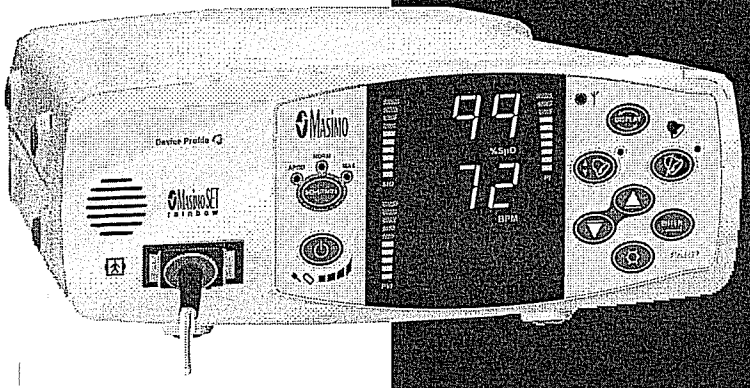
Rad-87™

Pulse CO-Oximeter

OPERATOR'S MANUAL

Contains:

Oxyhemoglobin
Carboxyhemoglobin
Methemoglobin
and
Pulse Rate
parameters



MASIMO SET®
rainbow

The Rad-87 Operating Instructions provide the necessary information for proper operation of all models of the Rad-87 device.

General knowledge of pulse CO-Oximetry and an understanding of the features and functions of the Rad-87 are a prerequisite for its proper use.

Do not operate the Rad-87 without completely reading and understanding the instructions in this manual.

If a Rad-87 device has been upgraded to include the latest available parameters by utilizing the upgrade tool (sold separately), please discontinue using the previous Rad-87 manual and use the new manual provided.

NOTICE:

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

CAUTION:

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

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

CE 0123

FCC ID: VKF-RAD87

IC ID: 7362A-RAD87

EU Authorized Representative for Masimo Corporation:

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
Tel.: +49-511-62 62 86 30
Fax.: +49-511-62 62 86 33

CLASSIFIED c UL us

MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 No. 601.1

Covered by one or more of the following U.S. Patents: RE38,492, RE38,476, 7,215,986, 7,215,984, 7,186,966, 6,850,787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,850, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 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. Other patents pending.

- The Rad-87 can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.
- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC and Class B digital device, Part 15, FCC Rules/USA. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving device.
  - Increase the separation between the equipment.
  - Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer for help.
- Changes or modifications to the wireless radio feature whether intentional or unintentional are prohibited without written approval from Masimo Corporation.
- The Rad-87 (device with optional radio) wirelessly transmits real-time sensor connectivity status, indicating a connect and/or disconnect state If the device is in a failure mode then the radio power is disabled and an error message is indicated on the device display. The device does not have a powered state where no information is transmitted.
- In accordance with FCC requirements, the Rad-87 (device with optional radio) must be placed greater then 20 cm from the patient's head.
- In accordance with FCC requirements, radio accessories on the Rad-87 (device with optional radio) cannot be attached directly to the patient using any accessory containing metal components.
- In accordance with international telecommunication requirements, the frequency band of 5,150 MHz to 5,250 MHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.
- A functional tester cannot be utilized to assess the accuracy of the Pulse CO-Oximeter or any sensors.

Blank Page

Warnings, cautions and notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels are as follows:

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

Sample of Warning:

WARNING: THIS IS A SAMPLE OF A WARNING STATEMENT.

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

Sample of Caution:

CAUTION: THIS IS A SAMPLE OF A CAUTION STATEMENT.

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

Sample of Note:

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

Product Description

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

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

FEATURES

These features are common to Rad-87 monitors:

- Rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure oxygen saturation (SpO_2) and pulse rate (BPM), as well as providing a more reliable probe-off detection.
- Perfusion Index (PI) with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.
- Accurate on cyanotic patients when used with an LNOP® Blue Sensor.
- Signal IQ® waveform provides signal identification and quality indication during excessive motion and low signal to noise situations.
- Variable pitch provides tonal variance for every 1% change in saturation.
- Remote alarming interface.
- Up to 72 hours of trending.
- Allows user to customize the default settings and set the device to retain these settings through a power off/on cycle.

*Optional features: SpCO, SpMet, PVI, Wireless radio

- Rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (*SpCO®) and methemoglobin (*SpMet™), as well as providing a more reliable probe-off detection.
- Masimo SET is clinically proven to be the highest sensitivity and specificity pulse oximeter in the world.
- Pleth Variability Index (PVI) may provide useful information concerning changes in the balance between intrathoracic airway pressure and intravascular fluid volume.
- Ability to connect wirelessly to Masimo Patient SafetyNet.

INDICATIONS FOR USE

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

Rad-87 specifications

PERFORMANCE

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

ELECTRICAL

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

ENVIRONMENTAL

Operating Temperature:	41°F to 104°F (5°C to 40°C)
Transport/Storage Temperature:	-40°F to 158°F (-40°C to +70°C)[7]
Operating Humidity:	5% to 95%, non-condensing
Operating Altitude:	500 mbar to 1060 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

PHYSICAL CHARACTERISTICS

Dimensions:	8.2" x 6.0" x 3.0" (20.8 cm x 15.2cm x 7.6 cm)
Weight:	2.1 lbs. = .908 Kg. = 32 oz
Trending	
72 hours of trending at 2 second resolution	
Mode	
Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[8]
Sensitivity:	Normal, Maximum[9], and APOD
Alarms	
High/low audible and visual alarms for parameters (SpO_2 range 1-99% then "---", SpCO range 1%-99% then "---", SpMet range 1%-99.9% then "---", pulse rate range 25-240 bpm)	
Sensor condition, system failure and low battery alarms	
High Priority:	800 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
Low Priority:	500 Hz tone, 3 pulse burst, repeat time: 5s
Alarm Volume:	High Priority: 70 dB (min)
Factory Default	Low Priority: 45 dB (min)
Display/Indicators	
Data display:	%SpO_2, %SpCO, %SpMet, pulse rate, alarm status, status messages, Signal IQ, perfusion idex, pleth variability index, APOD, sensitivity, wireless radio connection, system status light.
APOD, Norm, Max,	LED
Type:	LED
Display update rate:	1 second
Output Interface	
Serial RS-232	
Wireless Radio	802.11 a/b/g
Nurse Call	
Philips Vuelink, RadNet, Patient SafetyNet	
Compliance	
FCC Certification	FCC ID: VKF-RAD87
IC Certication	IC ID: 7362A-RAD87
EMC Compliance:	EN60601-1-2, Class B
Equipment Classification:	IEC 60601-1 / UL 60601-1
Type of Protection	Class 1 (on AC power), Internally powered (on battery power)
Degree of Protection-CO-Oximeter Cable:	Type BF-Applied Part
Mode of Operation:	Continuous

*Only with LNOP Rainbow Adhesive sensors.

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 Rainbow SET technology with LNOP Adt sensors has 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 weight.

3 The Masimo Rainbow SET technology with LNOP Adt sensors has 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 Masimo Rainbow SET technology with LNOP, LNOPv, LNCS and Rainbow sensors has 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.

5 The Carboxyhemoglobin has not been validated for neonatology.

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 Maximum sensitivity mode fixes perfusion limit to 0.02%.

Introduction

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

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

Use only Masimo sensors and cables with the Rad-87 Pulse CO-Oximeter. Other transducers, sensors and cables may effect Rad-87's performance.

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

CAUTIONS:

- DO NOT USE DAMAGED SENSORS OR PATIENT CABLES. DO NOT USE A SENSOR OR PATIENT CABLE WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS.
- DO NOT IMMERSE THE SENSOR OR PATIENT CABLE IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT 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 COMPATIBILIY OF THE MONITOR, CABLE AND SENSOR BEFORE USE, OTHERWISE PATIENT INJURY CAN RESULT.

SELECTING A MASIMO SET SENSOR

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

High intensity extreme lights (such as pulsating strobe lights) directed on the CO-Oximeter sensors, may not allow the sensor to obtain vital sign readings. High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

SENSOR APPLICATION INSTRUCTIONS

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

porated software/firmware and documentation in connection with PURCHASER' S use of the Masimo Products for their labeled purpose. MASIMO reserves all rights not expressly granted to Purchaser.

2. Ownership of Software/Firmware: Title to, ownership of, and all rights and interests in, any MASIMO software and/or firmware and the documentation, and all copies thereof, remain at all times vested in MASIMO Corporation, licensor to MASIMO, and they do not pass to Purchaser.
3. Assignment: Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise, without MASIMO's prior written consent; any attempt without such consent, to assign any rights, duties or obligations arising hereunder shall be void.
4. Copy Restrictions: The software/firmware and the accompanying written materials are copyrighted. Unauthorized copying of the software, including software that has been modified, merged, or included with other software, or other written materials is expressly forbidden. You may be held legally responsible for any copyright infringement that is cause or incurred by your failure to abide by the terms of this license. Nothing in this license provides any rights beyond those provided by 17 U.S.C. §117.
5. Use Restriction: As the Purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not electronically transfer the software/firmware from the products to any other device. You may not disclose, publish, translate, release or distribute copies of the software/firmware or accompanying written materials to others. You may not modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the software/firmware. You may not modify, adapt, translate, or create derivative works based on the written materials without the prior written consent of MASIMO.
6. Transfer Restrictions: The software/firmware is licensed to the Purchaser, and may not be transferred to anyone, except other end-users, without the prior written consent of MASIMO. In no event may you transfer, assign, rent, lease, sell, or otherwise dispose of the software/firmware or the products on a temporary basis.
7. Beneficiary: Masimo Corporation is a Beneficiary of this Agreement and has the right to enforce its provisions.
8. U.S. Government Rights: If you are acquiring software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the software is deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this agreement.

Part Numbers

PART NUMBER	DESCRIPTION
9132	Rad-87, Horizontal
9133	Rad-87, Vertical
9134	Rad-87, Horizontal with radio
9135	Rad-87, Vertical with radio

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

31743/4520A-1007