Rad-87™

Pulse CO-Oximeter

OPERATOR'S MANUAL

MASIMO®

The Rad-87 Operating Instructions provide the necessary information for proper operation of all models of the Rad-87 instrument. 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 instrument does not carry any express or implied license to use this instrument with replacement parts which would, alone or in combination with this instrument, fall within the scope of one of the patents relating to this instrument.

CAUTION:

- **Federal law (U.S.) restricts this instrument to sale by or on the order of a physician.**

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CONFORMS TO UL STD 60601-1,
CERTIFIED TO CAN/CSA STD C22.2 NO. 601.1

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

Safety Information, Warnings, Cautions and Notes

The Rad-87™ Pulse CO-Oximeter™ is designed to minimize the possibility of hazards from errors in the software program by following sound engineering design processes, Risk Analysis and Software Validation.

- Explosion hazard. Do not use the Rad-87 in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- High intensity extreme lights (including pulsating strobe lights) directed on the sensor, may not allow the Pulse CO-Oximeter to obtain readings.
- Excessive ambient noise may affect the accuracy of the respiration rate reading from the Acoustic Respiration Sensor.
- SpO_2 monitoring is required when monitoring RRa (Acoustic Respiration).
- 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 instrument. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- Ensure that the HF surgical neutral electrode is properly connected to help prevent unintended current return paths when using high frequency (HF) surgical equipment.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Use cables only from the instrument manufacturer to provide protection against the effects of discharge from a cardiac defibrillator and burns.
- Do not place the Rad-87 or accessories in any position that might cause it to fall on the patient. Do not lift the Rad-87 by the power cord or any other cable.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter can not measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.
  - For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present.

  NOTE: *High levels of COHb may occur with a seemingly normal SpO_2. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.*

  - For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 and SpCO® measurements.

Safety Information, Warnings, Cautions and Notes, continued

- Elevated levels of Carboxyhemoglobin (COHb) will lead to inaccurate SpO_2 measurements.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO_2, SpMet®, SpCO, SpHb® and SpOC™ measurements.
- Motion artifact may lead to inaccurate SpMet, SpCO, SpHb and SpOC measurements.
- Very low arterial Oxygen Saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements.
- Severe anemia may cause erroneous SpO_2 and SpOC 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 instrument 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 instrument to perform inaccurately or fail.
- Do not place containers with liquids on or near the Rad-87. Liquids spilled on the instrument may cause it to perform inaccurately or fail.
- If the Rad-87 fails any part of the setup procedures or leakage tests, remove the instrument from operation until qualified service personnel have corrected the situation.
- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- Do not monitor more than a single patient at a time on the Rad-87.
- Disposal of product - Comply with local laws in the disposal of the instrument 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, Medical Device Directive 93/42/EEC and Part 15, FCC Rules/USA.
    - This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This equipment 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 (instrument with optional radio) wirelessly transmits real-time sensor connectivity status, indicating a connect and/or disconnect state. If the instrument is in a failure mode then the radio power is disabled and an error message is indicated on the instrument display. The instrument does not have a powered state where no information is transmitted.
- In accordance with FCC requirements, the Rad-87 (instrument with optional radio) must be placed greater than 20 cm from the patient or nearby persons.
- In accordance with FCC requirements, radio accessories on the Rad-87 (instrument 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 instrument during operation.
- Ensure the speaker is not covered or the instrument 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 instrument on surfaces with visible liquid spills.
  - Do not soak or immerse the instrument in liquids.
  - Always turn off and disconnect the power cord from the AC power supply before cleaning the device.
  - Use cleaning solutions sparingly.
- Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) for noninvasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or cleared by the FDA, or in any manner inconsistent with the instructions for use or labeling. The device and related accessories are not intended for use in combination with other medical devices or in high-risk applications.

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SECTION 4 - OPERATION

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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 compatible Masimo sensors and cables.

SECTION 9 **Service & Maintenance** describes how to maintain, service and obtain repair for the Rad-87 instrument. The Sales and End User License Agreement, including Warranty, is also in this section.

SECTION 10 **Part Numbers** lists the part numbers of the different language ***Operator's Manuals*** that are available for 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 instrument 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, methemoglobin saturation, total hemoglobin concentration, total arterial oxygen content, pulse rate and respiration rate monitor. The Rad-87 features an LED display screen that continuously displays numeric values for SpO_2, SpCO*, SpMet*, SpHb*, total arterial oxygen content (SpOC*), perfusion index (PI), pleth variability index* (PVI), pulse rate and respiratory/respiration rate (RRa*). It also provides bar graph displays for quick visual identification of Signal I.Q.® (SIQ™), perfusion index (PI), acoustic Signal Identification Quality (SIQa*) and Respiration Indicator (RI*). 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 CO-Oximeter technology in the world.
- Rainbow technology continuously and noninvasively measures arterial oxygen saturation (SpO_2) and pulse rate (BPM), as well as providing a reliable probe-off detection.
- Perfusion Index (PI) with trending capability indicates arterial pulse signal strength during low perfusion.
- Accurate on cyanotic infants with congenital heart disease when used with an LNOP Blue Sensor.
- Signal I.Q. provides signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat® tracks rapid changes in arterial O2 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, *Trend Setup and Use*.)
- Allows user to customize the default settings and set the instrument 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.
- Rainbow Acoustic Monitoring uses acoustic monitoring technology to measure and display respiration rate (RRa) while providing the Respiration Indicator (RI) at the sensor site.
- Pleth Variability Index (PVI)† may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.
- 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 an 802.11a/b/g wireless radio interface with compatible systems (wireless radio model only).
- Ability to connect to Masimo Patient SafetyNet through a wireless network (wireless radio model only).

* Optional features: SpCO, SpMet, SpHb, SpOC, PVI, RRa, RI, SIQa

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

Indications for Use

The Masimo Rainbow SET® Rad-87 Pulse CO-Oximeter and accessories are indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration and/or respiratory rate (RRa).The Masimo Rainbow SET Rad-87 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile and home environments.

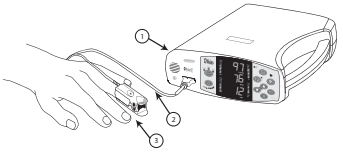
Note: Please refer to the sensor Directions for Use (DFU) for specific indications.

Pulse CO-Oximetry

SpO_2 General Description

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for neonates. The sensor is connected to the Pulse CO-Oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument.

The following figure shows the general monitoring setup.



1. Instrument
2. Patient Cable
3. Sensor

SpCO General Description

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carboxyhemoglobin 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.

SpHb (Total Hemoglobin) 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_2 monitor with other available parameters/measurements.

CaO_2 (Total Arterial Oxygen Content) General Description*

Oxygen (O2) 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 (CaO2) and is measured in units of ml O2/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:

$CaO_2 = 1.34$ (ml O_2/g Hb) x Hb (g/dL) x HbO_2 + PaO_2 (mm Hg) x (0.3 ml O_2/ 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_2 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_2) as measured by a pulse oximeter is given by:

$$SpO_2 = 1.02 \times HbO_2$$

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

SpOC (Pulse CO-Oximetry) General Description

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 SpO_2 + 0.3 ml/dl

† When ml O2/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.

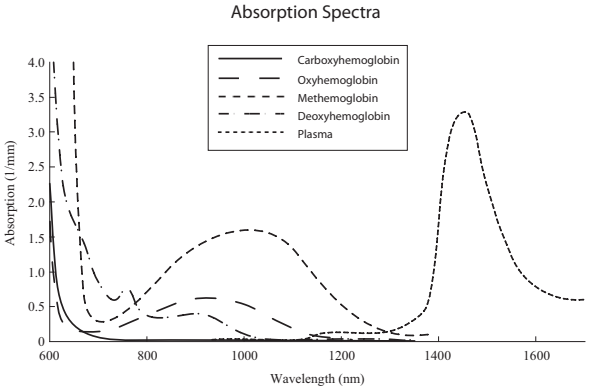
Rainbow Acoustic Monitoring General Description

Rainbow Acoustic Monitoring continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Respiration Sensor translates airflow sounds generated in the upper airway to an electrical signal that can be processed to produce a respiration rate, measured as breaths per minute.

Principle of Operation

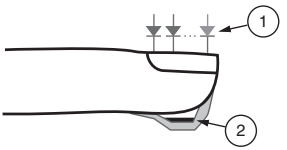
Pulse CO-Oximetry is governed by the following principles:

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



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

The Rad-87 Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma. The Rad-87 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a photodiode (detector). See figure below. Signal data is obtained by passing various visible and infrared lights (LED's, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25mW. The detector receives the light, converts it into an electronic signal and sends it to the Rad-87 for calculation.



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

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_2, 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_2, SpCO, SpMet and SpHb measurements of the Rad-87 Pulse CO-Oximeter. In the case of SpO_2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (PO2) 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 SpO_2, 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_2, 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 SpO_2 Measurements

Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the 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® (DST®) reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

SpMet, SpCO, and SpHb Measurements During Patient Motion

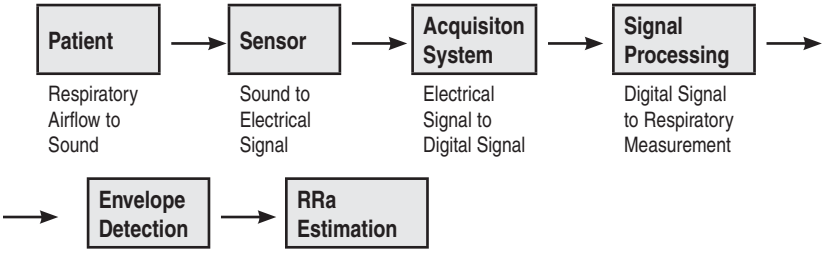
The Rad-87 displays measurements of SpCO, SpMet and SpHb during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive 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 "---".

Rainbow Acoustic Monitoring

Rainbow Acoustic Monitoring is a real time, continuous, non-invasive method for measuring respiration rate based on respiratory sounds. Respiratory sounds include sounds related to respiration such as breath sounds (during inspiration and expiration), adventitious sounds, cough sounds, snoring sounds, sneezing sounds, and sounds from the respiratory muscles [1]. These respiratory sounds often have different characteristics depending on the location of recording [2] and they originate in the large airways where air velocity and air turbulence induce vibration in the airway wall. These vibrations are transmitted, for example, through the lung tissue, thoracic wall and trachea to the surface where they may be heard with the aid of a stethoscope, a microphone or more sophisticated devices.

Rainbow Acoustic Monitoring Architecture

The following figure illustrates how a respiratory sound produced by a patient can be turned into a numerical measurement that corresponds to a respiratory parameter.



Patient

The generation of respiratory sounds is primarily related to turbulent respiratory airflow in upper airways. Sound pressure waves within the airway gas and airway wall motion contribute to the vibrations that reach the body surface and are recorded as respiratory sounds. Although the spectral shape of respiratory sounds varies widely from person to person, it is often reproducible within the same person, likely reflecting the strong influence of individual airway anatomy [2-6].

Sensor

The sensor captures and transmits respiratory sounds (and other biological sounds) much like a microphone does. When subjected to a mechanical strain, (e.g., surface vibrations generated during breathing), the sensor becomes electrically polarized. The degree of polarization is proportional to the applied strain. This is known as the 'Piezoelectric effect' in this manual. The output of the sensor is an electric signal that includes a sound signal that is modulated by inspiratory and expiratory phases of the respiratory cycle.

Acquisition System

The acquisition system converts the electrical signal provided by the sensor into a digital signal. This format allows the signal to be processed by a computing device.

Signal Processing

The digital signal produced by the acquisition system is converted into a measurement that corresponds to the respiratory parameter of interest. As shown in the figure on the previous page, this can be performed by, for example, determining the digital signal envelope or outline which in turn may be utilized to determine the respiratory rate. In this way, a real-time, continuous breath rate parameter can be obtained and displayed on a monitor which, in many cases, may be real-time and continuous.

The respiratory cycle envelope signal processing principle is similar to methods that sample airway gases and subsequently determine a respiratory rate.

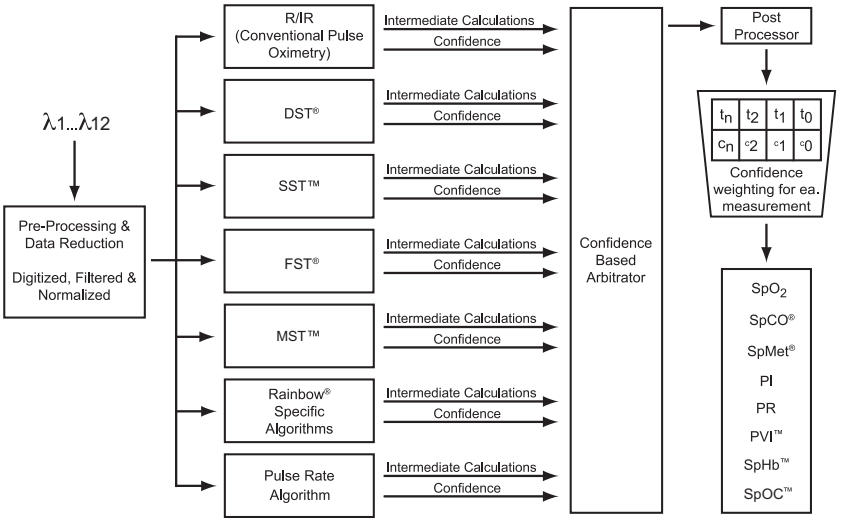
[1] A.R.A. Sovijärvi, F. Dalmasso, J. Vanderschool, L.P. Malmberg, G. Righini, S.A.T. Stoneman. Definition of terms for applications of respiratory sounds. Eur Respir Rev 2000; 10:77, 597-610.
[2] Z. Moussavi. Fundamentals of respiratory sounds analysis. Synthesis lectures on biomedical engineering #8. Morgan & Claypool Publishers, 2006.
[3] Olsen, et al. Mechanisms of lung sound generation. Semin Respir Med 1985; 6: 171-179.
[4] Pastercamp H, Kraman SS, Wodicka GR. Respiratory sounds – Advances beyond the stethoscope. Am J Respir Crit Care Med 1977; 156: 974-987.
[5] Gavriely N, Cugell DW. Airflow effects on amplitude and spectral content of normal breath sounds. J Appl Physiol 1996; 80: 5-13.
[6] Gavrieli N, Palti Y, Alroy G. Spectral characteristics of normal breath sounds. J Appl Physiol 1981; 50: 307-314.

FastSat

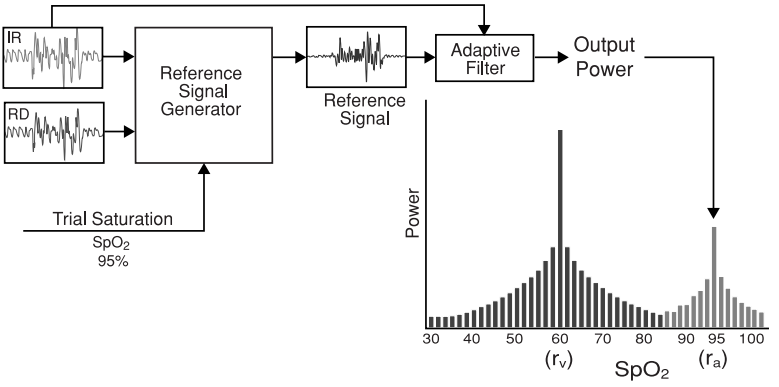
FastSat enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend. When the Rad-87 is set to FastSat “On”, the averaging algorithm evaluates all the saturation values providing an averaged saturation 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®



System Description

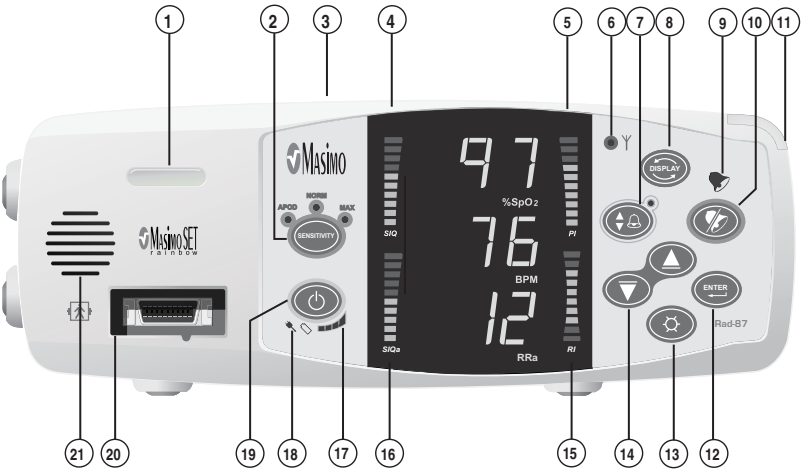
2

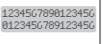
Introduction

The Rad-87 Pulse CO-Oximeters are full featured devices designed for ease of operation. All pulse CO-Oximetry measurement information, as well as instrument 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 instrument 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 instrument (Horizontal) or on the left of the instrument (Vertical).

Rad-87 Pulse CO-Oximeter - Horizontal

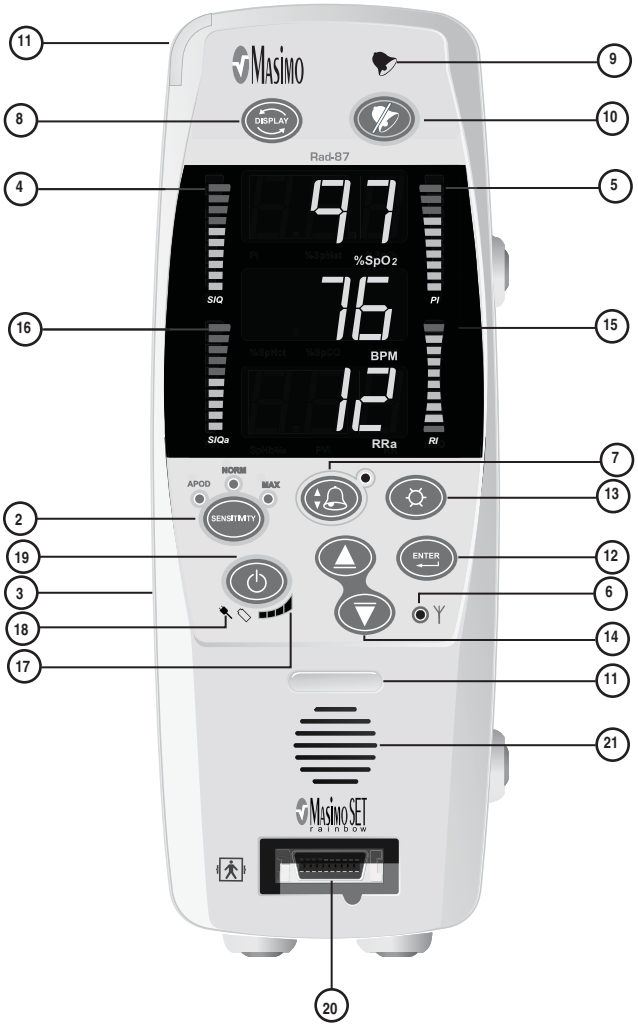


	CONTROL / INDICATOR		DESCRIPTION
1	Device Profile LED		The Device (instrument) Profile LED illuminates when the instrument has been set to user configured "default" settings. Upon power up, the user configured default settings are retained and the Device Profile LED remain lit. When user configured default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

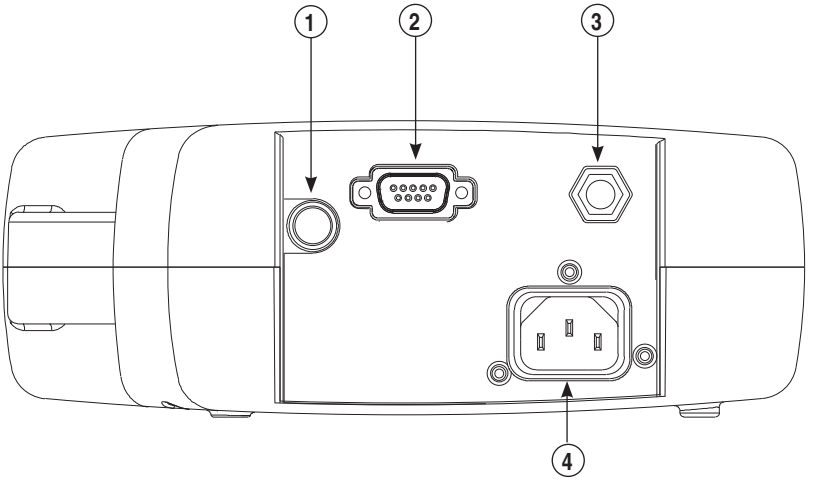
	CONTROL / INDICATOR		DESCRIPTION
6	Wireless Indicator		Off: No connection to Masimo Patient SafetyNet or other compatible interface system. Flashing Green: Rad-87 attempts to connect to Patient SafetyNet or other compatible interface system. Solid Green: Rad-87 is connected to the Patient SafetyNet or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

	CONTROL / INDICATOR		DESCRIPTION
(12)	Enter Button		Used to enter the setup menus and to select/activate certain entries within the menu/setup system.
(13)	Brightness Button		Controls the level of the brightness for the LED display by providing 4 levels of brightness. Each press of the button increases the brightness one level. Once level 4 is accessed, an additional press of the button returns the brightness to level 1. Press the Enter Button to save the desired choice.
(14)	Up Button Down Button		Use these buttons to adjust the volume of the pulse beep tone. Within the menu/setup system, these buttons are used to select values within each menu option or the numeric value for the parameter/measurement alarm feature. Pressing and holding down these buttons allow for the rapid scrolling of alarm limits.
(15)	Respiration Indicator		The Respiration Indicator (RI) displays the level of sound that is detected by the Acoustic Respiration Sensor. A tall vertical line indicates a high sound level, while a short vertical line indicates a low sound level. During SpO_2 only or combined SpO_2 and Rainbow Acoustic Monitoring, the bar will be green. During Rainbow Acoustic Monitoring only, the bar will be orange.
(16)	Rainbow Acoustic Monitoring Signal Quality		The Rainbow Acoustic Monitoring Signal Quality (SIQa) displays the confidence in the RRa value displayed on the monitor. A tall vertical line indicates high confidence, while a short vertical line indicates low confidence. During SpO_2 only or combined SpO_2 and Rainbow Acoustic Monitoring, the bar will be green. During Rainbow Acoustic Monitoring only, the bar will be orange.
(17)	Battery Charge Level Indicator		Provides a visual representation of the battery charge status. When plugged into an AC outlet, only the first bar is illuminated. 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.
(18)	AC Power Indicator		The AC Power Indicator is illuminated when the Rad-87 is connected to AC power and during battery charging.
(19)	Power Button		Used to turn the instrument on and off. Press the button once to power on the device. Press the button for 2 seconds to power off the device.
(20)	Pulse CO-Oximeter Patient Cable Connector		Connects to a Masimo Pulse CO-Oximeter sensor or Masimo Pulse CO-Oximeter Patient Cable with a sensor.
(21)	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, *Output Interface Specifications*. All external device connections to the Serial Output Connector must be IEC-60950 compliant.
3	**Equipotential Ground Connector**	Use the Equipotential Ground Connector for grounding.
4	**AC Power Receptacle**	For continuous operation and/or battery recharging, plug the AC power cord into an AC power receptacle.

Symbols

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

SYMBOLS	DEFINITION
	RS-232
	Equipotential Ground Terminal
	Consult accompanying documents
	Nurse Call Interface
	WEEE compliant
	Mark of Conformity to European Medical Device Directive 93/42/EEC
R_X Only	Federal law restricts this instrument to sale by or on the order of a physician (USA audiences only)
	Year of manufacture
	Storage humidity range: 10% to 95%
	Storage temperature range: -40˚C to +70˚C Storage altitude range: 500 mbar to 1060 mbar
	Keep dry
	Fragile/breakable, handle with care
	Indicates wireless Radio signal (wireless radio model only)
EC REP	EU authorized representative
	Defibrillation Proof Type BF
	Caution
	Manufacturer
	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 an 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 "Alarm Tones On" or "Alarm Tones Off".

***NOTE**: When the Rad-87 is interfaced to the Philips VueLink and the LCD Display shows "Alarm Tones On", audible alarms are active at the instrument. When the LCD Display shows "Alarm Tones Off", audible alarms are inactive at the instrument.*

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

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

Rad-87 Setup

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.

Verify the AC power voltage and frequency before use. Verify 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, 47-63 Hz. The instrument is rated at 20 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 the instrument 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 instrument from the main 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 instrument is operating on battery power. 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.

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

OPERATING ENVIRONMENTAL CONDITIONS	
Temperature	+0°C to +50°C, +32°F to +122°F
Humidity	10% to 95%, non-condensing
Operating Altitude	500 mbar to 1060 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

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

CAUTION:

- **The instrument must be configured to match your local power line frequency to allow for the cancellation of noise introduced by fluorescent lights and other sources.**

CAUTION:

- **The battery should be adequately charged to ensure backup power in case of AC power disruption.**

System Interface Setup

Philips VueLink Setup

(Also refer to the Masimo SET VueLink Module and Serial Cable Directions for Use for additional details)

1. Select the Philips VueLink selection (PHL) from the Serial Output menu on the Rad-87. After selecting, choose the preferred settings by stepping through menu options.
2. Connect one end of the VueLink cable to the Serial Output connector on the back of the Rad-87.
3. Insert the VueLink module into the monitor rack.
4. Disconnect the VueLink cable from the VueLink Module, if it is already connected, before proceeding.
5. Press the VueLink button on the VueLink Module and verify that “Open Interface” is the selected device on the HP/Agilent/Philips monitor screen.
6. Connect the VueLink cable to the VueLink Module and power on the Rad-87.
7. The SpO_2 and pulse rate values will automatically display on the Philips/Agilent/HP monitor. The Philips/Agilent/HP monitor may be configured to display PI (Perfusion Index), as well as optional Rainbow parameters if they are enabled in the Rad-87.
8. In order for the pleth waveform to be displayed on the Philips/Agilent/HP monitor, the user may need to configure the Philips/Agilent/HP monitor. Please see the Philips/Agilent/HP monitor's Operator's Manual for complete instructions.
9. The Rad-87 Pulse CO-Oximeter can be set up to audibly indicate all patient alarms while communicating with the Philips/ VueLink interface. Use the Interface Alarms setting in the Output menu to enable and disable audible alarms on the Rad-87.

***NOTE**: During VueLink operation, audible alarms will NOT be active in the bedside multiparameter monitor. If however, the Philips/Agilent/HP monitor is connected to a central monitoring system, audible alarms will be available at the central monitor. The Philips/Agilent/HP monitor may need to be configured to transfer alarms to the central monitor. Refer to the Philips, Agilent or HP Operator's Manual for information.*

RadNet Setup

1. Connect one end of the serial cable to the Serial Output connector on the back of the Rad-87.
2. Connect the other end of the serial cable to the RadNet Interface Module connector.
3. Turn the RadNet Interface Module on.
4. Select the ASCII 2 selection from the Serial options on the Rad-87.
5. A proper connection is shown by the RadNet Interface Module's Online LED being solid.
6. With a properly configured RadNet Interface Module, the Rad-87 will automatically display the SpO_2, 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.

Operation

4

Introduction

To operate the Rad-87 system effectively, the instrument 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. If damaged, refer to Section 9, *Service and Repair.*
2. Connect a patient cable, Dual Rainbow 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 or Dual Rainbow Cable, select a sensor that is compatible with the Rad-87 and the patient before connecting it to the cable. See section 8, *Sensors and Patient Cables*. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the detector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector. If using an Acoustic Respiration Sensor, ensure that the patient's neck area is clean and dry.
4. Follow the Indications, Instructions and Cautions in the sensor's ***Direction for Use*** when attaching, reattaching or disconnecting the sensor(s).
5. Press the Power button to turn the Rad-87 on.
6. Verify all front-panel indicators momentarily illuminate, a tone is heard, and the LED and LCD Displays show Sensor Time remaining (if applicable).
7. Verify the front-panel display is free of alarm and system failure messages (see Section 5, *Alarms and Messages*).
8. Verify that the 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):

LED:

- Mode setting: Standard (Std), Sleep (SLP), or Home (Hnn)

LCD:

- Mode setting: Standard, Sleep, or Home
- Pulse Rate Low Alarm Limit and Pulse Rate High Alarm Limit
- RespirationRate (RRa) Low and 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

Basic Operation, continued

- PI Low Alarm Limit and PI High Alarm Limit
- PVI Low Alarm Limit and PVI High Alarm Limit
- Sensor Time remaining (if applicable).

9. 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**: "- - -" initially shows in the numeric display fields for all the parameters/measurements when the Rad-87 is turned on. As the system starts monitoring, the numeric display fields update (refresh). The numeric display fields for the parameters/measurements begin to show numbers during the refresh cycles even though the numbers have not stabilized; during this period, the measurement label will begin to flash to indicate that the measurement value is being processed. When the flashing stops, the number has stabilized. In the case of SpHb, the numeric value will be displayed upon initial stabilization of the number, and the parameter label will continue to flash for an additional processing period to reach optimal confidence.*

Parameter/Measurement	Approximate Time (in seconds) until Number Stabilization
SpO2	20
SpCO, SpMet	45
SpHb, SpOC	120
PVI	90
RRa	60

10. 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.
11. Verify the sensor alarms are functional.
    - Remove the sensor from the sensor site.
    - The alarm tone sounds.
    - The Alarm Bell flashes red.

Basic Operation, continued

- 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.*

12. 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.
13. To begin patient monitoring:
    - Adjust the alarm limits.
    - Adjust the alarm volume.
    - Adjust the pulse beep volume.
14. Verify the sensor is applied correctly and that the measured data is appropriate, see Section 4, *Successful Monitoring*.
15. Monitor the patient.
16. After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to local laws. See the sensor's Directions for Use.
17. Press and hold the Power Button for 2 seconds to turn the Rad-87 off [3 seconds in the Home Mode].

Basic Operation, continued

Default Settings

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

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

Factory Default and User Configurable Settings

OPTION	FACTORY DEFAULTS	USER CONFIGURABLE DEFAULTS
SpO_2 high alarm limit	"---" Off	2 to 99%, then "--- "
SpO_2 low alarm limit	90%	1 to 98%
Pulse rate high alarm limit	140 BPM	35 to 235 BPM
Pulse rate low alarm limit	50 BPM	30 to 230 BPM
RRa high alarm limit (breaths per minute)	30 breaths per minute	5 to 69 breaths per minute, then "---"
RRa low alarm limit (breaths per minute)	6 breaths per minute	4 to 68 breaths per minute
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 0.1 to 99
SpHb high alarm limit	17	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
Sensitivity	APOD	Max/Normal/APOD ***NOTE:*** *MAX sensitivity will default to APOD after a power cycle.*
Display brightness	Level 2	Levels 1 thru 4
Pulse tone volume	Level 2	Off, Levels 1 thru 3
Alarm Silence Time	120 seconds	30, 60, 90, or 120 seconds
Alarm Volume	Level 3, 70 db min	Levels 1 thru 4, 87 db max
Monitoring Mode	Standard (Normal)	Standard, Sleep, Home
Audible Alarm Off	Alarms active (On)	"On/Off or muted with reminder"
Optical Sensor Off Audible Alarm Latch	Off	On/Off
SpO_2 Alarm Delay	5 sec	0, 5, 10, or 15 seconds
RRa Alarm Delay	30	0, 10, 15, 30, 60 seconds
Rapid Desat Alarm	5%	5, 10, Off
Serial out	ASCII 2	Philips/ASCII 1/ASCII 2
Interface Alarm	Alarm Tones On	Alarm Tones, Off/On
Nurse Call Type	Alarm	Alarm and Low Signal I.Q./ Low Signal I.Q./ Alarm
Nurse Call Polarity	Normal	Normal/Invert

Basic Operation, continued

OPTION	FACTORY DEFAULTS	USER CONFIGURABLE DEFAULTS
Line Frequency	60 Hz	60 Hz, 50 Hz
SpO_2 Averaging time	8 sec	2, 4, 8, 10, 12, 14, 16
RRa Averaging Time	30	0, 10, 20, 30, 60
SmartTone	Off	On/Off
FastSat	Off	*Setting is retained after power cycle*
RRa Sensor Status Notifications	Off	On/Off
Device Profile settings	N/A	Blue, green, orange, pink or white
SpHb Precision	0.1	0.1/ 0.5/1
SpHb Averaging (Hb AV)	Medium	Long (Lng)/Medium (nnl)/Short (Sho)
SpHb Calculation (Hb Cal)	Arterial	Arterial (SpHb)/ Venous (SpHbv)
SpHb Display in Low SiQ	No	Yes (Display SpHb value) No (Display dashes)
PI Averaging	Long	Short (Sho), Long (Lng)
PVI Averaging	Long	Short (Sho), Long (Lng)
LCD Language	English	English (Default) French, German, Italian, Spanish, Swedish, Dutch, Danish, Portuguese

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).
- Follow the Indications, Instructions and Cautions in the sensor's ***Direction for Use*** when attaching, reattaching or disconnecting the sensor.

***NOTE**: When a Masimo Rainbow Sensor is properly connected to the patient, the instrument normally goes through a 20-30 second sensor calibration/pulse search routine and then displays numeric values installed on the instrument and supported by the sensor. However, if the sensor calibration/pulse search routine is unsuccessful for Rainbow parameters/measurements, the instrument automatically switches to a "SpO2 Only Mode" to provide SpO_2, PR, PI and PVI values.*

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

If a Masimo Rainbow Direct Connect Reusable Sensor is being used and "SpO2 Only Mode" appears on the LCD display screen, perform one of the following steps to obtain Rainbow values:

- Remove the sensor from the patient and properly reapply (recommended).
- Remove the cable connector from the instrument and reconnect.
- Turn the power off and on at the instrument.

If a Masimo Rainbow Adhesive Sensor is being used and "SpO2 Only Mode" appears on the display screen, perform one of the following steps to to obtain Rainbow values:

- Disconnect sensor cable connector from patient cable connector and reconnect (recommended).
- Verify proper sensor placement. Remove sensor from patient and reapply, if necessary.
- Remove patient cable connector from the instrument and reconnect.

When high intensity extreme lights (including pulsating strobe lights) are directed at the sensor or other sources of interference are present, cover the sensor by applying a Masimo Optical Light Shield.

Masimo Acoustic Respiration Sensors

Before use, carefully read the Masimo Acoustic Respiration Sensor's ***Directions for Use***. When monitoring Acoustic Respiration rate only (RRa mode) and the patient is within alarm limits, the Rad-87 will do the following:

- RRa sensor calibration: RI and SIQa will be green.
- Post RRa sensor calibration: RI and SIQa will be orange.
- System Status Light: yellow.

NOTE: *The lights will stay orange until monitoring is completed or an SpO_2 sensor is placed on the patient and active monitoring begins.*

NOTE: *SpO_2 monitoring is required when monitoring RRa (Acoustic Respiration).*

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's Directions for Use. See the cleaning instructions in the Directions for Use.**
- **Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide.**
- **Do not attempt to reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially**

leading to patient harm.

- **Excessive ambient noise may affect the accuracy of the respiration rate reading from the Acoustic Respiration Sensor.**

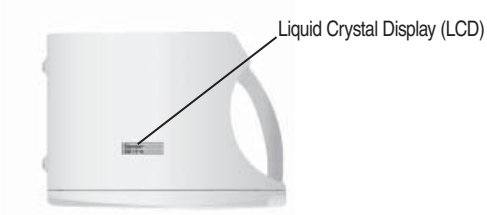
Sensor Time Remaining

Rad-87 instruments enabled with total hemoglobin (SpHb) and used with Masimo Rainbow reusable SpHb sensors will display the time remaining on the LCD Display. In addition to the display at the 4, 2, 1 hour and 0 minute marks, an audible tone will sound. To manually check the remaining time, press and hold the "Display" button for five seconds and the time remaining will be displayed through the cycling settings on the LCD.*

***NOTE**: Sensor Time will not be displayed for SpHb Rainbow Adhesive Sensors because they have been designed and labeled for single patient use only.*

The Rad-87 has two displays to communicate Sensor time remaining messages - LCD and LED Displays.

LCD



The Rad-87 LCD displays messages to communicate the remaining sensor time available to the user, as defined in the following table:

Message Number	LCD Message	Cause	Condition	Message Length	Audible Tone	Recommendation
1*	Sensor 000 Min	SpHb sensor is non-functional	0 minutes, no remaining time on sensor - *see note below*	Indefinitely until SpHb sensor replaced for monitoring of other parameters/measurements with compatible sensor takes place	Yes	Replace SpHb Sensor
2	Replace sensor	SpHb sensor is non-functional	Not monitoring patient, SpHb sensor is non-functional	Until new SpHb sensor attached	No	Replace SpHb Sensor

Message Number	LCD Message	Cause	Condition	Message Length	Audible Tone	Recommendation
3†	Sensor ### Hrs	4 hours, 2 hours, 1 hour remaining	Monitoring a patient	120 seconds	Yes	N/A
		Press and hold Display button for 5 seconds		Displayed 3 times in display of system settings (refer to Section 2, *LCD Display*)	No	
		SpHb sensor is connected after Rad-87 is powered on	Not monitoring a patient	120 seconds		
		SpHb sensor is applied to and/ or removed from the patient	Monitoring a patient	120 seconds	No	
4*†	Sensor ### Min	< 1 hour remaining	Monitoring a patient	120 seconds	Yes	Prepare replacement SpHb sensor
		Press and hold Display button for 5 seconds		Displayed 3 times in display of system settings (refer to Section 2, *LCD Display*)	No	
		SpHb sensor is connected after Rad-87 is powered on	Not monitoring a patient	120 seconds		
		SpHb sensor is applied to and/ or removed from the patient	Monitoring a patient	120 seconds	No	
5	Replace sensor	Sensor is non-functional	Not monitoring a patient	Until working sensor attached	No	Attach working sensor
			Monitoring a patient		Yes	
6	Incompatible sensor	Incompatible sensor	Monitoring or not monitoring a patient	Until compatible sensor attached	No	Replace with a compatible Masimo Sensor (Refer to Section 8)
						Contact your local Masimo Representative to learn more about the optional SpHb upgrade
		SpHb sensor attached to Rad-87 without SpHb installed		Until compatible SpHb sensor attached		Use a non-SpHb sensor

*While actively monitoring a patient, if the sensor time on the Rainbow reusable SpHb sensor reaches 0 minutes remaining, the sensor will not stop monitoring the patient until the sensor is off the patient and no pulse is detected.

† "###" represents the numerical value of either hours or minutes remaining on the attached Rainbow reusable SpHb sensor.

LED

The Rad-87 LED displays messages to communicate the remaining sensor time available to the user, as defined in the following table:

Message Number	LED Message	Cause	Condition	Message Length	Audible Tone	Recommendation
1*	SEN nin 000	SpHb sensor is non-functional	Not monitoring patient,SpHb sensor is non-functional	Until new SpHb sensor attached	No	Replace SpHb Sensor
2	SEN HrS ###	SpHb sensor is connected after Rad-87 is powered on	Not monitoring a patient	120 seconds	No	Replace SpHb Sensor
		SpHb sensor is removed from the patient				N/A
3†	SEN nin ###	SpHb sensor is connected after Rad-87 is powered on	Not monitoring a patient	120 seconds	No	Replace SpHb sensor
		SpHb sensor is removed from the patient				N/A
4*†	Rpl SEN	Sensor is non-functional	Not monitoring a patient	Until working sensor attached	No	Attach working sensor
			Monitoring a patient		Yes	
5	INC SEN	Incompatible sensor	Monitoring or not monitoring a patient	Until compatible sensor attached	No	Replace with a compatible Masimo sensor (Refer to Section 8)
		SpHb sensor attached to Rad-87 without SpHb installed		Until compatible SpHb sensor attached		Contact your local Masimo Representative to learn more about the optional SpHb upgrade OR use a compatible non-SpHb sensor

* While actively monitoring a patient, if the sensor time on the Rainbow reusable SpHb sensor reaches 0 minutes remaining, the sensor will NOT stop monitoring the patient until the sensor is off the patient and no pulse is detected.

† "###" represents the numerical value of either hours or minutes remaining on the attached Rainbow reusable SpHb sensor.

Numeric Display - SpO_2

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

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

Numeric Display - Pulse Rate

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

Numeric display - RRa

Rainbow Acoustic Monitoring continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. SpO_2 monitoring is required when monitoring RRa (Acoustic Respiration). When SpO_2 monitoring is not available, RRa values will appear as "- -". Inaccurate measurements may be caused by:

- Excessive ambient or environmental noise.
- Improper sensor placement.

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_2 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.

Numeric Display - 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%).

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*. 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.**

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

Signal Indication and Quality Indicator (SIQ)

The height of the Signal I.Q. Index indicates the quality of the measured signal. A high Signal I.Q. Index indicates that the SpO_2 measurement is based on a good quality signal. A small Signal I.Q. 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 I.Q. is low the bar turns red and the parameter label flashes; 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 I.Q. 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.

Low SpCO SIQ and Low SpMet SIQ

When the signal quality for SpCO and/or SpMet is very low the accuracy of the SpCO and/or SpMet measurement(s) may be compromised. In a low SpCO and/or low SpMet SIQ state, the parameter label(s) will flash.

Low SpHb

When the signal quality for SpHb is very low the accuracy of the measurement may be compromised. In a low SpHb SIQ state, the parameter label will flash and either the SpHb value will be displayed or there will be dashes depending on how the user has configured this feature. Refer to the *Factory Default and User Configurable Settings* section for details.

Signal Indication and Quality Indicator - Acoustic (SIQa)

SIQa displays the confidence level of the measured signal. A high confidence level displays as a tall signal. When the SIQa is high and the parameter label flashes, there may be interference from excessive ambient or environmental noise. A low confidence level displays as a small signal. A very small signal, with a red bar, may indicate that the accuracy of the respiration rate measurement may be compromised.

Whenever the parameter label flashes, proceed with caution and do the following:

- Assess the patient.
- Check the Acoustic Respiration Sensor and ensure proper sensor application. The Acoustic Respiration Sensor must be well secured to the site for the Rad-87 to maintain accurate readings. Refer to the Acoustic Respiration Sensor's ***Directions for Use*** for proper sensor placement.
- Identify and remove excessive ambient or environmental noise sources affecting the Acoustic Respiration value.

Respiration Indicator (RI)

The Respiration Indicator (RI) displays the sound level of the measured signal. A high sound level displays as a tall signal. A low sound level displays as a small signal. When the signal quality is very small the accuracy of the respiration rate measurement may be compromised. When the RI is small the bar turns red and the parameter label flashes; proceed with caution and do the following:

- Assess the patient.
- Check the Acoustic Respiration Sensor and ensure proper sensor application. The Acoustic Respiration Sensor must be well secured to the site for the Rad-87 to maintain accurate readings. Refer to the Acoustic Respiration Sensor's ***Directions for Use*** for proper sensor placement.

Acoustic Respiration Sensor Placement

- Only use on adult patients weighing > 30 kg.
- The preferred measuring site is to either side of the larynx, in the area just above the thyroid cartilage and below the jaw line. Refer to the Acoustic Respiration Sensor's ***Directions for Use*** for proper sensor placement.
- Site should be hair-free, cleaned of debris and dry prior to sensor placement. Use an alcohol swab to clean the neck area, if needed.
- Ensure that the Acoustic Respiration Sensor, Acoustic Respiration Patient Cable and Dual Rainbow Cable are all securely connected.

NOTE: *When the Acoustic Respiration Sensor is off the patient and is connected to the system the Sensor may pick up periodic ambient sounds and report a measurement. The sensor should only be connected to the Acoustic Respiration Patient Cable while performing patient monitoring. If the patient is not being monitored, the sensor should be disconnected from the Acoustic Respiration Patient Cable.*

Rainbow SET, Masimo SET Sensor Placement

If the SpO_2, 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 instrument 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 SpO_2 sensitivity modes. Each mode allows the clinician to change the SpO_2 sensitivity settings of the instrument 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 instrument is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental 'noise' such as light, vibration and excessive air movement.**

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:

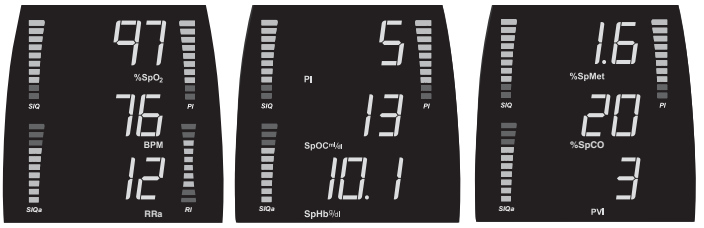
- **The battery should be adequately charged to ensure backup power in case of AC power disruption.**

Normal Patient Monitoring

When all optional parameters/measurements are installed, the Rad-87 displays Screen 1 containing arterial oxygen saturation (%SpO_2), pulse rate in beats per minute (BPM) and respiration rate (RRa)*. By pressing the Display Button once, the display changes to show Screen 2 containing perfusion index (PI), total arterial oxygen content (SpOC ml/dl)* and total hemoglobin (SpHb g/dl)*. Pressing the Display Button again changes the display to show Screen 3 containing methemoglobin (%SpMet)* and carboxyhemoglobin (%SpCO)* and Pleth Variability Index (PVI)*. 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, RRa, SIQa, RI

Display Screens showing all Parameters/Measurements -Default Locations



Screen 1
Home display screen

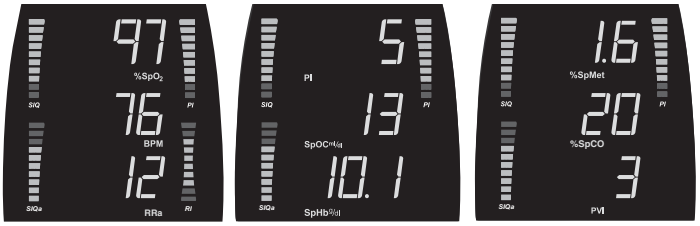
Screen 2

Screen 3

Parameter/Measurement Selection

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

Display Screens Showing RRa on Screen 1, SpHb on Screen 2 and PVI on Screen 3



Display Screens Showing PVI on Screen 1 and SpHb on Screen 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 instrument 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 30 seconds with no button presses.*

Setup Menu Level 1

Setup Menu Level 1 contains the parameters/measurements and settings that are adjusted most often for patient monitoring; alarm limits, display brightness, and sensitivity settings. Pressing the Display Button while viewing alarm limit settings allows the user to exit the Setup Menu and return to Screen 1.

Parameter/Measurement Alarm Limits - Screen 1

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

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

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

Setup Menu Level 1, continued

Parameter/Measurement Alarm Limits - Screen 2

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

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

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

Setup Menu Level 1, continued

Parameter/Measurement Alarm Limits - Screen 3

To access alarm limits for 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		
Use the Alarm Limits Button to access the alarm limits options and move between options. 	Press once 	%SpMet LO	Use Up or Down Buttons to adjust the value to the desired setting AND press the Alarm Limits Button or Enter Button to accept the setting and move to the next option. Once the High Pulse rate limit is accessed an additional press of the Alarm Limits Button or Enter Button will return the instrument to Screen 3. OR press the Display Button to exit at any time and return to Screen 3.
	Press 2x 	%SpMet HI	
	Press 3x 	%SpCO LO	
	Press 4x 	%SpCO HI	
	Press 5x 	PVI LO	
	Press 6x 	PVI HI	

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

LED Brightness

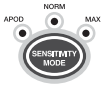
The Display screen and all active LED indicators are effected while adjusting this setting.

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

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

Setup Menu Level 1, continued

SpO_2 Sensitivity

BUTTONS	SETTING		
Use the SpO_2 Sensitivity Button to access the sensitivity options and move between options. 	Press once 	APOD (Default)	Use the SpO_2 Sensitivity Button to move between menu options and accept the setting.
	Press 2x 	NORM	
	Press 3x 	MAX (The MAX Indicator flashes in this mode.)	

Setup Menu Level 2

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

Alarm Volume

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

SpO_2 Alarm Delay

The SpO_2 alarm delay allows the user to adjust the time in which the audible status indicator will occur after a SpO_2 alarm condition has been initiated.

BUTTONS	SETTINGS		
Press the Enter Button again to move to the next menu.  2x		5 seconds (Default)	Use Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		0 seconds	
		15 seconds	
		10 seconds	

Setup Menu Level 2, continued

RRa Alarm Delay

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

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

Clear Trend

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

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

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

Setup Menu Level 2, continued

Button Volume

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

FastSat

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

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

Trend Setup and Use

Introduction

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

NOTE: Rainbow Acoustic Monitoring trending is not available.

TrendCom Utility Installation

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

TrendCom Utility Operation

NOTE: Patient monitoring must be suspended while downloading trend data from the instrument. Ensure the appropriate USB-Serial software driver is installed on the PC, if using a USB-Serial cable. The PC must have Microsoft Excel spreadsheet software, or another program capable of opening a .csv (comma separated value) file to view trend information. Trend information data is limited by the instrument's parameters.

Download Trend Data from Rad-87

A) Attach the USB-Serial or Serial-Serial Cable

1. Turn the Instrument off.

   NOTE: If using a USB-Serial cable, connect the serial cable from the RS-232 serial port on the back of the instrument to a USB port on the PC. If using a Serial-Serial cable, connect the cable from the RS-232 serial port on the back of the instrument to a serial port on the PC.

2. Press firmly to ensure the cable is fully engaged to the instrument.

B) Identify Correct COM Port

***NOTE**: Instructions provided are for the Windows XP Operating System. To locate the COM Port in other Operating Systems, please refer to the Operator's Manual for that Operating System.*

1. From the Windows Desktop, click "Start" > "Settings" >"Control Panel" > "System".
2. Click the "Hardware" tab.
3. Click the "Device Manager" button.
4. In the list, find "Ports (COM & LPT)"
5. Click the "+" next to "Ports (COM & LPT)"
6. Find “USB Serial Port” (USB Serial) or “Communications Port” (Serial-Serial). The COM Port ID number will be to the right of “Communications Port”.
7. Note the COM Port number.

Trend Setup and Use, continued

C) Start the TrendCom Utility and Initiate Download

1. Turn on the Masimo Rad-87.
2. Make sure the Rad-87 is set to ASCII 2 Output mode.
3. Open the TrendCom Software on the PC.
4. Under the “Instrument” menu in TrendCom, select “Rad-87”.

   NOTE: TrendCom will display an “Invalid Data” message if the incorrect instrument is selected.
5. Under the “COM Port” menu, select the appropriate COM Port (ID number from Step B).
6. Click on “Retrieve Trend”.
7. Name the file.
8. Save the file to the appropriate folder. Rad-87 trend information will consist of Date, Time, SpO_2, Pulse Rate and Perfusion Index. Trend information will include Pleth Variability Index, SpCO, SpMet and/or SpHb, if the parameters are installed.

D) Disconnecting the Cable

1. Turn the instrument off to exit the trend download mode.
2. Disconnect the USB-Serial or Serial-Serial cable from the Instrument and PC.
3. Re-attach the patient cable to the instrument to begin patient monitoring.

   ***NOTE**: See the specific cable’s Directions for Use for instructions on attaching the patient cable to the Instrument*

Erasing Trend Memory

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.

1. Press "Enter" until the "CLr trd NO" message is displayed.
2. Press the Up Arrow to display "CLr trd YES".
3. Press "Enter" to display "yES CLr trd" (yes clear trend).
4. Press "Enter" to clear the trend.
5. Press "Display" to return to the main screen.

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)
Rad-87 Trend Exception Messages	The exceptions are displayed as a hexadecimal value.

Setup Menu Level 3

Enter Button + Down Button

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.

SpO_2 Averaging Time

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

Setup Menu Level 3, continued

SpHb Averaging

BUTTONS	SETTINGS		
Press the Enter Button again to move to the next menu. 		Short	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.
		Medium (Default)	
		Long	

PVI Averaging

BUTTONS	SETTINGS		
Press the Enter Button again to move to the next menu. 		Short	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.
		Long (Default)	

Setup Menu Level 3, continued

PI Averaging

BUTTONS	SETTINGS		
Press the Enter Button again to move to the next menu. 		Short	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.
		Long (Default)	

RRa Averaging

BUTTONS	SETTINGS		
Press the Enter Button again to move to the next menu. 		0	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.
		10 seconds	
		20 seconds	
		30 seconds (Default)	
		60 seconds	

Setup Menu Level 3, continued

RRa Sensor Status Notifications

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

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

Alarm On/Off

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

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

Setup Menu Level 3, continued

Optical Sensor Off Audible Alarm Latch

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

* Set this option to "On" when it is a requirement for the clinician to go to the instrument bedside and acknowledge a Sensor Off alarm. Pressing the Alarm Silence Button is ***required*** to silence the audible tone upon correcting the Sensor Off alarm. In the situation where there are valid values ***after*** a Sensor Off alarm has occurred and the instrument is alarming, it is ***required*** to press the Alarm Silence Button to silence the audible tone.

Default Settings

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

* 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.

Setup Menu Level 3, continued

Device Profile Setup and Use

The Rad-87 can be configured to save changes to the instrument 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 instrument settings after the Device Profile feature has been enabled, the Device Profile LED will turn off until the instrument is returned to the user configured default settings or powered off, indicating a change from the Device Profile settings.

To set a instrument 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

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

Year

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

Setup Menu Level 3, continued

Month

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

Day

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

Hour

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

Setup Menu Level 3, continued

Minute

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu. 		30 minutes (Default)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and move to the next menu. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		Use Up or Down Button to adjust the setting.	

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

Setup Menu Level 3, continued

Interface Alarms

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

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

<table>
<tr><th>BUTTONS</th><th colspan="3">SETTING</th></tr>
<tr><td rowspan="2">Press the Enter Button again to move to the next menu.
 
</td><td>  </td><td>On
(Default)
NOTE: LCD shows Alarm Tones On.</td><td rowspan="2">Use Up or Down Button to move between settings
AND
press the Enter Button to accept the setting and
move to the next menu.
OR
press the Display Button to exit without saving the new setting and to return to the home display screen.</td></tr>
<tr><td>  </td><td>Off
NOTE: LCD shows Alarm Tones Off.</td></tr>
</table>

Setup Menu Level 3, continued

Nurse Call

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

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

Polarity

Refer to Section 7, *Nurse Call Specifications* for additional information.

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

Line Frequency

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

Setup Menu Level 3, continued

Parameter/Measurement Select - Screen 1

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

Parameter/Measurement Select - Screen 2

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

Setup Menu Level 3, continued

Parameter/Measurement Select - Screen 3

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

SpHb Precision

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option. 		Hb Pcn 0.1 (Default)	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.
		0.1, 0.5, 1	

SpHb Calculation

BUTTONS	SETTING		
Press the Enter Button again to move to the next menu option. 		Hb CAL Art (Default) (Arterial)	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.
		Hb CAL VEn (Venous)	

Setup Menu Level 3, continued

LCD Language

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

SpHb Display

BUTTONS	SETTING		
Press the Enter Button again to return to first menu option. 		Hb dPL No (Default)	Use Up or Down Button to move between settings AND press the Enter Button to accept the setting and return to first menu option. OR press the Display Button to exit without saving the new setting and to return to the home display screen.
		No (display dashes), Yes (Display SpHb value)	

Enter Button + Up Button Set Mode

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

***CAUTION:**

- **Alarms are disabled in this mode.**

Home Mode Operation

The Rad-87 can be placed into the Home Mode to protect unqualified users from changing the Rad-87 alarm settings and operation. Only the following menu and front panel functions are available: display brightness, pulse beep volume adjustment and alarm silence. Alarm volume is at highest setting. All default and user defined default settings are locked to their current values when home mode is selected and return to those values after a power cycle. Upon power up, the Hnn mode will be displayed along with a 10 second display of parameters/measurements. To turn the instrument 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 instrument 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 parameter/ 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

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

Enable/Disable Radio

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

LCD Display Function with Radio Configured and Enabled

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

- Network Mode
- Radio Mode
- Channel
- SSID
- IP address
- Subnet
- Gateway
- MAC Address
- Encryption
- Authentication
- Destination IP
- Destination Port
- Signal Strength
- Connected Access Point
- Radio Diagnostics
- Radio Error
- Error 1
- Error 2
- Error 3
- Error 4

Alarm Identification

The Rad-87 identifies alarms visually and audibly based on alarm conditions that the system detects. The 'system' includes the instrument, cables and sensors. Alarm conditions that occur depend upon the parameters monitored on the patient. Audible alarms will continue to sound until a valid parameter value is displayed on the instrument. The Rad-87 alarms are categorized into the following: Alarm Limit Alarms, System Monitoring Alarms, System Function Alarms, Instrument Errors/Warnings and RRa Sensor Status Notifications.

- Parameter Threshold Alarms occur when a patient's measurement exceeds the parameter threshold setting in the instrument.
- System Monitoring Alarms occur when the sensor from a channel is off the patient or a sensor and/or cable is disconnected. Examples include Sensor Off or No Cable.
- System Function Alarms occur when a component in the signal path fails or the parameter is not installed on the instrument. An example would be Incompatible Sensor.
- Instrument Error/Warning Alarms occur when there are instrument hardware issues. Examples include a hardware error code or a low battery.

The Alarm Category Table below details the Rad-87 alarms by alarm category and channel.

Alarm Category Table

ALARM CATEGORY	CHANNEL	ALARM		
Parameter Threshold Alarms	Optical	High SpO_2 Low SpO_2	High SpCO Low SpCO	High PI Low PI
		High Pulse Rate Low Pulse Rate	High SpMet Low SpMet	High PVI Low PVI
			High SpHb Low SpHb	
	Acoustic	High RRa Low RRa		
System Monitoring Alarms	Optical	Sensor Off	No Adhesive	
		No Sensor	No Cable	
	Acoustic	Sensor Off		
		No Sensor	No Cable	

Alarm Category Table, continued

ALARM CATEGORY	CHANNEL	ALARM		
System Function Alarms	Optical	Incompatible Sensor	Replace Sensor	Sen 000
		Incompatible Adhesive	Replace Adhesive	Adh 000
		Incompatible Cable	Replace Cable	Cbl 000
				Interference Detected
	Acoustic	Incompatible Sensor	Replace Sensor	Sen 000
		Incompatible Cable	Replace Cable	Cbl 000
Instrument Error/Warning Alarms	N/A	Err ##	Low Battery	
RRa Sensor Status Notifications	Acoustic	No Sensor	Interference Detected	

NOTE: *There are no alarms associated with SpOC.*

Alarm Limits

CAUTION:

- **To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the Rad-87 is used.**

NOTE: *The following alarm limits may be set to "---": High SpO_2, High SpCO, Low SpCO, High SpMet, Low SpMet, High SpHb, Low SpHb, High PI, Low PI High PVI and Low PVI. When the setting of "---" is made on the instrument, the alarm limit is disabled.*

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

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

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

Alarm Limit: User Configurable Settings

SETTING	FACTORY DEFAULT	RANGE	INCREMENTS
High SpO_2 Limit	"---" Off	2% - 99%	1%
Low SpO_2 Limit	90%	1% - 98%	1%
High Pulse Rate Limit	140 BPM	35 BPM - 235 BPM	5 BPM
Low Pulse Rate Limit	50 BPM	30 BPM - 230 BPM	5 BPM
High SpCO Limit	10	2% - 98%	1%
Low SpCO Limit	"---" Off	1% - 97%	1%
High SpMet Limit	3	1% - 99.5%	0.1% for values 0.1% - 2% 0.5% for values 2% - 99.5%
Low SpMet Limit	"---" Off	0.1% - 99%	0.1% for values 0.1% - 2% 0.5% for values 2% - 99.5%
High SpHb Limit	17	2 g/dl - 24.5 g/dl	0.1 g/dl for values 2 g/dl - 20 g/dl 0.5 g/dl for values 20 g/dl - 24.5 g/dl
Low SpHb Limit	7	1 g/dl - 24 g/dl	0.1 g/dl for values 0.1 g/dl - 20 g/dl 0.5 g/dl for values 20 g/dl - 24 g/dl
High PI Limit	"---" Off	0.04% - 19%	0.01% for values 0.02% - 0.1% 0.1% for values 0.1% - 1% 1% for values 1% - 19%
Low PI Limit	"---" Off	0.03% - 18%	0.01% for values 0.03% - 0.1% 0.1% for values 0.1% - 1% 1% for values 1% - 18%
High PVI Limit	"---" Off	2% - 99%	1%
Low PVI Limit*	"---" Off	1% - 98%	1%
High RRa Limit (breaths per minute)	30	5 - 69 breaths per minute	1 breath per minute
Low RRa Limit (breaths per minute)	6	4 - 68 breaths per minute	1 breath per minute

Alarm Priorities

The Rad-87 has three levels of alarm priority implemented: high, medium and low. The alarm priorities reflect how the instrument will behave when an alarm is present. The following table outlines instrument attributes within the alarm priorities.

ALARM PRIORITY	ALARMS	INSTRUMENT ATTRIBUTES				
		SYSTEM STATUS LIGHT	PARAM-ETER VALUE	PARAM-ETER LABEL	ALARM BELL	AUDIBLE TONE
High	Low SpO_2	Flashing Red	Flashing	Flashing	Flashing Red	Active
	High pulse rate Low pulse rate					
	High SpCO					
	High SpMet					
	High SpHb Low SpHb					
	High RRa Low RRa					
	Sensor Off, No Sensor, Incompatible Sensor or Adhesive, Replace Sensor, Adhesive, or Reusable, SEN 000, Adh 000					
	No cable, Incompatible Cable, Replace Cable, Cbl 000					
	Instrument failures					
Medium	High SpO_2	Flashing Yellow			Off	
	High PI Low PI					
	High PVI Low PVI					
	Low battery, monitoring patient					
Low	Low SpCO	Solid Yellow				
	Low SpMet					
	Low battery, not monitoring patient					

The Rad-87 offers the ability to monitor multiple 'channels' on a patient. The Rad-87 has an optical based channel and an acoustic based channel. The optical based channel provides SpO_2, pulse rate, SpCO, SpMet, SpHb, SpOC, PI and PVI. The acoustic based channel provides respiration rate (RRa). When both the optical and acoustic channels are monitoring the patient together, the optical channel is considered 'primary' and the acoustic 'secondary'.

***NOTE**: SpO_2 monitoring is required when monitoring RRa (Acoustic Respiration).*

***NOTE**: When both the optical and acoustic channels are present and the RRa Sensor Status Notifications are set to 'Off', the RRa Sensor Status Notifications do NOT activate an audible tone. Refer to the Alarm Category Table earlier in this section for the RRa Sensor Status Notifications.*

Multiple Parameter/Measurement Alarms

When multiple parameters/measurements alarm, the screen with the highest alarm priority (and with a parameter/measurement in alarm status) will show on the display. Refer to the table Alarm Priority for Display Screens located below.

Additional parameters/measurements in alarm status (competing alarms) that are not contained on the active screen will show as flashing parameter/measurement labels (names). The parameters/measurements with competing alarms can be viewed by pressing the Display Button to scroll through the screens. When an alarm is resolved, the parameter/measurement label stops flashing. When all parameters/measurements in alarm status on a display screen are resolved, the screen changes to show the next priority screen with active alarms.

Alarm Priority for Display Screens

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

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

Alarm Silence

Audible alarms may be silenced, while visual alarms remain active. The alarm silence function is controlled by pressing the Alarm Silence button. The Alarm Bell and the System Status Light provide visual feedback when the Rad-87 audible alarms are silenced.

When monitoring a patient with both the optical and acoustic channels present

Action: Alarm event occurs; press Alarm Silence button once (audible alarms silenced for configured Alarm Silence period. Default is 120 seconds.)

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
High	Flashing Red	Flashing Red
Medium	Off	Flashing Yellow
Low	Off	Off

Action: Press Alarm Silence button a second time during Alarm Silence period

State: Audible alarms become active

Action: Removal of an optical patient cable/sensor

State: Alarm active

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
High	Flashing Red	Flashing Red

Action: Press Alarm Silence button

State: Alarms silenced

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
Any	Off	Solid Yellow

Action: Removal of an acoustic patient cable/sensor

State: Alarm active

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
High	Flashing Red	Flashing Red

Action: Press Alarm Silence

State: Alarms silenced

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
Any	Off	Solid Green

Action: Removal of both patient cables/sensors

State: Alarms active

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
High	Flashing Red	Flashing Red

Action: Press Alarm Silence button

State: Alarms silenced

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
Any	Off	Solid Yellow

When not monitoring a patient

Action: Press Alarm Silence button

State: Alarms silenced

ALARM PRIORITY	ALARM BELL	SYSTEM STATUS LIGHT
Low	Off	Solid Yellow

this State remains until active patient monitoring begins.

Alarm Bell

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

System Status Light

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

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

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

Alarm Mute

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

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

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

NOTE: *Audible Alarm Tones are not active in the multiparameter patient monitor when used with the VueLink interface. Refer to the Philips VueLink Setup section for details.*

Messages

The Rad-87 Pulse CO-Oximeter will indicate other data or system errors. LED messages for the optical channel occupy the top two LED segments on the instrument. LED messages for the acoustic channel occupy the third LED segment.

Message conditions for the Rad-87 follow:

MESSAGE/DISPLAY	POSSIBLE CAUSE(S)	RECOMMENDATION(S)
LCD: Replace Sensor **LED:** SEN HrS 000	SpHb reusable sensor is non-functional.	Replace sensor.
LCD: Replace Sensor **LED:** rPL SEN	Sensor is non-functional. Emitter temperature out of range. Sensor current limit exceeded.	Replace sensor.
LCD: Incompatible Sensor **LED:** INC SEN	Unrecognized sensor. Not a compatible Masimo sensor.	Replace with a compatible Masimo sensor. Refer to Section 8.
	SpHb Sensor is attached to an instrument without SpHb installed.	Use a non-SpHb sensor.
		Contact your local Masimo Representative to learn more about the optional SpHb upgrade.
LCD: Sensor Calibrating **LED**: The number "**0**" scrolls across the screen during sensor calibration when not actively monitoring a patient Status Light: Solid Yellow (Long Calibration Only)	Instrument is checking the sensor for proper functioning and performance.	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.
LCD: Sensor Off **LED:** SEN OFF	Sensor off patient.	Reconnect sensor.
LCD: Latched Sensor Off **LED:** SEN (or valid values) OFF	Optical Sensor Off Audible Alarm Latch is set to 'On'. The Alarm Silence button has ***not*** been pressed to acknowledge the Sensor Off alarm.	Reapply the sensor according to the sensor's ***Directions for Use***. Press the Alarm Silence button to acknowledge the Sensor Off alarm.

MESSAGE/DISPLAY	POSSIBLE CAUSE(S)	RECOMMENDATION(S)
LCD: No Sensor **LED:** nO SEn	No sensor connected.	Connect sensor to patient.
LCD: Check Sensor **LED:** CHc SEn	Sensor is not connected firmly into patient cable or the instrument.	Reconnect sensor firmly into patient cable, or to the instrument.
LCD: No Adhesive Reconnect* **LED:** nO AdH*	When using the Masimo ReSposable Sensor System, the adhesive part is not connected.	Connect the ReSposable adhesive to the ReSposable reusable sensor.
LCD: Replace Adhesive* **LED:** AdH 000*	When using the Masimo ReSposable Sensor System, the adhesive part is non-functional.	Replace the ReSposable adhesive of the sensor system.
LCD: Invalid Adhesive* **LED:** InC AdH*	When using the Masimo ReSposable Sensor System, the adhesive part is incompatible or unrecognized.	Replace the ReSposable adhesive of the sensor system.
LCD: Replace Adhesive* **LED:** rPL AdH*	When using the Masimo ReSposable Sensor System, the adhesive portion is non-functional.	Replace the ReSposable adhesive of the sensor system.
LCD: Replace Reusable* **LED:** rPL rEu*	When using the Masimo ReSposable Sensor System, the resuable sensor is non-functional.	Replace the ReSposable resusable sensor of the sensor system.
LCD: Replace Cable **LED:** rPL CbL	The patient cable is non-functional.	Replace the patient cable.
LCD: Replace Cable **LED:** CbL 000	Cable is non-functional.	Replace cable.

* Messages do not apply to Masimo Rainbow R Series Adhesive Sensors

MESSAGE/DISPLAY	POSSIBLE CAUSE(S)	RECOMMENDATION(S)
LCD: No Cable **LED:** nO CbL	No cable is connected.	Reconnect cable.
LCD: Invalid Cable **LED:** InC CbL	Incompatible or unrecognized cable.	Connect appropriate cable to instrument.
LCD: Interference Detected (Optical Channel) **LED:** Int **D**Et	Improperly applied sensor.	Reapply the sensor according to the sensor's ***Directions for Use***.
	High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.	Place a Masimo Optical Light Shield over the sensor.
	Incorrect monitor line frequency setting (Hz).	Adjust the Line Frequency to the correct Hz setting as described in Section 4.
LCD: Interference Detected (Acoustic Channel) **LED:** Int **D**Et	Improperly applied sensor.	Reapply the sensor according to the sensor's ***Directions for Use***.
	Excessive ambient or environmental noise.	Identify and remove the excessive ambient or environmental noise.
LCD: RR Invalid SpO_2 not avail **LED: "--"** (RRa parameter)	There are no valid SpO_2 values.	Apply a sensor to obtain valid SpO_2 values, according to the sensor's ***Directions for Use***.
LCD: System Fault **LED:** Err **##**	There are several error codes. All errors codes require returning the instrument to an authorized service center for repair.	Return for service. Refer to Section 9, *Service and Repair*.
LCD: SpO2 Only Mode	"SpO2 Only Mode" message occurs during an unsuccessful sensor calibration/pulse search routine, or during monitoring.	Refer to: the sensor's ***Directions for Use***, Section 4, *Successful Monitoring*, and Section 8, *Selecting a Masimo SET Sensor.*
Scrolling Zeros	Pulse search.	Wait for found pulse. This search should occur whenever a sensor is first applied to a patient.
Pulse Bar (SIQ) Turns Red	Low Signal I.Q.	Rule out occusion of blood flow. Verify placement of sensor.

MESSAGE/DISPLAY	POSSIBLE CAUSE(S)	RECOMMENDATION(S)
Bottom Two Segments of Perfusion Bar (PI) are Red	Low Perfusion.	Rule out occusion of blood flow. Attempt to warm patient. Move sensor to better perfused site. ***NOTE**: Masimo recommends using an adhesive sensor whenever low perfusion is expected or evident.*
Parameter/Measurement Label and Number Flash	Alarm Limit Exceeded.	Assess/address patient condition. Reset alarms limits, if indicated. Refer to Section 4 for instructions.
Single Battery Level Indicator Flashes (With Audible Alarm)	Battery level too low.	Connect instrument to AC power to charge the battery.

Troubleshooting

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

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION(S)
Instrument does not power on	Low battery/ not plugged into AC power supply.	Connect the AC power cord to the Rad-87 and to an AC outlet. Make sure that the AC power indicator light is on.
Battery run-time Is significantly reduced	Low battery	Contact Technical Services or your local Masimo representative.
Continuous Speaker Tone	Internal Failure.	Instrument requires service. Press the Alarm Silence button. If alarm continues to sound, power down device. If the power button does not turn the instrument off, press and hold the power button for 5 seconds. Return the instrument for service.
No Speaker Tone	Pulse tone set to “mute”.	Press Up arrow or Alarm Volume adjust.
No Alarm Tone	Alarm Silence Enabled.	The System Status Light flashes yellow. See Section 4, *Alarm Silence.*
Buttons fail to work when pressed	Internal Failure.	Use auxilary power down method by pressing and holding Sensitivity and Display buttons simultaneously. Return for service.
No Sensor message	Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.	Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.
Low Perfusion (PI Bar Turns Red)	Improper sensor type. Poorly perfused site. Sensor is too tight. A disorder such as hypothermia, vasoconstriction, hypovolemia, peripheral vascular disease or anemia. Sensor is damaged.	Verify proper sensor and sensor size for the patient. Check and see if blood flow to the site is restricted. Be sure that the sensor is not on too tight. Set unit to MAX sensitivity. Warm the patient or sensor site. Move sensor to better perfused site.
Low SIQ	Improper sensor type or application. Excessive motion relative to perfusion. Sensor or cable is damaged or not functioning.	Check and see if blood flow to the site is restricted. Check the placement of the sensor. Re-apply sensor or move to a different site. Replace sensor or cable.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION(S)
Low SIQa and flashing RRa parameter*	Low confidence in RRa value (Last confident value displayed). May occur during patient activity (e.g. talking).	Check for proper sensor placement. Reduce patient activity. Reduce excessive ambient or environmental noise.
Low RI	Improperly applied sensor. Patient may have shallow breathing.	Assess the patient.
SpO_2 values do not correlate with clinical assessment Or abgs.	Low perfusion or sensor displacement.	Check for error messages. See section 5 *Messages* for recommended corrections Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely on the patient Refer to sensor's ***Directions For Use***.
Pulse Search message	Instrument is searching for pulse.	If instrument fails to display within 30 seconds, disconnect and reconnect sensor to patient. If pulse search continues, move sensor to better perfused site.
Unexpected SpO_2, SpCO, SpMet Or SpHb reading	Low SIQ or Perfusion Index (PI) values.	Reposition sensor to site with strong SIQ and PI. Submit blood sample for laboratory CO-Oximetry test for comparison.
	Inappropriate sensor size or sensor measurement location.	Verify proper sensor for patient size. Verify proper sensor site.
Unexpected High SpCO reading	Possible elevated methemoglobin level.	Submit blood sample for laboratory CO-Oximetry test.
Difficulty Or No SpO_2/SpCO/ SpMmet/SpHb reading	Low battery/ not plugged into AC power supply.	Connect the AC power cord to the Rad-87 and to an AC outlet. Make sure that the AC power indicator light is on.
	Excessive motion.	Minimize or eliminate motion at the monitoring site.
	Interference from line-frequency induced noise.	Verify/set 50/60Hz menu setting. See section 3, Rad-87 *Power Requirements*.
	Inappropriate sensor or sensor size.	Verify proper sensor and sensor size for the patient.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.
	Also, see Section 4, *Successful Monitoring* for additional information.	
Print Function does not work	Wrong serial cable is used.	Make sure a null modem cable is used.
Wireless Radio no connection	Radio off.	Confirm the wireless radio is on.
	Network settings are not configured correctly.	Confirm wireless network settings.
	No/inadequate wireless coverage.	Confirm wireless coverage.

* If a confident RRa value has not been detected after 5 minutes, the RRa value will display as double dashes (- -) and an audible alarm will become active. This will occur if the acoustic channel is the primary channel and also when RRa Sensor Status Notifications are set to 'On'.

Rad-87 Specifications

PERFORMANCE

Measurement Range	
SpO_2:	0 -100%
SpMet:	0 - 99.9%
SpCO:	0 - 99%
SpHb	0 - 25 g/dl
SpOC	0 - 35 ml of O_2/dl of blood
Pulse Rate:	25 - 240 (bpm)
RRa (Respiration Rate):	0 - 70 breaths per minute
SIQa	0% - 100%
Perfusion Index:	0.02% - 20%
Pleth Variability Index:	0 - 100%
Accuracy:	
Arterial Oxygen Saturation Accuracy[1]	
Saturation	60% to 80%
No Motion	
Adults, Infants, Pediatrics	±3%
Saturation	70% to 100%
No Motion[2]	
Adults, Infants, Pediatrics	± 2%
Neonates*	± 3%
Motion[3]	
Adults, Infants, Pediatrics, Neonates	± 3%
Low Perfusion[4]	
Adults, Infants, Pediatrics, Neonates	± 2%
Pulse Rate Accuracy[5]	
Pulse Rate:	25 - 240 (bpm)
No Motion	
Adults, Infants, Pediatrics, Neonates	± 3 bpm
Motion[3]	
Adults, Infants, Pediatrics, Neonates	± 5 bpm
Low Perfusion[4]	
Adults, Infants, Pediatrics, Neonates	± 3 bpm
Carboxyhemoglobin saturation accuracy (%SpCO)[1]	
Adults, Infants, Pediatrics	1% - 40% ± 3%
Methemoglobin saturation accuracy (%SpMet)[1]	
Adults, Infants, Pediatrics, Neonates	1% - 15% ± 1%
Total Hemoglobin accuracy (SpHb g/dl)[9]	
Adults, Pediatrics	8 - 17 g/dl ±1 g/dL
Respiratory Rate Accuracy (RRa, breaths per minute)[10]	
Adults	4 to 70 ± 1 breath per minute
Resolution	
Arterial Oxygen Saturation (%SpO_2)	1%
Carboxyhemoglobin Saturation (%SpCO)	1%
Methemoglobin Saturation (%SpMet)	0 .1%
Total Hemoglobin (SpHb g/dl)	0 .1 g/dl

Respiration Rate (RRa)	1 breath per minute
Pulse Rate (bpm)	1 bpm

* Only Rainbow sensors provide ± 2% for Neonates

ELECTRICAL

AC Power requirements:	100 - 240 VAC, 47-63 Hz
Power consumption:	20 VA max.
Batteries	
Type:	Sealed lead acid
Capacity (battery life)[6]:	
Rad-87 (stand-alone)	up to 3 hours
Rad-87 with Rainbow Acoustic Monitoring	up to 2 hours
Rad-87 with wireless radio and Rainbow Acoustic Monitoring	up to 1 hour
Charging time:	minimum 8 hours

ENVIRONMENTAL

Operating Temperature:	32°F to 122°F (0°C to 50°C)
Transport/Storage Temperature:	-40°F to 158°F (-40°C to +70°C)[7]
Operating Humidity:	10% to 95%, non-condensing
Operating Altitude:	500 mbar to 1060 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

PHYSICAL CHARACTERISTICS

Dimensions:	8.2" x 6.0" x 3.0" (20.8 cm x 15.2cm x 7.6 cm)
Weight:	2.1 lbs. = .908 Kg. = 32 oz
Trending	
72 hours of trending at 2 second resolution (Rainbow Acoustic Monitoring trending is not available)	
Mode	
SpO_2 Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[8]
SpO_2 Sensitivity:	Normal, Maximum[9], and APOD
RRa Averaging mode:	0, 10, 20, 30, 60 seconds
Alarms	
Audible and visual alarms for high low saturation and pulse rate (SpO_2 range 1% - 99%, SpCO range 1% - 98%, SpMet range 1% - 99.5%, SpHb range1 g/dl - 24.5 g/dl, RRa range 4 - 70 breaths per minute, PI range 0.03% - 19%, PVI range 1% - 99%, pulse rate range 30 - 235 BPM)	
Sensor condition, system failure and low battery alarms	
High Priority Audible Alarm:	800 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
Medium Priority Audible Alarm	500 Hz tone, 3 pulse burst, repeat time: 5s
Low Priority Audible Alarm:	500 Hz tone, 3 pulse burst, repeat time: 5s
Alarm Volume	High: 85 dB (min) Low: 45 dB (min)
High Priority Visual Alarm:	Red flashing 2 sec. (0-5 Hz)
Medium Priority Visual Alarm	Yellow flashing 4 sec (0.25 Hz)
Low Priority Visual Alarm:	Solid yellow

Display/Indicators	
Type:	LED
Display Language	English (default)
Data display:	%SpO_2, %SpCO, %SpMet, SpHb g/dl, SpOC ml/dl, pulse rate, pleth variability index (PVI), RRa, alarm status, status messages, Signal I.Q. (SIQ), acoustic Signal I.Q. (SIQa), perfusion index (PI),Respiration Indicator (RI), sensitivity modes, wireless radio connection, system status light.
Display update rate:	1 second
Output Interface	
Serial RS-232	
Wireless Radio (if installed)	802.11 a/b/g
Nurse Call	
Philips VueLink, RadNet, Patient SafetyNet	
Compliance	
Safety Standard for Medical Equipment	IEC 60601-1 2nd Edition IEC 60601-2-49 1st Edition UL 60601-1 CAN/CSA C22.2 No. 601-1 JIS 0601-1
Type of Protection	Class 1 (AC power), Internally powered (battery power)
Degree of Protection-(Pulse CO-Oximeter Cable):	Type BF, Defib Proof Applied-Part
Mode of Operation:	Continuous
EMC Standard	EN 60601-1-2
Wireless Radio (if installed)	
Compatibility Standard	802.11 a/b/g
USA	FCC ID VKF-Rad87 FCC Parts 15.247 and 15.407
Canada	IC ID 7362A-Rad87 RSS-210
Europe	EN 300328, EN 301893, EN 301489-17

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

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

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

4 The Rad-87 has been validated for low perfusion accuracy in bench-top testing against a Fluke Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations and pulse rates within the stated accuracy specifications. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

5 Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

6 This represents approximate run time at the lowest indicator brightness and pulse tone turned off using a fully charged battery.

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

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

9. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against a laboratory CO-Oximeter. The variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

10. Respiration rate accuracy for the Masimo Acoustic Respiration Sensor and Instrument has been validated for the range of 4 to 70 breaths per minute in bench top testing. Clinical validation for up to 30 breaths per minute was also performed with the Masimo Acoustic Respiration Sensor and Instrument.

Serial Interface Specifications

The digital interface for serial communication is based on the standard RS-232 protocol. The Rad-87 Pulse CO-Oximeter by default always outputs ASCII 1 text data through the serial port, unless the user selects a different output mode in the Output menu. To interface with the Rad-87 and receive serial text data, simply connect a serial interface cable with a serial output connector located on the back of the Rad-87.

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

Serial Interface Setup

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

PARAMETER	SETTING
Baud Rate	9600 Baud bidirectional
Number of bits per character	8
Parity	None
Bits	1 start, 1 stop
Handshaking	None
Connector type	Female DB-9

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

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

Serial Printer Setup

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

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

Nurse Call Specifications

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

Nurse Call

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

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

PARAMETER	SPECIFICATION
Max Voltage	36 VDC or 24 VAC peak

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

Introduction

This section covers the use and cleaning of Masimo sensors and patient cables. Before use of any sensor, carefully read the sensor's ***Directions for Use***. Use only Masimo sensors and cables with the Rad-87 Pulse CO-Oximeter. Other transducers, sensors and cables may affect Rad-87's performance.

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

CAUTIONS:

- **Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.**
- **Do not immerse the sensor or patient cable in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof).**
- **Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide. See the cleaning instructions in the directions for use for reusable Masimo sensors.**
- **Do not attempt to reprocess, recondition or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.**
- **All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise patient injury can result.**
- **To avoid damage to the cables, always hold the cable by the connector rather than the cable when connecting or disconnecting either end.**

Selecting a Masimo SET Sensor

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following tables or contact your Sales Representative. Use only Masimo sensors and sensor cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the ***Directions for Use*** accompanying the sensor. Monitor, cables and sensors must be compatible to ensure optimal performance. Incompatible components affect operation or data recovery.

High intensity extreme lights (such as pulsating strobe lights) directed on the Pulse CO-Oximeter sensors, may not allow the sensor to obtain measurements. Excessive ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight, as well as other monitor displays can interfere with the performance of the sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with a Masimo Optical Light Shield. Failure to take this precaution in excessive ambient light conditions may result in inaccurate measurements.

Sensor Application Instructions

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

Masimo Acoustic Respiration Sensor

Acoustic Respiration Sensor, Acoustic Respiration Patient Cable and Dual Rainbow Cable

The Acoustic Respiration Sensor and Rainbow acoustic cables are indicated for continuous, noninvasive monitoring of respiration rate (RRa) for adult patients, in hospitals, hospital-type facilities, mobile and home environments.

Sensor	Weight Range	Breaths per Minute, Accuracy Range
RAS-125	Adult > 30 kg	4 to 70 ± 1 breath per minute

Masimo Rainbow Sensors

Rainbow sensors will only measure SpO_2 and pulse rate on devices without Masimo Rainbow SET Technology.

Rainbow Reusable Sensors

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

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

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpMet Accuracy	SpHb Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion	
DCI	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%	± 1 g/dl
DCIP	10 - 50 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%	± 1 g/dl

Rainbow Direct Connect Sensors

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

Rainbow Direct Connect sensors connect to the instrument directly.

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpCO Accuracy	SpMet Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion	No Motion
DCI-dc3 DCI-dc8 DCI-dc12	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
DCIP-dc3 DCI-dc8 DCIP-dc12	10 - 50 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%

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

Rainbow Direct Connect sensors connect to the instrument directly.

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

Rainbow R Series Adhesive Sensors

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

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

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpCO Accuracy	SpMet Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion	No Motion
R25	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
R25-L	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
	< 3 kg*	70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	N/A	± 1%
R20	10 - 50 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
R20-L	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
	10 - 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%

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

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

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpMet Accuracy	SpHb Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion	No Motion
R1 25 R1 25L	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%	1 g/dL
R1 20	10 - 50 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%	1 g/dL
R1 20-L	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1%	1 g/dL
	10 - 30 kg								

Rainbow ReSposable™ Pulse CO-Oximeter Sensor System

SpO_2, SpMet, SpHb and pulse rate accuracy for the Rainbow sensors is specified in the following table.
The R2-25a must be used with a R2-25r and the R2-20a must be used with a R2-20r.

Sensor	Weight Range	Saturation Accuracy	Pulse Rate Accuracy	Low Perfusion Accuracy		SpMet Accuracy	SpHb Accuracy
				Saturation	Pulse Rate		
R2-25a R2-25r	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm	± 1%	± 1 g/dl
R2-20a R2-20r	10 - 50 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm	± 1%	± 1 g/dl

Masimo SpO_2 Sensors

Masimo SpO2 sensors measure arterial saturation and pulse rate.

ReSposable™ Pulse CO-Oximeter Sensor System

The S2-25a must be used with a S2-25r and the S2-20a must be used with a S2-20r.

Sensor	Weight Range	Saturation Accuracy	Pulse Rate Accuracy	Low Perfusion Accuracy	
				Saturation	Pulse Rate
S2-25a S2-25r	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm
S2-20a S2-20r	10 - 50 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm

Red Direct Connect Sensors

Red sensors will only function with CO-Oximeter devices equipped with Masimo Rainbow SET technology.

Red Direct Connect sensors connect to the instrument directly.

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
Red DCI-dc3 Red DCI-dc12	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
Red DCIP-dc3 Red DCIP-dc12	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOP® Reusable Sensors

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

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

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

LNOPv™ Adhesive Sensors

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

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

LNOP Specialty Sensors

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

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Newborn Infant	3 - 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
Infant	10 - 30 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Newborn Neonatal	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Trauma	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Blue	2.5 - 30 kg	60 - 80% ± 4%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		70 - 100% ± 3.3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		80 - 100% ± 3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm

M-LNCS™/LNCS® Reusable Sensors

M-LNCS sensors must be used in conjuction with M-LNC or Rainbow patient cables or M-LNC adapter cables.

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

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

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

M-LNCS™/LNCS® Adhesive Sensors

M-LNCS sensors must be used in conjuction with M-LNC or Rainbow patient cables or M-LNC adapter cables.

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

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

M-LNCS™/LNCS® Specialty Sensors

M-LNCS sensors must be used in conjuction with M-LNC or Rainbow patient cables or M-LNC adapter cables.

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

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

Sensor Accuracy

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

Complete accuracy specifications are located in the sensor's *Directions For Use* and are specific for the type of Masimo sensor used.

Cleaning And Reuse Of Masimo Reusable Sensors and Cables

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

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

CAUTION:

- **Carefully route patient cables to reduce the possibility of patient entanglement or strangulation.**

Reattachment of a Single Use Acoustic Respiration Sensor

■ A single use Acoustic Respiration Sensor may be reapplied to the same patient if it is dry, clean, free of debris and oil and the adhesive still adheres to the skin

Reattachment of a Single Use Rainbow SET or Masimo SET Adhesive Sensor

■ A single use Rainbow SET or Masimo SET sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

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

CAUTION:

- **Do not attempt to reprocess, recondition or recycle any masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.**

CAUTION:

- **To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize by irradiation, steam, autoclave or any method other than ethylene oxide as indicated.**

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

Introduction

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

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

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

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

Cleaning

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

CAUTIONS:

- **Do not autoclave, pressure sterilize, or gas sterilize the Rad-87.**
- **Do not soak or immerse the monitor in any liquid.**
- **Use the cleaning solution sparingly. Excessive solution can flow into the monitor and cause damage to internal components.**
- **Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the panel.**
- **Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the Pulse CO-Oximeter.These substances affect the device's materials and instrument failure can result.**

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

Battery Service

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

Performance Verification

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

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

POWER-ON SELF-TEST:

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

KEY PRESS BUTTON TEST:

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

ALARM LIMIT TEST:

1. With the monitor turned on, depress the alarm limits button and enter the alarm menu. Change the High Saturation Alarm parameter to a value below the currently selected value, and accept the change.
2. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display.
3. Return the High Saturation Alarm parameter to its original setting.
4. Repeat steps 1 to 3 for the following alarm parameters:
   - Low SpO_2
   - Low and High pulse rate
   - High SpMet (optional feature)
   - High SpCO (optional feature)
   - Low and High SpHb
5. Reset the alarm limits again to the original settings.

LED BRIGHTNESS:

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

Testing the Rad-87 with Masimo Set Tester (Optional):

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

Service and Repair

Repair Policy

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

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

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

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

Return Procedure

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely – in the original shipping container if possible – and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the Rad-87. Please include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the instrument is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the Rad-87 has been decontaminated for bloodborne pathogens.

Return the Rad-87 to the following shipping address:

For USA and Asia Pacific:	For Europe:	All other locations:
Masimo Corporation 40 Parker Irvine, California 92618 Tel: 949-297-7000 FAX: 949-297-7001	Masimo International Sàrl Puits-Godet 10 2000 Neuchatel - SWITZERLAND Tel: +41 32 720 1111 Fax.: +41 32 724 1448	Contact your local Masimo Representative

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Warranty

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

Batteries are warranted for six (6) months.

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

Exclusions

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

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Part Numbers

Part Numbers

PART NUMBER	DESCRIPTION
34156	Rad-87 Operator's Manual (SpHb), French
34157	Rad-87 Operator's Manual (SpHb), German
34158	Rad-87 Operator's Manual (SpHb), Italian
34159	Rad-87 Operator's Manual (SpHb), Spanish
34165	Rad-87 Operator's Manual (SpHb), Japanese
34160	Rad-87 Operator's Manual (SpHb), Dutch
34162	Rad-87 Operator's Manual (SpHb), Portuguese
34161	Rad-87 Operator's Manual (SpHb), Danish
34163	Rad-87 Operator's Manual (SpHb), Swedish
34164	Rad-87 Operator's Manual (SpHb), Chinese

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

www.masimo.com

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

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