RAD-5_M & RAD-5V_M Signal Extraction Pulse Oximeter

SERVICE MANUAL

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RAD-5™ & RAD-5V™ Signal Extraction Pulse Oximeter

Service Manual

The Rad-5/5v Service Manual is intended to provide the necessary information for proper servicing of all models of the Rad-5™ class of pulse oximetry systems. This manual is structured to support troubleshooting to the assembly or module level. This manual does not provide instructions for troubleshooting to the printed circuit board component level. There may be information provided in this manual that is not relevant for your system. Do not service the Rad-5 class of pulse oximeters without completely reading and understanding these instructions. Service training provided by Masimo is required prior to utilization of this manual.

CAUTION:

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

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Covered by one or more of the following U.S. Patents: RE38,492, RE38,476, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 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.

Table of Contents

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Overview	1-1
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Maintenance	2-1
Battery Operation and Maintenance	3-1
Performance Verification	4-1
Power-On Self-Test	4-1 4-1 4-1 4-1 4-2 4-3
Repair	5-1
General Procedures Troubleshooting	5-1 5-2
Repair and Returns	6-1
Return Procedure	6-1
	About this Manual Warnings, Cautions and Notes Maintenance Introduction Cleaning Battery Operation and Maintenance Overview Replacing the Batteries Performance Verification Overview Power-On Self-Test Key Press Button Test Alarm Limit Test (Rad-5 only) Display Contrast Test Testing with Masimo Set Tester Battery Test Repair Safety Precautions: General Procedures Troubleshooting Service Messages: Repair and Returns Repair Policy

1. Overview

1.1. About this Manual

This manual explains how to service the Rad-5 class of pulse oximeters. However, when a differentiation between models is required, the actual model type will be identified prior to the explanation (For example, the difference between a Rad-5 or Rad-5v). Important safety information relating to general use of the Rad-5 class of pulse oximeters appears in the Rad-5 Operator's Manual. Other important safety information is located throughout this manual where appropriate.

1.2. Warnings, Cautions and Notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels is 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 statement.

2. Maintenance

2.1. Introduction

2.1.1. This chapter covers, how to test the operation of the Rad-5 oximeters, how to properly clean the Rad-5 pulse oximeters, how to replace the batteries and how to obtain service under normal operation. No internal adjustment or recalibration is required. Service should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

WARNING: BEFORE CLEANING THE OXIMETER, TURN THE UNIT OFF.

2.2. Cleaning

- 2.2.1. To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.
- 2.2.2. To clean the outer surface of the oximeter, use a soft cloth moistened with a 70% isopropyl alcohol. Do not allow liquids to enter the interior of the instrument.
- 2.2.3. To decontaminate unit, refer to Section 6.2.2.

CAUTIONS:

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

3. Battery Operation and Maintenance

3.1. Overview

- 3.1.1. The Rad-5 Handheld includes (4) AA alkaline batteries.
- 3.1.2. Before using the Rad-5 as a handheld or transport monitor, it is best to verify the charge level of the batteries. Please reference the Rad-5 Operators manual for specifications of battery life.
- 3.1.3. The battery charge LED indicators on the keypad of the Rad-5 will indicate the approximate life left with the batteries.
- 3.1.4. As a precaution against memory effects, it is advisable to replace the batteries as soon as the final indicator starts flashing.

3.2. Replacing the Batteries

- 3.2.1. Turn the Rad-5 Handheld off and remove the patient cable connection.
- 3.2.2. Place the Handheld face down on a soft surface such that no cosmetic damage occurs to the unit.
- 3.2.3. Depress the battery cover release and slide the cover off.
- 3.2.4. Install the replacement batteries into the Handheld. Verify proper positioning of the (+) positive and (-) negative contacts.
- 3.2.5. Depress the battery cover release button and slide the battery cover back onto the unit. Verify the battery cover release button pops up assuring a secure fit.
- 3.2.6. Verify the unit turns on, that all the LEDs momentarily light, that all (4) four battery charge LEDs remain lit, and that the unit stabilizes to a normal operation mode.

CAUTION: Follow local governing guidelines for proper disposal of internal batteries. Do not incinerate.

4. Performance Verification

4.1. Overview

- 4.1.1. To test the performance of the Rad-5 pulse oximeter following repairs or during routine maintenance, follow the procedure outlined in this section. If the Rad-5 fails any of the described tests, discontinue its use and correct the problem before returning the unit back to the user.
- 4.1.2. Before performing the following tests be sure to have fully charged batteries installed. Disconnect any patient cables or pulse oximetry probes

4.2. Power-On Self-Test

- 4.2.1. Depress the Power/Standby button and verify the unit turns on. Depress the button again and verify the unit turns off.
- 4.2.2. Turn the unit on by depressing the Power/Standby button. Verify all indicators illuminate and speaker sounds a brief tone.

4.3. Key Press Button Test

4.3.1. With the unit on and with the exception of the Power/Standby button, press each soft key button and verify that the Rad-5 acknowledges each key-press with an audible beep tone or by indicating an associated change on the display.

4.4. Alarm Limit Test (Rad-5 only)

- 4.4.1. With the unit turned on, select the MODE-ENTER button. Scroll through the limits by depressing the NEXT button. At each parameter, use the up and down arrow keys and verify the limits change accordingly. The limits will remain set until the unit is cycled off and on at which time the original settings will be restored.
- 4.4.2. Reset the alarm limits.

4.5. Display Contrast Test

- 4.5.1. With the unit turned on, depress the MODE-ENTER button (3) three times. When the display appears as 888, use the up and down arrows to verify the contrast both brightens and dims accordingly.
- 4.5.2. Return the Contrast setting to the original value, or a value that allows maximum viewing contrast.

4.6. Testing with Masimo Set Tester

- 4.6.1. Turn the Radical off and then on again.
- 4.6.2. Set the alarm limits to:

	% SpO ₂	Pulse Rate
High	OFF	140
Low	90	50

- 4.6.3. Connect the Masimo Set Tester to the Patient connecter.
- 4.6.4. Verify that within 20 seconds, the display shows numeric readings and the Signal IQ bar display is pulsing.
- 4.6.5. Verify that the SpO₂ measurement is between 79% and 84%.
- 4.6.6. Verify that the pulse rate measurement is between 55 bpm and 65 bpm.
- 4.6.7. Verify an audible alarm occurs and the SpO₂ measurement is flashing.
- 4.6.8. Press the Alarm Silence button once and verify the alarm is silenced and the little yellow LED is flashing.
- 4.6.9. Wait 120 seconds and verify that the alarm silence times out and the audible alarm is activated again and the little yellow LED is off.
- 4.6.10. Depress the Alarm Silence button twice(Alarm mute). Verify that a momentary beep is heard and the little yellow LED is on and not flashing. Wait more than 120 seconds to verify the audible alarm does not return.
- 4.6.11. To disable Alarm mute, press the Alarm button once and verify an audible alarm is heard.
- 4.6.12. Depress the up and down arrows while the unit is actively measuring vitals. Verify an increase and decrease in pulse volume. Continue depressing the down arrow to verify the pulse beep can be silenced.

4.7. Battery Test

- 4.7.1. Install four (4) "AA" alkaline batteries. Verify the unit turns on immediately after installation.
- 4.7.2. Turn the unit off then on.
- 4.7.3. If the Rad-5 was installed with four (4) brand new batteries, then, the four (4) Battery charge LED indicators should all be illuminated.
- 4.7.4. If all four (4) LEDs are not lit, then, remove the four (4) batteries and try another set of four (4) brand new batteries and repeat steps 4.7.2 and 4.7.3.
- 4.7.5. If all four (4) indicators are still not lit, then, return unit to Masimo for repair. Contact Masimo Corporation using the information in Section 6.2.11

Repair

5.1. Safety Precautions:

WARNING: DO NOT DISASSEMBLE OR ASSEMBLE THE UNIT

WHILE THE BATTERIES ARE STILL INSTALLED.

WARNING: ENSURE THE UNIT HAS BEEN CLEANED PER THE CLEANING INSTRUCTIONS.

5.2. General Procedures

- 5.2.1. Examine the unit prior to disassembly or troubleshooting and inspect for cosmetic damage. External damage may be helpful in determining the root cause of the failure.
- 5.2.2. Note any markings or labeling the end user may have placed on the unit that may need to be duplicated or transferred in the event the housing or ancillary components are to be replaced.
- 5.2.3. Make note of the unit serial number.
- 5.2.4. Make note of the software versions in the event the Oximeter board or system boards are replaced, as these boards require software updates to make them compatible with the end users version of software.
- 5.2.5. Contact Masimo Corporation using the information in Section 6.2.11 to research the warranty history of the unit to determine if the unit will be covered under warranty.

5.3. Troubleshooting

- 5.3.1. The troubleshooting procedures in this manual instruct the technician to isolate the failure down to the sub-assembly level. The intention is to have the Unit Under Test (UUT) repaired with minimal steps. The Masimo Set Tester is needed to perform the Performance Verification in Section 4 upon completion of repairs.
- 5.3.2. Tools required are as follows:

Phillips head screwdriver #0 Multimeter

- 5.3.3. The troubleshooting steps below are presented in order of the most probable cause first. Proceed to the next step only if unit continues to fail.
- 5.3.4. Always note the software versions of boards prior to repair.
- All units must have Performance Verification Section 4 performed after repairs have been affected.

5.4. Service Messages:

Upon detection of a system error, the main software alerts the user with an audible alarm indicator and displays the appropriate error code on the Handheld's main display. The MS-X board is held in reset and no other runtime functionality is available to the user until the Handheld is power cycled by the user (with power on and off key) or until power is completely removed and reapplied to the system (removal and replacement of batteries).

System Error	System Error Code
MS-X Board Failure	1
MS-X Board Communication Failure	2
5V Voltage Supply Out of Range	3
Red Voltage Supply Out of Range	4
Blue Voltage Supply Out of Range	5
Battery Drop Voltage Out of Range	6
Battery Voltage Out of Range	7

Symptom	Cause and Corrective Action Steps
Speaker Alarming (very lovel) and unit is not.	Probable Watchdog error.
loud) and unit is not functioning or displaying.	Replace System Board.
Alarm LED does not Illuminate Unit must be in alarm state Audible alarm can be heard	Replace System Board.
Alarm Condition But No	1. Replace Speaker
Audible Indication.	2. Replace System Board
1. Unit is in alarm condition.	
Display Missing Segments	1. Replace Display.
	Replace System Board
Button Function Error	Replace Keypad
Any front panel button affected	2. Replace System Board
2. Buttons do not activate feature.	
"No Sen", or "Sen Off"	1. Replace sensor.
Displayed.	Replace patient cable.
Cable is connected with	3. Replace oximeter board.
sensor attached.	4.
Rad-5 Will Not Turn Off	Replace System Board
	Replace Keypad

If unable to repair unit, then please call (800)326-4890 option #2 to arrange for return to Masimo Corporation.

6. Repair and Returns

6.1. Repair Policy

- 6.1.1. Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. The product must be repaired.
- 6.1.2. Please clean contaminated/dirty equipment before returning. Make sure it is fully dry before packing the equipment.
- 6.1.3. To return the Rad-5 unit for service, please follow the Return Procedure outlined in this section.

6.2. Return Procedure

- 6.2.1. Please clean contaminated/dirty equipment before returning and make sure it is completely dry before packing the equipment.
- 6.2.2. Recommended decontamination procedure for Rad-5 equipment that has the potential for being exposed to blood or other potentially infectious materials.
 - 6.2.2.1. Put on Lab coat or other protective garment.
 - 6.2.2.2. Put on gloves.
 - 6.2.2.3. Place equipment on the designated decontamination table.
 - 6.2.2.4. Apply cleaning agent to paper towel or use Cidex wipes.
 - 6.2.2.5. Wipe down all aspects of the equipment.
 - 6.2.2.6. Let the equipment air dry completely.
 - 6.2.2.7. Remove gloves.
 - 6.2.2.8. Move equipment to the area designated for equipment that has been through the decontamination process.
 - 6.2.2.9. Dispose of all contaminated products properly.
- 6.2.3. Package the equipment securely in the original shipping container if possible – and enclose the following information and items:
- 6.2.4. Call Masimo "domestically" at (800)326-4890, option #2, "internationally" at 949-297-7498, option #2 and ask for an RMA number.

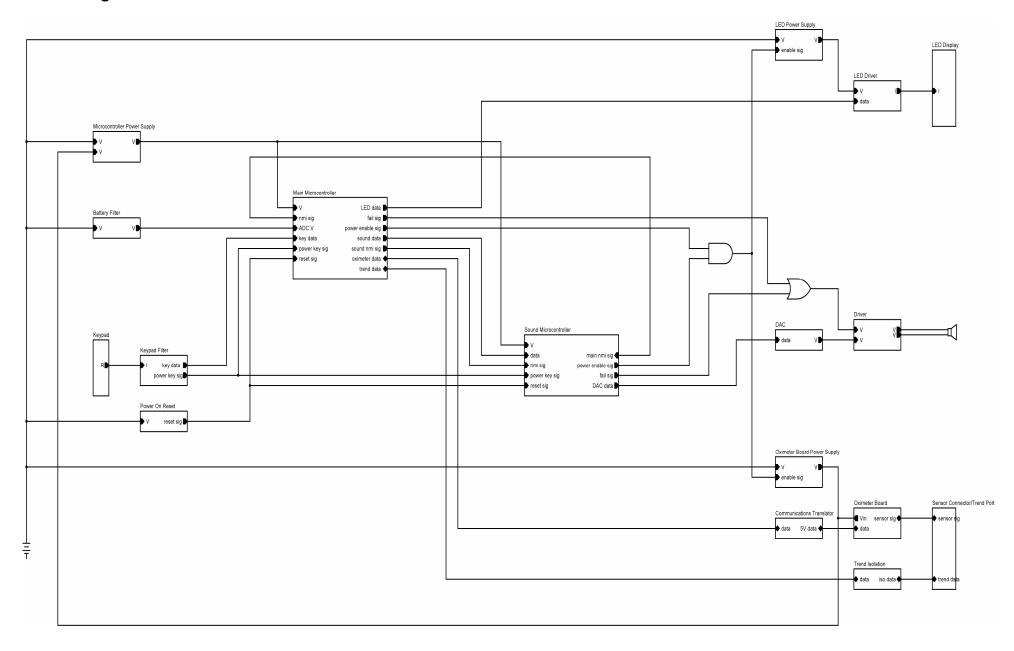
- 6.2.5. A letter or email describing in detail any symptoms or difficulties experienced with the pulse oximeter. Please include the RMA number in the letter.
- 6.2.6. Warranty information a copy of the invoice or other applicable documentation must be included.
- 6.2.7. Purchase order number to cover repair if the oximeter is not under warranty, or for tracking purposes if the warranty is in effect.
- 6.2.8. Ship-to and bill-to information.
- 6.2.9. Person (name, telephone/Telex/fax number, email and country) to contact for any questions about the repairs.
- 6.2.10. A document stating the oximeter has been decontaminated for bloodborne pathogens.
- 6.2.11. Return pulse oximeter to the following shipping address:

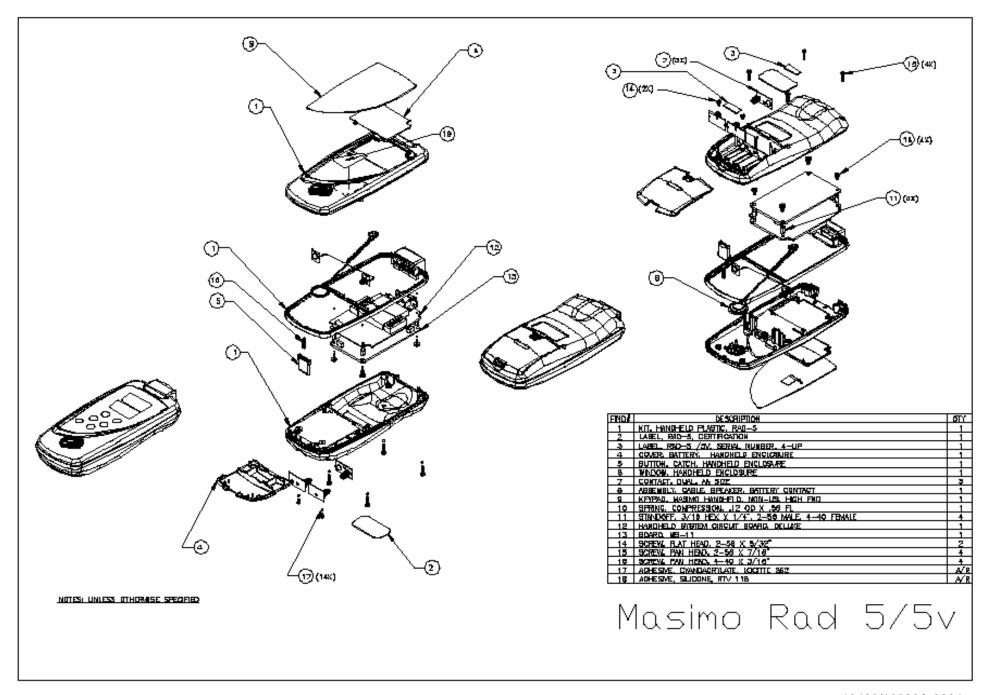
Masimo Corporation 40 Parker Irvine, California USA 92618

(Domestic Toll Free): 800-326-4890, option #2 (International): 949-297-7498, option #2

FAX: 949-297-7499

7. Drawings and Schematics





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