

# OPERATOR'S MANUAL







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. Masimo Corporation 40 Parker Irvine, CA 92618 USA Tel.: 949-297-7000 Fax.: 949-297-7001 www.masimo.com

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#### 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<sub>2</sub> 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<sub>2</sub> measurement.
  - For increased COHb: COHb levels above normal tend to increase the level of SpO<sub>2</sub>. 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<sub>2</sub>. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - NOTE: High levels of COHb may occur with a seemingly normal SpO<sub>2</sub>. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - For increased MetHb: the SpO<sub>2</sub> may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO<sub>2</sub> 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<sub>2</sub> and SpCO measurements.
- Elevated levels of Carboxyhemoglobin (COHb) will lead to inaccurate SpO2 measurements.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO<sub>2</sub>, SpMet, SpCO, SpHb and SpOC measurements.
- Motion artifact may lead to inaccurate SpMet, SpCO, SpHb and SpOC measurements.

#### SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES (CONTINUED)

- Very low arterial Oxygen Saturation (SpO<sub>2</sub>) levels may cause inaccurate SpCO and SpMet measurements.
- Severe anemia may cause erroneous SpO<sub>2</sub> readings.
- Hemoglobin synthesis disorders may cause erroneous SpHb 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 radiation, 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 irradiation 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.
- 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.

#### SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES (CONTINUED)

- 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) wirelessly 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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# 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 & 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 ACCESSORIES 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, total hemoglobin concentration, total arterial oxygen content and pulse rate monitor. The Rad-87 features a multicolored LED display that continuously displays numeric values for SpO<sub>2</sub>, SpCO<sup>®</sup>\*, SpMet<sup>™</sup>\*, SpHb<sup>™</sup>\*, total arterial oxygen content (SpOC\*), 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<sup>®</sup>), 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.

### 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<sub>2</sub>) 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<sup>®</sup> Blue Sensor.
- Signal IQ<sup>®</sup> provides signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat<sup>®</sup> tracks rapid changes in arterial O<sub>2</sub> 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) and total hemoglobin (SpHb), 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.<sup>1</sup>
- Total arterial oxygen content (SpOC) provides a calculated measurement of the amount of oxygen in arterial blood which may provide useful information for both oxygen dissolved in plasma and combined with hemoglobin.
- 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).

<sup>1</sup> 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.

\*Optional features: SpCO, SpMet, SpHb, SpOC, PVI

# INDICATIONS FOR USE

The Rad-87 Pulse CO-Oximeter and accessories are indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), carboxyhemoglobin and methemoglobin concentration expressed in percentage (SpCO and SpMet) and total hemoglobin concentration expressed in grams per deciliter (SpHb). 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<sub>2</sub> 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 concentration (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through an instrument patient cable. The sensor collects signal data from the patient and sends it to the instrument. The 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.

### TOTAL HEMOGLOBIN (SpHb) GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make the SpHb measurement. The measurement is taken by a sensor capable of measuring SpHb, usually on the fingertip for adults and pediatric patients. The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as measurement of total hemoglobin concentration. The Rad-87 can be configured to be a combined SpO<sub>2</sub> monitor with other available parameters/measurements.

### TOTAL ARTERIAL OXYGEN CONTENT (CaO<sub>2</sub>) GENERAL DESCRIPTION<sup>2</sup>

Oxygen ( $O_2$ ) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The amount of oxygen in the arterial blood is termed the oxygen content (CaO<sub>2</sub>) and is measured in units of ml O<sub>2</sub>/dl blood. One gram of hemoglobin (Hb) can carry 1.34 ml of oxygen, whereas 100 ml of blood plasma may carry approximately 0.3 ml of oxygen. The oxygen content is determined mathematically as:

CaO<sub>2</sub> = 1.34 (ml O<sub>2</sub>/g Hb) x Hb (g/dl) x HbO<sub>2</sub> + PaO<sub>2</sub> (mm Hg) x (0.3 ml O<sub>2</sub>/ 100 mm Hg/dl)

Where  $HbO_2$  is the fractional arterial oxygen saturation and  $PaO_2$  is the partial pressure of arterial oxygen.

For typical PaO<sub>2</sub> values, the second part of the above equation  $[PaO_2 (mm Hg) x (0.3 ml O_2/100 mm Hg/dl]$  is approximately 0.3 ml/dl. Furthermore, for typical carboxyhemoglobin and methemoglobin levels, the functional saturation (SpO<sub>2</sub>) as measured by a pulse oximeter is given by:

$$SpO_2 = 1.02 \times HbO_2$$

<sup>2</sup> Martin, Laurence. All You Really Need to Know to Interpret Arterial Blood Gases, Second Edition. New York: Lippincott Williams & Wilkins, 1999.

#### SpOC General Description (Pulse CO-Oximetry)

The above approximations result in the following reduced equation for oxygen content via the Pulse CO-Oximeter:

SpOC (ml/dl\*) = 1.31 (ml  $O_2/g$  Hb) x SpHb (g/dl) x Sp $O_2$  + 0.3 ml/dl

\*When ml  $O_2/g$  Hb is multiplied by g/dl of Hb, the gram unit in the denominator of ml/g cancels the gram unit in the numerator of g/dl resulting in ml/dl (ml of oxygen in one dl of blood) as the unit of measure for SpOC.

#### PRINCIPLE OF OPERATION

Pulse CO-Oximetry is governed by the following principles:

 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).



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  $\leq$  25mW. The detector receives the light, converts it into an electronic signal and sends it to the Rad-87 for calculation.



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 35° C the maximum skin surface temperature has been measured at less than 106° F (41° 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.

# RAD-87 vs. DRAWN WHOLE BLOOD MEASUREMENTS

When SpO<sub>2</sub>, SpCO, SpMet and SpHb 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<sub>2</sub>, SpCO, SpMet and SpHb measurements of the Rad-87 Pulse CO-Oximeter. In the case of SpO<sub>2</sub>, 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<sub>2</sub>) and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO2), 2,3-DPG, and fetal hemoglobin. In the case of SpCO, different results are also expected if concentration of methemoglobin in the blood gas sample is elevated. High levels of bilirubin may cause erroneous SpO2, SpMet, SpCO and SpHb 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<sub>2</sub>, SpCO, SpMet and SpHb may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn, whole-blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

# MASIMO SET SIGNAL EXTRACTION TECHNOLOGY FOR SpO2 MEASUREMENTS

Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET pulse oximetry utilizes parallel engines and adaptive 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<sup>®</sup> (DST<sup>®</sup>) 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, SpCO, AND SpHb MEASUREMENTS DURING PATIENT MOTION

The Rad-87 displays measurements of SpCO, SpMet and SpHb 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		ATOR	DESCRIPTION
	Device Profile		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.
	LED		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	1234567898123456 8123456789123456	The LCD display identifies system settings, monitoring modes, alarm limits, and information from Patient SafetyNet or Philips VueLink (when connected.)
4	Signal IQ Index	SIQ	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	PI	The Perfusion Index provides an indication of the percentage of pulsatile signal to non pulsatile signal.

	CONTROL / INDICATOR		DESCRIPTION
6	Wireless Indicator	©Υ	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	<b>@</b> *	Used to enter the alarm menu to adjust Hi/Low SpO <sub>2</sub> , SpCO, SpMet, SpHb, 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	DISPLAY	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	Ø	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. <b>NOTE:</b> The alarm silence time can be set for 120, 90, 60 and 30 seconds. See Section 4 - Setup Menu Level 2.
1	System Status Light	٢	<ul> <li>Solid Green: Collecting data, no alarms.</li> <li>Solid Yellow: <ol> <li>low priority alarms.</li> <li>Not monitoring and no alarms.</li> <li>Sleep Mode.</li> <li>Interface Alarms "Off".</li> </ol> </li> <li>Flashing Yellow: <ol> <li>Low parameter/measurement confidence.</li> <li>Medium priority alarms.</li> </ol> </li> <li>Flashing Red: High priority alarms.</li> </ul>

	CONTROL / INDIC	ATOR	DESCRIPTION
(12)	Enter Button	ENTER	Used to enter the setup menus and to select/activate certain entries within the menu/setup system.
13	Brightness Button	Ø	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.
(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. <i>Pressing and holding down these buttons allow for the rapid</i> <i>scrolling of alarm limits.</i>
(15)	Pleth Variability Index	PVI	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 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	٩	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, or PC, to the Rad-87. See Section 7, <i>Output Interface Specifications</i> . 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	
4	Equipotential Ground Terminal	
$\triangle$	Consult accompanying documents	
÷\$€	Nurse Call Interface	
	WEEE compliant	
<b>CE</b> 0123	Mark of Conformity to European Medical Device Directive 93/42/EEC	
R <sub>x</sub> Only	Federal law restricts this device to sale by or on the order of a physician (USA audiences only)	
	Year of manufacture	
Studots RH	Storage humidity range: 5% to 95%	
*70 C +00 C *100 D/m - 400 D/m 756 montly - 210 montly	Storage temperature range: +70°C to -40°C Storage altitude range: +1600hPa to +500hPa	
	Keep dry	
	Fragile/breakable, handle with care	
Ϋ́	Indicates wireless Radio signal (wireless radio model only)	
EC REP	EU authorized representative	
	Defibrillation Proof Type BF	
4	Caution	
(I).	Electrical Testing Laboratory certification	

#### 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/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<sub>2</sub> & PR AI On" or "SpO<sub>2</sub> & PR AI Off".

**NOTE:** When the Rad-87 is interfaced to the Philips VueLink and the LCD Display shows "SpO<sub>2</sub> & PR AL On", SpO<sub>2</sub> and BPM audible alarms are active at the device and patient monitor. When the LCD Display shows "SpO<sub>2</sub> & PR AL Off", SpO<sub>2</sub> 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.

- Label: 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.
- 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 device is operating on battery power. Once the battery is fully charged, the device has up to 4 hours of battery life. See Section 7-2, *Specifications*.

#### 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.

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)	

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

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 BACKUP 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 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.
- Verify the front-panel display is free of alarm and system failure messages (see Section 5, Alarms and Messages).

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

- 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<sub>2</sub> Low Alarm Limit and SpO<sub>2</sub> High Alarm Limit,
  - Pulse Rate Low Alarm Limit and Pulse Rate High Alarm Limit,
  - SpCO Low Alarm Limit and SpCO High Alarm Limit,
  - SpMet Low Alarm Limit and SpMet High Alarm Limit,
  - SpHb Low Alarm Limit and SpHb High Alarm Limit,
  - PI Low Alarm Limit and PI High Alarm Limit,
  - PVI Low Alarm Limit and PVI High Alarm Limit.

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).

# **Basic operation continued**

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 3* in this chapter).

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

- 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 is disconnected.
- 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.

# **Basic operation continued**

- 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 <sub>2</sub> high alarm limit	"" Off	2 to 99%
SpO <sub>2</sub> 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
SpHb high alarm limit	16	2 to 24.5, then ""
SpHb low alarm limit	7	"", then 1 to 24
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
		Max/Normal/APOD
Sensitivity	APOD	NOTE: MAX sensitivity will default to APOD after
Display brightness		l evels 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 On	Alarm, Off/On

Nurse Call Type	Alarm	Alarm and Low 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	Setting is retained after power cycle.
Device Profile settings	N/A	Light blue, purple, pink, orange or green
LCD Language	English	English (Default) French, German, Italian, Spanish, Swedish, Dutch, Danish, Portuguese
PVI Bar	On	On/Off

# FACTORY DEFAULT AND USER CONFIGURABLE SETTINGS (CONTINUED)

# Successful Monitoring

The following general points will aid in ensuring monitoring success.

NOTE: See Safety Information, Warnings, Cautions and Notes for additional information.

- 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<sub>2</sub>

Stability of the SpO<sub>2</sub> 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<sub>2</sub> 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:

- Elevated levels of methemoglobin.
- 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 - SpHb

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

A stable SpOC reading is associated with stable readings for both SpO<sub>2</sub> and SpHb which comes with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

Inaccurate 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.
- Elevated levels of carboxyhemoglobin.
- Elevated levels of methemoglobin.
- Severe anemia may cause erroneous SpOC readings.

### 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

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<sup>3</sup>. 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.

<sup>3</sup> Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction. Anesthesiology 1990; 73:532-537

#### SIGNAL IQ - (SIQ)

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<sub>2</sub>, SpCO, SpMet or SpHb 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.
- 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-until power cycle 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, the 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 BACKUP 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<sub>2</sub>) and pulse rate in beats per minute (BPM) and total hemoglobin (SpHb g/dl)\*. By pressing the Display Button once, the display changes to show Screen 2 containing total arterial oxygen content (SpOC ml/dl)\* perfusion index (PI) and pleth variability index (PVI)\*. 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, SpHb, SPOC, PVI

Display Screens showing Parameters/Measurements -Default Locations



Screen 1 Home display screen





# Normal patient monitoring continued

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

Display Screens with All Parameters and Measurements



Display Screens when SpMet, SpCO and PVI Are Not Installed



Screen 1 Home display screen

No Screen 3

Display Screens with SpHb and PVI Installed and SpMet and SpCO Not Installed



No Screen 3

# PARAMETER/MEASUREMENT SELECTION

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

Display Screens Showing PVI on Screen 1



Screen 1 Home display screen Screen 2

Screen 3

Display Screens Showing SpHb on Screen 1 and 2



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 is pressed. Pressing the Display Button exits the menus and returns the device to 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 <sub>2</sub> LO	
	Press 2x	%SpO <sub>2</sub> HI	Use Up or Down Buttons to adjust the value to the desired setting
	Press 3x	Pulse rate (BPM) LO	Press the Alarm Limits Button or Enter Button to accept the setting and move to the next option. Once the last option
	Press 4x	Pulse rate (BPM) HI	is accessed an additional press of the Alarm Limits Button or Enter Button will return the device to Screen 1. OR
	Press 5x	SpHb g/dl LO	press the Display Button to exit at any time and return to Screen 1.
	Press 6x	SpHb g/dl HI	

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

#### 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
	Press 2x	PI HI	AND press the Alarm Limits Button or Enter Button to accept the setting and move to the next option. Once
	Press 3x	PVI LO	the last option is accessed an additional press of the Alarm Limits Button will return the device to Screen 2.
	Press 4x	PVI HI	press the Display Button to exit at any time and return to Screen 2.

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

### PARAMETER/MEASUREMENT ALARM LIMITS - SCREEN 3

To access alarm limits for parameters/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 parameters/measurements.

BUTTONS	SETTINGS		
	Press once		
	¢Ð*	%SpMet LO	Use Up or Down Buttons to adjust the value to the desired setting
Use the Alarm Limits Button to	Press 2x		AND press the Alarm Limits Button or Enter
access the alarm limits options and	œ.	%SpMet HI	Button to accept the setting and move to the next option. Once the High Pulse
move between	Press 3x		rate limit is accessed an additional
	œ.	%SpCO LO	Enter Button will return the device to Screen 3.
	Press 4x		OR
		%SpCO HI	time and return to Screen 3.

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

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

### SENSITIVITY

BUTTONS	SETTING		
Use the Sensitivity Button	Press once	Default APOD	
to access the sensitivity options and move between options.	Press 2x	NORM	Use the Sensitivity Button to move between menu options and accept the setting.
	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		
		Default	
		Level 3	
Use the Enter Button			Use Up or Down Button to move between
to access the Alarm Volume menu and to move between Level		Level 4	settings and the Enter Button to accept the setting and move to the next menu screen.
2 menus.		Level 1	OR press the Display Button to exit without saving the new setting and to return to
		Level 2	the nome display screen.

# ALARM SILENCE

BUTTONS	SETTINGS		
		Default 120 seconds	
Press the Enter Button again to move to the next menu.		90 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.
execution 2x		60 seconds	press the Display Button to exit without saving the new setting and to return to the
		30 seconds	

# 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		
		Default 5 seconds	
Press the Enter Button again to move to the next menu.		0 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.
George States St		15 seconds	press the Display Button to exit without saving the new setting and to return to the
		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.		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
4x		YES (Clear trend)	OR press the Display Button to exit without saving the new setting and to return to the home display screen.

#### **BUTTON VOLUME**

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

#### FASTSAT

BUTTON	SETTING		
Press the Enter Button again to move to the next menu.		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.
6x		On	OR press the Display Button to exit without saving the new setting and to return to the home display screen.

# Trend setup and use

#### INTRODUCTION

The Rad-87 can store up to 72 hours of trend data captured at 2 second intervals. 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**.

# Trend setup and use continued

 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.

# TREND DATA FORMAT (CONTINUED)

PARAMETER	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)
	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
Exception Messages	<ul> <li>001 = No Sensor</li> <li>002 = Defective Sensor</li> <li>004 = Low Perfusion</li> <li>008 = Pulse Search</li> <li>010 = Interference</li> <li>020 = Sensor Off</li> <li>040 = Ambient Light</li> <li>080 = Unrecognized Sensor</li> <li>100 = reserved</li> <li>200 = reserved</li> <li>200 = reserved</li> <li>200 = Low Signal IQ</li> <li>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</li> </ul>

# SAMPLE TREND OUTPUT

07/21/08	09:56:08	Sp02=000	PR=000	PI=00.00	EXC=820:OffPat,SET
07/21/08	09:56:10	Sp02=000	PR=000	PI=00.00	EXC=828:Search,OffPat,SET
07/21/08	09:56:12	Sp02=097	PR=069	PI=04.69	EXC=800:SET
07/21/08	09:56:14	Sp02=096	PR=074	PI=02.28	EXC=C00:LowSigIQ,SET
07/21/08	09:56:16	Sp02=098	PR=078	PI=03.64	EXC=800:SET
07/21/08	09:56:18	Sp02=000	PR=000	PI=00.00	EXC=800:SET
07/21/08	09:56:20	Sp02=000	PR=000	PI=00.00	EXC=820:OffPat,SET
07/21/08	09:56:22	Sp02=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	3	
		Default 8 seconds	
		4 seconds	
Hold down the Enter Button and press the		2 seconds	Use Up or Down Button to move between settings AND
Down Button		16 seconds	press the Enter Button to accept the setting and
+		10 3000103	move to the next menu option.
		14 seconds	press the Display Button to exit without saving the new setting and to
		12 seconds	rearried the norme display screen.
		10 seconds	
		(The cycling function for the menu options is not available.)	

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

### ALARM ON/OFF

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

\*When Alarm On/Off is set to "Off rE", the audible alarm "beeps" twice every three 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.

#### **DEFAULT SETTINGS**

BUTTONS	SETTING		
		No change (Do not adjust factory default settings.)	Use Up or Down Button to move between settings
Press the Enter Button again to move to the next menu.		User Default (Set to user settings.*)	AND press the Enter Button to accept the setting and
		Factory Default (Restore factory default settings.)	OR press the Display Button to exit without saving the new
		Set Device Profile (One or more pre-defined device profiles)	setting and to return to the home display screen.

\*Set the Factory Default to this setting when configuring a Device Profile. 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.

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 Default Settings screen is displayed. Press the Up or Down Arrow Button until "User Default – Set" is displayed on the LCD. The user can press the Enter Button again to save the settings.

Using an external configuration application, the user can save up to five profiles. The user may select a color for the Device Profile LED to associate with the saved profiles. 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 until the device is returned to the user configured default settings or powered off, indicating a change from the Device Profile settings.

To set a device profile, the user enters Menu Level 3 by pressing and holding the Enter Button and Down Arrow Button at the same time for 5 seconds. Then, by pressing the Enter Button three times, the Default Setting screen is displayed. The user can use the Up or Down Arrow Button to select the desired profile and press the Enter Button to save the setting.

# SETUP MENU LEVEL 3 (CONTINUED) PVI BAR ON/OFF (IF AVAILABLE)

BUTTONS	SETTING		
Press the Enter Button again		Default On	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and
next menu.		Off (No PVI Bar or parameter/ measurement label displayed)	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.

# 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.		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.
ENTER		On (Smart Tone)	press the Display Button to exit without saving the new setting and to return to the home display screen.

YEAR

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

# MONTH

BUTTONS	SETTING		
Press the Enter Button again to move to the		Default     Use Up or Down Button to settings       Month     AND       Workh     AND       Press the Enter Button to a and move to the next ment of to adjust the setting.	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.

DAY

BUTTONS	SETTING	_	
Press the Enter Button again to move to the		Default Use Up or Down settings days AND press the Enter E	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting
next menu.		Use Up or Down Button to adjust 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.

# HOUR

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.		Default hour Use Up or Down Button to adjust the setting.	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.

# MINUTE

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu.		Default 30 minutes Use Up or Down Button to adjust the setting.	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.
Button again to move to the next menu.		30 minutes Use Up or Down Button to adjust the setting.	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.

# SOFTWARE VERSION

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

### SERIAL OUTPUT

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

#### 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<sub>2</sub> and BPM audible alarms when connection to the interfaced system becomes compromised.

BUTTONS	SETTING		
Press the Enter Button again to move to the next		Default On <b>NOTE:</b> LCD shows SpO <sub>2</sub> and BPM alarms On.	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and
		Off (only SpO <sub>2</sub> /BPM) <b>NOTE:</b> LCD shows SpO <sub>2</sub> and BPM alarms Off.	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.

# 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.
- Connect one end of the VueLink cable to the Serial Output connector on the back of the Rad-87.
- 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<sub>2</sub> and pulse rate values will automatically appear on the HP/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.
- 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.
- With a properly configured RadNet Interface Module, the Rad-87 will automatically display the SpO<sub>2</sub>, PVI, PI and Pulse Rate parameters/measurements 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.

# NURSE CALL\*

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

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

# **POLARITY**\*

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu		Default Normal	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting
option.		Inverse	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.

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

# LINE FREQUENCY

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

### **PARAMETER/MEASUREMENT SELECT - SCREEN 1**

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

# PARAMETER/MEASUREMENT SELECT - SCREEN 2

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.		SpHb (if available) 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
		(no parameter/ measurement displayed)	press the Display Button to exit without saving the new setting and to return to the home display screen.

# SETUP MENU LEVEL 3 (CONTINUED) PARAMETER/MEASUREMENT SELECT - SCREEN 3

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

#### LCD LANGUAGE

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option.		Default English Scrolls through available languages displayed on the LCD	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.

# 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
		Sleep Mode*	
		Home Mode	press the Display Button to exit without saving the new setting and to return to the home display screen.

\*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

### **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.

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	

# ENABLE/DISABLE RADIO

# 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