

RAD-87 POWER REQUIREMENTS

Always use a hospital grade, AC power cable to connect the Rad-87 to an AC power source.

CAUTION: DO NOT CONNECT THE RAD-87 TO AN AC OUTLET CONTROLLED BY A SWITCH.

Verify the AC power voltage and frequency before use. Verify that the power source can provide adequate power rating as indicated on the rear panel of the Rad-87.

The Rad-87 is designed to operate on 100 to 240VAC, 47-83 Hz. The device is rated at 15 VA max.

Connect a hospital grade power cable to the power entry module of the Rad-87 device(IEC-320 connector type at the device). Connect the power cable to an AC power source. Ensure that the device is adequately powered by verifying that the AC power indicator on the Rad-87 is illuminated.

CAUTION:

- CONNECT THE RAD-87 ONLY TO A HOSPITAL-GRADE RECEPTACLE (FOR HOSPITAL USE).
- DO NOT UNDER ANY CIRCUMSTANCES REMOVE THE GROUNDING CONDUCTOR FROM THE POWER PLUG.
- DO NOT USE EXTENSION CORDS OR ADAPTERS OF ANY TYPE. THE POWER CORD AND PLUG MUST BE INTACT AND UNDAMAGED.
- USE THE POWER CORD AS THE MEANS TO DISCONNECT THE DEVICE FROM THE MAINS POWER SUPPLY.

RAD-87 POWER REQUIREMENTS (CONTINUED)

- IF THERE IS ANY DOUBT ABOUT THE INTEGRITY OF THE PROTECTIVE EARTH CONDUCTOR ARRANGEMENT, OPERATE THE RAD-87 ON INTERNAL BATTERY POWER UNTIL THE AC POWER SUPPLY PROTECTIVE CONDUCTOR IS FULLY FUNCTIONAL.
- TO ENSURE PATIENT ELECTRICAL ISOLATION, CONNECT ONLY TO OTHER EQUIPMENT WITH ELECTRICALLY ISOLATED CIRCUITS.
- DO NOT CONNECT TO AN ELECTRICAL OUTLET CONTROLLED BY A WALL SWITCH OR DIMMER.

INITIAL BATTERY CHARGING

Before use, the Rad-87 battery needs to be fully charged.

To charge the internal battery, connect the AC power cord to an AC outlet and to the Power Entry Module located on the back of the Rad-87. The AC Power Indicator illuminates. The AC Power Indicator will remain illuminated while the battery is charging. The Battery Charge Level Indicator will not be illuminated unless the unit is operating on battery power. Once the battery is fully charged, the device has approximately 4 hours of battery life.

INITIAL INSTALLATION

Place the Rad-87 on a stable hard flat surface near the patient. Always place the Rad-87 on a dry surface. Maintain a minimum of 1 inch (2.54 cm) free space around the device. Make sure that Rad-87 loudspeaker is not covered to avoid a muffled alarm sound.

The Rad-87 should not be operated outside the following environmental conditions:

OPERATING ENVIRONMENTAL CONDITIONS	
TEMPERATURE	+5°C to +40°C, +41°F to +104°F
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)

Configure the Rad-87 for your regional power line frequency (50 or 60 hz) if needed. Default is 60 hz (standard for the United States). See Section 4, *Operation, Setup menu Level 3, Line Frequency.*

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

CAUTION: THE BATTERY SHOULD BE ADEQUATELY CHARGED TO ENSURE BACK-UP POWER IN CASE OF AC POWER DISRUPTION.

Introduction

To operate the Rad-87 system effectively, the device must be set up correctly and the operator must:

- Know how the Rad-87 derives its readings (see Section 1).
- Be familiar with its controls, components and operation.
- Understand its status and alarm messages (see Section 5, **Alarm and Messages** and Section 6, **Troubleshooting**).

Basic operation

GENERAL SETUP AND USE

1. Inspect the Rad-87 case for damage.
2. Connect a patient cable or a direct connect sensor to the Rad-87 device. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
3. If utilizing a patient cable, select a sensor that is compatible with the Rad-87 and the patient before connecting it to the patient cable. See section 8, **Sensors and Patient Cables**. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the detector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
4. Refer to the Directions for Use of the sensor before attaching the sensor to the patient.
5. Attach the sensor to the Patient. With a Masimo Pulse CO-Oximetry sensor, connect the sensor to the patient cable with the logos lining up; make sure it is a firm connection.
6. Press the Power button to turn the Rad-87 on.
7. Verify all front-panel indicators momentarily illuminate and a tone is heard.

   NOTE: *The number "0" scrolls across the screen as the system calibrates and obtains patient data (approximately 20 seconds).*
8. Verify the front-panel display is free of alarm and system failure messages (see Section 5, **Alarms and Messages**).
9. Verify the LED and the LCD displays shows the following (see **Setup Menu Level 1;** *Parameter/Measurement Alarm Limits - Screen 1, Parameter/Measurement Alarm Limits - Screen 2, Parameter/Measurement Alarm Limits - Screen 3,* and **Setup Menu Level 3;** *Set Mode* located in this chapter):
   - Mode setting: Standard (Std) or Sleep (SLP) or Home (Hnn),
   - SpO_2 Low Alarm Limit and SpO_2 High Alarm Limit,
   - Pulse Rate Low Alarm Limit and Pulse Rate High Alarm Limit,

GENERAL SETUP AND USE (CONTINUED)

- PVI Low Alarm Limit and PVI High Alarm Limit.
- PI Low Alarm Limit and PI High Alarm Limit,
- SpCO Low Alarm Limit and SpCO High Alarm Limit,
- SpMet Low Alarm Limit and SpMet High Alarm Limit,

10. On the LED and the LCD displays, verify the alarm limit settings (see **Setup Menu Level 1,** *Parameter/Measurement Alarm Limits - Screen 1, Parameter/ Measurement Alarm Limits - Screen 2, Parameter/Measurement Alarm Limits - Screen 3* in this chapter).

NOTE: *The number "0" scrolls across the screen as the system calibrates and obtains patient data (approximately 20 seconds).*

11. Verify that the patient alarms are functional by setting the high and low alarm limits beyond the patient readings (see **Setup Menu Level 1,** *Parameter/Measurement Alarm Limits - Screen 1, Parameter/Measurement Alarm Limits - Screen 2, Parameter/Measurement Alarm Limits - Screen 3* in this chapter).
    - An alarm tone sounds.
    - The Alarm Bell flashes red for high priority alarms.
    - The System Status Light flashes red for high priority alarms, flashes yellow for medium priority alarms and is solid yellow for low priority alarms.
    - The number value and parameter/measurement label for the violated alarm limit will flash on the LED display.
12. Verify the sensor alarms are functional.
    - Remove the sensor from the sensor site.
    - The alarm tone sounds.
    - The Alarm Bell flashes red.
    - The System Status Light flashes red.
    - The display shows "SEN OFF" message.

Disconnect the sensor from the patient cable or Rad-87.

- The alarm tone sounds.
- The Alarm Bell flashes red.
- The System Status Light flashes red.
- The display shows "NO SEN" message.

NOTE: *"NO SEN" or "SEN OFF" conditions will only generate a high priority alarm if the Rad-87 is actively monitoring a patient when the sensor or cable is disconnected.*

GENERAL SETUP AND USE (CONTINUED)

13. Verify that the audible alarm can be silenced when a parameter/measurement alarm is exceeded.
    - Create an alarm condition by lowering the high alarm limit for the pulse rate so that it is lower than the patient value.
    - Press the Alarm Silence button.
    - The alarm tone ceases for 120 seconds (default).
    - The Alarm Bell flashes red for a high pulse rate (high priority alarm).
    - The System Status Light flashes red.
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 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 local laws. See the Directions for Use of the sensor.
18. Press and hold the Power Button for 2 seconds to turn the Rad-87 off [3 seconds in the Home Mode].

DEFAULT SETTINGS

The Rad-87 Pulse CO-Oximeter stores two types of default values that the device automatically retains after a power cycle.

1. Factory defaults set by Masimo.
2. Default settings that can be changed by the user which will be remembered after a power cycle.

FACTORY DEFAULT AND USER CONFIGURABLE SETTINGS

OPTION	FACTORY DEFAULTS	USER CONFIGURABLE DEFAULTS
SpO_2 high alarm limit	"---" Off	2 to 99%, then "---"
SpO_2 low alarm limit	90%	1 to 98%
Pulse rate high alarm limit	140 BPM	35 to 235 BPM
Pulse rate low alarm limit	50 BPM	30 to 230 BPM
SpCO high alarm limit	10	2 to 98, then "---"
SpCO low alarm limit	"---" Off	"---", then 1 to 97
SpMet high alarm limit	3	1 to 99.5, then "---"
SpMet low alarm limit	"---" Off	"---", then .1 to 99
PI high alarm limit	"---" Off	0.04 to 19, then "---"
PI low alarm limit	"---" Off	"---", then 0.03 to 18
PVI high alarm limit	"---" Off	2 to 99, then "---"
PVI low alarm limit	"---" Off	"---", then 1 to 98
Sensitivity	APOD	Max/Normal/APOD ***NOTE:*** *MAX sensitivity will default to APOD after a power cycle.*
Display brightness	Level 2	Levels 1 thru 4
Pulse tone volume	Level 2	Off, Levels 1 thru 3
Alarm Silence Time	120 seconds	30, 60, 90, or 120 seconds
Alarm Volume	Level 3, 70 db min	Levels 1 thru 4, 87 db max
Monitoring Mode	Standard (Normal)	Standard, Sleep, Home
Audible Alarm Off	Alarms active (On)	"On/Off or muted with reminder"
Alarm Delay	5 sec	0, 5, 10, or 15 seconds
Rapid Desat Alarm	5%	5, 10, Off
Serial out	ASCII 2	Philips/ASCII 1/ASCII 2
Interface Alarm	Alarm	Alarm, Off/On
Nurse Call Type	Alarm	Alarm and Signal IQ/ Low Signal IQ/ Alarm
Nurse Call Polarity	Normal	Normal/Invert
Line Frequency	60 Hz	60 Hz, 50 Hz
Averaging time	8 sec	2, 4, 8, 10, 12, 14, 16
SmartTone	Off	On/Off
FastSat	Off	Not Customer Configurable ***NOTE:*** *Defaults to Off after a power cycle.*
Device Profile settings	Light blue	Light blue (Default), purple, dark purple, teal, pink or light pink
LCD Language	English	English (Default) French, German, Italian, Spanish, Swedish, Dutch, Danish, Portuguese
PVI Bar	On	On/Off

Successful Monitoring

The following general points will aid in ensuring monitoring success.

- Place the sensor on a site that has sufficient perfusion and provides proper alignment of the LED's and detector.
- 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 (electro-surgical device, for example).
- Read the sensor Directions for Use for proper sensor application.

MASIMO PULSE CO-OXIMETRY SENSORS

Before use, carefully read the Masimo sensor Directions for Use.

Use only Masimo sensors for pulse oximetry or pulse CO-Oximetry measurements.

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

CAUTIONS

- DO NOT USE DAMAGED SENSORS. DO NOT USE 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 IN THE SENSOR DIRECTIONS FOR USE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR ALL MASIMO REUSABLE SENSORS.
- DO NOT USE DAMAGED PATIENT CABLES. DO NOT IMMERSE THE PATIENT CABLES IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE PATIENT CABLE CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE.
- DO NOT 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 confidence in 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 device and reduce the measured variations of SpO_2. Inaccurate measurements may be caused by:

- Elevated levels of Carboxyhemoglobin
- Elevated levels of Methemoglobin
- Severe anemia
- Elevated Total Bilirubin levels
- Low arterial perfusion
- Motion artifact

NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Rad-87 Pulse CO-Oximeter may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed on the Rad-87 to be significantly different than the ECG heart rate.

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 measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the arterial oxygen saturation, blood concentration and perfusion.

Inaccurate measurements may be caused by:

- Levels of methemoglobin approximately 1.5% or above.
- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal hemoglobin levels.
- Low arterial perfusion.
- Low arterial oxygen saturation levels.
- Elevated Total Bilirubin levels.
- Motion artifact.

NUMERIC DISPLAY - SpMet

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

Inaccurate measurements may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue.
- Low arterial perfusion.
- Low arterial oxygen saturation levels.
- Elevated Total Bilirubin levels.
- Motion artifact.

NUMERIC DISPLAY - PI

The perfusion index (PI) display and bar graph indicator provide a relative numeric indication of the pulse strength at the monitoring site. It is a calculated percentage between the pulsatile signal and non-pulsatile 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 an operating range of 0.02 percent to 20.00 percent. A percentage greater than 1.00 percent is desired. Extreme changes in the display number are due to motion artifact and changes in physiology and blood flow.

PLETH VARIABILITY INDEX - (PVI)

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%).

The PVI bar graph is a representation of the calculated value. The lower the height of the bar, the less variability there is in the PI over a respiratory cycle. Press the Display key to toggle to the PVI numeric measurement.

LOW PERFUSION - (SIQ)

The Rad-87 indicates perfusion on a 10-bar LED indicator. The lower two segments of the bar will turn red when the amplitude of the arterial pulsations is very low (low perfusion).

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation[3]. This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

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

[3] Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction. Anesthesiology 1990; 73:532-537

SIGNAL IQ

The Rad-87 Pulse CO-Oximeter display provides a visual indicator of signal quality and an alert when the displayed SpO_2 values are not based on adequate signal quality. The signal quality indicator displayed on the Rad-87 is called the Signal IQ. The Signal IQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement.

The Signal IQ is represented as a bar indicator where the height of the bar coincides with the strength of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Rad-87 locates the arterial pulsation. The pulse tone (when enabled) coincides with the rise of the Signal IQ Index.

The height of the Signal IQ Index indicates the quality of the measured signal. A high Signal IQ Index indicates that the SpO_2 measurement is based on a good quality signal. A small Signal IQ Index indicates that the SpO_2 measurement is based on data with low signal quality. When the signal quality is very low, the accuracy of the SpO_2 measurement may be compromised. When the Signal IQ is low and the bar turns red, 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-87 to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals.

- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or an episode of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. Interruption, for example, may occur while lifting or crossing their legs, during a diaper change.

After performing the above, if the Low Signal IQ message is displayed frequently or continuously obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the arterial oxygen saturation value.

SENSOR PLACEMENT

If the SpO_2, SpCO or SpMet readings are questionable or unavailable, do the following:

- Make sure the emitter and detector are aligned directly opposite each other.
- Select a site where the distance between the emitter and detector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds to increase perfusion. However, strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electro-surgical devices or other electrical/electronic equipment. If these solutions are not possible, operate the Rad-87 on battery power, or try plugging the device into a different electrical outlet.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient light. Although the Rad-87 with integrated Masimo Rainbow SET technology has significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.

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

SENSITIVITY

The Rad-87 Pulse CO-Oximeter is equipped with 3 different sensitivity modes. Each mode allows the clinician to change the sensitivity settings of the device to meet the increased demands of the patient's physiological condition or enable it to work during periods of low perfusion and/or motion. They are as follows:

- **Normal Sensitivity (NORM)** – This is the recommended mode for patients that are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).
- **Adaptive Probe Off Detection (APOD)** – This is the recommended start-up monitoring mode for most patients with acceptable perfusion or where a more robust sensor off detection is desired. It is the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient.

SENSITIVITY (CONTINUED)

- **Maximum Sensitivity (MAX)** - This mode is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed on the screen in 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. Also, after a power off and on cycle, the sensitivity will change from the MAX to the factory default or user configured default setting of APOD or NORM.

CAUTION: WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. IF THE DEVICE IS IN THIS SETTING AND THE SENSOR BECOMES DISLODGED FROM THE PATIENT, THE POTENTIAL FOR FALSE READINGS MAY OCCUR DUE TO ENVIRONMENTAL 'NOISE' SUCH AS LIGHT, VIBRATION AND EXCESSIVE AIR MOVEMENT.

LOW BATTERY AUDIBLE ALARM

If a low battery condition occurs the audible alarm can be silenced for 120 seconds (default) by pressing the Alarm Silence Button. Refer to Setup Menu Level 2 in this section to change setting.

If a low battery condition occurs while not monitoring a patient, a low priority audible alarm will sound and can be silenced by pressing the Alarm Silence Button. The audible alarm is silenced until the power is cycled or patient monitoring begins.

While audible alarms are silenced, first Battery Level Indicator bar to the left flashes green and the System Status Light flashes yellow to provide a visual alert for the user.

When a low battery condition occurs, immediately discontinue patient monitoring and plug the Rad-87 into AC power. The AC Power Indicator on the Rad-87 illuminates and remains illuminated while the battery is charging, however, the Battery Charge Level Indicator does not illuminate. Once the battery is fully charged all Battery Charge Level Indicators illuminate green when unplugged.

During normal patient monitoring, the Battery Charge Bars (Battery Charge Level Indicator) illuminate green from left to right to indicate the approximate amount of battery charge when unplugged.

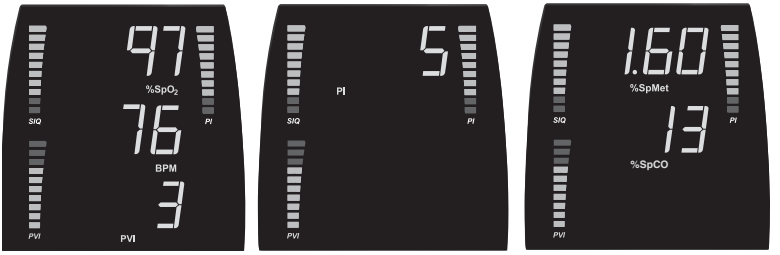
CAUTION: THE BATTERY SHOULD BE ADEQUATELY CHARGED TO ENSURE BACK-UP POWER IN CASE OF AC POWER DISRUPTION.

Normal patient monitoring

When all optional parameters/measurements are installed and during normal operation, the Rad-87 display shows Screen 1 containing arterial oxygen saturation (%SpO_2), pulse rate in beats per minute (BPM) and pleth variability index (PVI)*. By pressing the Display Button once, the display changes to show Screen 2 containing perfusion index (PI). Pressing the Display Button again changes the display to show Screen 3 containing methemoglobin (%SpMet)* and carboxyhemoglobin (%SpCO)*. An additional press of the Display Button returns the display to Screen 1, the home display screen.

*Optional parameters/measurements: SpCO, SpMet, PVI

Display Screens Showing Parameters/Measurements - Default Locations



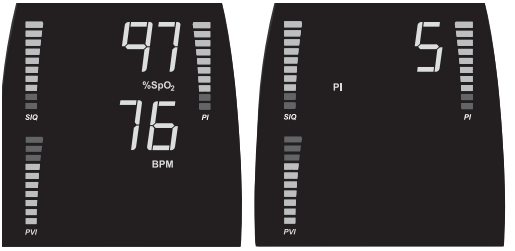
Screen 1
Home display screen

Screen 2

Screen 3

If SpMet and/or SpCO are not installed, the display will move from Screen 1 to Screen 2 when the Display Button is pressed; Screen 3 will not show. By pressing the Display Button again, the display will move from Screen 2 to Screen 1.

Display Screens When SpMet, SpCO and PVI Are Not Installed



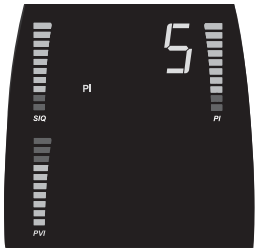
Screen 1
Home display

Screen 2

No Screen 3

Display Screens With PVI Installed and SpMet and SpCO Not Installed

Screen 1
Home display screen

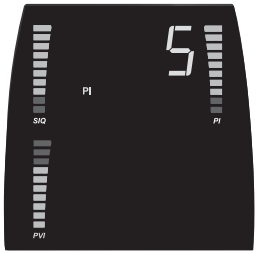


Screen 2

No Screen 3

Display Screens When SpMet, SpCO and PVI are Not Installed

Screen 1
Home display screen



Screen 2

Screen 3

PARAMETER/MEASUREMENT SELECTION

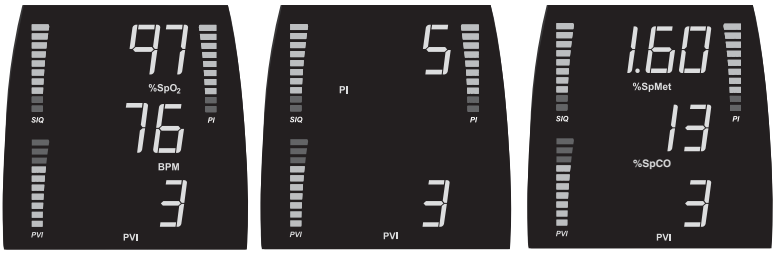
The bottom field of any display screen may be configured to show PVI (see Parameter /Measurement Select menus). Once PVI is configured to show on a screen different from the default location, the alarm limit menu for PVI can be accessed from the new screen by pressing the Alarm Limits Button.

PVI may be configured to show on one, two or three screens simultaneously (see Parameter/Measurement Select menus). However, when placing PVI on multiple screens, the alarm limit menu for PVI must be accessed from the default location.

NOTE: *When one parameter/measurement is configured for all three screens, the other parameter/measurement will not show or alarm. A parameter/measurement must show on a screen so that the alarm limit options can be accessed and set for that parameter/measurement.*

NOTE: *SpMet and/or SpCO must be configured and PVI set to show on Screen 3 for Screen 3 to show. If SpMet and SpCO are not configured and PVI is not set to show on Screen 3, Screen 3 will not show. The display screens only move between Screen 1 and Screen 2.*

Display Screens Showing PVI on Screen 1, 2 and 3



Screen 1
Home display screen

Screen 2

Screen 3

SETUP MENU

This section gives an overview of the Rad-87 menu selections available. To access the menu levels and navigate through the menu selections, use the front panel buttons, Enter Button and Up/Down Buttons as indicated in the following sections. Sub-sections describe each menu item in more detail. The Rad-87 has options that allow user configuration to accommodate specific needs.

MENU NAVIGATION

The Rad-87 set-up and configuration options are accessed through the menu system. Three levels of menus are available to the user. Once a menu level is accessed, a front panel button (Level 1 only) or the Enter Button (Level 2 and 3) is used to move from one option to the next allowing repeated cycling through the options. The Up and Down Buttons are used to adjust values within each option. The parameter/measurement value is set when the Enter Button (or Alarm Limits Button for Alarm Limits only) is pressed. Pressing the Display Button exits the menus and returns the device to the Screen 1.

When accessing the Rad-87 menu, each selection will be communicated visually on the LED (front of device) and LCD (top of device) displays, simultaneously.

***NOTE**: The Rad-87 will automatically 'time out' of the setup menu after 10 seconds with no button presses.*

SETUP MENU LEVEL 1

Setup Menu Level 1 contains the parameters/measurements and settings that are adjusted most often for patient monitoring; alarm limits, display brightness, and sensitivity settings.

Pressing the Display Button while viewing alarm limit settings allows the user to exit the Setup Menu and return to Screen 1.

PARAMETER/MEASUREMENT ALARM LIMITS - SCREEN 1

To access alarm limits for parameters/measurements contained on Screen 1, press the Alarm Limits Button to access the Alarm Limits menu for Screen 1 parameters/measurements.

BUTTONS	SETTINGS		
Use the Alarm Limits Button to access the alarm limits options and move between options. 	Press once 	$\%SpO_2$ LO	Use Up or Down Buttons to adjust the value to the desired setting AND press the Alarm Limits Button to accept the setting and move to the next option. Once the last option is accessed an additional press of the Alarm Limits Button will return the device to Screen 1. OR press the Display Button to exit at any time and return to Screen 1.
	Press 2x 	$\%SpO_2$ HI	
	Press 3x 	Pulse rate (BPM) LO	
	Press 4x 	Pulse rate (BPM) HI	
	Press 5x 	PVI LO	
	Press 6x 	PVI HI	

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

SETUP MENU LEVEL 1 (CONTINUED)

PARAMETER/MEASUREMENT ALARM LIMITS - SCREEN 2

To access alarm limits for parameters/measurements contained on Screen 2, press the Display Button to move from Screen 1 to Screen 2. From Screen 2, press the Alarm Limits Button to access the Alarm Limits menu for Screen 2 parameters/measurements.

BUTTONS	SETTINGS		
Use the Alarm Limits Button to access the alarm limits options and move between options. 	Press once 	PI LO	Use Up or Down Buttons to adjust the value to the desired setting AND press the Alarm Limits Button to accept the setting and move to the next option. Once the last option is accessed an additional press of the Alarm Limits Button will return the device to Screen 2. OR press the Display Button to exit at any time and return to Screen 2.
	Press 2x 	PI HI	

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

SETUP MENU LEVEL 1 (CONTINUED)

PARAMETER/MEASUREMENT ALARM LIMITS - SCREEN 3

To access alarm limits for parameter/measurements contained on Screen 3, press the Display Button two times to move from Screen 1 to Screen 3. Press the Alarm Limits Button from Screen 3 to access the Alarm Limits menu for Screen 3 parameter/measurements.

BUTTONS	SETTINGS		
Use the Alarm Limits Button to access the alarm limits options and move between options. 	Press once 	%SpMet LO	Use Up or Down Buttons to adjust the value to the desired setting AND press the Alarm Limits Button to accept the setting and move to the next option. Once the last option is accessed an additional press of the Alarm Limits Button will return the device to Screen 3. OR press the Display Button to exit at any time and return to Screen 3.
	Press 2x 	%SpMet HI	
	Press 3x 	%SpCO LO	
	Press 4x 	%SpCO HI	

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

LED BRIGHTNESS

The Display screen and all active LED indicators are effected while adjusting this setting.

BUTTONS	SETTINGS		
Use the Brightness Button to access the LED brightness options and move between options. 	Press once 	Default Level 2	Use the Brightness Button to move between menu options and the Enter Button to accept the setting and return to the home display screen.
	Press 2x 	Level 3	
	Press 3x 	Level 4	
	Press 4x 	Level 1	

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

SETUP MENU LEVEL 1 (CONTINUED)

SENSITIVITY

BUTTONS	SETTING		
Use the Sensitivity Button to access the sensitivity options and move between options. 	Press once 	Default APOD	Use the Sensitivity Button to move between menu options and the Enter Button to accept the setting and return to the home display screen.
	Press 2x 	NORM	
	Press 3x 	MAX (The MAX Indicator flashes in this mode.)	

SETUP MENU LEVEL 2

Level 2 menu contains parameters and settings that are not changed as frequently as Level 1. These include alarm volume, alarm silence, alarm delay, clear trend and button volume parameters.

ALARM VOLUME

BUTTONS	SETTINGS		
Use the Enter Button to access the Alarm Volume menu and to move between Level 2 menus. 		Default Level 3	Use Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Level 4	
		Level 1	
		Level 2	

ALARM SILENCE

BUTTONS	SETTINGS		
Press the Enter Button again to move to the next menu.  2x		Default 120 seconds	Use Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		90 seconds	
		60 seconds	
		30 seconds	

SETUP MENU LEVEL 2 (CONTINUED)

ALARM DELAY

Alarm delay allows the user to adjust the time in which the audible status indicator will occur after an alarm condition has been initiated.

BUTTONS	SETTINGS		
Press the Enter Button again to move to the next menu.  3x		Default 5 seconds	Use Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		0 seconds	
		15 seconds	
		10 seconds	

CLEAR TREND

The Rad-87 only stores data in the trend memory while the device is turned on. Trend data saves to the memory until the memory is full or cleared by the user.

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

BUTTON	SETTING		
Press the Enter Button again to move to the next menu.  4x		Default NO	Use Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		YES (Clear trend)	

SETUP MENU LEVEL 2 (CONTINUED)

BUTTON VOLUME

BUTTON	SETTING		
Press the Enter Button again to move to the next menu.  5x		Default Level 2	Use Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Level 1	
		Off	
		Level 3	

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-87 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.

BUTTON	SETTING		
Press the Enter Button again to move to the next menu.  6x		Default Off	Use Up or Down Button to move between settings and the Enter Button to accept the setting and move to the Alarm Volume menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		On	

Trend setup and use

INTRODUCTION

The Rad-87 can store up to 72 hours of trend data captured at 2 second intervals. (Additional parameters/measurements may affect trending capacity). The trend data can then be transferred to a PC for evaluation.

A serial cable is required to connect the Rad-87 to a PC. Patient monitoring is not possible while trend memory is being transferred to a PC.

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

A trend data download is initiated using the TrendCom utility which downloads the trend data and saves it to an ASCII text (.out) file with an output delimiter option.

NOTE: *Rad-87 Serial Ouput must be set to ASCII 2 for successful download of trending data. Refer to the Serial Output menu and settings located farther in this chapter.*

TRENDCOM UTILITY INSTALLATION

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

TRENDCOM UTILITY OPERATION

1. Turn Rad-87 off if not already off.
2. Connect serial cable to Rad-87 and other end to a com port on the PC.
3. Turn the Rad-87 on.
4. Start the TrendCom utility on the PC.
5. Select Rad-87 from the first pull-down menu.
6. Select the appropriate com port number from the second pull-down menu, if necessary.
7. Select the Output Delimiter Option (Tab, Comma or Space).
8. Select the **RETRIEVE TREND** button on the TrendCom utility. Select the desired location and assign a file name for the trend file. Select **SAVE**.
9. The Rad-87 will display “dat out” while trend data is being transferred. A progress bar will advance to indicate the status of the download. Larger trend files will take longer to download. Transfer time is approximately 20 seconds per hour of trend data.

NOTE*: During download of trend information, all normal Rad-87 functions are unavailable and the keypad is locked, except for the power button.*

10 When trend data transfer is complete, close TrendCom and disconnect the Rad-87 from the serial cable.

11. Turn the Rad-87 off to exit the trend download mode.

NOTE: *Contact USB to serial port adapter manufacturer for assistance or support.*

ERASING TREND MEMORY

To erase (clear) the trend memory, set the Clear Trend option to Yes and press the Enter Button to accept the setting and clear the data from the memory. Refer to the Clear Trend menu located before this Trend setup and use section.

The Rad-87 continuously trends data. When performing a new study and gathering data on a new patient, it is highly recommended the "clear function" be utilized in order for the results to be separate. *Turning the Rad-87 off will not erase the trend data.*

TREND DATA FORMAT

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

PARAMETER/ MEASUREMENT	SPECIFICATION
Date	MM\DD\YY
Time	HH:MM:SS
Installed Parameter/ Measurement	Numeric value (see the display ranges in the Factory and User Configurable Default Settings table located at the beginning of this section)
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 SET sensor and needs to acquire some clean data for this flag to be set

SAMPLE TREND OUTPUT

```
07/21/08 09:56:08 SpO2=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/08 09:56:10 SpO2=000 PR=000 PI=00.00 EXC=828:Search,OffPat,SET
07/21/08 09:56:12 SpO2=097 PR=069 PI=04.69 EXC=800:SET
07/21/08 09:56:14 SpO2=096 PR=074 PI=02.28 EXC=400:LowSigIQ,SET
07/21/08 09:56:16 SpO2=098 PR=078 PI=03.64 EXC=800:SET
07/21/08 09:56:18 SpO2=000 PR=000 PI=00.00 EXC=800:SET
07/21/08 09:56:20 SpO2=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/08 09:56:22 SpO2=096 PR=078 PI=02.68 EXC=800:SET
```

SETUP MENU LEVEL 3

ENTER BUTTON + DOWN BUTTON MENU SETTINGS

The Level 3 menu contains advanced parameter/measurement settings.

To access Level 3 parameters/measurements, hold down the Enter Button and press the Down Button for 5 seconds. After entering menu Level 3, use the Enter Button to save new settings and move to the next menu.

The user may cycle through the menu options by continuing to press the Enter Button. Pressing the Display Button will exit the menu and return the display to home display screen.

AVERAGING TIME

BUTTONS	SETTINGS		
Hold down the Enter Button and press the Down Button for 5 seconds. 		Default 8 seconds	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		4 seconds	
		2 seconds	
		16 seconds	
		14 seconds	
		12 seconds	
		10 seconds (The cycling function for the menu options is not available.)	

SETUP MENU LEVEL 3 (CONTINUED)

RAPID DESAT LIMIT

The Rapid Desat Limit is designed to detect rapid desaturations of 5% or 10% below the low alarm limit and overrides the Alarm Delay feature when activated.

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  1x		Default 5%	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new settings and to return to the home display screen.
		Off	
		10 %	

ALARM ON/OFF

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  2x		Default On	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Off	
		Off rE* (alarm off with reminder.)	

*When Alarm On/Off is set to "Off rE", the audible alarm "beeps" twice every two minutes to remind the user that the Rad-87 is currently in alarm status but the audible alarm is muted. Visual alarms are active in this mode. If an alarm limit is violated, the associated parameter/measurement label and value flash, the alarm bell flashes red for high priority alarms and the System Status Light is solid yellow for low priority alarms, flashes yellow for medium priority alarms or flashes red for high priority alarms.

SETUP MENU LEVEL 3 (CONTINUED)

FACTORY DEFAULT

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  3x		No Change (Do not adjust factory default settings.)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		User Default (Set to user settings*)	
		Factory Default (Restore factory default settings.)	

*Set the Factory Default to this setting when configuring a Device Profile and selecting a color for the Device Profile LED. Refer to the Device Profile Setup and Use section of this chapter for additional information and instructions.

Device Profile Setup and Use

The Rad-87 can be configured to save changes to the device settings as a Device Profile. Using the Rad-87 button menu or an external configuration application, users can adjust Rad-87 settings and parameter/measurement alarm limits. After changing settings, the user may save the settings as a Device Profile. This Device Profile becomes the new default settings and the saved (Device Profile) settings will be retained after a power cycle.

The user may select a color for the Device Profile LED to associate with the saved profile. The Device Profile LED (located on the front panel of the Rad-87 above the sensor connector) will illuminate with the selected color, allowing the user to verify at a glance that a Device Profile has been set on the Rad-87. If changes are made to the device settings after the Device Profile feature has been enabled, the Device Profile LED will turn off, indicating a change from the Device Profile settings.

To save the settings as a profile from the Rad-87 button menu, the user must enter Setup Menu Level 3 by pressing and holding the Enter Button and Down Button at the same time for 5 seconds. Then, by pressing the Enter Button three times, the Factory Default setting screen is displayed. Pressing the Up Arrow once will change the display from the default "Factory Default – Set", to "User Default – Set" (see LCD display). The user can press the Enter Button again to save the settings, and the Rad-87 will prompt the user to select a color (for the Device Profile LED) to associate with the saved profile. The default color is light blue. On the LCD display, a message alerts the user that light blue is selected, "User Default – light blue". By using the Up or Down Arrows, the user can select from a list of colors The user selects and saves one color by pressing the Enter Button. The Device Profile Light on the front panel of the Rad-87 will illuminate with the selected color.

When user configured default settings are active, any changes to the default settings cause the Device Profile LED to turn off until the device is returned to the user configured default settings or powered off.

SETUP MENU LEVEL 3 (CONTINUED)

PVI BAR ON/OFF

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  4x		Default On	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Off (No PVI Bar or parameter/measurement label displayed)	

SMART TONE ON/OFF

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.

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  5x		Default Off (Normal Tone)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		On (Smart Tone)	

SETUP MENU LEVEL 3 (CONTINUED)

YEAR

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  6x		Default year 00	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Use Up or Down Button to adjust the setting.	

MONTH

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu  7x		Default month 00	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Use Up or Down Button to adjust the setting.	

SETUP MENU LEVEL 3 (CONTINUED)

DAY

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  8x		Default days 00	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Use Up or Down Button to adjust the setting.	

HOUR

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  9x		Default hour 00	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Use Up or Down Button to adjust the setting.	

SETUP MENU LEVEL 3 (CONTINUED)

MINUTE

<table>
<tr><th>BUTTONS</th><th colspan="3">SETTING</th></tr>
<tr><td rowspan="2">Press the Enter Button again to move to the next menu.
 
10x</td><td>  </td><td>Default
minutes 00</td><td rowspan="2">Use Up or Down Button to move between settings
AND
press the Enter Button to accept the setting and move to the next menu.
OR
press the Display Button to exit without saving the new setting and to return to the home display screen.</td></tr>
<tr><td>  </td><td>Use Up or Down Button to adjust the setting.</td></tr>
</table>

SOFTWARE VERSION

BUTTONS	SETTING
Press the Enter Button again to move to the next menu  11x	Displays software version

SETUP MENU LEVEL 3 (CONTINUED)

SERIAL OUTPUT

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  12x		Default AS2 (ASCII 2)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		AS1 (ASCII 1)	
		PHL (Philips VueLink)	

INTERFACE ALARMS

When Rad-87 is interfaced to another system and the Interface Alarms are set to "Off", SpO_2 and BPM audible alarms are muted at the Rad-87 and active at the interfaced system. This prevents both systems from producing SpO_2 and BPM audible alarms at the same time.

NOTE: *The Rad-87 reverts to Interface Alarms "On" during power interruptions or when the interface connection is lost. This ensures that the Rad-87 provides SpO_2 and BPM audible alarms when connection to the interfaced system becomes compromised.*

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.  13x		Default On ***NOTE:*** *LCD shows SpO_2 and BPM alarms On.*	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Off (only SpO_2/BPM) ***NOTE:*** *LCD shows SpO_2 and BPM alarms Off.*	

System interfaces

PHILIPS VUELINK SETUP

1. Select the Philips VueLink selection from the Serial Output menu on the Rad-87. After selecting, choose the preferred settings by stepping through menu options.
2. Connect one end of the VueLink cable to the Serial Output connector on the back of the Rad-87.
3. Connect the other end of the VueLink cable to the VueLink module and insert the module into the Philips/Agilent monitor rack.
4. The SpO_2 and pulse rate values will automatically appear on the Philips/Agilent monitor.
5. In order for the pleth waveform to be displayed on the Philips/Agilent monitor and for the Philips/Agilent monitor to indicate the alarm conditions measured by the pulse oximeter, the user must configure the Philips/Agilent monitor. Please see the Philips/Agilent Operator's manual for complete instructions.
6. The Rad-87 Pulse CO-Oximeter can be set up to audibly indicate all patient alarms while communicating with the Philips/ VueLink module. Use the Interface Alarms setting in the Output menu to enable and disable audible alarms on the Rad-87**.**

RADNET SETUP

1. Connect one end of the serial cable to the Serial Output connector on the back of the Rad-87.
2. Connect the other end of the serial cable to the RadNet Interface Module connector
3. Turn the RadNet Interface Module on.
4. Select the ASCII 2 selection from the Serial options on the Rad-87.
5. A proper connection is shown by the RadNet Interface Module's Online LED being solid.
6. With a properly configured RadNet Interface Module, the Rad-87 will automatically display the SpO_2, PVI and Pulse Rate parameters on the screen at the RadNet Central Station.
7. The Rad-87 Pulse CO-Oximeter can be set up to audibly indicate all patient alarms while communicating with the RadNet Interface module.

PATIENT SAFETYNET SETUP

1. Select the ASCII 2 selection from the Serial options on the Rad-87.
2. Contact Masimo installation personnel for proper installation guidance.

SETUP MENU LEVEL 3 (CONTINUED)

NURSE CALL*

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.  14x		Default Alarm	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Signal IQ	
		Alarm and Signal IQ	

*Refer to Section 7, *Nurse call specifications* for additional information.

POLARITY*

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.  15x		Default Normal	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Inverse	

*Refer to Section 7, *Nurse call specifications* for additional information.

SETUP MENU LEVEL 3 (CONTINUED)

LINE FREQUENCY

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.  16x		Default 60	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		50	

SETUP MENU LEVEL 3 (CONTINUED)

PARAMETER/MEASURMENT SELECT - SCREEN 1

NOTE: *When one parameter/measurement is configured for all three screens, the other parameter/measurement will not show or alarm. A parameter/measurement must show on a screen so that the alarm limit options can be accessed and set for that parameter/measurement.*

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.  17x		PVI (if available)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		(no parameter/ measurement displayed)	

PARAMETER SELECT - SCREEN 2

NOTE: *When one parameter/measurement is configured for all three screens, the other parameter/measurement will not show or alarm. A parameter/measurement must show on a screen so that the alarm limit options can be accessed and set for that parameter/measurement.*

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.  18x		PVI (if available)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		(no parameter/ measurement displayed)	

SETUP MENU LEVEL 3 (CONTINUED)

PARAMETER SELECT - SCREEN 3

NOTE: *When one parameter/measurement is configured for all three screens, the other parameter/measurement will not show or alarm. A parameter/measurement must show on a screen so that the alarm limit options can be accessed and set for that parameter/measurement.*

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.  19x		PVI (if available)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		(no parameter/ measurement displayed)	

LCD LANGUAGE

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.  20x		Default English	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Scrolls through available languages displayed on the LCD	

SETUP MENU LEVEL 3 (CONTINUED)

ENTER BUTTON + UP BUTTON MENU SETTING

SET MODE

BUTTONS	SETTING		
Hold down the Enter Button and press the Up Button for 5 seconds. 		Default Standard	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Sleep Mode*	
		Home Mode	

*__CAUTION:__ ALARMS ARE DISABLED IN THIS MODE.

HOME MODE OPERATION

The Rad-87 can be placed into the Home Mode to protect unqualified users from changing the Rad-87 alarm settings and operation. Only the following menu and front panel functions are available: display brightness, pulse beep volume adjustment and alarm silence. Alarm volume is at highest setting. All default and user defined default settings are locked to their current values when home mode is selected and return to those values after a power cycle. Upon power up, the Hnn mode will be displayed along with a 10 second display of parameters/measurements. To turn the device off the Power Button must be depressed and held for 3 seconds. The Enter and Up Buttons held simultaneously for 5 second will put it back into the special menu to select a different mode.

SLEEP MODE OPERATION

The Rad-87 can be placed into the Sleep Mode to allow the device to capture normal and abnormal patient data without triggering the alarms. This mode will blank out the LED and the LCD Displays with the exception of the AC Power Indicator, the System Status Light, and the Battery Level Indicator and disables the alarms even after a power cycle. However, pressing any button illuminates the display and the System Status Light (solid yellow) for 10 seconds. Upon power up, the SLP mode will be displayed along with a 10 second display of parameterr/measurement settings. The Enter and Up Buttons held simultaneously for 5 seconds will put it back into the special menu to select a different mode.

CAUTION: ALARMS ARE DISABLED IN THIS MODE.

SETUP MENU LEVEL 3 (CONTINUED)

BRIGHTNESS BUTTON + DOWN BUTTON MENU SETTING

Access the Enable/Disable Radio menu by holding down the Brightness Button and the Down Button for 5 seconds.

ENABLE/DISABLE RADIO

BUTTONS	SETTING		
Hold down the Brightness Button and press the Down Button for 5 seconds. 		Default Off	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and exit to the home display screen.
		On	

LCD DISPLAY FUNCTION WITH RADIO CONFIGURED AND ENABLED

When the Radio feature is enabled (set to "On") and configured with the required network information, the LCD Display shows the following information for 20 seconds:

- SSID
- IP address
- Subnet
- Gateway
- MAC Address

Alarm identification

The Rad-87 visually and audibly indicates alarm conditions that the system detects. Audible alarms may be silenced, without affecting the operation of visual alarms.

Three levels of alarm priority are implemented: high, medium and low priority. The following table outlines the alarm priority specifications.

ALARM PRIORITY	PARAMETER/MEASUREMENT — ALARM SETTING RANGE	ALARM TYPE
High	Low saturation	Audible and visual
	High carboxyhemoglobin saturation	
	High methemoglobin saturation (SpMet range1 - 99.5%, then "---")	
	Low pulse rate High pulse rate	
	Sensor off and no sensor	
	Defective Sensor	
	System failures	
Medium	High saturation	
	Low PI High PI	
	Low PVI (PVI range "---", then 1 - 98%) High PVI (PVI range 2 - 99%, then "---")	
	Low battery, monitoring patient	
Low	Low carboxyhemoglobin saturation Low methemoglobin saturation	
	Low battery, not monitoring patient	

Alarm indication

An alarm condition caused by an out-of-limit parameter/measurement is indicated by:

- Audible alarm tone
- Flashing Out-of-limit parameter/measurement label and value
- System Status Light flashes red for high priority alarms, flashes yellow for medium priority alarms or shows solid yellow for low priority alarms
- Red flashing Alarm Bell for high priority alarms

Alarm limits

CAUTION: TO ENSURE THAT ALARM LIMITS ARE APPROPRIATE FOR THE PATIENT BEING MONITORED, CHECK THE LIMITS EACH TIME THE RAD-87 IS USED.

When an alarm limit is exceeded, an audible alarm activates and the Alarm Bell flashes red for high priority alarms and the System Status Light is solid yellow for low priority alarms, flashes yellow for medium priority alarms or flashes red for high priority alarms. When a sensor is not connected to a patient, “SEN OFF” message will show on the display. When a sensor is not connected to its cable, “NO SEN” message will show on the display.

NOTE: *An audible alarm will accompany the visual indicators unless the Rad-87 has been set to Interface Alarms "Off" (only SpO_2 and BPM alarms muted) or to Sleep Mode (all alarms muted).*

ALARM LIMIT: USER CONFIGURABLE SETTINGS

SETTING	RANGE
SpO_2 High Limit	The SpO_2 high alarm limit can be set anywhere between 2% and 99%, then "---" (Off), 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 98%, with a 1% step size.
SpCO High Limit	The SpCO high alarm limit can be set anywhere between 2% and 98%, then "---" (Off), with a 1% step size..
SpCO Low Limit*	The SpCO low alarm limit can be set anywhere between "---" (Off), then 1% and 97%, with a 1% step size. In the “----” (Off) setting, the SpCO Low Limit alarm is disabled.
SpMet High Limit	The SpMet high alarm limit can be set anywhere between 1% and 99.5%, then "---" (Off). Adjust in increments of 0.1% for values between 0.1% to 2%. Adjust in increments of 0.5% for values between 2% and 99.5%.
SpMet Low Limit*	The SpMet low alarm limit can be set anywhere between "---" (Off), then 0.1% and 99%. Adjust in increments of 0.1% for values between 0.1% to 2%. Adjust in increments of 0.5% for values between 2% and 99.5%. When SpMet is placed in the “----” (Off) setting, the SpMet Low Limit alarm is disabled.

ALARM LIMIT: USER CONFIGURABLE SETTINGS (CONTINUED)

SETTING	RANGE
PI High Limit	The PI high alarm limit can be set anywhere between 0.04% and 19%, then "----" (Off). Adjust in increments of 0.01% step size between 0.04% 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.
PI Low Limit*	The PI low alarm limit can be set anywhere between "---" (Off), then 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.
PVI High Limit	The PVI high alarm limit can be set anywhere between 2% and 99%, then "----" (Off). Adjust in increments of 1% step size. When PVI is placed in the "----" (Off) setting, the PVI High Limit alarm is disabled.
PVI Low Limit*	The PVI low alarm limit can be set anywhere between "---" (Off), then 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.
Pulse Rate 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.
Pulse Rate 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.

** The low alarm limit must always be set below the high alarm setting. Attempting to set the high alarm limit below the low alarm limit, the low alarm limit will automatically adjust the low limit to the next setting below the newly entered high alarm limit setting.*

***NOTE:** Pressing and holding down the up and down buttons allow for the rapid scrolling of changing alarm limits.*

***NOTE:** If there is a loss of power for any length of time, the Alarm settings will be set back to the User set defaults. If the user has not utilized this option, then all parameters/measurements will be set back to the factory defaults.*

SINGLE ALARM

When an alarm is activated, the display shows the screen containing the parameter/measurement in alarm status. The number value and the label (name) for the parameter/measurement in alarm status flash, an audible alarm activates, the Alarm Bell flashes red for high priority alarms and the System Status Light is solid yellow for low priority alarms, flashes yellow for medium priority alarms or flashes red for high priority alarms.

MULTIPLE PARAMETER/MEASUREMENT ALARMS

When multiple parameters/measurements alarm, the screen with the highest alarm priority (and with an parameter/measurement in alarm status) will show on the display. Refer to the table *Alarm Priority for Display Screens* located below. The number value and the label (name) for the parameter/measurement in alarm status flash, an audible alarm activates, the Alarm Bell flashes red for high priority alarms and the System Status Light is solid yellow for low priority alarms, flashing yellow for medium priority alarms and flashing red for high priority alarms. Additional parameters/measurements in alarm status (competing alarms) that are not contained on the active screen will show as flashing parameter/measurement labels (names). The parameters/measurements with competing alarms can be viewed by pressing the Display Button to scroll through the screens. When an alarm is resolved, the parameter/measurement label stops flashing. When all parameters/measurements in alarm status on a display screen are resolved, the screen changes to show the next priority screen with active alarms.

ALARM PRIORITY FOR DISPLAY SCREENS

PRIORITY	DISPLAY SCREEN	PARAMETERS / MEASUREMENTS SHOWN
1	Screen 1	%SpO_2, BPM, PVI
2	Screen 2	PI, PVI
3	Screen 3	%SpMet, %SpCO, PVI

The display screens are assigned alarm priority according to the table above. Screen 1 has first priority and displays if it contains a parameter/measurement in alarm status with other competing parameter/measurement alarms. When Screen 2 contains the competing parameter/measurement alarms, Screen 2 will take priority and show on the display. Screen 3 has the lowest priority.

ALARM SILENCE

Audible alarms may be silenced, while visual alarms remain active. The alarm silence function is controlled by pressing the Alarm Silence Button.

The Alarm Bell and the System Status Light provide visual feedback when the Rad-87 audible alarms are silenced.

Alarm Silence function when monitoring a patient:

Power-On – Alarms active, Alarm Bell flashes red for high priority alarms and the System Status Light is solid yellow for low priority alarms, flashes yellow for medium priority alarms or flashes red for high priority alarms.

Press Once – Alarm suspended for 120 seconds, audible alarms are silenced.

Press Twice – Return to audible alarms active, audible alarms return.

Repeated pressing of the Alarm Silence Button will cycle though alarm silence options above.

Alarm Silence function when not monitoring a patient:

Power-On – Alarms active, Alarm Bell is not flashing and the System Status Light is solid yellow.

Press Once – Device is silenced until it is cycled off/on or until monitoring begins.

– The Alarm Bell is not flashing and the System Status Light is solid yellow for low priority alarms.

ALARM BELL

The Alarm Bell flashes red for high priority alarms. Pressing the Alarm Silence Button once silences the audible alarm for 120 seconds (default) while the Alarm Bell flashes to indicate an alarm condition. If the high priority alarm condition is resolved during the Alarm silence interval, the Alarm Bell stops flashing. If the high priority alarm condition remains (Alarm Bell flashing red), pressing the Alarm Silence button again activates the audible alarms and the Alarm Bell continues to flash red. The Alarm Bell stops flashing when the high priority alarm conditions are resolved.

SYSTEM STATUS LIGHT

While monitoring a patient and an alarm condition occurs, an audible alarm activates and the System Status Light shows solid yellow for low priority alarms, flashes yellow for medium priority alarms or flashes red for high priority alarms. Pressing the Alarm Silence Button (one time) silences the alarm tone for 120 seconds (default). Pressing the Alarm Silence Button a second time activates the audible alarms and the System Status Light shows solid yellow for low priority alarms, flashes yellow for medium priority alarms or flashes red for high priority alarms. When all alarm conditions are resolved, the System Status Light changes to solid green.

When monitoring a patient and there are no alarm conditions, the System Status light shows green. Pressing the Alarm Silence Button (one time) silences the alarm tone for 120 seconds and the System Status Light flashes yellow if there is no alarm condition. Pressing the Alarm Silence Button a second time returns the device to normal monitoring status and the System Status Light illuminates green when patient monitoring begins.

While not monitoring a patient, the System Status Light illuminates solid yellow. If an alarm condition occurs the System Status Light shows solid yellow for low priority alarms. Pressing the Alarm Silence Button will permanently silence the alarm tone and the System Status Light is solid yellow until the power is cycled or patient monitoring begins.

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

ALARM MUTE

When the Rad-87 is set to Interface Alarms "Off" (muting the SpO_2 and BPM audible alarms at the device) and SpO_2 or BPM alarms occur, the Alarm Bell flashes red and the System Status Light is solid yellow for low priority alarms, flashes yellow for medium priority alarms or flashes red for high priority alarms. The audible alarm (SpO_2, BPM) activates at the interfaced system while the audible alarm is muted at the device. Once the SpO_2 or BPM alarm condition is resolved and there are no other system or parameter/measurement alarms, the Alarm Bell stops flashing, the System Status Light changes to solid green and the audible alarm at the interfaced system deactivates.

NOTE: *The Rad-87 reverts to Interface Alarms "On" during power interruptions or when the interface connection is lost. This ensures that the Rad-87 provides SpO_2 and BPM audible alarms when connection to the interfaced system becomes compromised.*

Messages

The Rad-87 Pulse CO-Oximeter will indicate other data or system errors. Message conditions for the Rad-87 follow:

DISPLAY	TYPE	SOLUTION
SCROLLING ZEROS	Pulse Search	Wait for found pulse. (This Search should occur whenever a sensor is first applied to a patient).
PULSE BAR (SIQ) TURNS RED	Low Signal IQ	1. Rule out occlusion of blood flow. 2. Verify placement of sensor.
PERFUSION BAR (PI) TURNS RED	Low Perfusion	1. Rule out occlusion of blood flow. 2. Attempt to warm patient. 3. Move sensor to better perfused site. ***NOTE:*** *Masimo recommends using an adhesive sensor whenever low perfusion is expected or evident.*
PARAMETER/ MEASUREMENT LABEL AND NUMBER FLASH	Alarm Limit Exceeded	Assess /address patient condition. Re-set alarm limits if indicated.
Err ##	System Fault	Return for service. There are several error codes, all error codes require return of the device to an authorized service center for repair. See Section 9, *Service and Repair.*
bAd SEn	Defective Sensor	Replace sensor.
SEn (Blinking)	Unrecognized Sensor	Connect appropriate cable.
Int dEt (Blinking)	Interference Detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.

Messages continued

DISPLAY	TYPE	SOLUTION
NO SEN	No Sensor Connected	Connect sensor to cable.
SEN OFF	Sensor off patient	1. Reattach sensor to patient. 2. Verify proper sensor placement.
SINGLE BATTERY LEVEL INDICATOR FLASHES (WITH AUDIBLE ALARM)	Battery level too low	Connect device to AC Power to charge the battery.
NO CbL	No Cable Connected	Connect appropriate cable to unit.
bAd CbL	Defective cable	Replace cable

Troubleshooting

The following chart describes what to do if the Rad-87 system does not operate properly or fails.

PROBLEM	TYPE	SOLUTION
DEVICE DOES NOT POWER ON	Low battery/ not plugged into AC power supply	Connect the AC Power Cord to the Rad-87 and to an AC outlet. Make sure that the AC Power Indicator light is on.
BATTERY RUN-TIME IS SIGNIFICANTLY REDUCED	Low battery	Contact Technical Services or your local Masimo representative.
CONTINUOUS SPEAKER TONE	Internal Failure	Device requires service. Press the Alarm Silence Button. If alarm continues to sound, power down device. If the power button does not turn the device off, press and hold the Power Button for 5 seconds. Return the device for service.
NO SPEAKER TONE	Pulse tone set to "mute"	Press Up Arrow or Alarm Volume Adjust.
NO ALARM TONE	Alarm Silence Enabled	The System Status Light flashes yellow. See Section 4, *Alarm Silence*.
BUTTONS FAIL TO WORK WHEN PRESSED	Internal Failure	Use auxiliary power down method by pressing and holding Sensitivity and Display Buttons simultaneously. Return for service.
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 unit 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.

Troubleshooting continued

PROBLEM	TYPE	SOLUTION
LOW PERFUSION (PI BAR TURNS RED)	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 unit 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 or cable 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. Replace sensor or cable.
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.
PULSE SEARCH MESSAGE	Device is searching for pulse.	If device fails to display within 30 seconds, disconnect and reconnect sensor to patient. If pulse search continues, move sensor to better perfused site.
UNEXPECTED 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.

* Elevated methemoglobin levels may cause falsely elevated carboxyhemoglobin values.

Troubleshooting continued

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
UNEXPECTED 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.	Connect the AC Power Cord to the Rad-87 and to an AC outlet. Make sure that the AC Power Indicator light is on.
	Interference from line-frequency induced noise.	Verify/set 50/60hz menu setting. See section 3, Rad-87 Power Requirements.
	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.	
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.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.
PRINT FUNCTION DOES NOT WORK	Wrong serial cable is used.	Make sure a null modem cable is used.
WIRELESS RADIO NO CONNECTION	Radio Off.	Confirm the Wireless Radio is ON.
	Network settings are not configured correctly.	Confirm wireless network settings.
	No/inadequate wireless coverage.	Confirm wireless coverage.

Rad-87 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:	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

ELECTRICAL

AC Power requirements:	100 - 240 VAC, 47-83 Hz
Power consumption:	15 VA max.
Batteries	
Type:	Sealed lead acid
Capacity (battery life):	up to 4 hours[6]
Charging time:	8 hours

* Only Rainbow sensors provide ± 2% for neonates

ENVIRONMENTAL

Operating Temperature:	41°F to 104°F (5°C to 40°C)
Transport/Storage Temperature:	-40°F to 158°F (-40°C to +70°C)[7]
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:	8.2" x 6.0" x 3.0" (20.8 cm x 15.2cm x 7.6 cm)
Weight:	2.1 lbs. = .908 Kg. = 32 oz
Trending	
72 hours of trending at 2 second resolution	
Mode	
Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[8]
Sensitivity:	Normal, Maximum[9], and APOD
Alarms	
Audible and visual alarms for low and high parameter/measurement/values: (SpO_2 range 1% - 99% and "---", SpCO range 1% - 98% and "---", SpMet range .1% - 99.5% and "---", PI range 0.03% - 19% and "---", PVI range 1% - 99% and "---", pulse rate range 30 - 235 bpm)	
Sensor condition, system failure and low battery alarms	
High Priority Audible Alarm:	800 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
Medium Priority Audible Alarm	500 Hz tone, 3 pulse burst, repeat time: 5s
Low Priority Audible Alarm:	500 Hz tone, 3 pulse burst, repeat time: 5s
Alarm Volume:	High: 85 dB (min) Low: 45 dB (min)
High Priority Visual Alarm:	Red flashing 2 sec. (0.5 Hz)
Medium Priority Visual Alarm	Yellow flashing 4 sec (0.25 Hz)
Low Priority Visual Alarm:	Solid yellow
Display/Indicators	
Display language	English (Default)
Data display:	%SpO_2, %SpCO, %SpMet, pulse rate, alarm status, status messages, Signal IQ, perfusion index, pleth variability index, sensitivity modes, wireless radio connection, system status light.
Device Profile LED	Light blue LED (Default)
Type:	LED
Display update rate:	1 second
Output Interface	
Serial RS-232	
Wireless Radio **(if installed)**	802.11 a/b/g
Nurse Call	
Philips VueLink, RadNet, Patient SafetyNet	

PHYSICAL CHARACTERISTICS (CONTINUED)

Compliance	
Safety Standard for Medical Equipment	~~FCC ID: VKF-RAD87~~ IEC 60601-1 2nd Edition
	UL 60601-1
	CAN/CSA C22.2 No. 601-1
	JIS 0601-1
Type of Protection	Class 1 (-AC power) Internally powered (battery power)
Degree of Protection (Pulse CO-Oximeter Cable):	Type BF, Defib Proof (Applied-Part)
Mode of Operation:	Continuous
EMC Standard	60601-1-2
Radio	
USA	FCC ID VKF-RAD87
	FCC parts 15.247 and 15.407
Canada	IC ID 7362A-RAD87
	RSS-210
Europe	EN 300328
	EN 301893
	EN 301489-17

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% SaO_2 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-87 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 the lowest indicator brightness and pulse tone turned off using a fully charged battery without radio power.

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

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.

*Registered trademark of Fluke Biomedical Corporation, Everett, Washington.

Serial interface specifications

The digital interface for serial communication is based on the standard RS-232 protocol.

The Rad-87 Pulse CO-Oximeter by default always outputs ASCII 2 text data through the serial port, unless the user selects a different output mode in the Output menu. To interface with the Rad-87 and receive serial text data, simply connect a serial interface cable with a serial output connector located on the back of the Rad-87.

NOTE: *Trend data packets are collected at 2 second intervals. Each data packet contains: the date, time, SpO_2, perfusion index, SpMet, SpCO, PI, pulse rate, and alarm and exception values (in ASCII 2 format).*

SERIAL INTERFACE SETUP

To interface with the Rad-87 serial port, set the following communication parameters on the interfacing serial device:

PARAMETER	SETTING
BAUD RATE	9600 Baud bidirectional
NUMBER OF BITS PER CHARACTER	8
PARITY	None
BITS	1 start, 1 stop
HANDSHAKING	None
CONNECTOR TYPE	Female DB-9

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

PIN	SIGNAL NAME
1	No Connection
2	Receive data – RS-232 ±9 V (±5 Vmin)
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground Reference for COM signals
6	No Connection
7	No Connection
8	No Connection
9	No Connection

SERIAL PRINTER SETUP
To print the SpO_2 and pulse rate data in ASCII 2 format on a serial printer, simply connect the serial printer to the serial port and set output mode to ASCII 2. Once serial communication is established, the Rad-87 will automatically start printing the ASCII 2 text data.

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

Nurse call specifications

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

NURSE CALL
The nurse call feature on the Rad-87 Pulse CO-Oximeter is based on the relay closing or opening depending on alarm, Low Signal IQ events or both. In addition the nurse call polarity can be inverted to accommodate various nurse call stations requirements.

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

PARAMETER	SPECIFICATION
MAX VOLTAGE	36 VDC or 24 VAC peak

WARNING: THE NURSE CALL FEATURE IS DISABLED WHEN THE AUDIBLE ALARMS ARE SILENCED AND NURSE CALL SETTING IS SET TO "ALARMS".

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 sensors and cables with the Rad-87 Pulse CO-Oximeter. Other transducers, sensors and cables may effect Rad-87's 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, 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 WATER-PROOF).
- UNLESS OTHERWISE SPECIFIED, 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 ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY MASIMO SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.
- ALL SENSORS AND CABLES ARE DESIGNED FOR USE WITH SPECIFIC MONITORS. VERIFY THE COMPATIBILITY OF THE MONITOR, CABLE AND SENSOR BEFORE USE, OTHERWISE PATIENT INJURY CAN RESULT.

SELECTING A MASIMO SET SENSOR

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following tables 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**. Monitor, cables and sensors must be compatible to ensure optimal performance. Incompatible components effect operation or data recovery.

High intensity extreme lights (such as pulsating strobe lights) directed on the Pulse CO-Oximeter sensors, may not allow the sensor to obtain vital sign readings. 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 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 for the Rad-87 Pulse CO-Oximeter parameters to enable measurement of oxyhemoglobin (SpO_2), carboxyhemoglobin (SpCO), and methemoglobin (SpMet). Rainbow sensors will only measure SpO_2 and pulse rate on devices without Masimo Rainbow SET Technology.

Rainbow sensors connect directly to the device, or with a cable (Rainbow RC).

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	Application Site	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
DC-3 DC-12 DCI	Middle or ring finger	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
DCP-3 DCP-12 DCIP	Middle or ring finger, or thumb	10 - 50 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 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
R1 25	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
R1 25L	> 30 kg < 3 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
R1 20	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
R1 20L	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
	10 - 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%

Masimo SpO_2 Sensors

The Rad-87 may use standard Masimo LNOP, LNOPv and LNCS SpO_2 sensors, when used with Red PC, Red LNC or Rainbow RC cables respectively.

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

RED REUSABLE SENSORS

Masimo Red sensors can be used with the Rad-87 to enable measurement of SpO_2 and pulse rate only. Red sensors will only function with oximeter devices equipped with Masimo Rainbow SET technology. Red reusable sensors must be used in conjunction with Red PC cables.

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

LNOP® REUSABLE SENSORS

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

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP DCIP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP YI	> 1 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	N/A	N/A
LNOP TCI	> 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 TFI	> 30 kg	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm

NOTE: *The LNOP TFI and TCI sensors were not validated under motion conditions.*

LNOP® ADHESIVE SENSORS

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

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

LNOPv™ ADHESIVE SENSORS

LNOPv adhesive sensors must be used in conjunction with Red PC cables.

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

LNOP® SPECIALTY SENSORS

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

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Newborn Infant/Pediatric	3 - 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Newborn Neonatal	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Trauma	< 3 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Blue	2.5 - 30 kg	60 - 80% ± 4%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		70 - 100% ± 3.3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		80 - 100% ± 3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm

LNCS® REUSABLE SENSORS

LNCS reusable sensors must be used in conjunction with Red LNC cables or Rainbow RPC cables.

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

NOTE: *The LNCS TFI and TCI sensors were not validated under motion conditions.*

LNCS® ADHESIVE SENSORS

LNCS adhesive sensors must be used in conjunction with Red LNC cables or Rainbow RPC cables.

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

LNCS® SPECIALTY SENSORS

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

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

SENSOR ACCURACY

Refer to Section 7, *Specifications* for SpO_2, SpMet, SpCO, and pulse rate accuracy. Unless otherwise specified in the previous tables:

Complete accuracy specifications are located in the sensor Directions For Use (DFU) and are specific for the type of Masimo sensor used.

CLEANING AND REUSE OF MASIMO REUSABLE SENSORS AND CABLES

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

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

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.*

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

CAUTION: DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY MASIMO SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.

CAUTION: TO PREVENT DAMAGE, DO NOT SOAK OR IMMERSE THE SENSOR IN ANY LIQUID SOLUTION. DO NOT ATTEMPT TO STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ANY METHOD OTHER THAN ETHYLENE OXIDE AS INDICATED.

Introduction

This chapter covers how to test the operation, properly clean and how to obtain service for the Rad-87 Pulse CO-Oximeter.

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

WARNING: ELECTRICAL SHOCK AND FLAMMABILITY HAZARD - BEFORE CLEANING THE RAD-87, ALWAYS TURN IT OFF AND DISCONNECT THE POWER CORD FROM THE AC POWER SUPPLY.

The Rad-87 Pulse CO-Oximeter is a reusable device. The device is supplied and used non-sterile.

Cleaning

The outer surface of the Rad-87 Pulse CO-Oximeter can be cleaned with a soft cloth dampened with a mild detergent and warm water solution. Do not allow liquids to enter the interior of the instrument. The outer surface of the instrument can also be wiped down using the following solvents: Cidex Plus (3.4% Glutaraldehyde), 10% Bleach, and 70% Isopropyl Alcohol.

CAUTIONS:

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THE RAD-87.
- 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 AFFECT 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.

Battery Service

WARNING: THE BATTERY SHOULD BE INSTALLED AND/ OR REMOVED FROM THE RAD-87 BY QUALIFIED PERSONNEL ONLY.

Performance verification

To test the performance of the Rad-87 after repairs or during routine maintenance, follow the procedure outlined in this section. If the Rad-87 fails any of the described tests, discontinue its use and correct the problem before returning the device back to the user.

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

POWER-ON SELF-TEST

1. Turn the monitor on by depressing the Power. For about 2 seconds all available LEDs are illuminated and a brief beep tone sounds.
2. The Rad-87 begins normal operation.

KEY PRESS BUTTON TEST

1. With the exception of the Power, press each button and verify that the device 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, depress the alarm limits button and enter the alarm menu. Change the High Saturation Alarm parameter to a value below the currently selected value, and accept the change.
2. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display.
3. Return the High Saturation Alarm parameter to its original setting.
4. Repeat steps 1 to 3 for the following alarm parameters:

- Low SpO_2
- Low and High pulse rate
- High SpMet (optional feature)
- High SpCO (optional feature)

5. Reset the alarm limits again to the original settings.

LED BRIGHTNESS

1. With the monitor turned on, press the Brightness Button once to enter the LED Brightness menu. The display will show the default setting Level 2.
2. Continue pressing the Brightness Button to scroll through the settings.
3. Press the Enter Button to accept the desired setting and exit to the home display screen.

TESTING THE RAD-87 WITH MASIMO SET TESTER (OPTIONAL)

1. Turn the Rad-87 off and then on again.
2. Connect the Masimo SET Tester to the Pulse CO-Oximeter Patient Cable Connector.
3. Verify that within 20 seconds all available pulse bars display.
4. Verify that the SpO_2 measurement is between 79% and 84%.
5. Verify that the pulse rate measurement is between 55 bpm and 65 bpm.
6. Set the SpO_2 low alarm limit to 90 (see Section 4, *Setup Menu Level 1, Parameter/ Measurement Alarm Limits - Screen 1,* and *Setup Menu Level 2, Alarm Volume*).
7. Verify that an audible alarm activates, the SpO_2 measurement and the SpO_2 parameter label are flashing, and the Alarm Bell and the System Status Light are flashing red.
8. Press the Alarm Silence Button once and verify that the alarm is silenced and the Alarm Bell is flashing red and the System Status Light is flashing red.
9. Wait 120 seconds and verify that the alarm silence times out, the audible alarm is activated again and the Alarm Bell and System Status Light are flashing red.
10. Press the up arrow button several times and verify that the loudness of the pulse beep tone increases.
11. Press the down arrow button and verify that the loudness of the pulse beep tone decreases until the pulse beep tone is turned off.
12. Reset the device to original settings and remove the tester to complete the procedure.

Service and repair

REPAIR POLICY

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

> **WARNING:** AN OPERATOR MAY ONLY PERFORM MAINTENANCE PROCEDURES SPECIFICALLY DESCRIBED IN THIS MANUAL. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TRAINED IN THE REPAIR OF THIS EQUIPMENT.

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

To return the Rad-87 Pulse CO-Oximeter for service, please follow the Return Procedure.

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 Rad-87. 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 device 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 Rad-87 has been decontaminated for bloodborne pathogens.

Return the Rad-87 to the following shipping address:

For USA and Asia Pacific:	For Europe:	All other locations:
Masimo Corporation 40 Parker Irvine, California 92618 Tel: 949-297-7000 FAX: 949-297-7001	Masimo Europe Limited 304 RN6, Le Bois des Cotes 2 69760 Limonest France Tel: +33 (0) 472 17 93 70 FAX: +33 (0) 478 35 78 08	Contact your local Masimo Representative.

Sales & End-User License Agreement

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Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: (i) each new Product and the Software media as delivered are free from defects in workmanship or materials, and (ii) the Product and Software will perform substantially as labeled in the directions for use. Masimo's sole obligation under this warranty is to repair or replace any Product or Software that is covered under warranty.

Batteries are warranted for six (6) months.

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

Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo's written authorization; b) supplies, devices or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone other than an authorized Masimo agent; d) use of the Product with sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

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Part Numbers

PART NUMBER	DESCRIPTION
9132	Rad-87, Horizontal
9133	Rad-87, Vertical
9134	Rad-87, Horizontal with radio
9135	Rad-87, Vertical with radio
32770	Rad-87 Operator's Manual, French
32771	Rad-87 Operator's Manual, German
32772	Rad-87 Operator's Manual, Italian
32773	Rad-87 Operator's Manual, Spanish
32774	Rad-87 Operator's Manual, Japanese
32775	Rad-87 Operator's Manual, Dutch
32776	Rad-87 Operator's Manual, Portuguese
32777	Rad-87 Operator's Manual, Danish
32778	Rad-87 Operator's Manual, Swedish
32779	Rad-87 Operator's Manual, Chinese

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

www.masimo.com

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

31743/4520C-0508