

Rad-97[®]
Pulse CO-Oximeter[®]



The Rad-97® Pulse CO-Oximeter® Service Manual provides the necessary information for proper service of Rad-97. There may be information provided in this Service Manual that is not relevant for your system.

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

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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005, CAN/CSA C22.2 No. 60601-1:2008, and applicable Particular (EN/ISO 80601-2-61:2011) and related Collateral (IEC 60601-1-8:2006) Standards for
which the product has been found to comply by Intertek.

Patents: www.masimo.com/patents.htm

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Service Manual, Rad-97

This Service Manual provides information to perform basic service procedures on the following devices:

- Rad-97® Pulse CO-Oximeter®
- Rad-97® Pulse CO-Oximeter® with noninvasive blood pressure
- Rad-97® Pulse CO-Oximeter® with NomoLine® Capnography

Refer to the Rad-97 Operator's Manual for comprehensive list of safety information, warnings, and cautions.

Contents

Service Manual, Rad-97	3
About This Manual	7
Safety Information, Warnings and Cautions	7
Identify Rad-97 Version	9
Chapter 1: Maintenance Procedures	11
Cleaning	11
Chapter 2: Software Procedures	13
Software Upgrade	13
Software Verification	13
Chapter 3: Service Procedures	15
Rad-97 Disassembly and Reassembly - All Versions and Models	15
Rad-97 Battery Replacement	19
Rad-97 TB-20 Connector Replacement	35
Chapter 4: Electrical Safety Testing	49
Electrical Safety Testing	49
Chapter 5: Performance Verification Procedures	53
Battery Test	53
Power-On Self Test	54
Touchscreen Function Test	54
Noninvasive Blood Pressure Module Tests	55
NomoLine® Capnography Verification	61
Alarm Limit Test	61
Nurse Call Setting Connections	61
Chapter 6: Troubleshooting and Repair	63
Repair	63
Troubleshooting	63
Chapter 7: Warranty and Service Information	65
Repair Policy	65
Return Procedure	65
Contacting Masimo	65
Appendix: Rad-97 Component Diagrams	67
Rad-97 - Version 1	67
Rad-97 - Version 2	70
Index	73

About This Manual

This Service Manual may contain technical information regarding troubleshooting, cleaning, electrical safety testing, functional verification and other pertinent service guidance. Keep this Service Manual in a convenient location for ready reference during service and maintenance. This Service Manual is intended for technical service, repair and biomedical personnel who maintain, troubleshoot and service this product as needed.

Important safety information relating to general servicing of Rad-97 appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *Warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the user.

WARNING: This is an example of a warning statement.

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

CAUTION: This is an example of a caution statement.

A *Note* is given when additional general information is applicable.

Note: This is an example of a note.

A *Service Warning* is given when service and maintenance actions may result in a serious outcome (for example, injury, serious adverse effect, and death) to the patient or user. The following is an example of a warning:

Service Warning: This is a sample of a service warning statement.

Authorized Service Personnel: Authorized Service Personnel is a user the manufacturer has deemed authorized to service products covered under the manufacturer's warranty. Service conducted by anyone other than an authorized service personnel voids the warranty. The authorized service personnel are allowed to only perform tasks outlined in this service manual.

Safety Information, Warnings and Cautions

WARNING: This manual is intended for use by authorized service personnel only.

WARNING: DO NOT service or make any modifications to Rad-97 other than those described in this manual.

WARNING: Always ensure that the AC power has been disconnected from Rad-97 prior to opening up the device for service.

WARNING: DO NOT use any device that appears to be damaged. Contact Masimo Technical Support in regards to any device that appears damaged.

CAUTION: Prior to service, precautions must be taken to minimize potential damage to the device through electrostatic discharge (ESD):

- Use a conductive wrist strap attached to a good earth ground.
- Always discharge yourself by touching a grounded bare metal surface or approved anti-static mat before working with the device.
- Use an approved anti-static mat to cover your work surface.

Identify Rad-97 Version

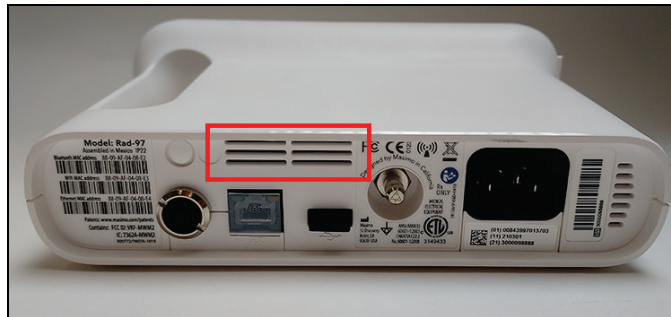
Two (2) versions of the Rad-97 device exist. The following procedure provides instructions for determining the version of the Rad-97. Determining the version of a Rad-97 determines how to follow the proper procedures for the device being serviced.

A simple way determine the version of the Rad-97 device is to look at the vents at the rear of the device:

- **Version 1** - The back of the device has three columns of vents.



- **Version 2** - The back of the device has two columns of vents.



Chapter 1: Maintenance Procedures

This chapter covers how to properly clean Rad-97.

WARNING: Electrical shock and flammability hazard. Before cleaning Rad-97, always turn the unit off and disconnect the power cord from the back of the unit.

CAUTION: Do not autoclave, pressure sterilize, or gas sterilize Rad-97.

CAUTION: Do not soak or immerse Rad-97 in any liquid.

CAUTION: Use the cleaning solution sparingly. Allow unit to air dry. Excessive solution can flow into Rad-97 and cause damage to internal components.

CAUTION: 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.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean Rad-97. These substances attack the device's materials and device failure can result.

Cleaning

Rad-97 is a non-sterile and reusable device. The surface of the Rad-97 should be cleaned when the device is visibly dirty, before and after each procedure, and/or according to hospital practice.

Do not allow liquids to enter the interior of Rad-97. Using the recommended cleaning solutions on the touchscreen will not affect the performance of Rad-97.

To clean the device:

1. Disconnect the AC Power Supply and ensure the sensor is not applied to the patient.
2. Wipe the outer surfaces using a dampened soft cloth with one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue.
3. Dry the device thoroughly prior to using on a patient.

The surfaces of the Rad-97 may be cleaned with the following solvents or cleaning agents:

- 70% Isopropyl Alcohol
- Glutaraldehyde
- 10% bleach (5% - 5.25% sodium hypochlorite) to 90% water solution
- Quaternary ammonium chloride solutions
- 0.5% hydrogen peroxide

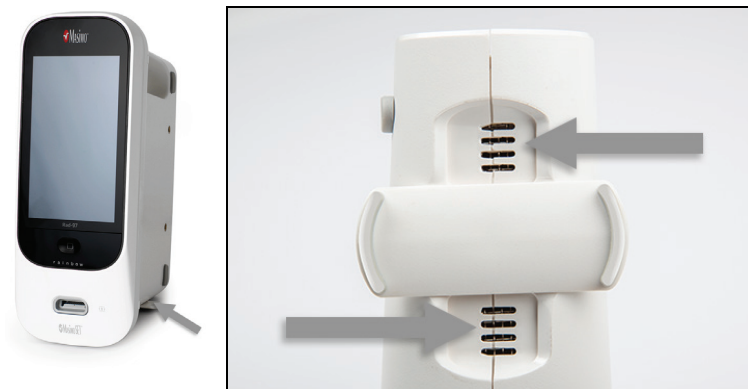
CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the device may occur.

CAUTION: To prevent damage, do not soak or immerse the device in any liquid solution.

CAUTION: Do not sterilize by irradiation, steam, and autoclave or ethylene oxide.

Vent Cleaning

The following procedure applies to Version 1 of Rad-97. Version 2 does not have these vents.



Vents may be cleaned using a small vacuum with brush attachment.

To clean, vacuum over the vents using a brush attachment, if available, to clear any debris.

Chapter 2: Software Procedures

This chapter covers how to properly upgrade the software on Rad-97 and verify the upgrade is successful. These procedures should be performed by authorized service personnel only.

Rad-97 software is updated using the Rad-97 Software Upgrade USB Drive and the USB port on the rear of Rad-97. The Software Upgrade USB Drive is available from Masimo for authorized service personnel by calling Masimo Technical Support. See **Contacting Masimo** on page 65.

Software Upgrade

Before performing the upgrade procedure, ensure Rad-97 is plugged in and has power.

CAUTION: Do not turn off Rad-97 during the upgrade process. Interruption of the Rad-97 software upgrade may cause a corruption of the device.

1. Completely turn off Rad-97 by holding down the Power Button for **8 seconds**, until the device emits two beeps.
2. Place the upgrade USB drive into the USB port on the back of Rad-97.
3. Turn on Rad-97 by pressing the Power Button once, and the upgrading process will initiate automatically. This process lasts approximately two minutes, and a programming message is displayed on the screen during that time. Once programming is completed, Rad-97 will automatically power off, indicating that the software upgrade has successfully completed.
4. Remove the upgrade USB drive from Rad-97 and verify the software is now at the proper version. See **Software Verification** on page 13.

Software Verification

To verify the software version, perform the following:

1. Turn on Rad-97 by pressing the Power Button once.
2. From the Main Screen, access the Main Menu and navigate to the About screen.
3. On the About screen in the Processor field, view the software version and confirm the software matches what has been installed.

Chapter 3: Service Procedures

This chapter covers how to service components on both Version 1 and Version 2 of the Rad-97. No internal adjustment or recalibration is required. Service should be done by authorized service personnel only.

Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

Rad-97 Disassembly and Reassembly - All Versions and Models

The following procedures instruct on opening up the device for service and assembling when service is complete. These procedures apply to all versions (V1 and V2) and all models (base, NIBP and ISA) of the Rad-97.

Required Tools

The following tools are required when disassembling and reassembling the Rad-97:

- Needle-nose pliers
- 3/32" Allen wrench (key)
- ESD conductive wrist strap
- ESD surface
- Small, flat-tipped screwdriver

Disassembly

CAUTION: Prior to service, precautions must be taken to minimize potential damage to the device through electrostatic discharge (ESD):

- Use a conductive wrist strap attached to a good earth ground.
 - Always discharge yourself by touching a grounded bare metal surface or approved anti-static mat before working with the device.
 - Use an approved anti-static work surface.
1. Turn off the device and unplug the power cord from the power entry module on the rear of the device.
 2. Place the device on a anti-static surface.
 3. Carefully pull the two (2) foot pads away from the case from to expose the housing screws.

CAUTION: The foot pads are easily damaged. Pull up from the outer end as indicated in the image.

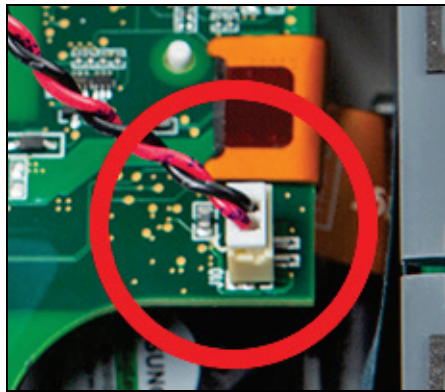


- 4. Using the Allen wrench, remove the four (4) case screws (A).

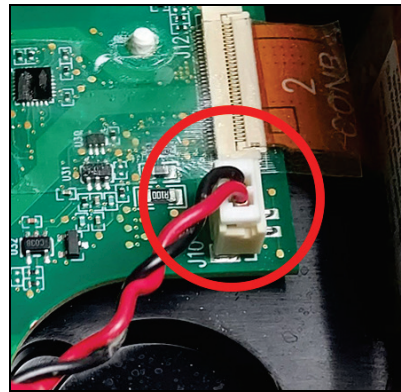


- 5. Separate the case halves by gently pulling upwards on the loose case half. Take care not to pull the speaker cable out when lifting this case half.
- 6. Disconnect the speaker connector from the circuit board and set the case half aside.

Note: Use care to not lose the case screws when handling the case half.



Speaker Connector Rad-97 Version 1



Speaker Connector Rad-97 Version 2

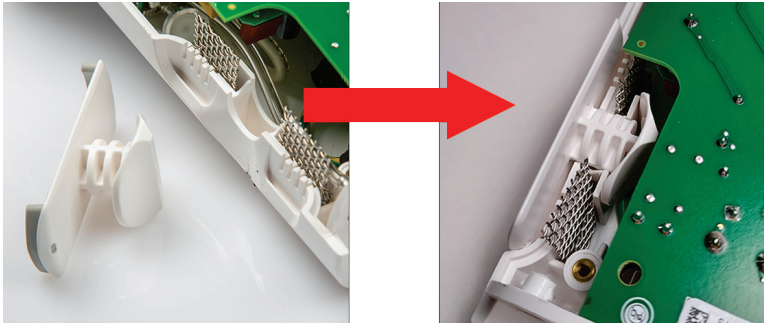
- 7. Remove the swivel foot from the case by pulling upwards (Version 1 shown, Version 2 similar).



- 8. After disassembly, follow the procedure for the service required.

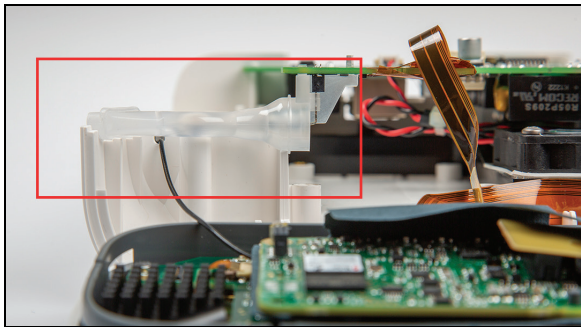
Reassembly

1. If removed, install the swivel foot into the case (Version 1 shown, Version 2 similar).

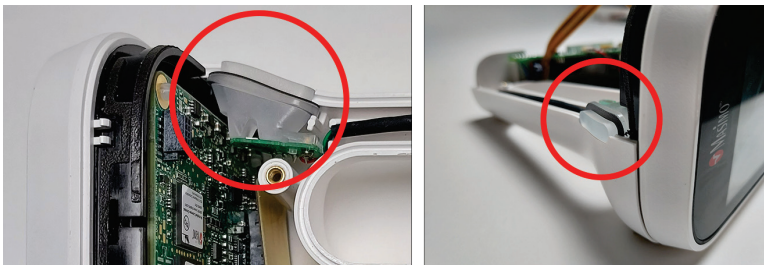


2. Verify that the status light is oriented in the case properly as shown.

- **Status Light Rad-97 Version 1**

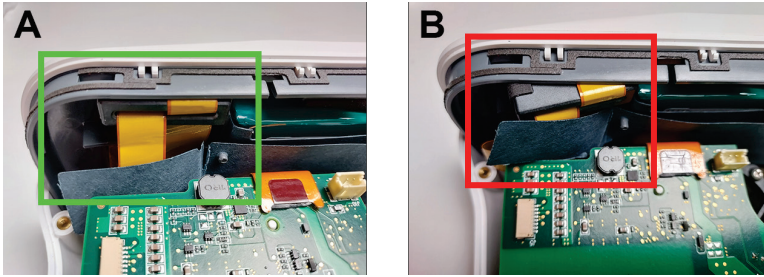


- **Status Light Rad-97 Version 2**

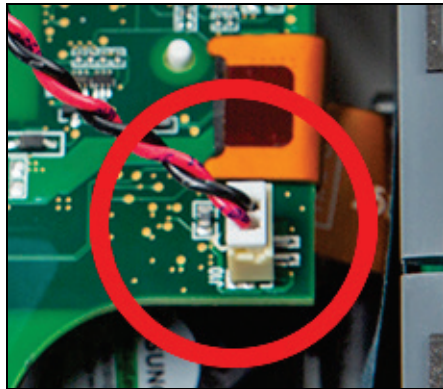


3. Verify that all cable connections within the device are securely connected before proceeding.
 - If any cables are not securely connected, adjust the cable such that it is reconnected securely.
4. **For Rad-97 Version 1:** Verify that this component in the picture below fits within the allotted slot in the chassis before proceeding. If the component is not aligned properly, push it into place gently.
 - In image A, the component sits within the slot and is not protruding outside of the designated area. This is the correct placement.

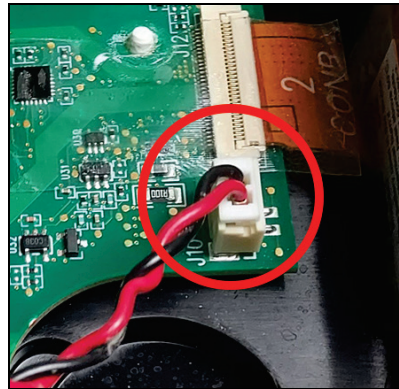
- In image B, the component is improperly aligned and protruding outside of the designated area. This is incorrect placement and must be corrected.



5. Connect the speaker connector.

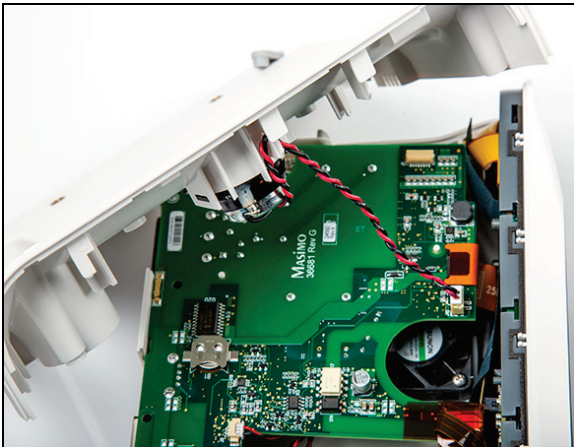


Speaker Connector Rad-97 Version 1



Speaker Connector Rad-97 Version 2

6. Place the case halves together. Ensure no components or wiring become pinched between the case halves or any components before installing the screws.



7. Install the four (4) case screws (A) and tighten using the Allen wrench.

CAUTION: DO NOT exceed 28 oz-in (1.75 in-lbs) of torque to the case screws or the Rad-97 case may be damaged.



8. Press the foot pads into the case.
9. This completes the Rad-97 service procedure. Perform electrical safety testing and verify proper operation of Rad-97. See **Chapter 4: Electrical Safety Testing** on page 49 and **Chapter 5: Performance Verification Procedures** on page 53.

Rad-97 Battery Replacement

The following procedure provides instructions for removing the existing battery and installing a replacement battery in Rad-97 devices.

Contact Global Services with questions regarding the Rad-97 battery replacement kit and/or the required tools part numbers. Contact information can be found at <http://service.masimo.com>.

Supplied Parts List

The following parts are supplied in the Rad-97 Battery Replacement Kit:



- 1 Battery
- 2 Battery Update USB Drive

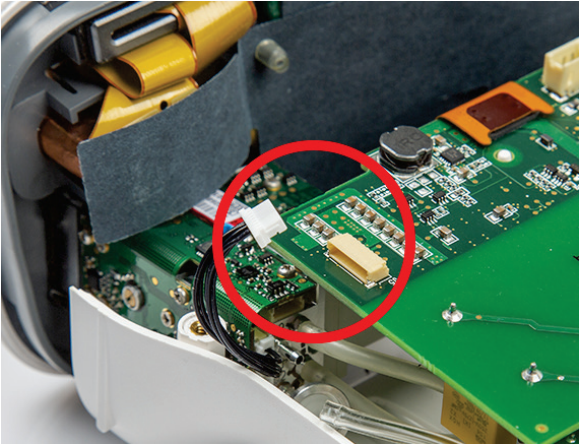
Required Tools

The following tools are required when servicing the battery on Rad-97:

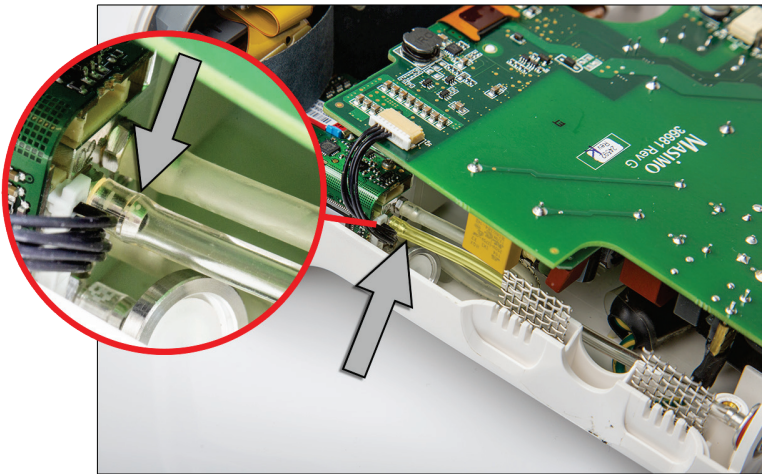
- Needle-nose pliers
- 3/32" Allen wrench (key)
- ESD conductive wrist strap
- ESD surface
- Small, flat-tipped screwdriver

Battery Removal (Version 1)

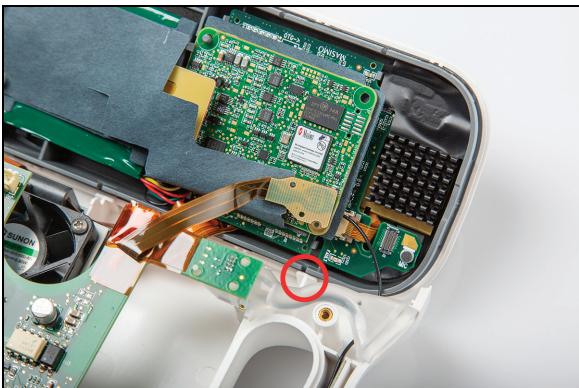
1. Disassemble the Rad-97 as instructed in **Disassembly** on page 15.
2. **On Rad-97 with NomoLine Capnography**, disconnect the capnography module electrical connector.



3. Lift the faceplate upwards from the case to disengage from the plastic T connections.
 - For Rad-97 with noninvasive blood pressure, the NIBP tube can remain connected during the battery replacement procedure.
 - For Rad-97 with NomoLine Capnography, the tubing will remain connected during the battery replacement procedure. Lift the faceplate very gently upwards to disengage from the plastic T connections. Do not force the front assembly upwards. The capnography module will hit the rest of the assembly if forced. Once the plastic T connections are disengaged, move the front assembly away from the rest of the assembly, being careful not to hit the capnography module against anything or to disconnect the capnography tubing by pulling the front assembly too far away from the rest of the assembly.

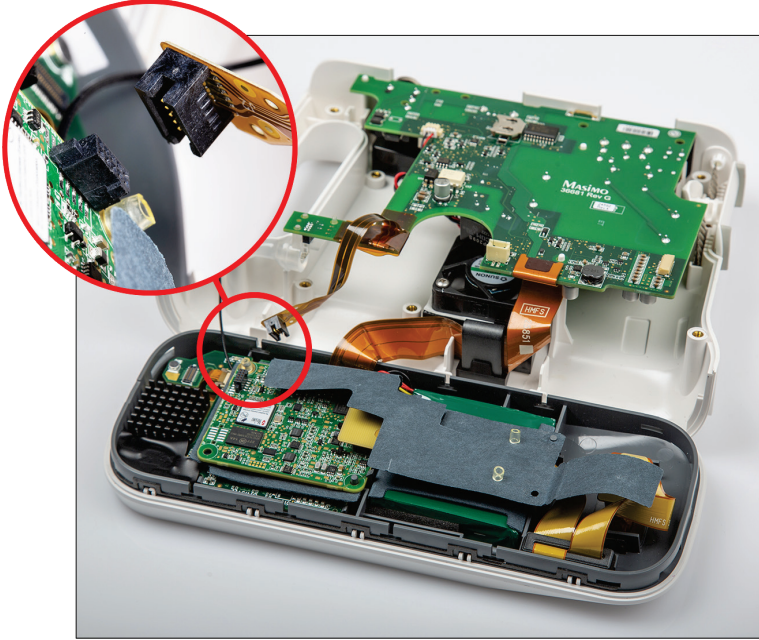


CAUTION: Use care not to pull the bezel off of the faceplate when removing from the case.



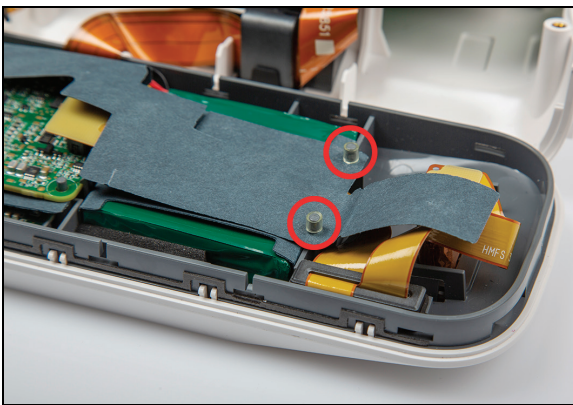
4. Carefully disconnect the ribbon cable from the circuit board.
 - For Rad-97 with **NomLine Capnography**, the capnography tubing will prevent the front assembly from lying flat on the working surface, but the procedure is the same. Work within the space between the front assembly and the main assembly with the tubing still connected.

CAUTION: Use care not to disconnect the capnography tubes.

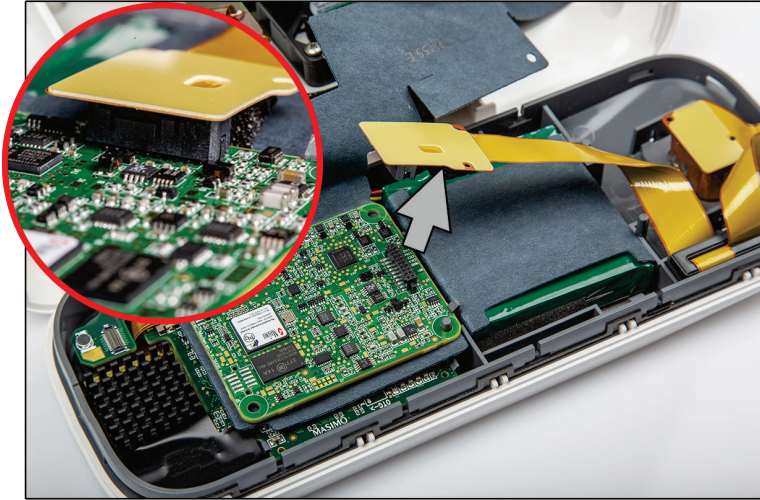


5. Rotate the faceplate and place it face-down on the anti-static mat. Use care not to damage the screen during battery replacement.
6. Working from the rear of the faceplate (where the battery is located), remove the two (2) rubber retainers from the posts at the bottom of the insulator as shown. It may be necessary to use the small, flat-tipped screwdriver and needle-nose pliers to remove the retainers.

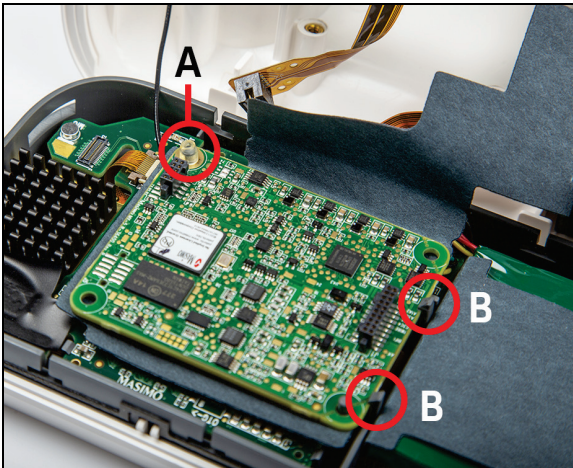
Note: Some models may only have one (1) rubber retainer.



7. Fold back the insulator to expose the ribbon cable as shown. Carefully disconnect the ribbon cable from the circuit board.



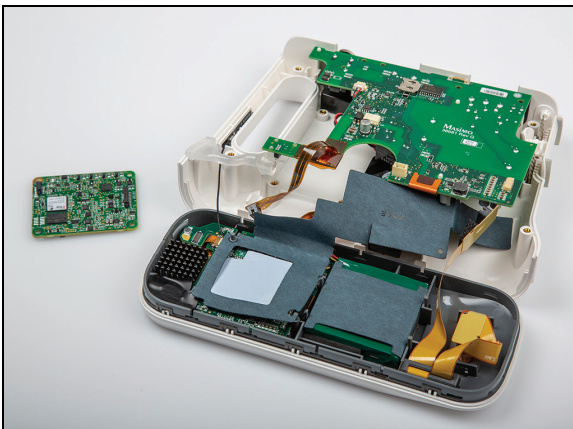
8. Remove the rubber retainer from the post (A) and gently pry the circuit board tabs (B) to release the circuit board from the faceplate.



9. Using care to only touch the sides of the circuit board, remove the circuit board from the face plate.

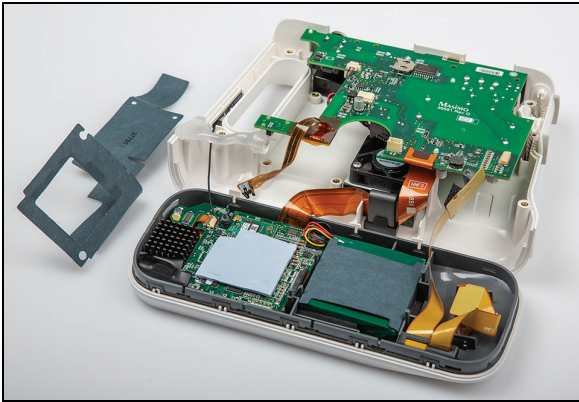
CAUTION: Do not touch the circuit board components to prevent damage.

CAUTION: Place the circuit board on the anti-static surface.



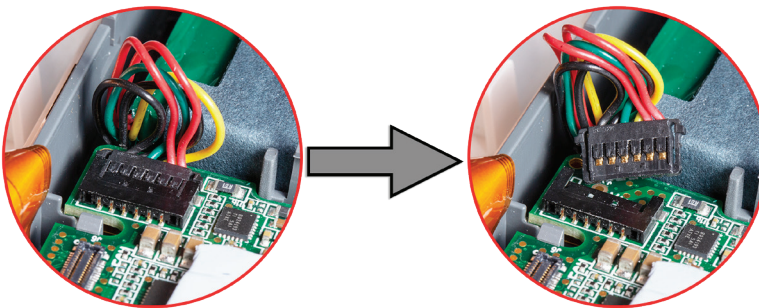
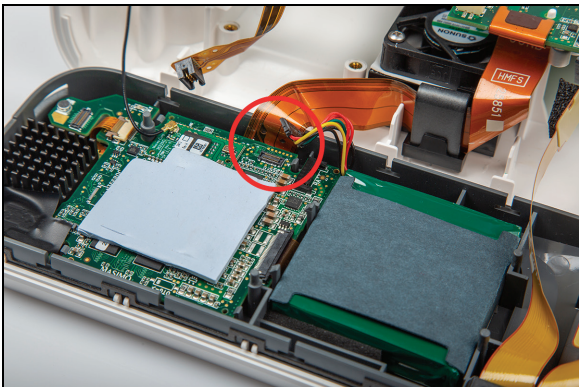
10. Remove the insulator from the Rad-97 faceplate.

CAUTION: The insulator may be partially attached to the circuit board with adhesive, use care when pulling away from the adhesive and removing.

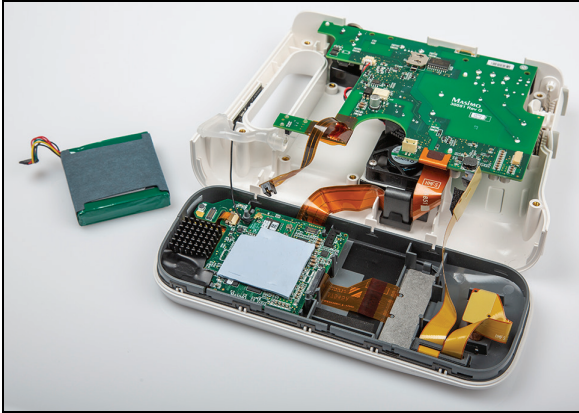


11. Disconnect the battery connector from the circuit board by pulling towards the battery.

• **On Rad-97 with NomoLine Capnography**, due to the limited working space it may be easier to remove the battery from the front assembly before disconnecting the cable, by gently pulling the battery out of its location to allow more room to disconnect the cable.



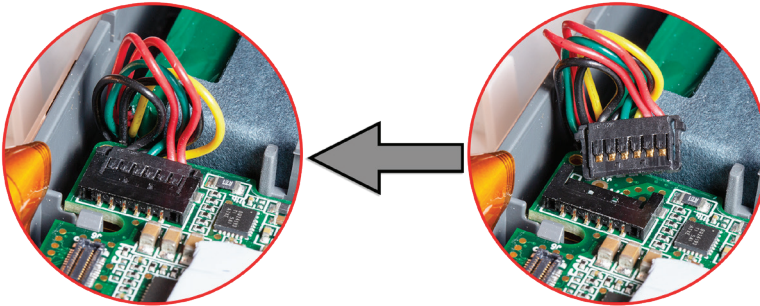
12. **On all models**, pull up and remove the battery from the Rad-97 faceplate. Note the position of the battery for installation.



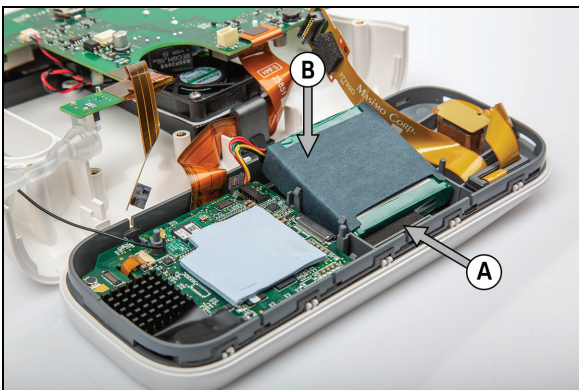
13. This completes the battery removal procedure for Rad-97 Version 1.

Battery Installation (Version 1)

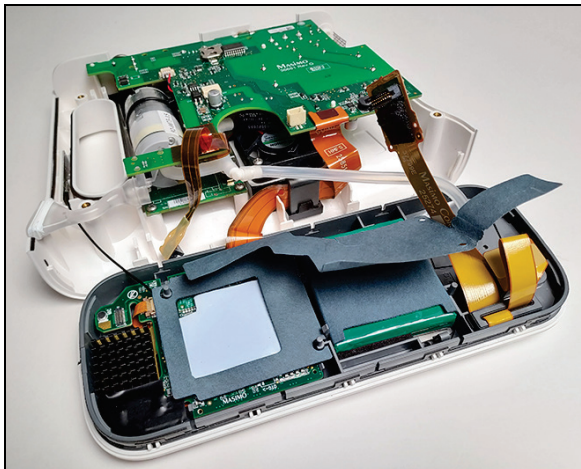
1. Prepare the new battery for installation by removing from the packaging.
2. Attach the battery connector.



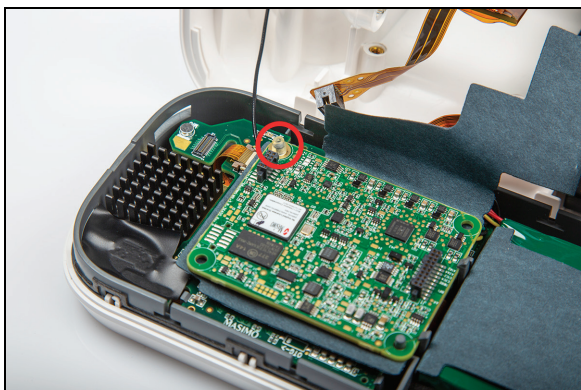
3. Noting the battery orientation during removal, install the battery into the Rad-97 faceplate at an angle against the foam (A). While applying slight pressure against the foam with the battery, press the battery into the faceplate (B). The foam secures the battery in the faceplate.



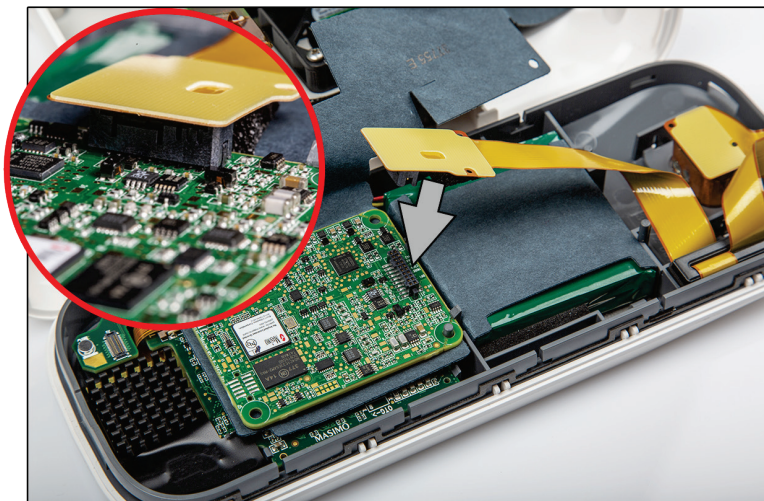
- 4. Install the insulator sheet to the faceplate.



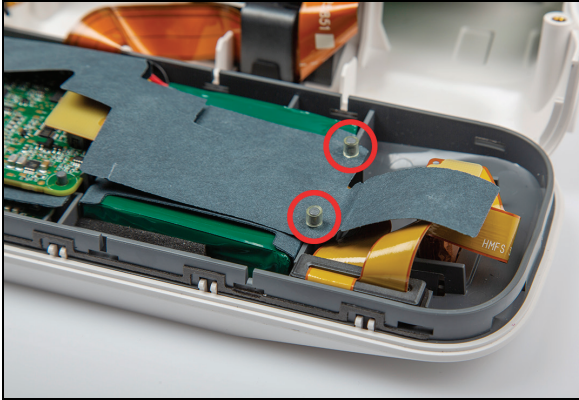
- 5. Install the circuit board ensuring the tabs are secure. Install the rubber retainer to the post as shown.



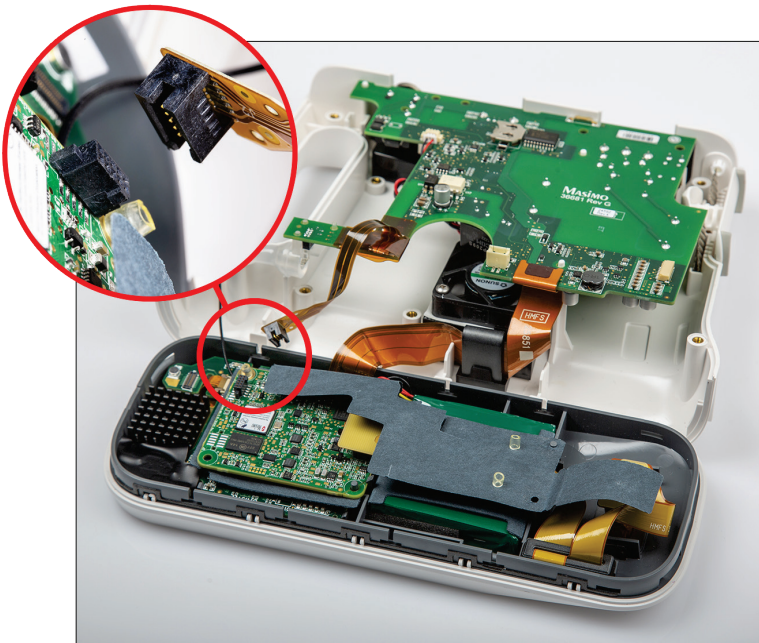
- 6. While pressing down slightly on the circuit board corner at the rubber retainer area, reconnect the ribbon cable.



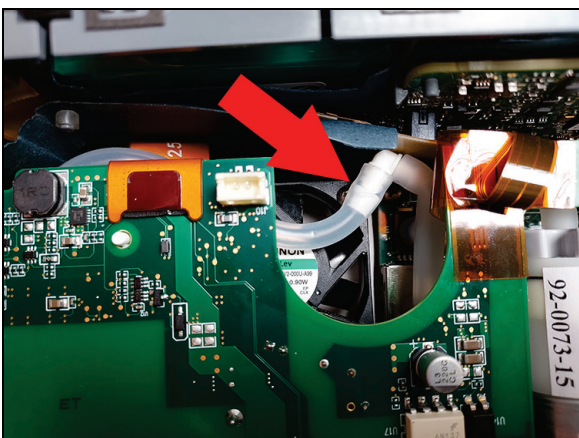
7. Fold the insulator back over and install the rubber retainer(s) on the posts at the bottom of the insulator and faceplate.



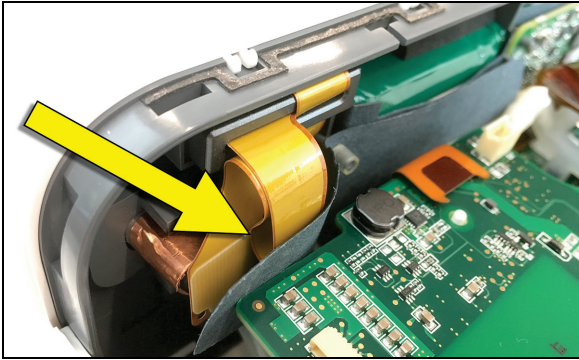
8. Reconnect the ribbon cable to the circuit board on the face plate.



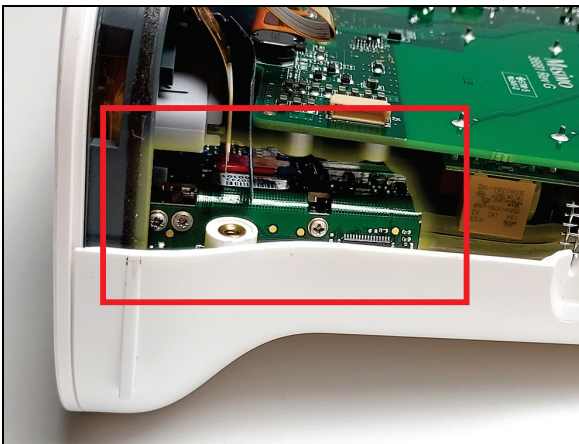
9. **On Rad-97 with noninvasive blood pressure**, route the NIBP hose as shown below the circuit board. Ensure the hose is not pinched, stretched or will not become restricted or pinched when the case halves are put back together.



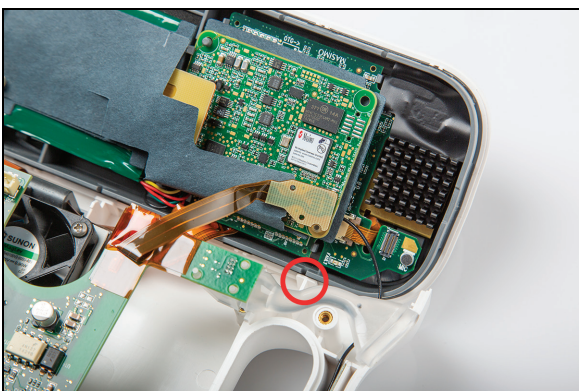
10. If applicable, ensure the ribbon cable is inserted below the insulator as shown.



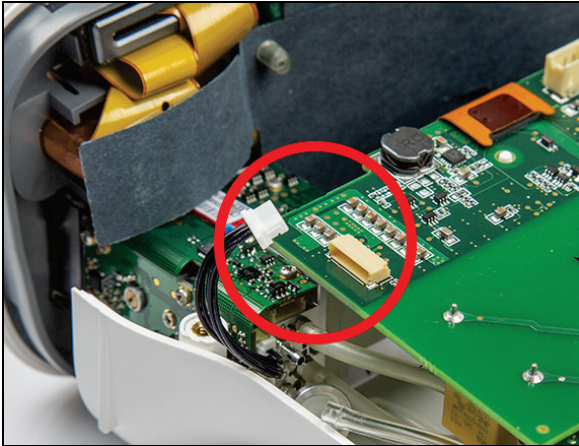
11. **On all models**, rotate the faceplate and attach to the case at the T connections as shown.
 - **On Rad-97 with NomoLine Capnography**, slide the capnography module into its place before sliding the cover down.



Slide down to fully engage the T connections in the case.



12. On Rad-97 with NomoLine Capnography, connect the capnography module electrical connector.



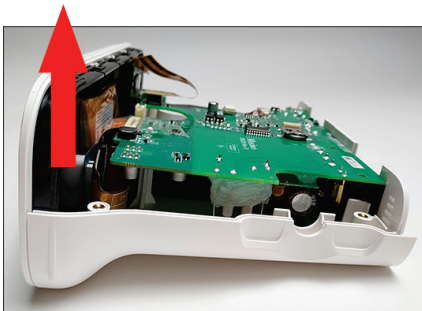
13. On all models, reassemble the device as instructed in **Reassembly** on page 17. After performing electrical safety testing and confirming proper operation as instructed in the reassembly procedure, perform the Gas Gauge Programming procedure. See **Gas Gauge Programming** on page 34.

Battery Removal (Version 2)

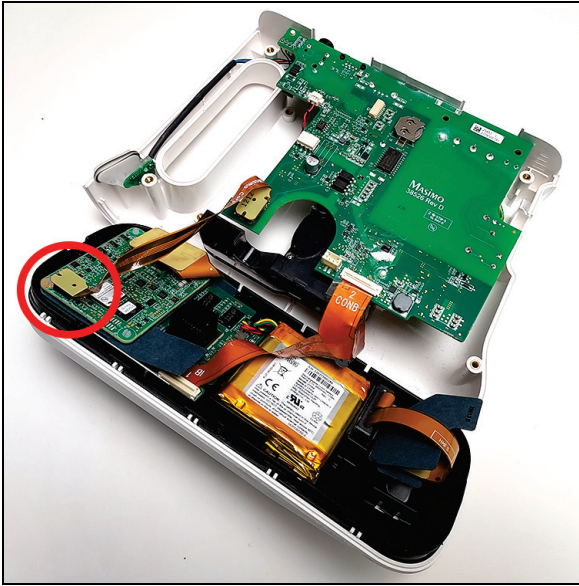
1. Disassemble the Rad-97 as instructed in **Disassembly** on page 15.
2. Lift the faceplate upwards to disengage from the plastic T connections.

CAUTION: Use care not to pull the bezel off of the faceplate when removing from the case.

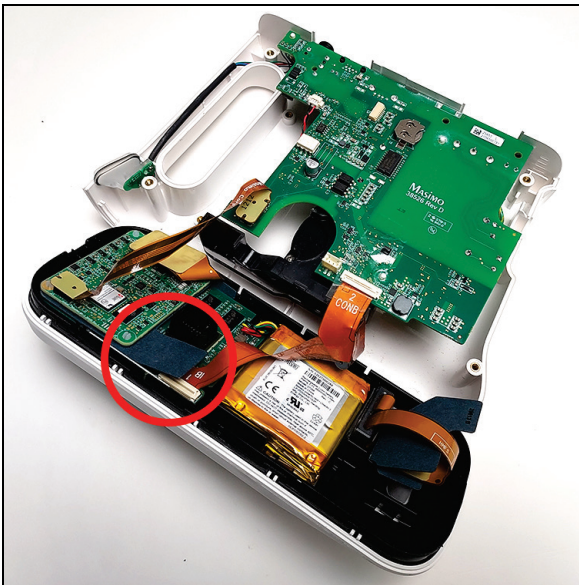
- On Rad-97 with noninvasive blood pressure, the NIBP tube can remain connected during the battery replacement procedure.
- On Rad-97 with NomoLine Capnography, the capnography tube can remain connected during the battery replacement procedure.



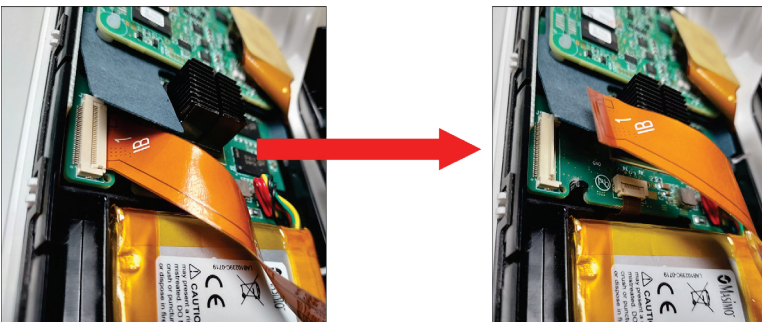
- Carefully disconnect the ribbon cable from the circuit board.



- Move the insulator sheet away to expose the ribbon cable connection.



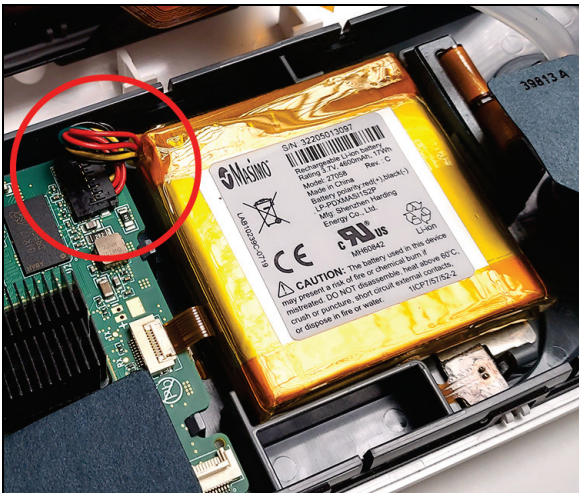
- Remove the ribbon cable from its connection to the board by lifting the tab and gently pulling the cable out from its position.



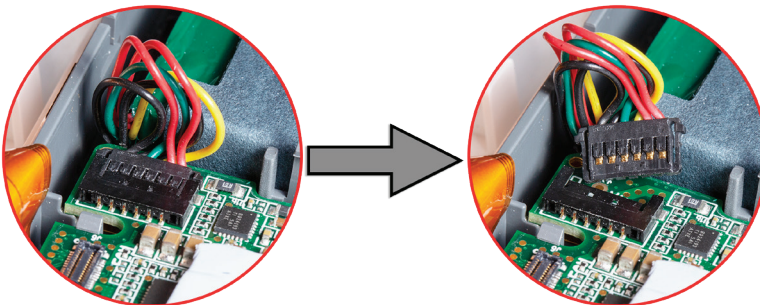
- 6. On Rad-97 with NomoLine Capnography, disconnect the capnography module electrical connector.



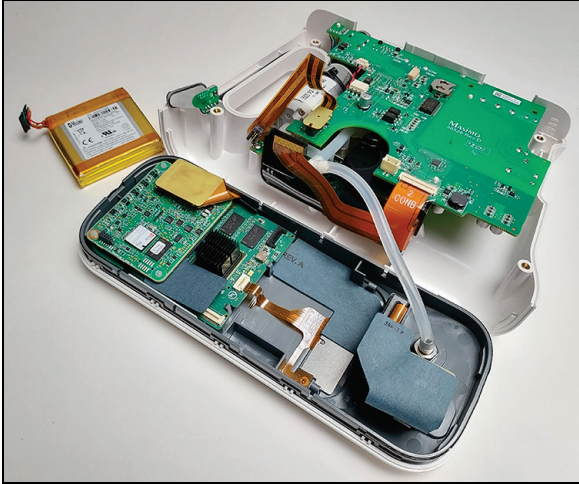
- 7. On all models, rotate the faceplate and place it face-down on the anti-static mat. Use care not to damage the screen during battery replacement.
- 8. Disconnect the battery connector from the circuit board by pulling towards the battery.



Note: Version 1 shown below, Version 2 is similar.



9. Pull up and remove the battery from the Rad-97 faceplate. Note the position of the battery for installation.

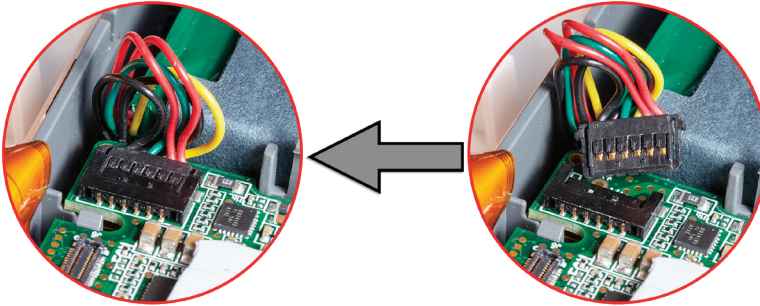


10. This completes the battery removal procedure for Rad-97 Version 2.

Battery Installation (Version 2)

1. Prepare the new battery for installation by removing from the packaging.
2. Attach the battery connector.

Note: Version 1 shown, Version 2 is similar.



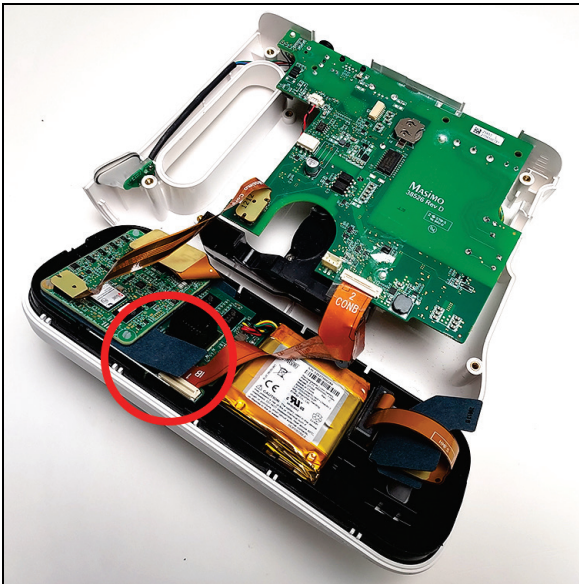
3. Noting the battery orientation during removal, install the battery into the Rad-97 faceplate at an angle and place it such that it fits snugly inside the slot. Rad-97 with noninvasive blood pressure (NIBP) shown, others similar.



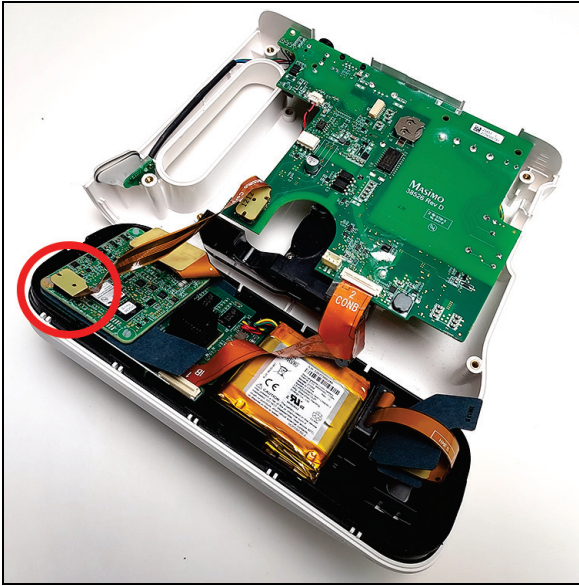
- 4. For Rad-97 with NomoLine Capnography, reconnect the cable to the capnography module. Needle-nose pliers may be necessary to position the cable correctly.



- 5. For all models, reconnect the ribbon cable by inserting it all the way into the connector, and then folding the tab downward to secure the cable into place. Double check to make sure that the cable cannot slide out of its position once this step is complete.



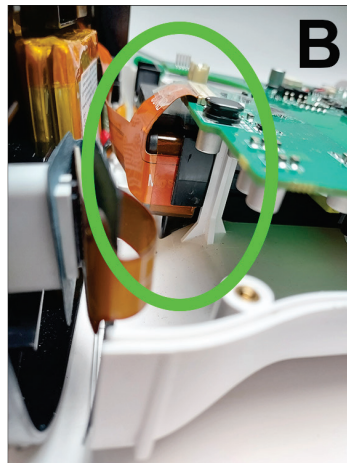
6. Reconnect the ribbon cable to the circuit board on the faceplate.



7. Verify that this component in the picture below fits within the allotted slot in the chassis before proceeding. If the component is not aligned properly, push it into place gently.
 - In image A, the component sits within the slot and is not protruding outside of the designated area.
 - In image B, the component is improperly aligned and protruding outside of the designated area.



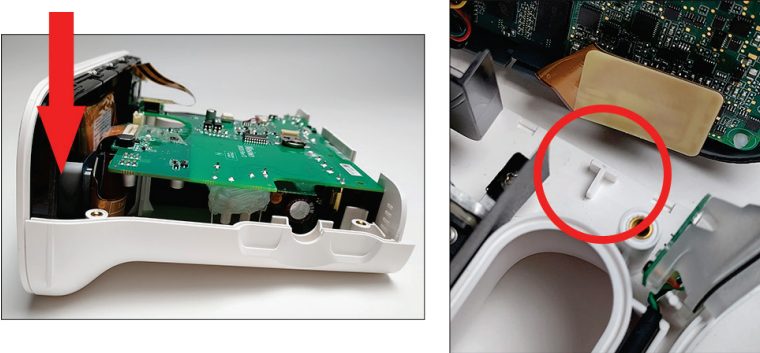
8. If this component becomes loose as shown in the picture below, reposition it such that it fits within the allotted space below the board.
 - In image A, the component is improperly aligned and protruding outside of the designated area.
 - In image B, the component sits within the slot and is not protruding outside of the designated area.



9. **On Rad-97 NIBP models**, ensure the hose is not pinched, stretched, or will not become restricted or pinched when the case halves are put back together. The NIBP tube should remain above the circuit board when reassembling the device as shown.



10. **On all models**, rotate the faceplate and attach to the case at the T connections as shown. Slide down to fully engage the connections in the case.



11. Reassemble the device as instructed in **Reassembly** on page 17. After performing electrical safety testing and confirming proper operation as instructed in the reassembly procedure, perform the Gas Gauge Programming procedure. See **Gas Gauge Programming** on page 34.

Gas Gauge Programming

CAUTION: Electrical Safety Testing must be performed prior to gas gauge programming.

Once the battery replacement procedure is complete, the safety tests (**Chapter 4: Electrical Safety Testing** on page 49), and all battery tests in the Battery Test section have been completed (**Chapter 5: Performance Verification Procedures** on page 53) the Rad-97 software must be updated with the Battery Update USB Drive that is included in the Battery Replacement Kit.

Update Procedure

To complete the battery software update, perform the following procedure:

1. Charge the device.
2. Power-on the device.
3. Plug the USB drive into the USB port on the back of the device.
 - The update will perform automatically.
 - A programming splash screen will appear and the device will power-off and power-on. The Home button on the front of the device will illuminate amber and blink.

CAUTION: Do not power off device during upgrade. Interruption during the programming phase may cause the board to be unusable.

- When the update is complete, the Home button illuminates a steady green along with a single beep sound. The device will then power-off.

4. Remove the USB drive.

Update Verification

Power-on the device and verify the gas gauge programming was successful.

1. Select the battery in the top right corner.

2. Select battery diagnostics and type the password "5664".
3. Verify battery version is 2001 or higher.

This completes the Gas Gauge Programming procedure. Refer to the Directions for Use provided in the Battery Replacement Kit for more information.

Rad-97 TB-20 Connector Replacement

The following procedure provides instructions for removing the existing TB-20 connector/insulator and installing a replacement TB-20 connector/insulator in Rad-97 devices.

Contact Global Services with questions regarding the Rad-97 TB-20 Replacement Kit and/or the required tools part numbers. Contact information can be found at <http://service.masimo.com>.

Supplied Parts List

The following parts are supplied in the Rad-97 TB-20 Replacement Kit:



Required Tools

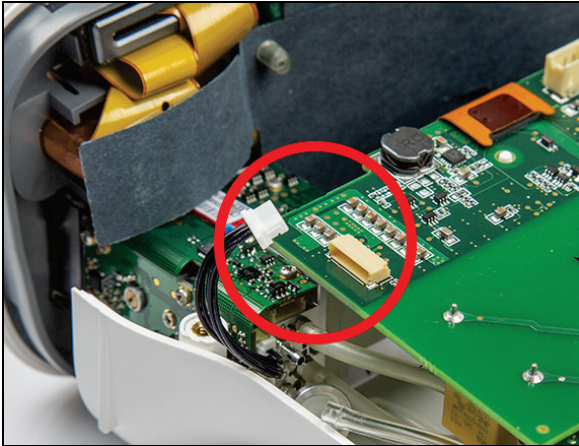
The following tools are required when servicing the TB-20 connector/insulator on Rad-97:

- Needle-nose pliers
- 3/32" Allen wrench (key)
- ESD conductive wrist strap
- ESD surface
- Small, flat-tipped screwdriver

TB-20 Connector Removal (Version 1)

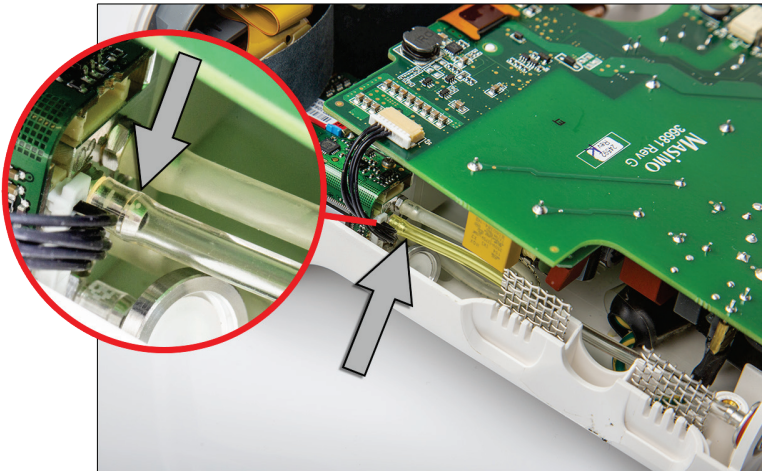
1. Disassemble the Rad-97 as instructed in **Disassembly** on page 15.

2. For Rad-97 with **NomoLine Capnography**, disconnect the capnography module electrical connector.

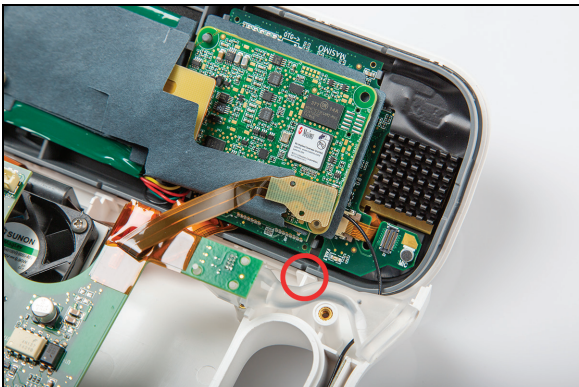


3. Lift the faceplate upwards from the case to disengage from the plastic T connections.

- For Rad-97 with **noninvasive blood pressure**, the NIBP tube can remain connected during the TB-20 replacement procedure.
- For Rad-97 with **NomoLine Capnography**, the tubing will remain connected during the TB-20 replacement procedure. Lift the faceplate very gently upwards to disengage from the plastic T connections. Do not force the front assembly upwards. The capnography module will hit the rest of the assembly if forced. Once the plastic T connections are disengaged, move the front assembly away from the rest of the assembly, being careful not to hit the capnography module against anything or to disconnect the capnography tubing by pulling the front assembly too far away from the rest of the assembly.

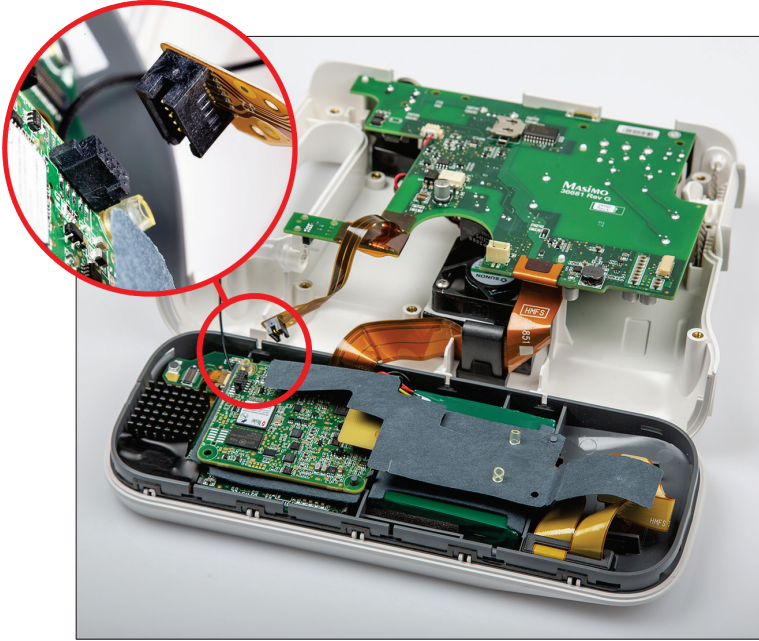


CAUTION: Use care not to pull the bezel off of the faceplate when removing from the case.



4. Carefully disconnect the ribbon cable from the circuit board.

- For Rad-97 with NomoLine Capnography, the capnography tubing will prevent the front assembly from lying flat on the working surface, but the procedure is the same. Work within the space between the front assembly and the main assembly with the tubing still connected. Take care not to disconnect the capnography tubes.



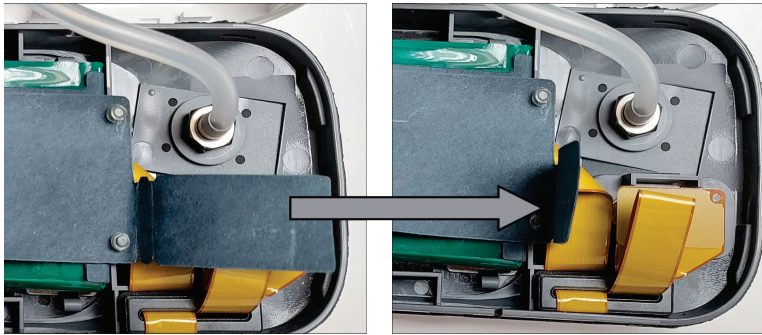
5. Remove the faceplate cover from the front assembly by carefully using two hands, one to hold the white faceplate, and the other to hold the front assembly, and pulling them gently apart to separate them.

Note: Rad-97 with NIBP shown, others similar.



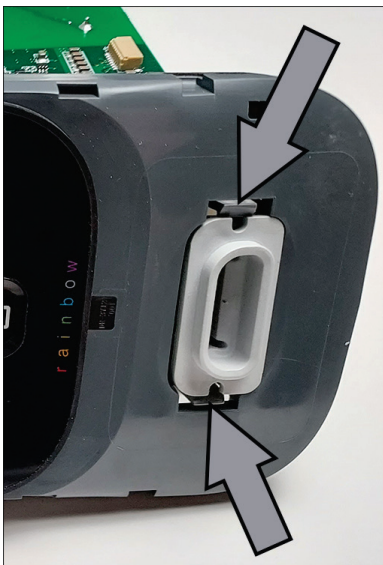
6. Fold the insulating sheet away from the connector and unplug the connector from the back of the TB-20.

Note: Rad-97 with NIBP shown, others similar.



7. Remove the TB-20 from the front assembly by pulling the tabs away from the TB-20 and pushing the connector outwards from the back of the front assembly.

Rad-97 Base

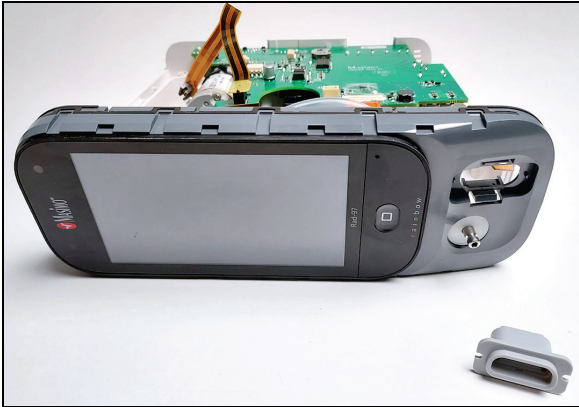


Rad-97 with NIBP or Rad-97 with NomoLine Capnography



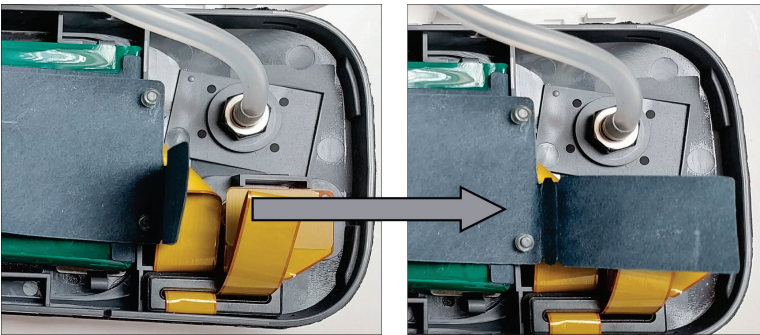
8. This completes the Rad-97 Version 1 TB-20 connector removal procedure.

Note: Rad-97 with NIBP shown.



TB-20 Connector Installation (Version 1)

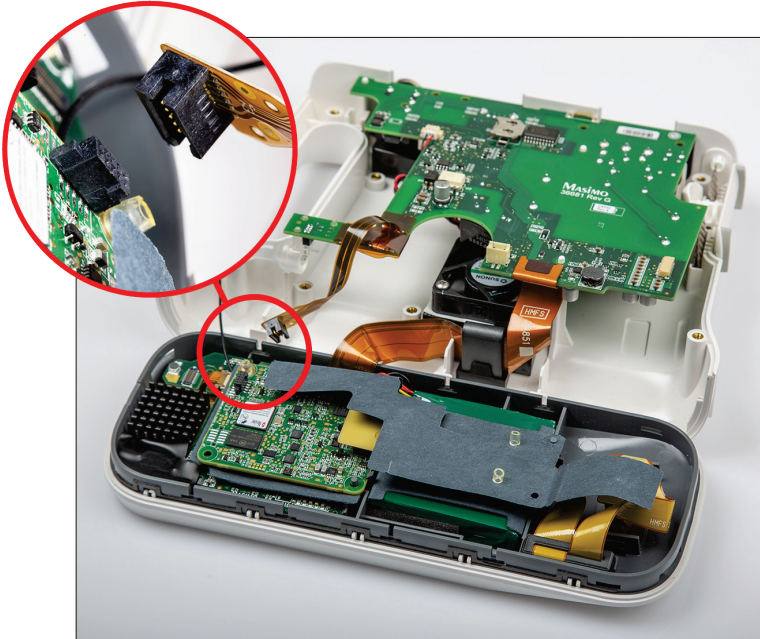
1. Prepare the new TB-20 connector and insulator for installation by removing from the packaging.
2. Insert the TB-20 connector into the slot until the connector snaps into place.
3. Plug the ribbon cable to the back of the TB-20 connector. Take care to connect the plug all the way, but not to push it too hard such that the TB-20 connector ejects from the front assembly. Cover the connector with the insulator sheet by folding it back over the connector.
 - If the insulator sheet on the Rad-97 is not damaged and can cover the back of the TB-20 connector, the additional insulator sheet is not necessary to install. If the insulator sheet cannot cover the back of the TB-20 connector, install the new insulator sheet by plugging the TB-20 connector through the slot and folding the sheet to cover the connection. Refer to the Version 2 instructions for visual aids to install the new insulator. See **TB-20 Connector Installation (Version 2)** on page 45.



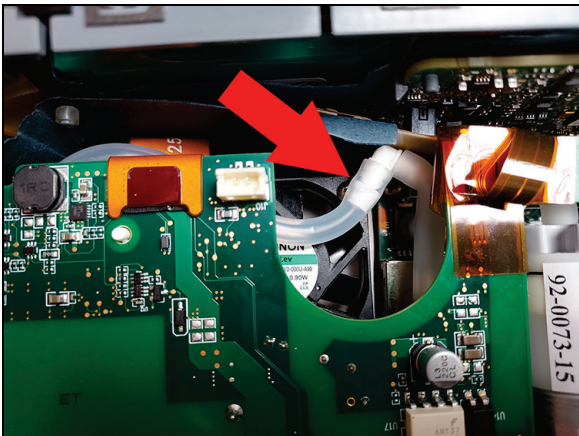
4. Put the faceplate back onto the front assembly of the Rad-97 by lining up the TB-20 port slot, (the capnography/NIBP plug if applicable), and all four edges correctly and pressing firmly until it snaps into place.



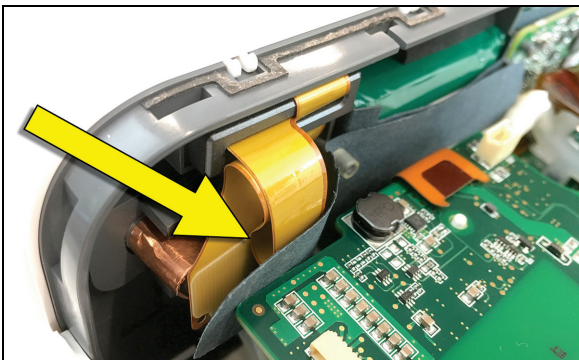
- 5. Reconnect the ribbon cable to the circuit board on the face plate.



- 6. **On Rad-97 with noninvasive blood pressure**, route the NIBP hose as shown below the circuit board. Ensure the hose is not pinched, stretched or will not become restricted or pinched when the case halves are put back together.

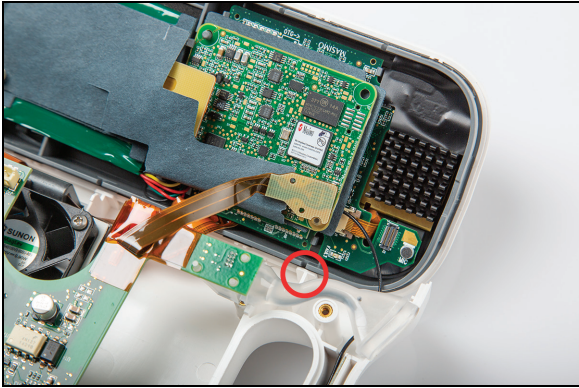


- 7. If applicable, ensure the ribbon cable is inserted below the insulator as shown.

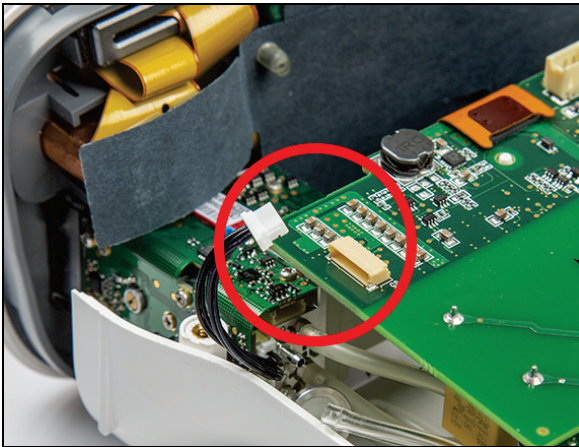


- 8. **On all models**, rotate the faceplate and attach to the case at the T connections as shown. Slide down to fully engage the connections in the case.

- On Rad-97 with NomoLine Capnography, slide the capnography module into its place before sliding the cover down.



9. On Rad-97 with NomoLine Capnography, connect the capnography module electrical connector.



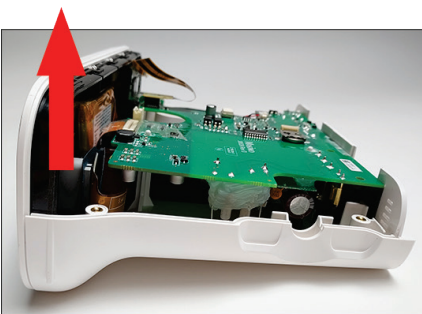
10. On all models, reassemble the device, perform the electrical safety testing and confirm proper operation as instructed in the procedure for **Reassembly** on page 17.

TB-20 Connector Removal (Version 2)

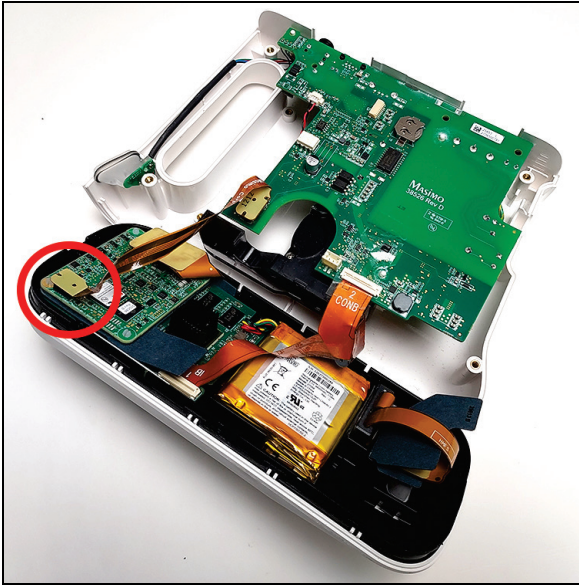
1. Disassemble the Rad-97 as instructed in **Disassembly** on page 15.
2. Lift the faceplate upwards to disengage from the plastic T connections.

CAUTION: Use care not to pull the bezel off of the faceplate when removing from the case.

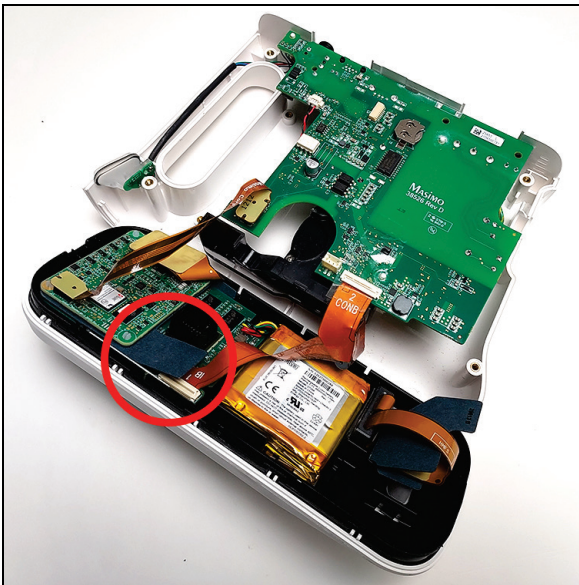
- On Rad-97 with noninvasive blood pressure, the NIBP tube can remain connected during the TB-20 replacement procedure.
- On Rad-97 with NomoLine Capnography, the capnography tube can remain connected during the TB-20 replacement procedure.



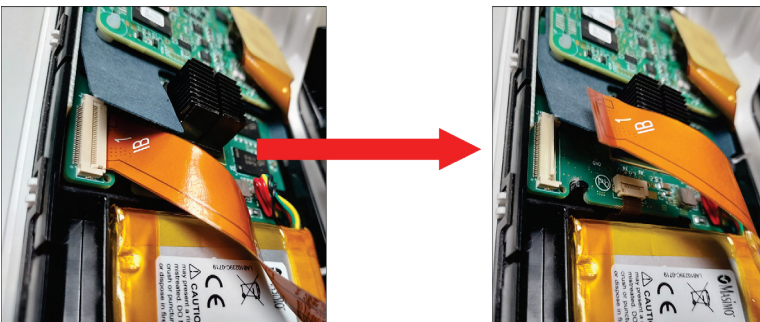
- Carefully disconnect the ribbon cable from the circuit board.



- Move the insulator sheet away to expose the ribbon cable connection.



- Remove the ribbon cable from its connection to the board by lifting the tab and gently pulling the cable out from its position.



- 6. **On Rad-97 with NomoLine Capnography**, disconnect the capnography module electrical connector.

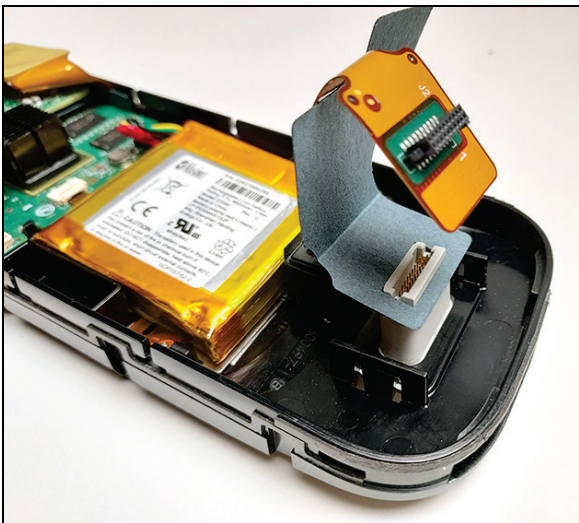


- 7. **For all models**, remove the faceplate cover from the front assembly by carefully using two hands, one to hold the white faceplate, and the other to hold the front assembly, and pulling them gently apart to separate them.

Note: Rad-97 with NIBP shown, others similar.

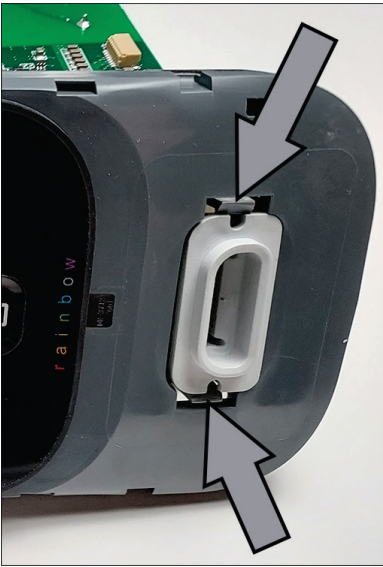


- 8. Fold the insulating sheet away from the connector and unplug the connector from the back of the TB-20. Remove the insulator sheet after unplugging the connector.



9. Remove the TB-20 from the front assembly by pulling the tabs away from the TB-20 and pushing the connector outwards from the back of the front assembly.

Rad-97

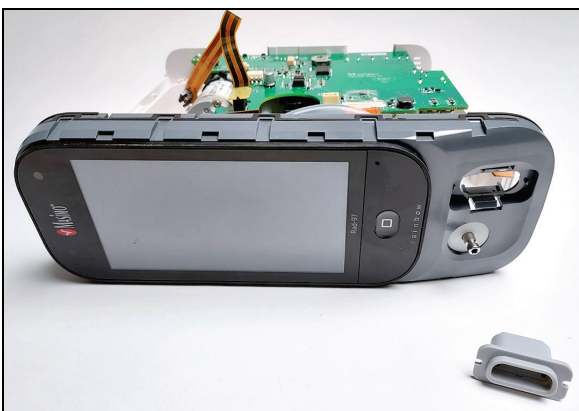


Rad-97 with NIBP or Rad-97 with NomoLine Capnography



10. This completes the Rad-97 Version 2 TB-20 connector removal procedure.

Note: Rad-97 with NIBP shown.



TB-20 Connector Installation (Version 2)

1. Prepare the new TB-20 connector and insulator for installation by removing from the packaging.
2. Insert the TB-20 connector into the slot until the connector snaps into place.
3. Insert the insulator such that the back of the connector fits through the slot in the insulator sheet, and the longer part of the insulator is oriented as shown in the pictures.

Rad-97 base model



Rad-97 with NIBP and Rad-97 with NomoLine Capnography

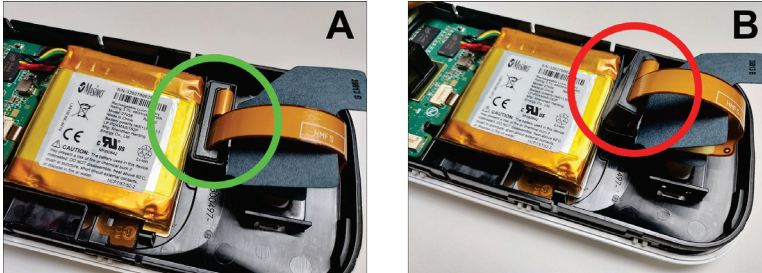


4. Plug the ribbon cable to the back of the TB-20 connector. Take care to connect the plug all the way, but not to push it too hard such that the TB-20 connector ejects from the front assembly. Cover the connector with the insulator sheet by folding it back over the connector.

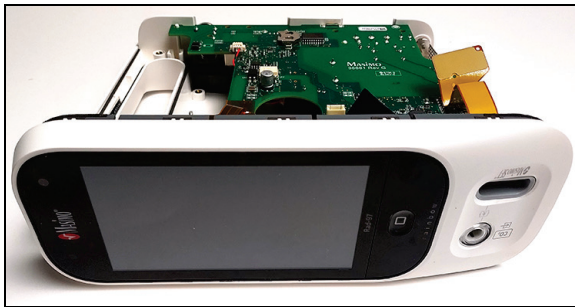
Note: Rad-97 base model shown, others similar.



5. Verify that this component in the picture below fits within the allotted slot in the chassis before proceeding. If the component is not aligned properly, push it into place gently.
 - In image A, the component sits within the slot and is not protruding outside of the designated area.
 - In image B, the component is improperly aligned and protruding outside of the designated area.



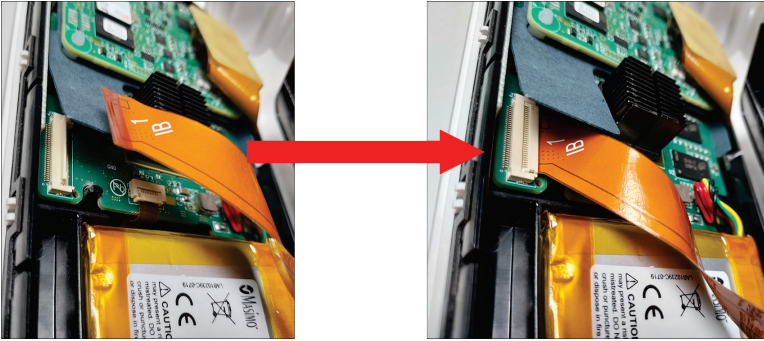
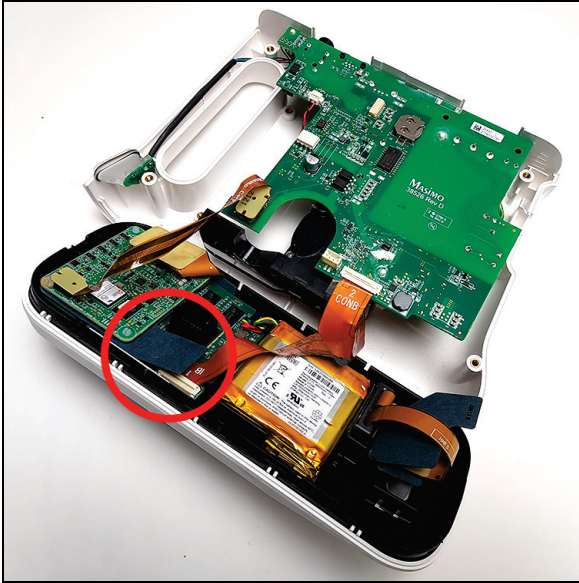
6. Put the faceplate back onto the front assembly of the Rad-97 by lining up the TB-20 port slot, (the capnography/NIBP plug if applicable), and all four edges correctly and pressing firmly until it snaps into place.



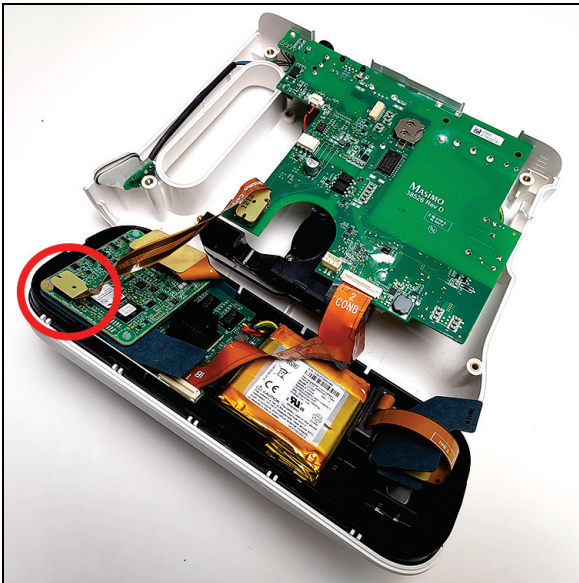
7. For Rad-97 with NomoLine Capnography, reconnect the cable to the capnography module. Needle-nose pliers may be necessary to position the cable correctly.



- 8. **For all models**, reconnect the ribbon cable by inserting it all the way into the connector, and then folding the tab downward to secure the cable into place. Double check to make sure that the cable cannot slide out of its position once this step is complete.

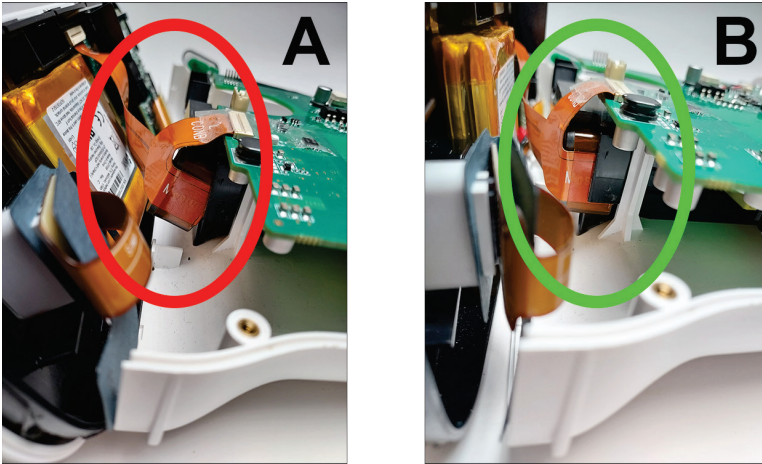


- 9. Reconnect the ribbon cable to the circuit board on the faceplate.

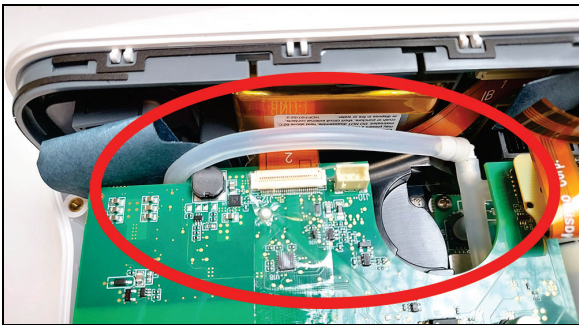


- 10. If this component becomes loose as shown in the picture below, reposition it such that it fits within the allotted space below the board.

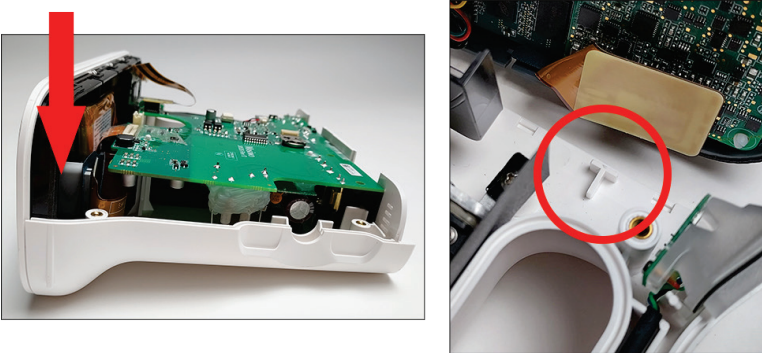
- In image A, the component is improperly aligned and protruding outside of the designated area.
- In image B, the component sits within the slot and is not protruding outside of the designated area.



11. **On Rad-97 NIBP models**, ensure the hose is not pinched, stretched, or will not become restricted or pinched when the case halves are put back together. The NIBP tube should remain above the circuit board when reassembling the device as shown.



12. **On all models**, rotate the faceplate and attach to the case at the T connections as shown. Slide down to fully engage the connections in the case.



13. Reassemble the device, perform the electrical safety testing and confirm proper operation as instructed in the procedure for **Reassembly** on page 17.

Chapter 4: Electrical Safety Testing

This chapter covers how to test the electrical safety of Rad-97. No internal adjustment or recalibration is required. These procedures should be done by authorized service personnel only. These safety checks should be performed after battery replacement and TB-20 replacement. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

To test the performance of Rad-97 following repairs or during routine maintenance, follow the procedure outlined in this section. If Rad-97 fails any of the described tests, discontinue its use and correct the problem before returning the unit back to the user.

The following procedures are performed to verify proper operation of the device and check for electrical safety after service procedures are complete. DO NOT dock or connect any devices to Rad-97 before or during these procedures unless instructed to do so.

Electrical Safety Testing

General

This section describes in general the electrical safety testing methodologies that can be performed on the instrument to detect potential electrical safety hazards.

The testing referenced in this chapter is in accordance with IEC 60601-1, 3rd Edition standard.

Test Equipment Recommended

1. Electrical Safety Tester (NIST certified or equivalent)
2. Digital Multimeter

Electrical Safety Tests

The schematics presented in this section are based upon the IEC 60601-1, 3rd Edition standard. The schematics are provided to give a general idea of the test setup. The actual configuration of the test setup may vary based on the Electrical Safety Tester being used.

Service Warning: Before starting the testing, it is important to place the device under test (DUT) on an insulating surface.

Service Warning: Refer to general safety considerations, warnings and cautions of the Electrical Safety Tester used before testing the DUT.

Service Warning: Follow the setup instructions provided as part for the Electrical Safety Tester's operating instructions before starting testing.

Service Warning: Make sure that the Electrical Safety Tester and DMM are under calibration before starting the testing.

Verification of Electrical Outlet and Power Cable

1. Check ratings (Maximum Current, Maximum Voltage, and Maximum Power) of power outlet and confirm safety test can be performed on that particular outlet.
2. Check power outlet wiring is good and according to local electrical code standards.
3. Always use power supply cord supplied by Masimo Corporation
4. Check power supply cord for kinks or any kind of damages or anomalies and always check continuity of line, neutral and earth conductors if in doubt and replace the power supply cord as necessary.
5. Accuracy of electrical safety testing performed is dependent on all the factors mentioned above in this section.

Device Classification per IEC-60601-1

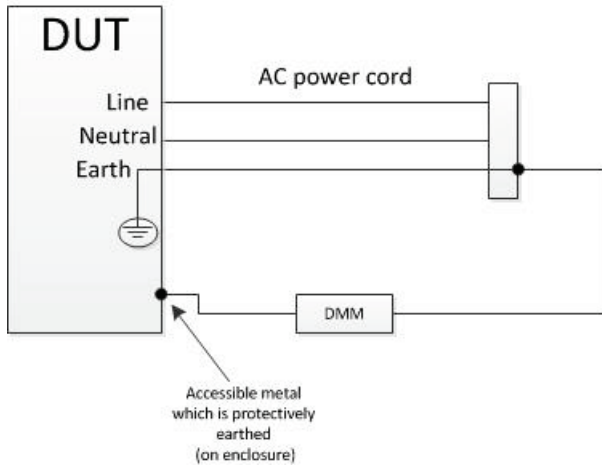
Product Name	Configuration	Power Source	Classification	Type of Patient Protection
Rad-97	NOT connected to AC Power	Battery Powered	Internally Powered	Type BF Applied Part
	Connected to AC power	AC Powered	Class I	Type BF Applied Part

The electrical safety tests mentioned below are applicable based on Classification and Type of Patient Protection.

Ground Continuity Test (Class I devices only)

Ground continuity should be detected from the potential equalization post of the device to the earth pin of the mains plug of the connected Masimo power supply cord or directly to the Earth pin of the appliance inlet of the DUT.

Refer to schematic below for this test setup:



The following steps should be followed to conduct the ground continuity test:

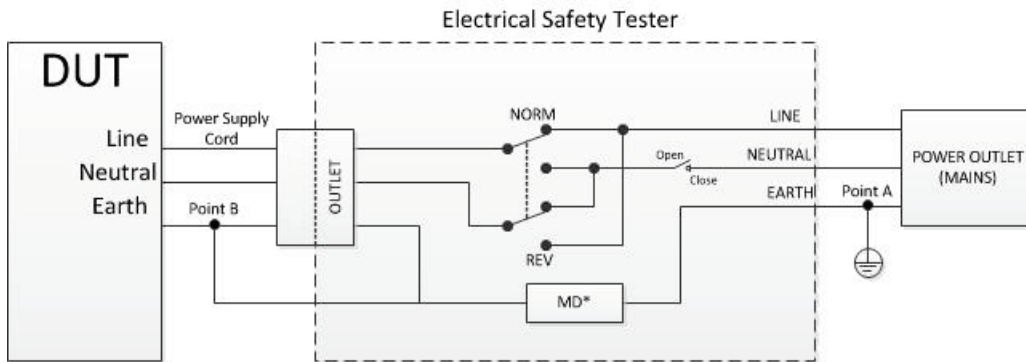
1. Connect Masimo power supply cord to appliance inlet on the DUT.
2. Connect Digital Multimeter (DMM) between the accessible earthed metal part and the earth pin of the Masimo power supply cord.
3. Check for continuity using the continuity test feature of the DMM.
4. Move the connected Masimo power cord around and confirm that there is no intermittent continuity.

Measuring Earth Leakage Current (Class I devices only)

Earth leakage current is the current that flows from the Mains Part through or across the insulation into the protective earth conductor.

The earth leakage current is measured in both "Normal" condition (NC) and as well as "Single Fault Condition" (SFC).

Refer to the schematic below for the general test setup:



For more specific test setup, follow the setup instructions as part of your Electrical Safety Tester.

The following test conditions should be considered for Earth Leakage Current testing:

Measuring Point A	Measuring Point B	Input Voltage	Frequency	Device State	Polarity	Neutral	Test Condition	Leakage Current Limit ¹
Protective Earth	DUT Earth	120 Vac or 240 Vac	50 or 60 Hz	ON	Normal	Closed	NC	5 mA
Protective Earth	DUT Earth	120 Vac or 240 Vac	50 or 60 Hz	ON	Reverse	Closed	NC	5 mA
Protective Earth	DUT Earth	120 Vac or 240 Vac	50 or 60 Hz	OFF	Normal	Closed	NC	5 mA

Measuring Point A	Measuring Point B	Input Voltage	Frequency	Device State	Polarity	Neutral	Test Condition	Leakage Current Limit ¹
Protective Earth	DUT Earth	120 Vac or 240 Vac	50 or 60 Hz	OFF	Reverse	Closed	NC	5 mA
Protective Earth	DUT Earth	120 Vac or 240 Vac	50 or 60 Hz	OFF	Normal	Open	SFC	10 mA
Protective Earth	DUT Earth	120 Vac or 240 Vac	50 or 60 Hz	OFF	Reverse	Open	SFC	10 mA

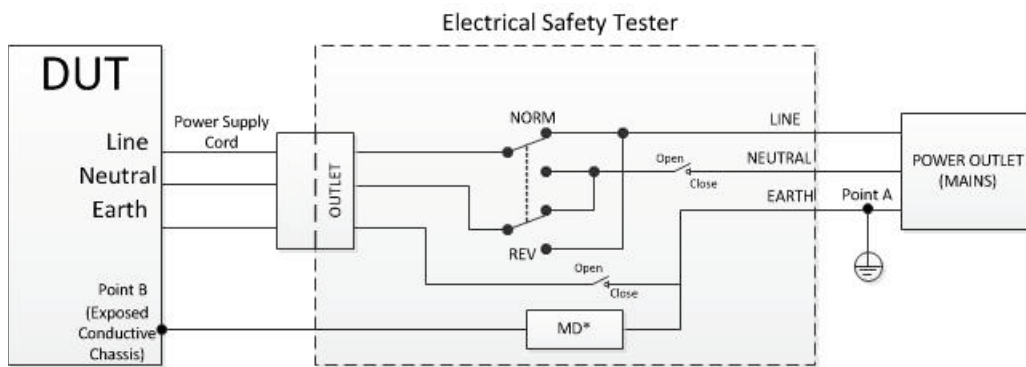
¹ Earth Leakage Current limits based upon IEC 60601-1, 3rd Edition.

* MD (Measuring Device) and its frequency characteristics should be based upon IEC 60601-1, 3rd Edition, Clause 8.7.4.4.

Measuring Touch Leakage Current

Enclosure or touch leakage current is the leakage current flowing from exposed surfaces on the DUT, excluding patient connections, through an external path other than the protective earth conductor to earth or another part of the enclosure.

Refer to schematic below for this test setup:



For more specific test setup, follow the setup instructions as part of your Electrical Safety Tester.

The following test conditions should be considered for Touch Leakage Current testing:

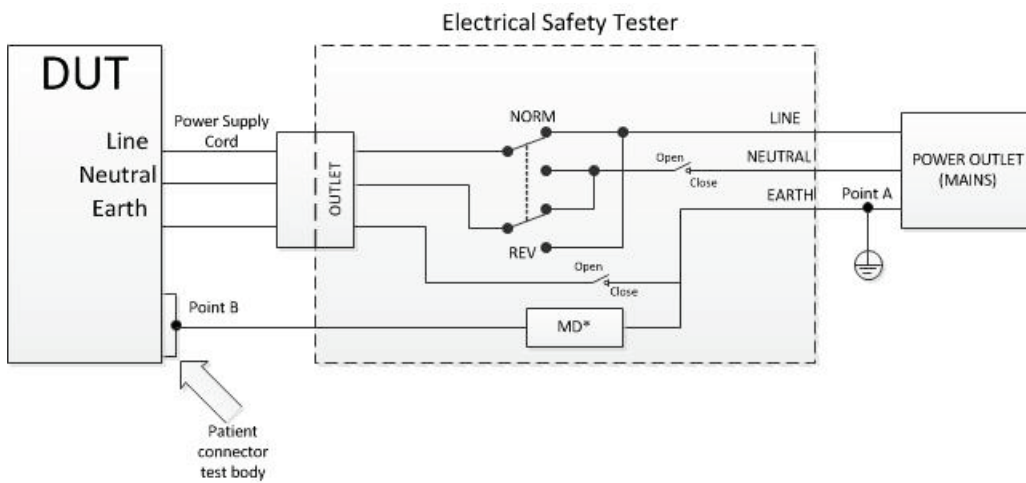
Measuring Point A	Measuring Point B	Input Voltage	Frequency	Device State	Polarity	Neutral	Earth	Test Condition	Leakage Current Limit ²
Protective Earth	DUT's exposed conductive Chassis	120 Vac or 240 Vac	50 or 60 Hz	ON	Normal	Closed	Closed	NC	100 µA
Protective Earth	DUT's exposed conductive Chassis	120 Vac or 240 Vac	50 or 60 Hz	ON	Reverse	Closed	Closed	NC	100 µA
Protective Earth	DUT's exposed conductive Chassis	120 Vac or 240 Vac	50 or 60 Hz	OFF	Normal	Open	Closed	SFC	500 µA
Protective Earth	DUT's exposed conductive Chassis	120 Vac or 240 Vac	50 or 60 Hz	OFF	Reverse	Open	Closed	SFC	500 µA
Protective Earth	DUT's exposed conductive Chassis	120 Vac or 240 Vac	50 or 60 Hz	ON	Normal	Closed	Open	SFC	500 µA
Protective Earth	DUT's exposed conductive Chassis	120 Vac or 240 Vac	50 or 60 Hz	ON	Reverse	Closed	Open	SFC	500 µA

² Touch Leakage Current limits based upon IEC 60601-1, 3rd Edition.

Measuring Patient Leakage Current

Patient leakage current is the leakage current that flows from the individual patient connector (Lead/probe) of the DUT via the patient to earth.

Refer to schematic below for this test setup:



For more specific test setup, follow the setup instructions as part of your Electrical Safety Tester.

The following test conditions should be considered for Patient Leakage Current testing:

Measuring Point A	Measuring Point B	Input Voltage	Frequency	Device State	Polarity	Neutral	Earth	Test Condition	Leakage Current Limit ³
Protective Earth	DUT's patient connector	120 Vac or 240 Vac	50 or 60 Hz	ON	Normal	Closed	Closed	NC	100 µA
Protective Earth	DUT's patient connector	120 Vac or 240 Vac	50 or 60 Hz	ON	Reverse	Closed	Closed	NC	100 µA
Protective Earth	DUT's patient connector	120 Vac or 240 Vac	50 or 60 Hz	OFF	Normal	Open	Closed	SFC	500 µA
Protective Earth	DUT's patient connector	120 Vac or 240 Vac	50 or 60 Hz	OFF	Reverse	Open	Closed	SFC	500 µA
Protective Earth	DUT's patient connector	120 Vac or 240 Vac	50 or 60 Hz	ON	Normal	Closed	Open	SFC	500 µA
Protective Earth	DUT's patient connector	120 Vac or 240 Vac	50 or 60 Hz	ON	Reverse	Closed	Open	SFC	500 µA

³ Patient Leakage Current limits based upon IEC 60601-1, 3rd Edition.

Chapter 5: Performance Verification Procedures

This chapter covers how to test the operation of Rad-97. No internal adjustment or recalibration is required. These procedures should be done by authorized service personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

To test the performance of Rad-97 following repairs or during routine maintenance, follow the procedure outlined in this section. If Rad-97 fails any of the described tests, discontinue its use and correct the problem before returning the unit back to the user.

Battery Test

Battery Replacement Verification

After battery replacement, verify the battery is identified by Rad-97.

1. Connect the power cord to the power entry module on the rear of Rad-97.
2. Verify the battery charge indicator on the home button of Rad-97 front panel illuminates.
 - If the battery charging indicator does not illuminate, this indicates the battery may not be properly connected.
3. Press the power button and turn on the device.
4. Verify the battery icon on the Main Screen indicates the battery is charging.
 - If the battery icon has a Red "X" through it, this indicates the battery may not be properly connected. Turn off the device and unplug the power cord, then remove the back panel and recheck the battery cable connection.

Battery Charging

Rad-97 includes a Rechargeable Li-Ion battery Rated at 10.8V 5000 mAh 54.0 Wh. Before use, the Rad-97 battery must be charged completely. As a precaution against memory effects, it is advisable to completely discharge and fully recharge the batteries periodically.

CAUTION: If the Rad-97 battery has not been charged for 1 month or more, then recharge the battery prior to use.

CAUTION: At low battery warning, connect Rad-97 to AC power to prevent interruption of power.

CAUTION: Additional information on the Rad-97 batteries may be found in the Operator's Manual for Rad-97.

Note: When battery run time is significantly reduced, it is advisable to completely discharge and fully recharge the battery.

To charge Rad-97

1. Plug the AC power cord into the power entry module. Make sure it is securely plugged in.
2. Plug the AC power cord into an AC power source.
3. Verify that the battery is charging:
 - When Rad-97 is ON and charging, the AC Power Indicator lightning bolt icon will appear on the screen.



- When Rad-97 is OFF and charging, the Home button will illuminate Orange.
4. When the battery is fully charged:
 - When Rad-97 is ON and fully charged, the AC Power Indicator will change to a plug icon.



Touch the AC Power Indicator icon to view battery charge details. Refer to the Operator's Manual for Rad-97 for complete information.

Battery Diagnostics

Battery diagnostics screen displays information about the current health of the battery. To view the *Rad-97 Battery Diagnostics* screen, perform the following:

1. With Rad-97 On, press/select the battery icon at the top of the Rad-97 *Main Screen*.
2. Next to *Battery Diagnostics*, select the *View* button.
3. When prompted for a password, enter **5664** and the enter key. The *Rad-97 Battery Diagnostics* screen displays the following information.

Item*	Description
Battery Version	Battery fuel gauge firmware version.
Temperature	Battery temperature (Kelvin 0.1K)
Voltage	Current battery voltage.
Flags	Battery charger status.
Remaining capacity	Battery capacity remaining.
Full charge capacity	Capacity of the battery when fully charged.
Average current	Battery current draw. Positive value indicates charging current, negative value indicates discharge current.
Time to empty	Time in minutes until battery is depleted at current load.
Time to full	Time in minutes until battery is charged.
Cycle count	How many times the battery has been discharged completely, and recharged.
State of charge	Battery state of charge.
State of health	Battery state of health.

* These fields are read-only and cannot be configured by the user.

Power-On Self Test







To conduct a Power-On Self Test

1. Connect Rad-97 to AC power, and verify that the AC Power Indicator is illuminated.
2. Power On Rad-97. Within five (5) seconds, all available indicators will illuminate, the device will emit a tone, and the Masimo logo will display.

Touchscreen Function Test

To conduct a Touchscreen Function Test

1. Connect the Rad-97 to AC power.
2. Perform the gestures outlined in the table below:

Action	Illustration	Description
Touch		Touch and release. Action performed once finger is released.
Touch and Hold		Touch and hold. Action performed once hold duration is reached. A notification is displayed.
Swipe (Touch and Move)		Touch, move (left, right, up or down), and release. Moves an object across the display.
Flick		Touch and quickly swipe (left, right, up or down), and release.
Pinch		Touch, move, and release via two touch points. Moving touch points apart zooms in, and moving them together zooms out.
Drag and Drop		Touch, hold, drag an object to desired position, and drop it by releasing.

Noninvasive Blood Pressure Module Tests

NIBP Module Calibration Test

Note: This section is provided as a reference and intended for authorized service personnel only.

Pass Criteria

International standards for automated NIBP devices require that the maximum static pressure accuracy shall be $\pm 3\text{mmHg}$ or 2% of the reading, whichever is greater. This is a stringent requirement and all test equipment must be in excellent working order to properly perform this test. It is important to verify the calibration before changing it. Historical data has shown that the transducers rarely need to be re-calibrated although we still suggest that the calibration be verified annually.

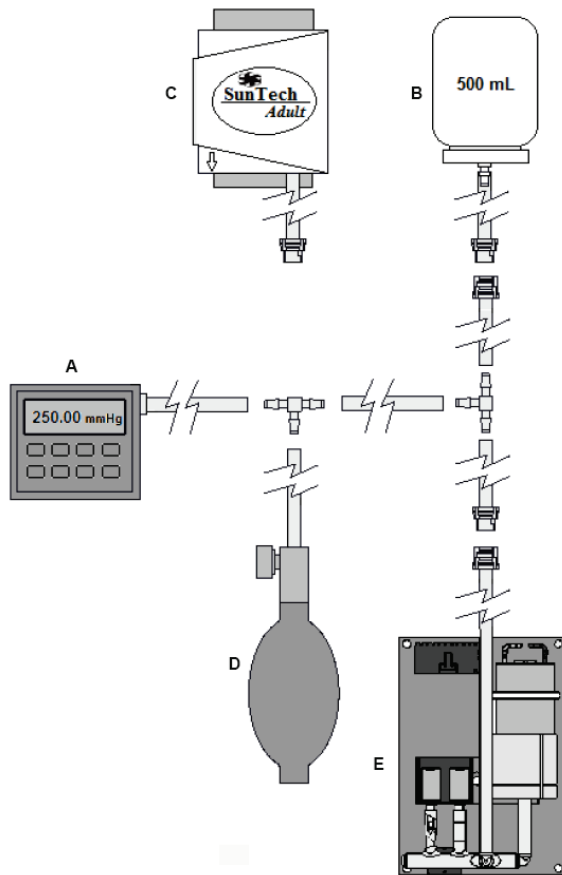
Equipment

- Calibrated Manometer*
- Pneumatic "T" Adapters
- 500mL bottle or regular-sized cuff wrapped around solid object
- Hand Bulb
- Connection Tubing





*Verify the manometer has been calibrated within the last 12 months. Calibration accuracy shall be within $\pm 0.02\%$ to $\pm 0.25\%$ FS (Full Scale) and a measurement uncertainty of ± 1 LSD (Least Significant Digit).

Procedure

1. Connect the manometer (A), 500mL bottle (B) or cuff wrapped around solid object (C), and hand bulb (D) to the NIBP module (E) using "T" adapters and connection tubing.




2. Power ON the manometer.
 - Verify the manometer has been zeroed.
 - Set the unit of measurement to mmHg.

- Verify the manometer has been calibrated.
3. Power ON the Rad-97.
 4. On the Rad-97 home screen, press the Main Menu icon .
 5. Press **NIBP** .
 6. Press **CALIBRATION** .
 - For the password, enter 4258.
 - Press the Enter key.
 7. Press **CALIBRATION TEST** .
 8. Press **Test**.
 9. Apply various pressures (0mmHg to 280mmHg) to the NIBP module with the hand bulb.
 10. Compare the NIBP module pressure to the manometer pressure:
 - If the NIBP module pressure and manometer pressure differ WITHIN the ± 3 mmHg tolerance, then the NIBP module has PASSED the calibration test and no further action is needed. Go to step 11.
 - If the NIBP module pressure and manometer pressure differ BEYOND the ± 3 mmHg tolerance, (1) perform the Zero Point Calibration, (2) then perform the Span Point Calibration. See **Zero Point Calibration** on page 56 and **Span Point Calibration** on page 56. If the NIBP module pressure and manometer pressure still differ BEYOND the ± 3 mmHg tolerance, contact Masimo Technical Services. See **Contacting Masimo** on page 65.
 11. Disconnect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb from the NIBP module.
 12. Power OFF the manometer.

Zero Point Calibration

Zero Point Calibration is performed when an NIBP module does NOT PASS the NIBP Module Calibration Test. See the **NIBP Module Calibration Test** on page 55.

Note: This section is provided as a reference and intended for authorized service personnel only.


1. Press the back button in the upper-left corner of the **CALIBRATION TEST** screen to go back to the **CALIBRATION** menu screen.
2. Select **ZERO POINT CALIBRATION** .
3. Apply 0 (zero) mmHg to the NIBP module.


Note: The 0 (zero) mmHg can be verified on the manometer.
4. Press **Calibrate** to start the Zero Point Calibration:
 - A "Success" message will appear if the calibration was successful. Go to step 5.
 - If a "Result Failure" message appears, verify the 0 (zero) mmHg is applied to the NIBP module and press **Calibrate** again. If the "Result Failure" message is repetitive, contact Masimo Technical Services. See **Contacting Masimo** on page 65.
5. After a successful Zero Point Calibration, complete the Span Point Calibration. See **Span Point Calibration** on page 56.

Span Point Calibration

Span Point Calibration is performed when an NIBP module does NOT PASS the NIBP Module Calibration Test, and after completing Zero Point Calibration. See the **NIBP Module Calibration Test** on page 55 and **Zero Point Calibration** on page 56 before completing the instructions below.

Note: This section is provided as a reference and intended for authorized service personnel only.

1. After successful completion of Zero Point Calibration, press the back button in the upper-left corner of the **ZERO POINT CALIBRATION** screen to go back to the **CALIBRATION** menu screen.
2. Select **SPAN POINT CALIBRATION** .
3. Press **Close Valve**.

4. Use the hand bulb to apply exactly 250mmHg to the NIBP module, then press **Calibrate**.
 - A "Success" message will appear if the calibration was successful. Go to step 5.
 - If a "Result Failure" message appears, repeat the test by applying 250mmHg to the NIBP module and pressing **Calibrate**. If the "Result Failure" message is repetitive, contact Masimo Technical Services. See **Contacting Masimo** on page 65.
5. After successful Span Point Calibration, press the back button to go back to the **CALIBRATION** menu screen.
6. Press **CALIBRATION TEST** 
7. Press **Test**.
8. Apply various pressures (0mmHg to 280mmHg) to the NIBP module with the hand bulb.
9. Compare the NIBP module pressure to the manometer pressure:
 - If the NIBP module pressure and manometer pressure differ WITHIN the ± 3 mmHg tolerance, then the NIBP module has PASSED the calibration test and no further action is required. Go to step 10.

Note: For pass criteria, see the **NIBP Module Calibration Test** on page 55.
 - If the NIBP module pressure and manometer pressure still differ BEYOND the ± 3 mmHg tolerance, contact Masimo Technical Services. See **Contacting Masimo** on page 65.
10. Disconnect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb from the NIBP module.
11. Power OFF the manometer.

NIBP Air Leak Test

Note: This section is provided as a reference and intended for authorized service personnel only.

Pass Criteria

International standards for automated NIBP devices require that air leakage within the pneumatic system must not exceed 6mmHg/minute.

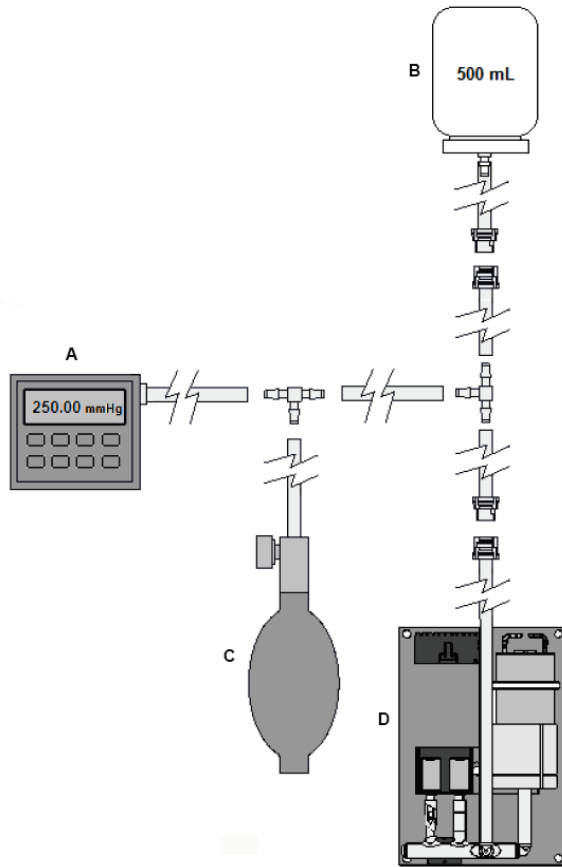
Equipment





- Calibrated Manometer*
- Pneumatic "T" Adapters
- 500mL bottle
- Hand Bulb
- Connection Tubing

*Verify the manometer has been calibrated within the last 12 months. Calibration accuracy shall be within $\pm 0.02\%$ to $\pm 0.25\%$ FS (Full Scale) and a measurement uncertainty of ± 1 LSD (Least Significant Digit).

Procedure

1. Connect the manometer (A), 500mL bottle (B), and hand bulb (C) to the NIBP module (D) using "T" adapters and connection tubing.



2. Power ON the manometer.
 - Set the unit of measurement to mmHg.
 - Verify the manometer has been calibrated.
3. Power ON the Rad-97.
4. On the Rad-97 home screen, press the Main Menu icon .
5. Press NIBP .
6. Press CALIBRATION .
 - For the password, enter 4258.
 - Press the Enter key.
7. Press AIR LEAK TEST .
8. To begin the air leak test, press **Test**.
 - Wait for the **countdown timer** to reach 0 second.
 - At the bottom of the screen, in the **Result** section, verify the **leak rate** is less than 6mmHg. If the leak rate is greater than 6mmHg, verify there are no leaks in the calibration equipment (tubing, 500mL container, arm cuff, etc.). If there are no leaks detected from the calibration equipment and the leak rate is still greater than 6mmHg, contact Masimo Technical Services. See **Contacting Masimo** on page 65.
9. Disconnect the manometer, 500mL bottle, and hand bulb from the NIBP module.
10. Power OFF the manometer.

Overpressure Test

Note: This section is provided as a reference and intended for authorized service personnel only.

Pass Criteria

International standards for automated NIBP devices require that the pressure must not exceed 300mmHg on adults and pediatric patients and 150mmHg on neonatal patients with a tolerance of 10% for 15 seconds or greater than 10% for 3 seconds. The overpressure pass criteria for the Advantage module are:

Adults, Pediatrics	300 ±10mmHg
Neonates	150 ±5mmHg

Equipment

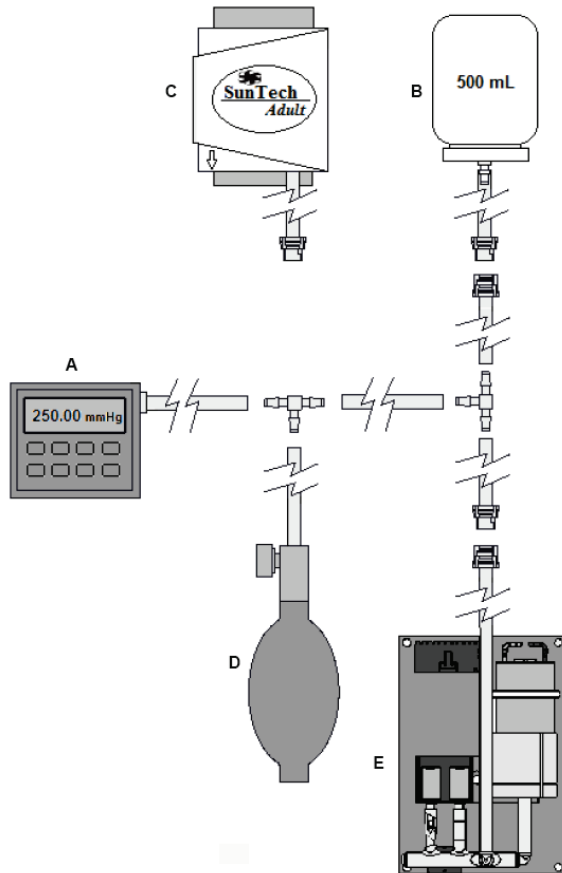
- Calibrated Manometer*
- Pneumatic "T" Adapters
- 500mL bottle or regular-sized cuff wrapped around solid object
- Hand Bulb
- Connection Tubing





*Verify the manometer has been calibrated within the last 12 months. Calibration accuracy shall be within ±0.02% to ±0.25% FS (Full Scale) and a measurement uncertainty of ±1 LSD (Least Significant Digit).

Test Method for Adults and Pediatrics

1. Connect the manometer (A), 500mL bottle (B) or cuff wrapped around solid object (C), and hand bulb (D) to the NIBP module (E) using "T" adapters and connection tubing.





Note: If using a cuff, verify the cuff is Adult or Pediatric. Do not use a Neonate cuff for this test method.



2. Power ON the manometer.
 - Set the unit of measurement to mmHg.
 - Verify the manometer has been calibrated.
3. Power ON the Rad-97.
4. On the Rad-97 home screen, press the Main Menu icon .
5. Press NIBP .
6. Press CALIBRATION .
 - For the password, enter 4258.
 - Press the Enter key.
7. Press OVERPRESSURE TEST .
8. To begin the overpressure test, press the **Test** button, then increase the pressure to the overpressure point:
 - Increase pressure to approximately 280mmHg using the hand bulb.
 - Very slowly increase the pressure as you approach the overpressure point.
 - When the overpressure point is reached, the valves will open (a faint click can be heard when this occurs) and the pressure will rapidly reduce to 0 (zero) mmHg. Be sure to observe the pressure measurement on the manometer when the valves open.
9. Determine if the NIBP module passed the overpressure test:
 - If the valves opened WITHIN the overpressure pass criteria, then the NIBP module PASSED the overpressure test for adults and pediatrics. Go to step 10.
 - If the valves opened BEYOND the overpressure point pass criteria, then press the **Test** button again to confirm the overpressure point. If the valves open repetitively beyond the pass criteria, contact Masimo Technical Services. See **Contacting Masimo** on page 65.
10. To stop testing, press **Stop**.
11. Disconnect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb from the NIBP module.
12. Power OFF the manometer.

Test Method for Neonates

1. Follow steps 1 through 3 from *Test Method for Adults and Pediatrics* above.

Note: If using a cuff, verify the cuff is Neonate. Do not use an Adult or Pediatric cuff for this test method.
2. On the Rad-97 Main Screen, touch the *Profiles* option in the Status Bar. See *About the Status Bar*.
3. Select **Neonates** in the *Profiles* screen, then touch **OK**.
4. Start the NIBP measurement then immediately abort:
 - Touch the Start NIBP button.
 - Touch the Start NIBP button again when then pump starts to inflate the system.
5. Press the Main Menu icon .
6. Press NIBP .
7. Press CALIBRATION .
 - For the password, enter 4258.
 - Press the Enter key.
8. Press OVERPRESSURE TEST .

9. To begin the overpressure test, press the **Test** button, then increase the pressure to the overpressure point:
 - Increase pressure to approximately 130mmHg using the hand bulb.
 - Very slowly increase the pressure as you approach the overpressure point.
 - When the overpressure point is reached, the valves will open (a faint click can be heard when this occurs) and the pressure will rapidly reduce to 0mmHg. Be sure to observe the pressure measurement on the manometer when the valves open.
10. Determine if the NIBP module passed the overpressure test:
 - If the valves opened **WITHIN** the overpressure pass criteria, then the NIBP module **PASSED** the overpressure test for neonates. Go to step 11.
 - If the valves opened **BEYOND** the overpressure point pass criteria, then press the **Test** button again to confirm the overpressure point. If the valves open repetitively beyond the pass criteria, contact Masimo Technical Services. See **Contacting Masimo** on page 65.
11. To stop testing, press **Stop**.
12. Disconnect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb from the NIBP module.
13. Power OFF the manometer.

NomoLine® Capnography Verification

Follow the verification procedures provided in:

- 301554/LAB-10824 - Service Manual, NomoLine ISA Maintenance Kit, English, Global

Alarm Limit Test

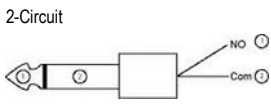
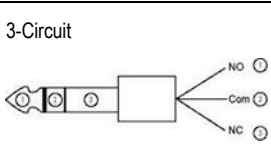
Alarm Limit Test

1. Connect a sensor to the Rad-97. Place the sensor on a finger to obtain an SpO₂ value.
2. Change the High SpO₂ Alarm parameter to a value two points below the currently selected value. Refer to the Operator's Manual for Rad-97 for complete information.
3. Verify that the newly set parameter is shown on the *Display* screen.
4. Return the parameter to its original setting.
5. Repeat steps 1 to 3 for all active parameters.
6. Reset the alarm limits again to the original settings.

Nurse Call Setting Connections

For maximum flexibility, either normally open or normally closed signals are available. During an alarm condition or a low Signal IQ event, depending on the configuration of the device output, the normally open pin will be connected to the common pin, and the normally closed pin will be disconnected. In addition, the Nurse Call Polarity can be inverted to accommodate various nurse call station requirements. See Device Output.


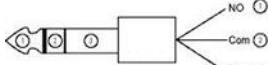
Only authorized service personnel should connect one of these two signals to a hospital's Nurse Call system.

Cable Type	Nurse Call Event	Menu Setting
2-Circuit 	2 contacts normally opened	Nurse Call Polarity Normal
	2 contacts normally closed	Nurse Call Polarity Inverse
3-Circuit 	1 and 2 contacts normally opened 2 and 3 contacts normally closed	Nurse Call Polarity Normal
	1 and 2 contacts normally closed 2 and 3 contacts normally opened	Nurse Call Polarity Inverse

Nurse Call Test

To conduct a Nurse Call test

1. Disconnect any patient cables, sensors, or accessories from the Rad-97.
2. Turn the Rad-97 Off and On again. Ensure that there are no audible alarms or audible alarms that are not paused.
3. Verify the Nurse Call polarity is set to normal. See Device Output.
4. Prepare a digital multi-meter to measure resistance.
5. Connect a 1/4" Nurse Call interconnection cable phone plug (2-circuit or 3-circuit) into the Nurse Call port of the Rad-97. See Back View.
6. Connect the common lead of a digital multi-meter to contact 2 of the of the Nurse Call interconnection cable phone plug (as shown in the table).
7. Connect the positive lead of the digital multi-meter to contact 1 of the of Nurse Call interconnection cable phone plug (as shown in the table). Verify that the resistance is as shown in the table.
8. Trigger an alarm on the Rad-97 (for example, by connecting and disconnecting a sensor while measuring data). Verify that the resistance is as shown in the table.
9. If using a 3 circuit Nurse Call interconnection cable phone plug, change the positive lead of the digital multi-meter to contact 3 of the of the phone plug (as shown in the table). Verify that the resistance is as shown in the table.
10. Trigger an alarm on the Rad-97. Verify that the resistance is as shown in the table.

Nurse Call Cable Type	Nurse Call Contact State	Multi-Meter Reading
2-Circuit 	1 and 2 contacts normally opened	OL (open circuit)
	1 and 2 contacts nurse call triggered	< 25 ohms
3-Circuit 	1 and 2 contacts normally opened	OL (open circuit)
	1 and 2 contacts nurse call triggered	< 25 ohms
	2 and 3 contacts normally closed	< 25 ohms
	2 and 3 contacts nurse call triggered	OL (open circuit)

Chapter 6: Troubleshooting and Repair

This chapter covers basic troubleshooting and repair information. Service should be done by authorized service personnel only.

Repair

WARNING: Do not disassemble or assemble the unit with the AC power cord attached.

WARNING: Ensure the unit has been cleaned per the cleaning instructions. See **Cleaning** on page 11.

WARNING: An Electrical Safety Test is required in the event the Rad-97 has been disassembled. See **Electrical Safety Testing** on page 49.

CAUTION: Prior to service, precautions must be taken to minimize potential damage to the device through electrostatic discharge (ESD):

- Use a conductive wrist strap attached to a good earth ground.
- Always discharge yourself by touching a grounded bare metal surface or approved anti-static mat before working with the device.
- Use an approved anti-static mat to cover your work surface.

General Procedures

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.
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.
3. Make note of the unit serial number.
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. Contact Masimo Corporation using the information in **Contacting Masimo** on page 65 to research the warranty history of the unit to determine if the unit will be covered under warranty.

Troubleshooting

Symptom	Possible Cause	Correction
<i>Rad-97 does not turn on</i>	<ul style="list-style-type: none"> • Power button not pressed long enough. • The battery may be depleted. 	<ul style="list-style-type: none"> • Press Power Button for two (2) seconds. • Connect Rad-97 to AC power to charge battery. See Charging the Battery.
<i>Rad-97 turns on, but Main Screen is dim or blank</i>	The brightness setting is not correct.	<ul style="list-style-type: none"> • Adjust the brightness setting. • If the condition persists, Rad-97 requires service. See Chapter 7: Warranty and Service Information on page 65.
<i>Touch functionality is not responsive</i>	Internal failure.	Rad-97 requires service. See Chapter 7: Warranty and Service Information on page 65.
<i>Rad-97 has a continuous speaker tone</i>	Internal failure.	<ul style="list-style-type: none"> • To silence an alarm, press the Power Button for eight (8) seconds. <p>If alarm continues to sound, Power Off Rad-97. Rad-97 requires service. See Chapter 7: Warranty and Service Information on page 65.</p>
<i>Home Button does not work when pressed</i>	Internal failure.	Rad-97 requires service. See Chapter 7: Warranty and Service Information on page 65.
<i>Battery does not charge.</i>	AC power cable may be disconnected.	Unplug and re-plug in the AC power cable.
<i>Rad-97 charging indicator illuminates red</i>	Internal failure.	Rad-97 requires service. See Chapter 7: Warranty and Service Information on page 65.
<i>Nurse Call does not communicate</i>	Connection error.	Unplug and re-plug in the Nurse Call connector. See Nurse Call Test on page 61.

Chapter 7: Warranty and Service Information

Repair Policy

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

Clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in **Cleaning** on page 11. Make sure the equipment is fully dry before packing.

To return the device for service, see **Return Procedure** on page 65.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in **Cleaning** on page 11. Make sure the equipment is fully dry before packing. Contact Masimo Technical Support through **Contacting Masimo** on page 65 and obtain 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-97. 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 Rad-97 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-97 has been decontaminated for bloodborne pathogens.
- Return the Rad-97 to the shipping address acquired through **Contacting Masimo** on page 65.

Contacting Masimo

Regional contact information can be found at <http://service.masimo.com>.

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Rad-97® Pulse CO-Oximeter®) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. 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 must be paid by purchaser.

Exclusions

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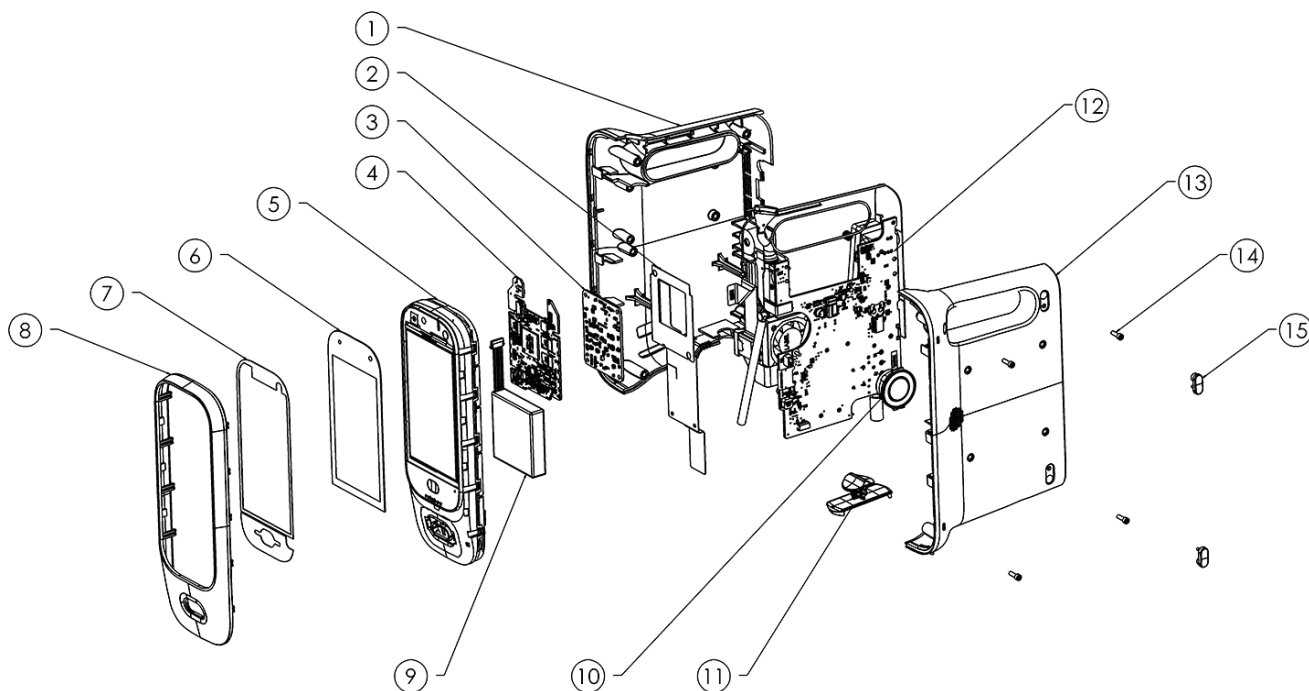
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Appendix: Rad-97 Component Diagrams

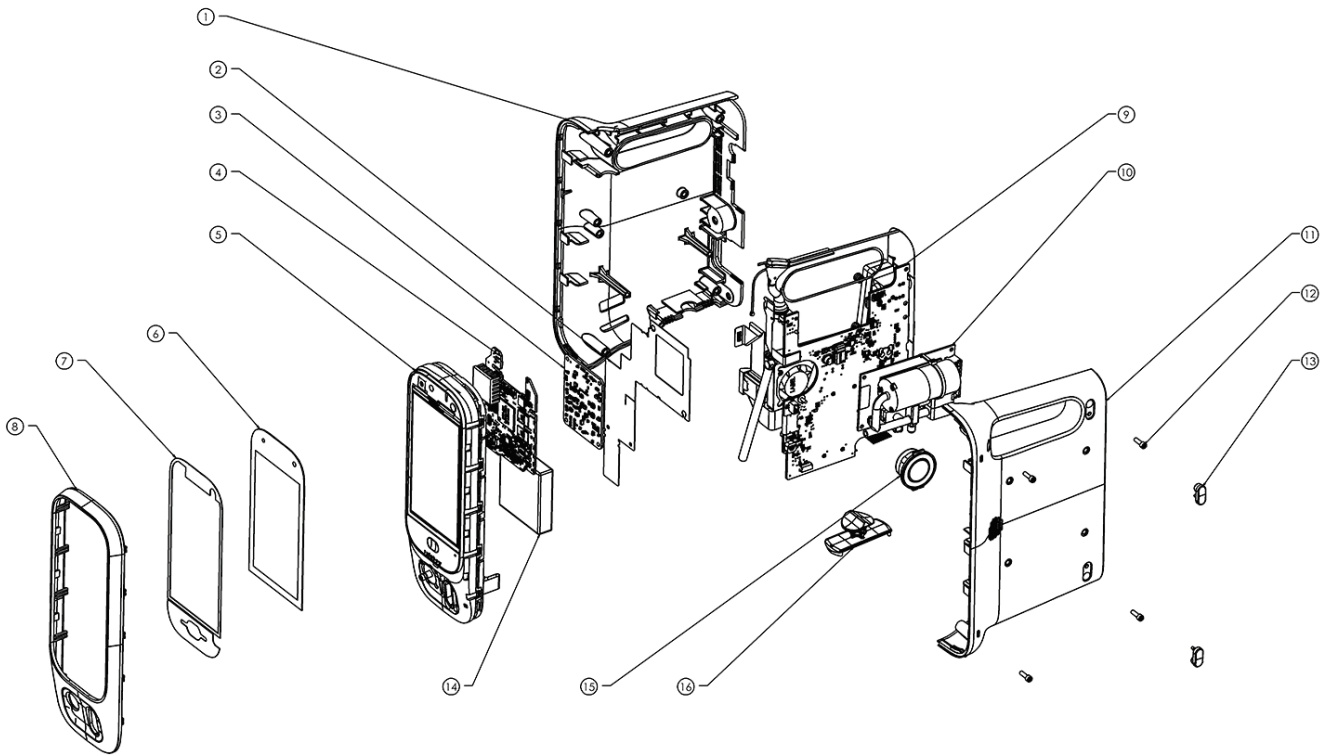
Rad-97 - Version 1

Rad-97 - Base



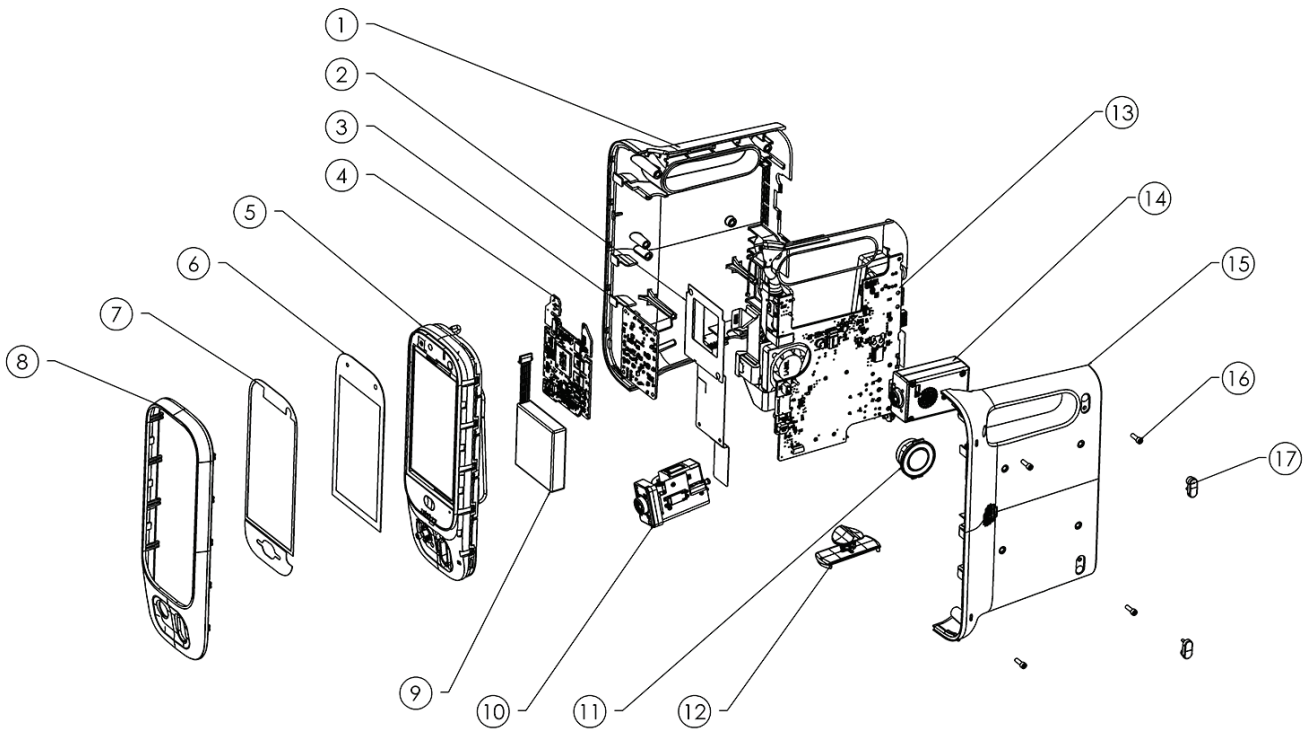
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1	Rear Rad-97 Housing	9	3.7V 4600mAh Rechargeable Li-Ion Battery
2	Insulation Sheet	10	Speaker
3	MX Board	11	Swivel Foot
4	Rad-97 Instrument Board	12	Rad-97 Connectivity Board Circuit Board Assembly
5	Rad-97 Faceplate Console	13	Top Rad-97 Housing
6	Rad-97 Touchscreen	14	Screw, #4-40 1/4 x 3/8, Socket HD, SS
7	Rad-97 Rubber Gasket	15	Foot Bumpers
8	Rad-97 Faceplate		

Rad-97 with noninvasive blood pressure



Ref	Description	Ref	Description
1	Rear Rad-97 Housing	9	Rad-97 Connectivity Board Circuit Board Assembly
2	Insulation Sheet	10	NIBP Module
3	MX Board	11	Top Rad-97 Housing
4	Rad-97 Instrument Board	12	Screw, #4-40 1/4 x 3/8, Socket HD, SS
5	Rad-97 Faceplate Console	13	Foot Bumpers
6	Rad-97 Touchscreen	14	3.7V 4600 mAh Rechargeable Li-Ion Battery
7	Rad-97 Rubber Gasket	15	Speaker
8	Rad-97 with NIBP Faceplate	16	Swivel Foot

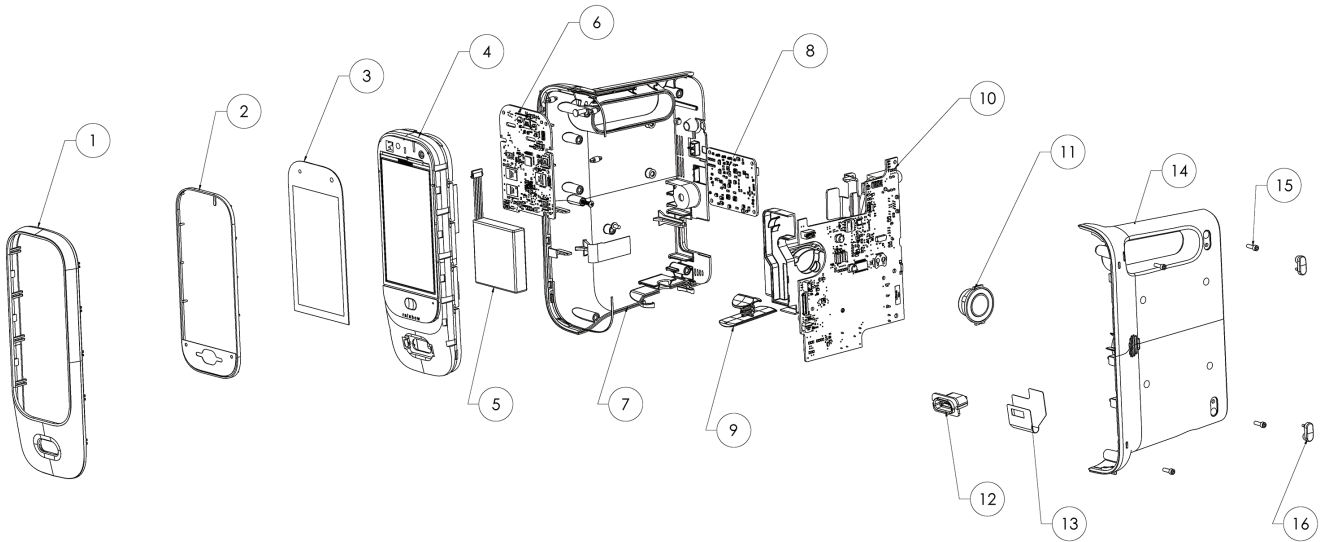
Rad-97 with NomoLine Capnography



Ref	Description	Ref	Description
1	Rear Rad-97 Housing	10	ISA Module
2	Insulation Sheet	11	Speaker
3	MX Board	12	Swivel Foot
4	Rad-97 Instrument Board	13	Rad-97 Connectivity Board Circuit Board Assembly
5	Rad-97 Faceplate Console	14	ISA Capno PCBA
6	Rad-97 Touchscreen	15	Top Rad-97 Housing
7	Rad-97 Rubber Gasket	16	Screw, #4-40 1/4 x 3/8, Socket Hd, SS
8	Rad-97 with NomoLine Capnography Faceplate	17	Foot Bumpers
9	3.7V 4600 mAh Rechargeable Li-Ion Battery		

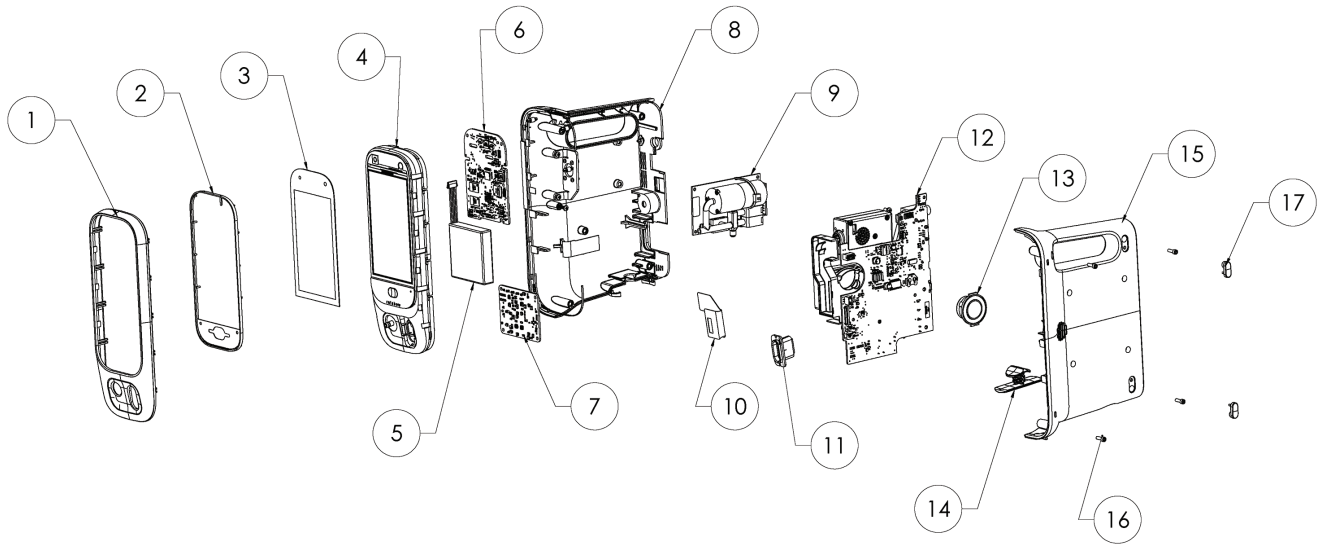
Rad-97 - Version 2

Rad-97 - Base



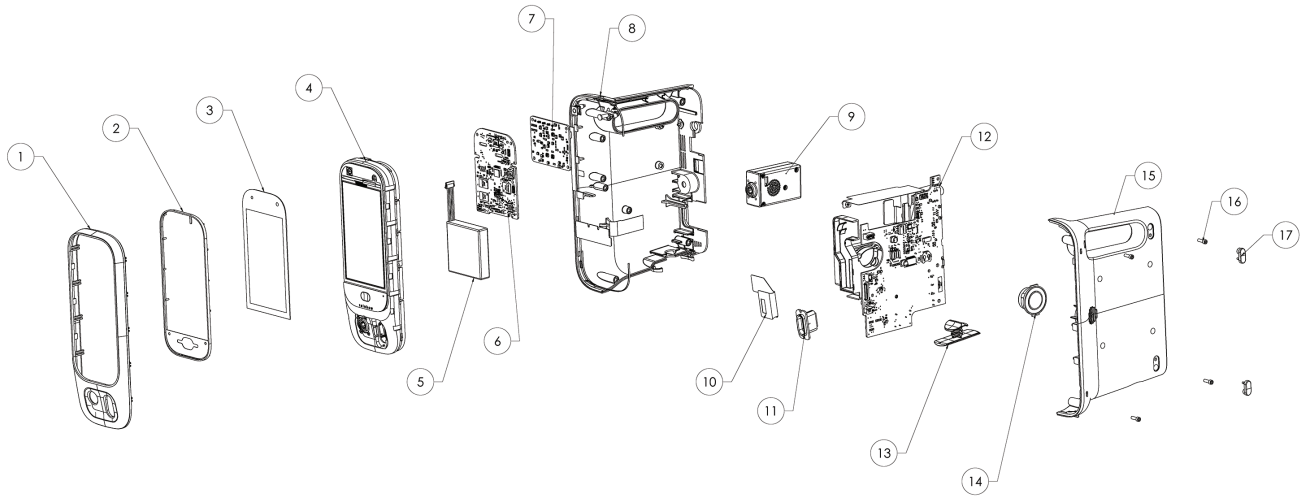
Ref	Description	Ref	Description
1	Rad-97 Faceplate	9	Swivel Foot
2	Rad-97 Rubber Gasket	10	Rad-97 Connectivity Board Circuit Board Assembly
3	Rad-97 Touchscreen	11	Speaker
4	Rad-97 Faceplate Console	12	TB-20 Connector
5	3.7V 4600mAh Rechargeable Li-Ion Battery	13	Insulation Sheet
6	Rad-97 Instrument Board	14	Top Rad-97 Housing
7	Rear Rad-97 Housing	15	Screw, #4-40 1/4 x 3/8, Socket HD, SS
8	MX Board	16	Foot Bumpers

Rad-97 with noninvasive blood pressure



Ref	Description	Ref	Description
1	Rad-97 Faceplate	10	Insulation Sheet
2	Rad-97 Rubber Gasket	11	TB-20 Connector
3	Rad-97 Touchscreen	12	Rad-97 Connectivity Board Circuit Board Assembly
4	Rad-97 Faceplate Console	13	Speaker
5	3.7V 4600mAh Rechargeable Li-Ion Battery	14	Swivel Foot
6	Rad-97 Instrument Board	15	Top Rad-97 Housing
7	MX Board	16	Screw, #4-40 1/4 x 3/8, Socket HD, SS
8	Rear Rad-97 Housing	17	Foot Bumpers
9	NIBP Module		

Rad-97 with NomoLine Capnography



Ref	Description	Ref	Description
1	Rad-97 Faceplate	10	Insulation Sheet
2	Rad-97 Rubber Gasket	11	TB-20 Connector
3	Rad-97 Touchscreen	12	Rad-97 Connectivity Board Circuit Board Assembly
4	Rad-97 Faceplate Console	13	Swivel Foot
5	3.7V 4600mAh Rechargeable Li-Ion Battery	14	Speaker
6	Rad-97 Instrument Board	15	Top Rad-97 Housing
7	MX Board	16	Screw, #4-40 1/4 x 3/8, Socket HD, SS
8	Rear Rad-97 Housing	17	Foot Bumpers
9	ISA Module		

Index

A

- About This Manual • 7
- Alarm Limit Test • 61
- Appendix
 - Rad-97 Component Diagrams • 67

B

- Battery Charging • 53
- Battery Diagnostics • 53
- Battery Installation (Version 1) • 24
- Battery Installation (Version 2) • 31
- Battery Removal (Version 1) • 20
- Battery Removal (Version 2) • 28
- Battery Replacement Verification • 53
- Battery Test • 53

C

- Chapter 1
 - Maintenance Procedures • 11
- Chapter 2
 - Software Procedures • 13
- Chapter 3
 - Service Procedures • 15
- Chapter 4
 - Electrical Safety Testing • 19, 34, 49
- Chapter 5
 - Performance Verification Procedures • 19, 34, 53
- Chapter 6
 - Troubleshooting and Repair • 63
- Chapter 7
 - Warranty and Service Information • 63, 65
- Cleaning • 11, 63, 65
- Contacting Masimo • 13, 56, 57, 58, 60, 61, 63, 65

D

- Device Classification per IEC-60601-1 • 49
- Disassembly • 15, 20, 28, 35, 41

E

- Electrical Safety Testing • 49, 63
- Electrical Safety Tests • 49
- Exclusions • 65

G

- Gas Gauge Programming • 28, 34
- General • 49
- Ground Continuity Test (Class I devices only) • 50

I

- Identify Rad-97 Version • 9

L

- Limitation of Warranty • 65
- Limited Warranty • 65

M

- Measuring Earth Leakage Current (Class I devices only) • 50

- Measuring Patient Leakage Current • 52
- Measuring Touch Leakage Current • 51

N

- NIBP Air Leak Test • 57
- NIBP Module Calibration Test • 55, 56, 57
- NomoLine® Capnography Verification • 61
- Noninvasive Blood Pressure Module Tests • 55
- Nurse Call Setting Connections • 61
- Nurse Call Test • 62, 63

O

- Overpressure Test • 59

P

- Power-On Self Test • 54

R

- Rad-97 - Version 1 • 67
- Rad-97 - Version 2 • 70
- Rad-97 Battery Replacement • 19
- Rad-97 Disassembly and Reassembly - All Versions and Models • 15
- Rad-97 TB-20 Connector Replacement • 35
- Reassembly • 17, 28, 34, 41, 48
- Repair • 63
- Repair Policy • 65
- Required Tools • 15, 19, 35
- Restrictions • 66
- Return Procedure • 65

S

- Safety Information, Warnings and Cautions • 7
- Sales & End-User License Agreement • 66
- Service Manual, Rad-97 • 3
- Software Upgrade • 13
- Software Verification • 13
- Span Point Calibration • 56
- Supplied Parts List • 19, 35

T

- TB-20 Connector Installation (Version 1) • 39
- TB-20 Connector Installation (Version 2) • 39, 45
- TB-20 Connector Removal (Version 1) • 35
- TB-20 Connector Removal (Version 2) • 41
- Test Equipment Recommended • 49
- Touchscreen Function Test • 54
- Troubleshooting • 63

V

- Vent Cleaning • 11
- Verification of Electrical Outlet and Power Cable • 49

Z

- Zero Point Calibration • 56



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