



Reason for Correction and Removal

Masimo has identified a very small number of Rad-8 instruments that, when moved, can power off without the operator pressing the power button. If a change in power status goes unnoticed by the caretaker, a delay of care could result. This medical device correction and removal notice applies to Masimo Rad-8 Pulse Oximeters manufactured from March 27, 2009 to January 24, 2013.

Scope of Rework

Addition of heat sink insulator (P/N: 35927) to power supply and Kapton tape (P/N: 24369) on ribbon cable.

Materials and Equipment Required

Masimo Part Number	Description
24369	Kapton tape, 3" Long, 1.25" Wide, with Release Liner
35927	Insulator, Heat Sink, Rad-8, Qty. 1

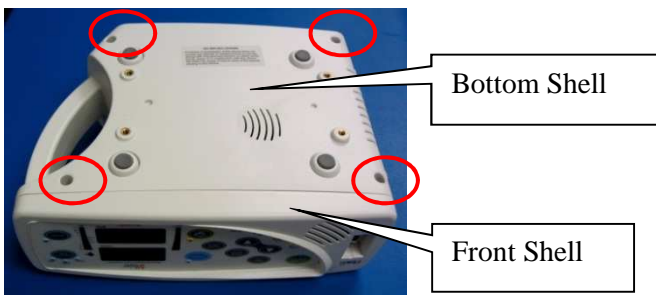
Equipment required: Philips screwdriver

Notes

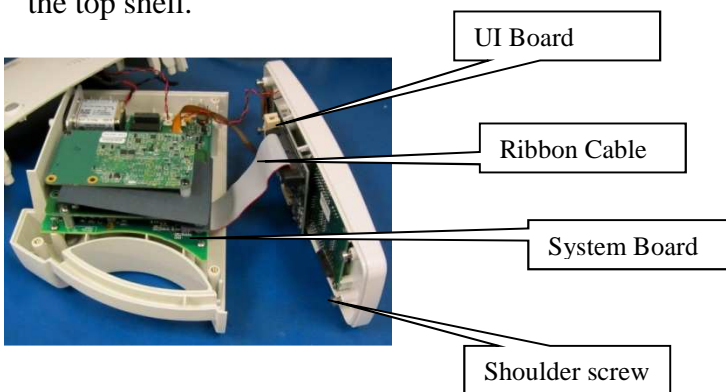
- All persons involved in the rework of a Masimo Rad-8 Pulse Oximeter must be certified and must utilize the procedure described in this document.
- To be eligible for certification, the technician must have a working knowledge of microprocessor-based medical electronics servicing and analog/digital electronics theory and must thoroughly review this document and demonstrate an understanding of the procedure by successfully completing the knowledge assessment available on <http://www.masimou.com>.
- Clean contaminated/dirty equipment before initiating rework using a soft cloth dampened with a mild detergent and warm water solution. Do not allow liquids to enter the interior of the Rad-8. The outer surface can also be wiped down using the following solvents: Cidex Plus (3.4% Glutaraldehyde), 0.25% Ammonium Chloride, 10% Bleach, and 70% Isopropyl Alcohol.
- Before performing the instructions provided below make sure that the workstation and the operator comply with all Electro Static Discharge (ESD) requirements (ANSI/ESD S20.20).
- After the rework has been completed and functionality verified, complete Attachment 2 and send it to Masimo.
- Pictures provided are for reference only to address specific instructions and may not represent product details that are not relevant to these instructions.

Rework Instructions

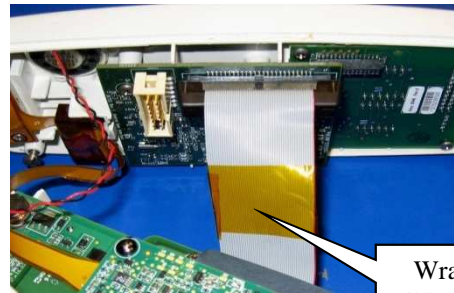
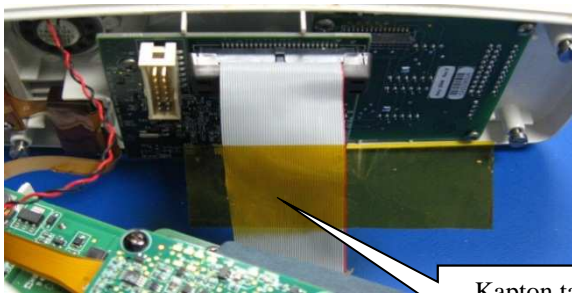
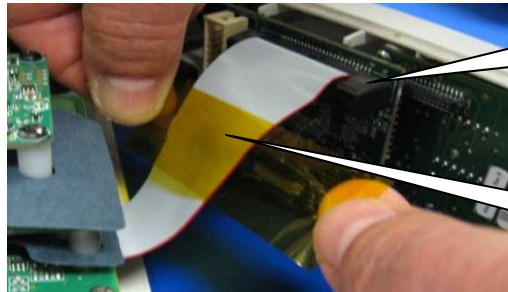
1. Disconnect the patient cable and sensor from the connector of the Rad-8 pulse oximeter and perform the following steps:
 - a. Turn the monitor on by depressing the Power Button. For about 5 seconds all available LEDs are illuminated and a brief beep tone sounds.
 - b. Verify all front-panel indicators momentarily illuminate and a tone is heard.
 - c. Verify the front-panel display is free of alarm and system failure messages.
 - d. See the picture for example of display being ON.
 - e. Record on form, attachment 2 of this document, the result of the test (pass if sections “b” and “c” above are confirmed, fail if either of these 2 sections is not confirmed).
2. Remove the four screws from the lower shell. Remove the bottom shell by lifting it away from the top shell. Keep the screws to be reused when the instrument is re-assembled.



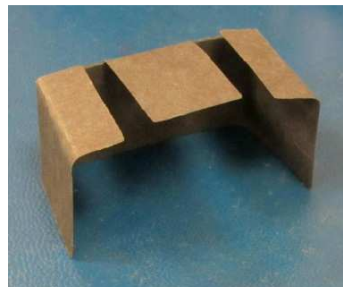
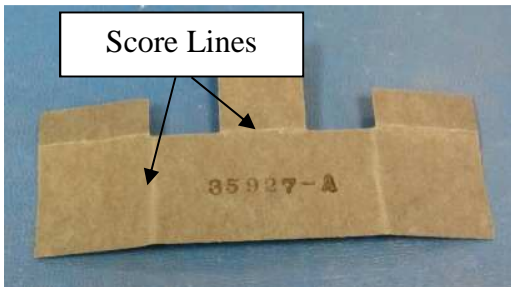
3. Lift the front shell off the top shell slots that captures the shoulder screws. Place the front shell next to the top shell.



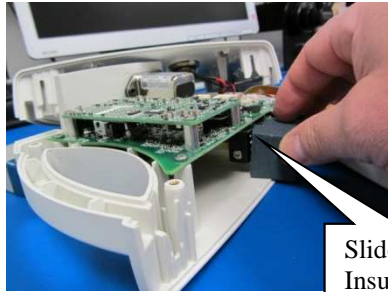
4. Inspect the ribbon cable to identify if the area is physically stressed. Remove the liner from the Kapton tape, P/N: 24369. Wrap the tape around the stress area of the ribbon cable. Ensure that the stress area is centered under the tape. If no stress is observed, measure down from the ejector header cap approximately 1.5” inches and place the tape (kapton tape positioned approximately in the middle of the cable). See pictures below for examples of wrapped cables:



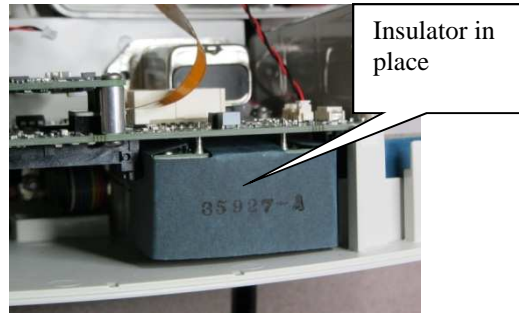
5. Bend the insulator, P/N: 35927, along scoring lines to approximately 90°. Ensure that the lines have a rounded edge and are not sharp. Ensure that the bends are not damaged. Discard insulator if damaged (split or cracked along any of the bends). See pictures below:



6. Insert the insulator into the gap between the system board and power supply board.



Slide the
Insulator in
this place



Insulator in
place

7. Verify that all connectors are in place inside the instrument. Place the front shell on the top shell. Insert the front shell shoulder screws into the slots on the top shell and push down.



8. Place the bottom shell in place by aligning the slots with the shoulder screws of the front shell. Push down until it is fully seated. Place the four screws removed in step 2 and tighten them. Do not use excessive force for tightening.



Performance Verification

9. To test the performance of the Rad-8 pulse oximeter following this rework, follow the procedure below (or as outlined in Section 9: Service and Maintenance of the Operators Manual). If the Rad-8 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 instrument is connected to AC power. Also disconnect any patient cables or pulse oximetry probes or serial cables from the instrument.
 - a. Power-On Self-Test:
 - i. Turn the monitor on by depressing the Power Button. For about 5 seconds all available LEDs are illuminated and a brief beep tone sounds.
 - ii. The oximeter begins normal operation.
 - b. Key Press Button Test:
 - i. With the exception of the Power Button, press each button and verify that the oximeter acknowledges each key-press with an audible beep tone or by indicating a change on the display.
 - c. Functional test:
 - i. With the monitor turned on, connect a Masimo SpO2 sensor to the patient sensor connector.
 - ii. Verify that the SpO2 and PR parameters are displayed.

Documentation

10. On Attachment 2 of this document, record the serial number of the instrument, the result of the functional test, and the lot numbers of both the insulator, P/N: 35927, and the Kapton Tape, P/N: 24369, that were installed in the instrument during this rework. Send the completed Attachment 2 form to Masimo Technical Services:
 - Email: Rad8@Masimo.com
 - Fax: 949-297-7700

