Puritan Bennett
Achieva® Ventilators
with Flow Acceleration and Apnea Backup
Service Manual

Part No. Y-102923-00A Rev C

10/2003

PURITAN
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Contents

Chapter 1: Introduction

This manual is intended for use only by biomedical technicians who have successfully completed Puritan Bennett training on this product.

Puritan Bennett believes the information herein is accurate but accepts no responsibility for errors, omissions, or misrepresentation.

PURITAN BENNETT FURTHER DECLINES ANY WARRANTIES, EXPRESSED OR IMPLIED, FOR THE REPAIRED PRODUCT, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

It is the user's responsibility to ensure that the product has been properly repaired and that it is in safe and proper operating condition before it is put into use.

Caution

It is highly recommended that oxygen with a minimum purity of 99% be used for the check-in calibration and final inspection processes. However, a compressed air system may be used in the check-in and calibration test processes if all of the following conditions are met: (1) An "oil-less" compressor is used; (2) The dew point of the compressed air shall be less than -5°F (-20°C); (3) The oil content of the system shall be less than .1 mg/cubic meter; (4) The compressed air shall be filtered to remove any oil before entering the Achieva ventilator. (The oil content of the compressed air entering the Achieva ventilator shall be 0 mg/cubic meter.); (5) Verification testing on all of the above parameters must be completed and documented; and (6) The system shall be placed on a regular preventive maintenance schedule to assure compliance with the above parameters.

Chapters

This manual consists of the following chapters:

Introduction: Provides an overview of the manual's intent and disclaimers.

Preventive Maintenance: Lists the processes that are necessary for performing preventive maintenance (PM) and recertification.

Note

Report forms and inspection data sheets appear in the manual only as illustrations. The actual forms are available in the *Achieva Service Forms Kit* (Model Y-103042-00A).

Check-in, Pre-calibration assembly, Calibration, Reassembly, Run-in, Safety test, and Final inspection: Provide processes for inspecting and verifying operation of the ventilator.

Repairs: Provides instructions to replace parts as needed in the ventilator.

Appendix A: Provides a table of the PTS2000 Menu Structure.

Appendix B: Provides a reference for torque settings.

Appendix C: Provides service and warranty information.

Conventions

Throughout this manual, Warnings, Cautions, and Notes mean the following:

Directions that warn of conditions that put the patient, caregiver, or other individuals at risk of injury.	Warning
Directions that help you avoid damaging the ventilator or losing data.	Caution
Directions that make it easier to use the ventilator.	Note

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Chapter 2: Check-in

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- Rp50 resistor
- 5-ft patient circuit (Model Y-6263) with exhalation manifold (Model Y-6353)
- Red Run-in plug, P/N L-003068-000
- SMS test lung, Model SMS0015001 or SMS0015201 (resistance set to 20 and compliance set to 20 ml/cmH_2O)
- Small flat-blade screwdriver
- Small flashlight
- 24-V external battery with battery cable
- Miscellaneous hand tools
- PTS2000™ test instrument* (calibration analyzer)
- IBM compatible computer with Windows Operating System (95, 98 or NT)
- Communications cable Y-6490 (RS232 null modem adapter cable with gender changer, or equivalent)
- MaSSII software, Version 2.0a (or greater)
- 18-in flex hose, P/N L-002777-000 (or equivalent, 18–24-in)
- High pressure / flow source, O_2 [up to 80 psi (5.52 bar) and 180 lpm]
- Miscellaneous patient circuit adapters
- Silicone adapter (L-004100-000)

**The PTS2000™ test instrument is used with respiratory care products to measure performance parameters, such as air and oxygen flow and volume, oxygen concentration, and barometric pressure. Throughout this manual, this device is referred to as the "PTS2000."*

Note

Clean the assembly as needed throughout the process.

Exterior visual inspection

1. Record the ventilator's serial number on the Field Service Report.
2. Verify all silk screens and labels are legible.
3. Examine the AC power cord for damage. There should be no cuts through the outer insulation. Only power cords with Hospital Grade plugs should be used on the units. Clean the AC cord, if it passes inspection.
4. Check the unit for loose or missing hardware (for example, cord wrap feet).
5. Examine the front panel overlays for damage. Examine exterior of unit for damage.
6. Examine the PATIENT AIR tube screen for damage.

General operation

1. Connect the ventilator to AC power and record the software version on the ventilator's display during Start up.
2. Verify that the Patient Pressure meter reading is within 1/2 of a needle's width of "0" cmH_2O. If it is not, remove the label covering the meter adjustment hole located below the meter. Using a small screwdriver, verify the meter needle can be adjusted above and below "0". Set the meter needle to "0". Apply a new label over the meter adjustment hole.
3. Set the unit to VENTILATE. Verify that all LEDs light up, and the alarm sounds; then set the unit to STANDBY. Verify that the front panel AC and BATTERY CHARGING LEDs are lit. Do not adjust any other settings.
4. If the ventilator's settings are not displayed, press ENTER. Record the settings on the Field Service Report. Also record the pressure trigger, flow acceleration, expiratory sensitivity, operating altitude, and alarm-latching status.
5. Press MENU/ESC and then press the up or down arrow key to select "VENTILATING HOURS SINCE LAST MAINTENANCE." Record the hours on the Field Service Report.
6. Press the up or down arrow key to select "DATE AND TIME," then press ENTER. Verify the

date and the time are correct. Record the current date and time along with the displayed date and time on the Field Service Report. It is not necessary to record the seconds. (This is important so that any discrepancy is recorded and can be adjusted for on the memory logs.)

Example:

CURRENT: 07/20/99 15:15 DISPLAYED: 07/20/99 15:12

Note

If the date and time are not correct, set the correct date and time and shut down the ventilator for at least 5 seconds. Turn the ventilator back on and verify that the date and time are correct.

Report generation

Notes

When using the computer with MaSSII software, the Enter key on the keyboard can be used instead of selecting OK with the pointing device, if the OK is highlighted.

Clear the computer windows as necessary.

1. Connect the ventilator to the computer using a communications cable.
2. Initiate a MaSSII session.
3. Enter your User ID and Password, then select “OK.”

Caution

Using the MaSSII "Setup…Initialize NVRAM…" command will reset all calibration parameters and unit information to defaults. This will also reset the Operating Hours to zero. A complete re-calibration will be required and the operating hours will have to be re-entered.

4. On the MaSSII screen, select “Report... Report...,” then select only the following:
   - Settings
   - Event Log

- Compliance Data
- Trended Data
- Flow Tables
- Unit ID
- Cumulative Data
- Repair History
- Calibration Parameters
- Error Log

5. On the MaSSII screen, select “Generate Report.” Save the file in a folder designated for Check-In.
6. A dialog box will appear to confirm the file was saved. Select “OK.”
7. On the Report Generator screen select “Quit.”

Operation verification

1. Evaluate and try to verify the reason for return. If the unit is returned for an internal battery problem, complete the Check-In process, allow the unit to charge for a minimum of 12 hours, and perform a battery run-down. Use the Battery Rundown section of the Achieva Run-in process.

Notes

The PTS2000 must be on at least 15 minutes prior to using the instrument.

Zero the PTS2000 as needed throughout the process.

2. Select and zero Screen 1 on the PTS2000.

Note

See Appendix A, “PTS2000 Menu Structure,” for PTS2000 screen setup.

3. Using a 5-ft (1.5 m) patient circuit with exhalation manifold, connect the test lung to the ventilator with the small striped/colored tubing going to both the ventilator and the PTS2000 Low Pressure “+” port.

All F_IO_2 settings in this process are only for PSO_2 units. Note

4. Set or verify the following parameters:
   - MODE A/C
   - VOLUME 1000 ml
   - BREATH RATE 10 bpm
   - INSPIRATORY TIME 1.0 second
   - SENSITIVITY 5 lpm
   - PRESSURE SUPPORT 0 cmH_2O
   - PEEP 0 cmH_2O
   - LOW PRESSURE 2 cmH_2O
   - HIGH PRESSURE 80 cmH_2O
   - OPERATING ALTITUDE Set to local elevation.
   - ALARM LATCHING STATUS Latching
   - F_IO_2 21%
   - PRESSURE TRIGGER 2 cmH_2O
   - EXPIRATORY SENSITIVITY 15%
   - FLOW ACCELERATION Off
5. Set the ventilator to VENTILATE. Verify the following:
   - All LEDs must light up and then go off except for the AC and BATTERY CHARGING LEDs which will remain lit.
   - The audible alarm must sound.

The Alarm Silence/Reset button on the ventilator may be used to silence alarms as needed. Note

6. Allow the unit to cycle at least 3 times.
7. Verify that the meter needle deflects and returns to “0” with each breath.
8. Check for unusual gearbox noise or any other unusual sounds or abnormal operation.
9. Set the unit to STANDBY. On the MaSSII screen, select “Parameters.... Measurements.“

Verify the Calculated Reading for Pressure is “0” (+/- 0.9) cmH_2O and the Calculated Reading for Secondary Pressure is “0” (+/- 0.9) cmH_2O. If the readings are out of specification, disconnect the patient circuit from the test lung to determine if the patient circuit is holding pressure.

10. Remove the patient circuit with test lung and the PTS2000 from the ventilator.
11. Select “Done” to clear the screen.
12. Close out the MaSSII software.
13. Disconnect the communications cable from the ventilator.

Self-test

1. Connect a 5-ft (1.5 m) patient circuit with exhalation manifold to the ventilator.
2. Press ENTER, then press MENU/ESC. The unit will display “Press ENTER to begin User Self-Test.”
3. Press ENTER and wait for the unit to display “Press ENTER when ready to begin test.” Block the open end of the exhalation manifold and press ENTER.
4. If the SELF-TEST passes, only the AC and BATTERY CHARGING LEDs will remain lit, and the ventilator's display will show “Test PASSED.” Any LED flashing at the end of the test means that a failure has occurred.
5. Remove the 5-ft patient circuit with exhalation manifold.

Volume test

1. Verify the Rp50 resistor is connected to the High Flow Inlet port of the PTS2000 with a 5-ft patient circuit and an exhalation manifold attached. Attach the other end of the patient circuit to the ventilator.
2. Select and zero screen 2 on the PTS2000.
3. Set the Inspiratory Time to 2.0 seconds.

4. Set the unit to VENTILATE and allow the PTS2000 reading to stabilize.
5. The average volume reading must be 1.000 +/- 0.050 (0.950 to 1.050) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume reading on the Field Service Report, line 1.
6. Set the unit to STANDBY, then back to VENTILATE. Allow the PTS2000 reading to stabilize. The average volume reading must be 1.000 +/- 0.050 (0.950 to 1.050) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume reading on the Field Service Report line 2.
7. Verify the two recorded readings for 1000 ml do not differ by more than 0.030 liters.
8. Set the unit to STANDBY.
9. Set the following parameters:
   - VOLUME 2000 ml
   - BREATH RATE 6 bpm
   - INSPIRATORY TIME 3.5 seconds
10. Set the unit to VENTILATE and allow the PTS2000 reading to stabilize.
11. The average volume reading must be 2.000 +/- 0.070 (1.930 to 2.070) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume reading on the Field Service Report, line 3.
12. Set the unit to STANDBY, then back to VENTILATE. Allow the PTS2000 reading to stabilize. The average volume reading must be 2.000 +/- 0.070 (1.930 to 2.070) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume reading on the Field Service Report, line 4.
13. Verify the two recorded readings for 2000 ml do not differ by more than 0.030 liters.
14. Set the unit to STANDBY and disconnect the patient circuit from the ventilator.
15. Set the following parameters:
    - VOLUME 1000 ml
    - INSPIRATORY TIME 2.0 seconds

- BREATH RATE 10 bpm

PEEP/support test

Note

A VOLUME cannot be set if the ventilator is in the PRESSURE mode or the SPONTANEOUS mode.

1. Select and zero screen 1 on the PTS2000.
2. Use a 5-ft (1.5 m) patient circuit with an exhalation manifold attached to connect the test lung to the ventilator with the small striped/colored tubing going to both the ventilator and the PTS2000 Low Pressure "+" port.

3. Set the ventilator to VENTILATE, and then set the following parameters:
   - LOW PRESSURE = 13 cmH_2O
   - PRESSURE SETTING = 20 cmH_2O
   - PEEP = 10 cmH_2O
4. Allow the ventilator to cycle for a minimum of 1 minute. Observe the continuous pressure readings on the PTS2000. Verify the readings alternate between a low of 10 cmH_2O (+/-2.5 cmH_2O), and a high of 30 cmH_2O (+/-2.5 cmH_2O). Disregard any readings between the low and the high readings.
5. Set the unit to STANDBY, then set the following parameters:
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 2 cmH_2O
6. Disconnect the patient circuit with test lung from the ventilator.

Leak test (to be performed only on ventilators with an internal oxygen blender)

Warning

High pressure compressed gas is used during this section. Pressurized gas lines can cause injury. DO NOT disturb tubing unless the high pressure source has been turned off and the lines have been purged. Do not apply more than 80 psi (5.518 bar) to the O_2 Inlet. Potential damage may occur.

1. Remove the cap over the O_2 inlet port. Connect the flow source to the O_2 inlet. Do not apply any inlet pressure.
2. Select and zero the menu item on the PTS2000:
   - Screen 3 if using Air source.
   - Screen 5 if using Oxygen source.
3. Using an adapter with tubing, connect the ventilator's patient air port to the PTS2000 Low Flow Inlet port.
4. Verify the PTS2000 reading is 0.000 lpm. Set the O_2 inlet pressure to 60 psi +/- 5 psi (3.79–4.48 bar). Allow the PTS2000 10 seconds to stabilize. Verify the PTS2000 reading is still 0.000 lpm.
5. Turn off the O_2 inlet pressure and slowly disconnect the flow source from the ventilator's O_2 inlet, allowing any pressure to escape.
6. Disconnect the adapter with tubing from the ventilator's patient air port.
7. Reinstall the O_2 inlet cap.

Operation completion

1. Attempt to isolate any problems to the proper assembly. Note any test results on the Field Service Report.

2. Disconnect the ventilator from AC power and allow it to shut down completely.
3. Press the ENTER button on the ventilator and verify proper start up operation on internal battery.
4. Allow the ventilator to shut down completely.

Disassembly

The ventilator may cycle when it is connected to AC or battery power. Keep hands and fingers clear of this area or injury may occur. Warning

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and top cover. Finger prints will damage the coating. Caution

Clean exterior of unit during disassembly. Note

Intake filter removal

1. Perform the following:
   - Remove the retainer ring.
   - Remove the FlatPak filter.
   - Remove the 3-in diameter “O” ring.

If the filter was excessively dirty or missing, record that fact on the Field Service Report. Note

2. Remove the certification sticker, if present, from the bottom of the ventilator. Move any stickers that are covering warnings, cautions, or dangers.

Power drivers may be used to remove screws.

Note

3. Use an 1/8-in hex driver to remove 2 screws from each side rail.
4. Remove both side rails and both side covers.
5. Use an 1/8-in hex driver to remove the 4 screws attaching the left end plate. Disconnect the alarm wires while carefully removing the left end plate.
6. Remove the handle.

Inspect internal parts for damage during disassembly.

Note

7. Use an 1/8-in hex driver to remove the 1 screw that secures the front panel to the right end.
8. Pivot the front panel outward and remove the top cover.
9. Disconnect all the connectors from the front panel.
10. Separate the unit into the following sections:
    - Front panel
    - Right end/back panel/bottom plate assembly
    - Left end plate with remaining covers and hardware
11. If the ventilator needs a PM or any repair that requires the right end assembly to be separated from the back panel/bottom plate assembly, disassemble as follows:
    a. Use a 5/64-in hex driver to remove the 3 screws that attach the vent housing/rear panel to the manifold assembly. (See *Pre-calibration*, Figure 5-3.)

    b. Remove the O_2 inlet port cap (if present).

The O_2 inlet grounding spring has tension when installed. Be careful when removing and installing the O_2 inlet grounding spring. Safety glasses are recommended.

Warning

c. Use a 3/32-in hex driver to remove the screw that secures the O_2 inlet port cap chain to the rear extrusion.

d. Remove the screw carefully from both leg end loops of the spring and the chain eyelet.

e. Bring the spring legs together to enlarge the opening and remove the spring from the O_2 inlet port.

Do not set the right end on the primary transducer as damage to the wires may occur.

Caution

f. Use an 1/8-in hex driver to remove the 3 screws that attach the right end assembly to the back panel/bottom plate assembly.

g. Separate the right end assembly from the back panel/bottom plate assembly.

Be careful not to lose the square gasket that goes between the O_2 blender and the rear extrusion.

Note

Achieva Field Service Report

ACHIEVA FIELD SERVICE REPORT

Serial Number: _____

Software Ver: _____ Ventilating Hours: _____

Settings as Received:

Mode:_____ Volume:_____ Insp Time: _____ Sensitivity:_____

Breath Rate: _____ Press: _____ PEEP: _____ Low Press: _____ High Press: _____

O_2: _____ Press Trigger: _____ Altitude: _____ Alarm Status: Latch Non-Latch

Flow Acceleration: _____ Expiratory Sensitivity: _____

Current Date/Time: _____ Displayed Date/Time :_____

Volume Readings: 1 _____ 2 _____ 3 _____ 4 _____

Comments: _____

_____

_____

_____

_____

_____

Parts Installed	Kit #	Test Performed	Performed By	Date
		Check-in		
		Pre-Cal Assy		
		Calibration		
		Reassy		
		Run-in		
		Safety Test		
		Final Inspection		

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Chapter 3: Preventive maintenance

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

PM operations

Notes

Steps 2 and 3 may be performed in any order.

Perform any other repairs as needed throughout process. For example, if you find a faulty AC-cord, replace it.

1. Perform Achieva Check-in Process according to Chapter 2.
2. Perform Achieva Kapseal Replacement according to Chapter 4.
3. Perform Achieva Battery Replacement according to Chapter 4.
4. Perform Achieva Pre-calibration Assembly according to Chapter 5.
5. Perform Achieva Calibration according to Chapter 6.
6. Perform Achieva Reassembly according to Chapter 7.
7. Perform Achieva Run-in according to Chapter 8.
8. Perform Achieva Safety Test according to Chaper 9.
9. Perform Achieva Final Inspection according to Chapter 10.

Recertification operations

1. Perform Achieva Check-in Process according to Chapter 2.
2. Perform Achieva Pre-calibration Assembly according to Chapter 5.
3. Perform Achieva Calibration according to Chapter 6.
4. Perform Achieva Reassembly according to Chapter 7.
5. Perform Achieva Run-in according to Chapter 8.
6. Perform Achieva Safety Test according to Chapter 9.
7. Perform Achieva Final Inspection according to Chapter 10.

Chapter 4: Repairs

Kapseal replacement

Equipment required

- X-ACTO knife (or equivalent)
- Single-edge razor blade
- Delrin screwdriver (P/N L-003075-000)
- Torque driver, 35 inch pounds (3.96 N-m)
- Torque driver, 22 inch pounds (2.49 N-m)
- Torque driver, 8 inch pounds (0.904 N-m)
- High Pressure Release (HPR) valve tool, P/N L-003071-000
- Twirlie wrench, P/N L-003072-000
- Right end assembly test stand, Model No. Y-101573-01, 115V; and Y-101573-02, 230V
- 7/64-in hex driver
- 7/64-in hex bit
- 9/64-in hex driver
- 9/64-in hex bit

Perform only those steps that are needed for the repair.

Notes

Inspect each part for damage before use.

Clean assemblies as needed throughout the process.

Power drivers may be used to remove screws.

Gearbox and piston removal

Caution

To avoid damage to the wires, do not set the right end on the primary transducer.

1. Push the piston all the way down into the cylinder.
2. Use a 9/64-in hex driver to remove the screw securing the crank arm to the output shaft.
3. Use a 7/64-in hex driver to remove the 4 screws securing the motor/gearbox assembly to the cylinder.

Caution

Be careful not to damage wires or the EOT sensor when handling the motor/gearbox.

4. Pull up on the motor/gearbox assembly until the dowel pins are clear of the cylinder. Remove the motor/gearbox from the crankarm, and set it aside.
5. Pull the piston assembly out of the cylinder.

Kapseal and seal ring removal

1. Remove and discard the old kapseal and seal ring from the piston. Remove any kapseal and piston guide residue from the piston assembly.
2. Inspect the crankarm bearing and the connecting rod bearing for roughness. Replace the crankarm assembly if bearings need to be replaced.
3. Inspect the manifold leafs for damage. Replace them if necessary.

Cylinder preparation

1. Use a single-edge razor blade to carefully scrape out the residue build-up from the inside of

the cylinder. Do not damage or cut the cylinder gasket.

2. Clean out the inside of the cylinder (with alcohol if necessary), being careful not to damage the leafs on the inside of the cylinder. Verify the inside of the cylinder is clean and free of scratches that would cause air leaks around the kapseal. Inspect the cylinder for smoothness.

Piston guide replacement

1. Remove and discard the set screws from the piston angle brackets. Remove the piston guides.
2. Use an X-ACTO knife (or equivalent) to clean the Loctite residue out of the piston angle brackets.

3. Remove and discard the plastic piston guides. Clean any silicone adhesive from the steel piston guides and clean the guides with alcohol.

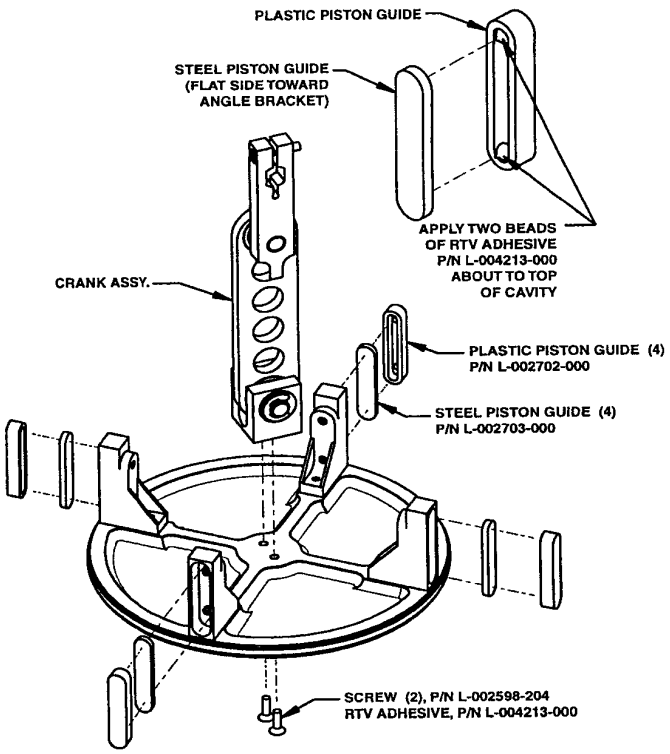

FIGURE 4-1.

4. Apply 2 beads of RTV adhesive (*GE Translucent 108*, P/N L-004213-000) into each of 4 new plastic piston guides (P/N L-002702-000). See Figure 4-1. Fasten the plastic piston guides to the steel guides, making sure no silicone is exposed. Wipe clean if necessary.
5. Insert the piston guides fully into the angle brackets; steel guide before plastic guide.
6. Install 2 new 8-32 x3/8-in set screws (P/N L-002693-307) into each of the piston angle brackets until the screws make contact with the steel piston guides.

Seal ring installation

1. Inspect the new seal ring (P/N L-002709-000) and verify it is not damaged. See Figure 4-2.
2. Install the seal ring into the piston groove and verify it is not twisted.

Kapseal installation

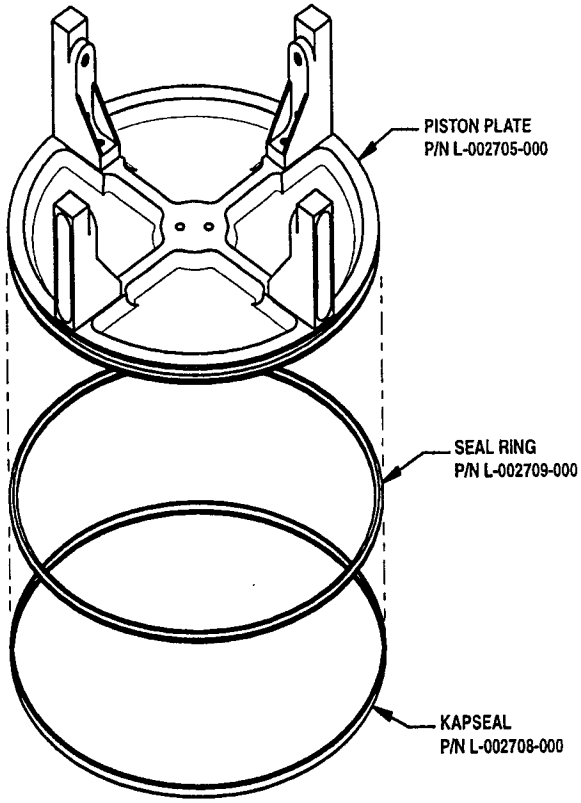

FIGURE 4-2.

The following illustrations depict both improper and proper seating of the kapseal on the seal ring of the piston. See Figure 4-3. It is a cutaway view shown from the side of the seal ring as the kapseal is placed onto it.

NOT SEATED SEATED

FIGURE 4-3.

1. Inspect the new kapseal (P/N L-002708-000) and verify it is free of creases, nicks, scratches, or any other damage.
2. Slip the kapseal gently over the piston plate, being careful not to stretch the kapseal. Use a Delrin screwdriver to carefully work the kapseal over the piston plate and the entire seal ring. See Figure 4-3.
3. Verify the flanges at the edges of the kapseal are seated between the seal ring and the flange of the piston plate.
4. Verify the seal ring is not twisted by running a finger around the kapseal, checking for bumps or gaps. Verify the kapseal is properly installed.

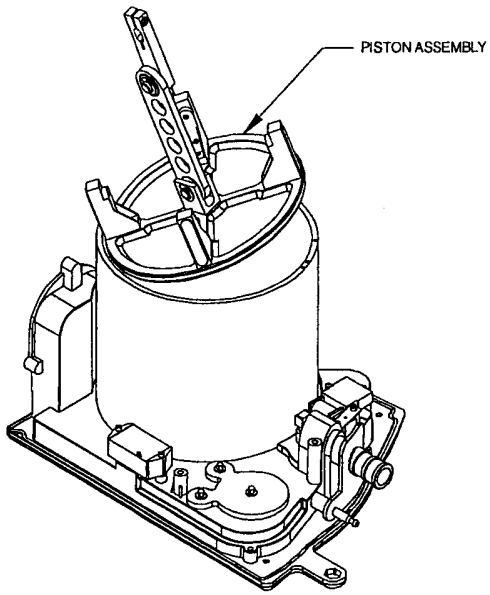

FIGURE 4-4.

Right end test set-up

1. Use the high pressure relief (HPR) adjustment tool to tighten the high pressure relief by turning it one complete revolution clockwise.

Cautions

Do not tighten the HPR screw completely. Damage to the HPR valve may occur.

When moving the piston up and down in the cylinder by hand, the patient air port must not be connected to the right end tester. Excessive pressure could result in damage to the pressure transducers.

All wires and connectors on the right end assembly are fragile at this stage of assembly. Unnecessary pinching or bending of wires may cause damage.

2. Position the right end assembly on its right end panel with the motor/gearbox mounting holes on the cylinder away from you. See Figure 4-4. Place the right end tester on either side of the right end assembly.
3. Orient the piston assembly so the crankarm is away from you and movement of the connecting rod is aligned with 2 sets of motor mounting holes.

4. Dip 1 edge of the piston assembly down into the cylinder. Press the piston against the cylinder wall so that the kapseal will not catch on the cylinder as you gently ease the remainder of the piston into the cylinder. Avoid wrinkling or twisting of the kapseal upon insertion. Push the piston into the cylinder.
5. Connect the PATIENT port connector tube of the right end tester to the patient air port and the patient pressure port on the right end assembly.
6. Seal the exhalation valve port on the right end assembly.

For Achieva PSO_2,

1. Connect the BLENDER valve connector tube to the O_2 inlet port on the right end assembly.
2. Connect the Blender/PEEP valve connector to the right end tester valve interface cable (note polarity and keying of the connector).

For Achieva PS and Base Achieva

1. Use a 7/64th-in hex driver to remove the 2 screws that secure the blender filler block to the manifold.
2. Secure the blender adaptor to the manifold.
3. Connect the blender valve connector tube of the right end tester to the blender adaptor.

4. Connect the PEEP valve connector to the right end tester valve interface cable (note polarity and keying of the connector).

Leak test

1. Connect the Right End tester to AC power. Turn on the power switch.
2. Turn selector knob to LEAK TEST.
3. Press and hold the PRESSURE CONTROL button until the TEST PRESSURE meter reads greater than 80 cmH_2O.

Note

If the meter needle does not rise when the PRESSURE CONTROL button is pressed, 1 or more of the valves in the cylinder may be leaking. A momentary pull on the piston usually results in the proper seating of the valve, and the test can continue. If the problem is not corrected, check all connections and try again.

4. Release the button and verify the time it takes for the needle to drop from 80 to 60 is more than 3 seconds. (Operator may estimate the time. If questionable, use a calibrated stopwatch.)
5. Turn the selector knob to PEEP VALVE, once the pressure drops below 60, and verify the meter needle drops more quickly (which means the PEEP valve is functioning properly).
6. Disconnect the right end tester's patient port connector tube from the ventilator's patient air port.

Piston set test

1. Position the piston in the cylinder, so tops of all 4 piston angle brackets are even with the top of the cylinder.
2. Adjust the piston guide BOTTOM set screws as follows:

    - Turn the bottom set screw on one bracket until the plastic piston guide touches the cylinder wall. Repeat for all brackets in a cross pattern, making sure that the tops of all 4 brack-

ets are even with the top of the cylinder and that the piston remains centered within the cylinder.

3. Adjust the piston guide TOP set screws as follows:
   - Follow the same order as was used in setting the bottom set screws. Turn the TOP set screw on the first bracket until it contacts (applying very little pressure to) the piston guide. Repeat for all 4 brackets in a cross pattern, making sure the tops of all 4 brackets are even with the top of the cylinder, and the piston remains centered within the cylinder. Recheck the bottom set screws, and remove any slack that may have resulted during the TOP set screw adjustments.

4. When readjusting the piston set screws, be sure to use a cross pattern to ensure centering of the cylinder. Adjust the TOP set screws on all 4 brackets first. Verify the BOTTOM set screws on all 4 brackets are snug, but not overly tight.
5. Push the piston into the cylinder until it is approximately 1-in from the bottom.
6. Connect the right end tester's patient port connector tube to the ventilator's patient air port.
7. Turn the selector knob to PISTON SET.
8. Press and hold the PRESSURE CONTROL button.
9. Verify the TEST PRESSURE meter needle remains in the 22 to 27 cmH_2O range. Hold the button down until the tops of the piston angle brackets are approximately even with the top of the cylinder.
10. If the tops of the piston angle brackets are within 1/32-in (.794 mm) from the top of the cylinder, and the meter needle remains in the range of 22 to 27 cmH_2O, then the brackets are adjusted correctly. Proceed to step 1, *Right end test completion*.
11. If the piston angle brackets are not adjusted correctly, adjust the set screws as follows:

CASE 1

Needle is in the correct range, and one or more brackets are too high, and one or more brackets are too low.

- On the high bracket, loosen the TOP set screw slightly. Verify that the BOTTOM set screw is still snug but not overly tight.
- On the low bracket, tighten the TOP set screw slightly. Verify that the BOTTOM set screw is still snug but not overly tight.

CASE 2

Needle is below 22 cmH_2O, and the tops of all angle brackets are even.

- Tighten all TOP set screws slightly. Verify the BOTTOM set screws are snug but not overly tight.

CASE 3

Needle is above 27 cmH_2O, and the tops of all angle brackets are even.

- Loosen all TOP set screws slightly. Verify the BOTTOM set screws are snug but not overly tight.

12. After the proper adjustments have been made, recheck the piston pressure as described in steps 7 to 12.

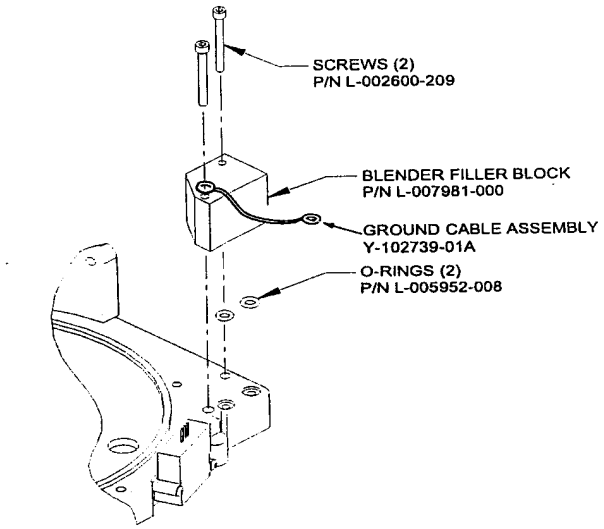

FIGURE 4-5.

Right end test completion

1. Turn off the right end tester. Disconnect all pneumatic tubing and the valve interface cable from the right end assembly.

for Achieva PS, and Base

1. Remove the blender adaptor from the manifold.
2. Install and seat each of 2 O-rings (P/N L-005952-008) into 2 manifold ports. See Figure 4-5., *Right End/Manifold Repairs*.
3. Orient and install the blender filler block (P/N L-007981-000) onto the manifold. See Figure 4-5., *Right End/Manifold Repairs*.
4. Insert 1 screw (P/N L-002600-209) 6-32 x 1 1/4-in (31.75 mm) through the ground cable

assembly (P/N Y-102739-01A) and blender filler block as shown in Figure 4-5. Insert another screw same size, into the other filler block hole. Secure the blender filler block to the manifold, using a Milwaukee battery-powered screwdriver set at “2” (or equivalent) with a 7/64-in hex bit to install screws until the screw heads just make contact with the blender filler block. Alternately tighten each screw with a torque driver set at 8 in-lbs (.904 N-m) with a 7/64-in hex bit.

Motor and piston assembly

1. Apply Loctite 242 (P/N L-002688-000) on all 8 piston angle bracket set screws, allowing Loctite to flow into threads.
2. Position the right end assembly on the right end plate with motor/gearbox mounting holes on the cylinder away from you.
3. Push the piston approximately halfway into the cylinder.

Caution

Be careful not to damage wires or EOT sensor when handling the motor/gearbox.

4. Apply Loctite Primer N7649 (P/N L-002697-000) to the shaft hole in the crank arm and allow it to dry for a minute or two.
5. Apply a drop of Loctite 648 adhesive (P/N L002696-000) on each of the two flats on the gearbox output shaft.
6. Slide the output shaft into the crankarm until it is flush with the underside of the crankarm. Rest the motor/gearbox assembly on the left side of the cylinder so the right side of the crankarm faces up.
7. Apply a drop of Loctite 242 adhesive (P/N L-002688-000) on the crankarm Nylok patch screw (P/N L-002600-305) 8-32 x 5/8-in (15.88 mm). Install the screw with the bottom of the output shaft flush with the underside of the crankarm. Torque the screw using a torque driver set at 35 in-lbs (3.96 N-m) with a 9/64-in hex bit. Verify output shaft is still flush

with crankarm. Wipe off any excess adhesive.

8. Hold the wires out of the way and push the piston into the cylinder. Align and insert the motor/gearbox dowel pins into the cylinder mounting holes.
9. Start 4, 6-32 x 1/2-in (12.7 mm) Nylok patch screws (P/N L-002600-204) to secure the motor/gearbox to the cylinder. Torque screws in a cross pattern, using a torque driver set at 22 in-lbs (2.49 N-m) with a 7/64-in hex bit.
10. Verify the following:
    - The motor wires are not damaged or pinched.
    - The rotor is able to turn and the piston glides tightly and smoothly.

Battery replacement

Equipment required

- 3/32-in hex driver
- Makita battery-powered torque driver (or equivalent)
- Milwaukee battery-powered screwdriver (or equivalent)

Inspect each part for damage before use.

Clean assembly as needed throughout the process.

Power drivers may be used to remove screws.

Battery removal

1. Use a 3/32-in hex driver to remove the 4 screws that secure the battery support bracket.

Be careful not to short out the battery connectors at either end of the battery.

2. Disconnect the wires and the jumper wire from the internal battery terminals.
3. Slide the battery and bracket out far enough to remove the battery without shorting the terminals. Remove the battery.
4. Dispose of the battery properly, in accordance with local disposal regulations.
5. Replace the battery pad (P/N L-007763-000) as needed.

Battery installation

1. Write the serial number of the unit into which the battery will be installed, and the date of

installation, on the surface of the new battery (P/N L-007762-000).

Warning

The gearbox may cycle when the battery is connected.

2. Insert the battery into the support bracket (P/N L-007741-000) carefully. Connect the wires to the terminals, attaching the red wire to the positive (“+”) terminal.
3. Slide the battery and bracket back into place and verify that the battery pad is in place under the battery.
4. Use a Milwaukee screwdriver set at 4 (or equivalent) with a 3/32-in hex bit to secure the battery bracket. Use 4, 8-32 x 3/8-in (9.525 mm) screws (P/N L-004090-304) to secure the battery bracket to the bottom plate.

Front panel replacement

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- 5/64-in hex driver
- 5/16-in nut driver
- 5/16-in socket and adapter
- Milwaukee battery-powered screwdriver (or equivalent)
- Small flat-blade screwdriver
- Torque driver, 5 in-lbs (.565 N-m)

Caution

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and the top cover. Finger prints will damage the coating.

Notes

Perform only the steps needed for the repair.

Inspect each part for damage before use.

Clean the assembly as needed throughout the process.

Power drivers may be used to remove screws and spacers.

Front panel disassembly

1. Remove circuit boards according to the section, *Front panel circuit boards replacement*.

2. Remove the patient pressure meter according to the section, *Front panel meter replacement*.
3. Use a 5/16-in nut driver to remove the two hex spacers on the front panel that are used to support the power circuit assembly.
4. Use a 5/64-in hex driver to remove the top extrusion by removing the three screws securing it to the front enclosure. The extrusion should have two EMI gaskets installed.
5. Remove the door by sliding the right side hinge pin out of the hole in the front panel and removing the door at an angle.
6. Disassemble the door hinge assemblies by using a needlenose pliers to remove the two crescent retaining rings.

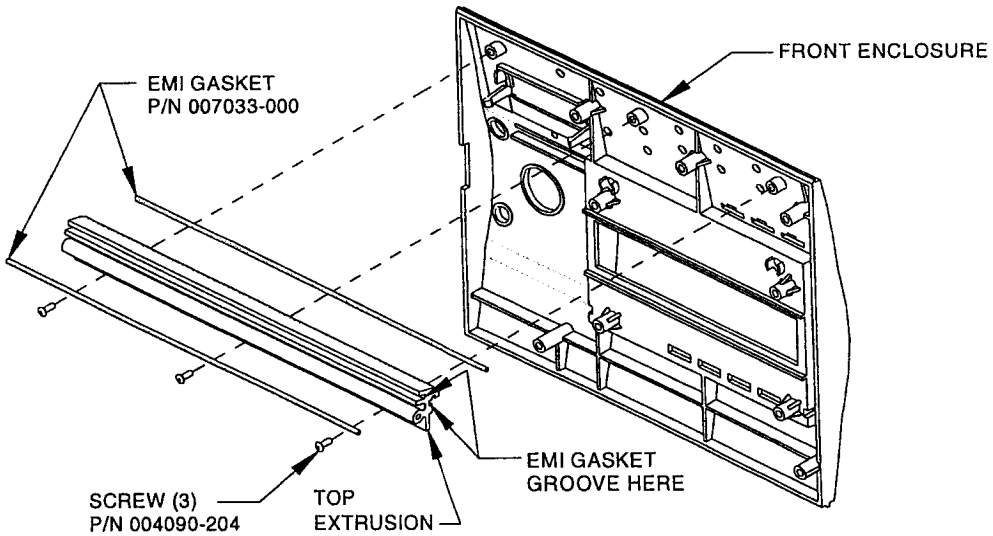

FIGURE 4-6.

Front panel assembly

Note

A damaged section of EMI gasket can be removed and replaced without replacing the whole gasket. If a section is replaced, verify that any gaps are no larger than 1/4-in (6.35 mm) between any gasket sections. Do not stretch the gasket.

1. Verify the top extrusion has both EMI gaskets in place. See Figure 4-6. Replace if needed. Use a Milwaukee battery-powered screwdriver set at “4” (or equivalent) with a 5/64-in hex bit to secure the top extrusion to the front enclosure with three screws, 6-32 x 3/8 in (9.525 mm).
2. Verify the top extrusion still has both EMI gaskets in place.
3. Attach the front membrane switch overlay and LCD membrane switch overlay as follows:
   - Remove the protective film, if present, from the rear side of the meter window and the LCD window.

Warning

Removal of either overlay from the front panel will damage the EMI coating of the front panel. Replacement of the front panel is required if either overlay is replaced.

- Clean the windows on the rear sides of the overlays with anti-static spray (P/N 002667-000). Verify the windows are clean and all moisture has been removed.

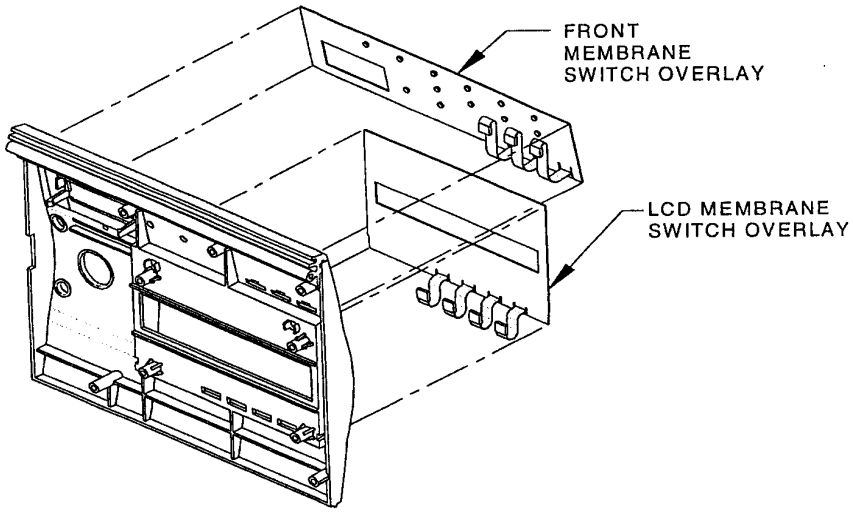

FIGURE 4-7.

- Orient the overlays and feed the flex cables through the appropriate slots in the front panel. See Figure 4-7.
- On the back of the overlays, verify that the ground tabs are folded and will make contact with the panel's surface when applied. Peel the backing off of the adhesive of the overlays and carefully apply the overlays to the front panel.
- Carefully smooth out the overlays by hand. Do not use any tools that may damage the LEDs or membrane switches.

4. Orient the top of the door label towards the location for the hinge pins. Remove the backing from the adhesive and apply the overlay to the inside of the door.
5. Install two hinge pins (P/N L-007102-000), two crescent retaining rings (P/N L-007101-001), and a compression spring (P/N L-007294-000) into the door holes. See Figure 4-8.

Observe care when installing retaining clips.

Warning

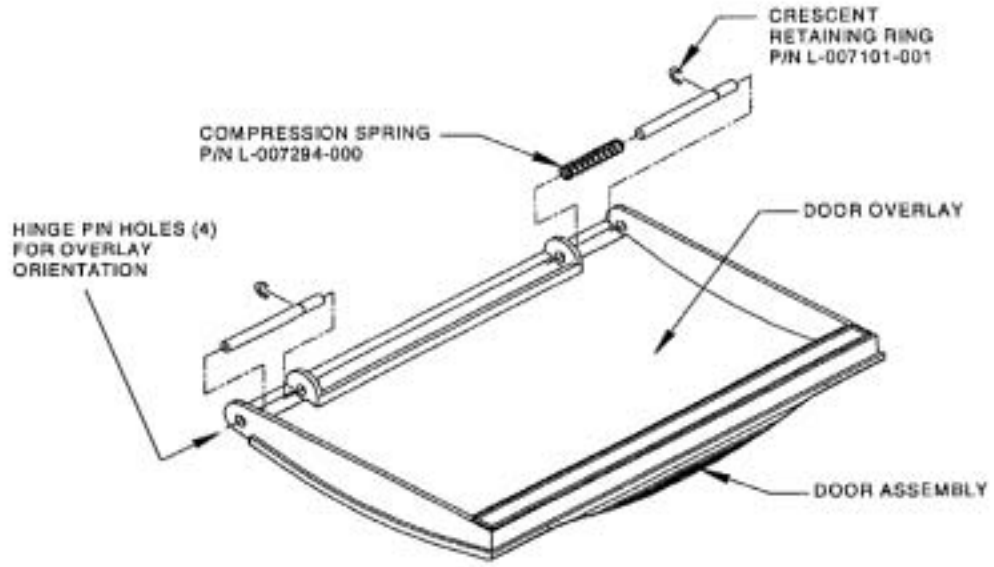

FIGURE 4-8.

6. Insert the left side door hinge pin into the corresponding hole on the front panel. Compress the right side door hinge pin, while positioning the door into place, and release the pin into the corresponding hole on the front panel.
7. Install the patient pressure meter according to the *Front panel meter replacement* process.
8. Install logic circuit assembly according to the *Front panel circuit boards replacement* process, steps 2-8 of the *Logic circuit assembly installation* section.
9. Use a torque driver set at 5 in-lbs with a 5/16-in socket with adapter to install 2, 6-32 x 1/2-in hex spacers (P/N L-002009-505) into the designated locations on the front enclosure that are used to support the power circuit assembly.
10. Install the power circuit assembly according to the *Front panel circuit boards replacement* process

and the *Power circuit assembly installation* section.

11. Install the modem circuit assembly, if applicable, according to the *Front panel replacement* process, *Modem circuit assembly installation* section.

Front panel circuit boards replacement

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- 5/64-in hex bit
- 1/4-in nut driver
- 5/16-in socket and adapter
- Small flat-blade screwdriver
- Small Phillips screwdriver
- Milwaukee battery-powered screwdriver (or equivalent)
- Torque driver, 5 in-lbs (.565 N-m)

Caution

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and the top cover. Finger prints will damage the coating.

Notes

Perform only steps needed for repair.

Inspect each part for damage before use.

Clean assembly as needed throughout process.

Power drivers may be used to remove screws and spacers.

Circuit board removal

1. Use a small Phillips screwdriver to remove the 4 screws that secure the modem circuit assembly, if applied.
2. Remove the modem circuit assembly from hex spacers making sure not to damage any connector pins, if applied.
3. Use a 5/64-in hex driver to remove the 4 screws that secure the power circuit assembly.
4. Remove the power circuit assembly from the hex spacers, making sure not to damage any connector pins.

5. Use a 5/16-in nut driver to remove the 2 hex spacers on the logic circuit assembly that secure the power circuit assembly.
6. Disconnect the following from logic circuit assembly:
   - Meter cable assembly from J18.
   - Flex tape connectors P23–P29 from J23–J29.
7. If the logic circuit assembly will not be reinstalled, remove the battery from socket on logic circuit assembly, and install it on a new logic circuit assembly. Install a new battery if it is needed. Discard the old battery in accordance with local disposal regulations.
8. Use a 5/64-in hex driver to remove 5 screws securing logic circuit assembly to front enclosure. Remove logic circuit assembly.
9. If logic circuit assembly will not be reinstalled, remove 4 hex spacers used for mounting modem by using 1/4-in nut driver to remove 4 kep nuts.
10. Use a small Phillips screwdriver to remove 4 screws securing LCD assembly to logic circuit assembly.
11. Remove the LCD assembly from the hex spacers, making sure not to damage any connector pins.

Caution

Be careful not to damage the circuit board components when you remove the LCD assembly hex spacers.

12. If logic circuit assembly will not be reinstalled, remove 4 hex spacers used for mounting LCD assembly by using a 1/4-in nut driver to remove the 4 kep nuts.

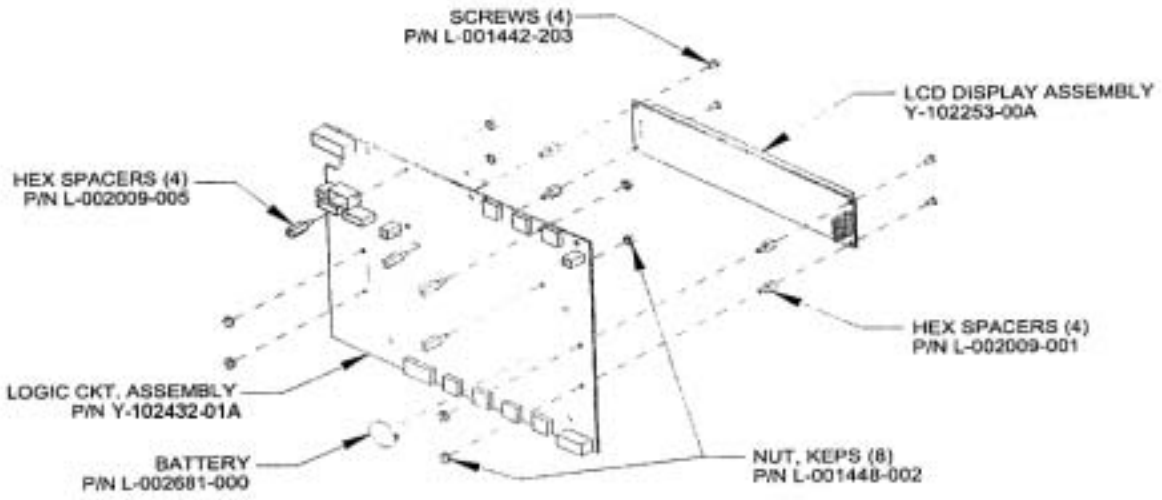

FIGURE 4-9.

LCD assembly installation

1. On the noncomponent side of the Logic Circuit Assembly, P/N Y-102432-01A, insert 4, 4-40 x 1/4-in (6.35 mm) hex spacers (P/N L-002009-001) through the designated holes. See Figure 4-9. Use a 1/4-in nut driver to secure the spacers to the logic circuit assembly from the component side with 4, 4-40 kep nuts (P/N 001448-002). Do not tighten.
2. Set the LCD Display Assembly, P/N Y-102253-00A, onto the spacers, while aligning and inserting connector pins into the logic circuit assembly connectors J22 (16-pin) and J20 (2-pin).

3. Use a small Phillips screwdriver to secure LCD assembly by starting 4, 4-40 x 3/16-in (4.762 mm) screws (P/N L-001442-203). Tighten until snug and hand-tighten the 4 kep nuts on the component side installed in step 1.

Logic circuit assembly installation

1. On the component side of the logic circuit assembly, insert 4, 4-40 x 1/2-in hex spacers (P/N L-002009-005) through designated holes. Use a 1/4-in nut driver to secure the spacers to the logic circuit assembly from the noncomponent side with 4, 4-40 kep nuts (P/N L-001448-002). Tighten until snug.
2. Clean the LCD window on the back of the overlay with anti-static spray (P/N L-002667-000). Verify no moisture or streaks are left on the window.
3. Remove protective film, if present, from the LCD assembly window. Clean the LCD assembly window with anti-static spray. Verify no moisture or streaks are left on window.
4. Connect the flex tape connectors P23–P25 to the logic circuit assembly, J23–J25.
5. Install the logic circuit assembly by aligning the LCD display into the rectangular hole in the front enclosure. Verify no cables are being pinched.

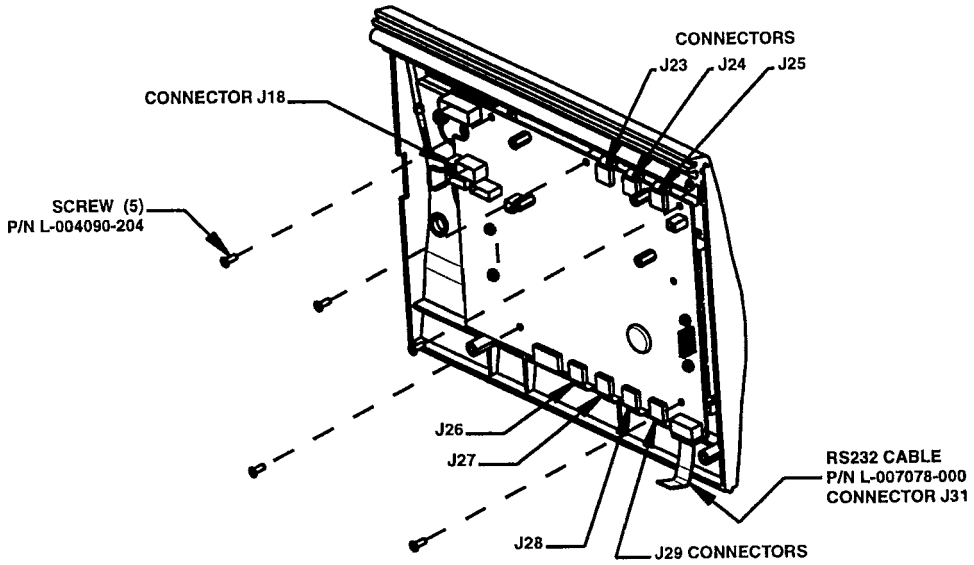

FIGURE 4-10.

6. Secure the logic circuit assembly to the front enclosure by starting 5, 6-32 x 3/8-in (9.525 mm) screws (P/N L-004090-204). See Figure 4-10. Use a Milwaukee screwdriver set at 1 (or equivalent) with a 5/64-in hex bit to tighten screws.
7. Install the battery (P/N L-002681-000), if needed, into the socket provided on the logic circuit assembly, "+" side up. See Figure 4-10.
8. Connect the following to the logic circuit assembly. See Figure 4-10.
    - Meter cable assembly to J18.
    - Flex tape connectors P26–P29 to J26–J29.

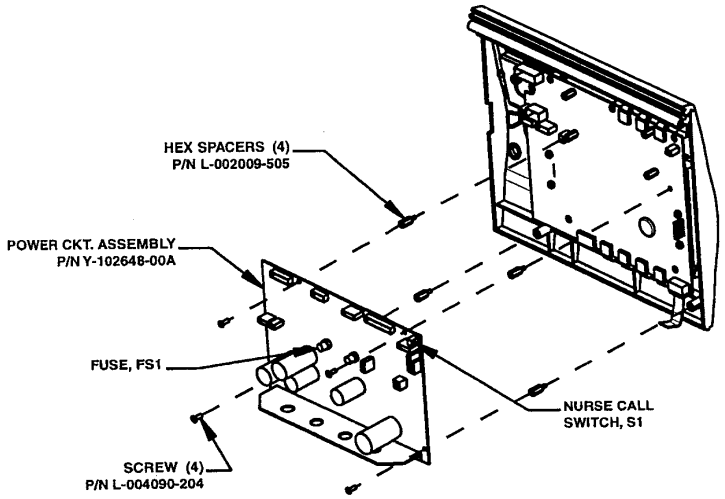

FIGURE 4-11.

Power circuit assembly installation

1. Use a torque driver set at 5 in-lbs with a 5/16-in socket and adapter to install 2, 6-32 x 1/2-in hex spacers (P/N 002009-505) into the designated locations on the logic circuit assembly used to support the power circuit assembly. See Figure 4-11.
2. Install the power circuit assembly (P/N Y-102648-00A) onto the hex spacers, making sure all connector pins insert into the connectors properly.
3. Use a torque driver set at 5 in-lbs with a 5/64-in hex bit to secure the power circuit assembly with 4, 6-32 x 3/8-in (9.525 mm) screws (P/N 004090-204). If the ventilator will be used with the nurse call system, verify that switch S1 on the power circuit assembly is set in proper position for nurse call system being used. See Figure 4-11.

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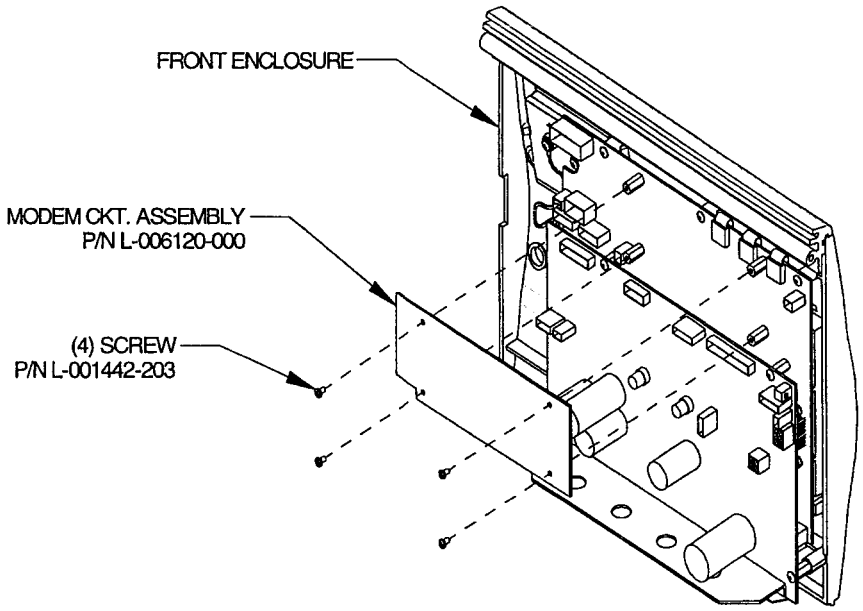

FIGURE 4-12.

Modem circuit assembly installation

If the modem circuit assembly was removed, reinstall it. See Figure 4-12.

Note

1. Install Modem Circuit Assembly (P/N L-006120-000) onto the hex spacers, making sure all connector pins insert into the connectors properly. See Figure 4-12.
2. Use a small Phillips screwdriver to secure the modem circuit assembly by starting 4, 4-40 x 3/16-in (4.762 mm) screws (P/N L-001442-203). Hand-tighten until snug. See Figure 4-12.

Front panel meter replacement

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- Small flat-blade screwdriver
- Scissors

Caution

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and the top cover. Finger prints will damage the coating.

Notes

Perform only steps needed for repair.

Inspect each part for damage before use.

Clean assembly as needed throughout the process.

Meter removal

1. Unplug the meter cable connector from J18 on the logic board.
2. Remove the circuit boards according to the *Front panel circuit boards replacement* process, *Circuit board removal* section, steps 1-8.
3. Use a Phillips screwdriver to remove the two small screws, two washers, and 2 lock washers that secure the meter cable to the meter.
4. Gently spread meter retainer clips and remove meter from front panel.

Meter installation

1. Inspect the meter (P/N L-006797-000) for damage or contamination on the meter face.
2. Use a small screwdriver to verify meter needle can be adjusted at least 1 division above and below -10. Adjust the meter to -10.
3. Clean the meter face with anti-static spray (P/N L-002667-000). Verify no moisture or streaks are on the meter.
4. Apply a piece of foam rubber (P/N 001485-004) cut to size to the bottom of the meter. Figure 4-13.
5. Clean the meter window on the back of overlay with anti-static spray. Verify no moisture or streaks are on the window.

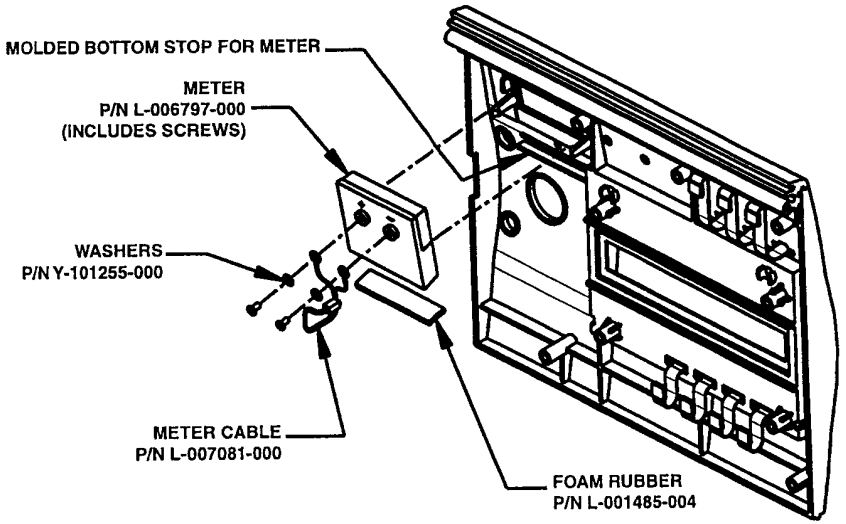

FIGURE 4-13.

6. Set foam rubber along bottom of meter against molded bottom stop in front panel. Snap the meter into place.

7. Inspect meter cable (P/N L-007081-000) for damage. Verify wires are properly crimped.
8. Use two small screws, two washers, and two star washers from old meter to secure red wire to the “+” connection on the meter and black wire to “-” connection on meter. Use a Phillips screwdriver to tighten until snug.
9. Install the circuit boards according to the *Front panel crcuit boards* process, circuit assembly sections.

Gearbox replacement

Equipment required

- Torque driver set at 22 in-lbs (2.48 N-m)
- Torque driver set at 35 in-lbs (3.96 N-m)
- 9/64-in hex bit
- 9/64-in hex driver
- 7/64-in hex driver
- 7/64-in hex bit

Perform only those steps that are needed for the repair.

Notes

Inspect each part for damage before use.

Clean assembly as needed throughout process. Loose kapseal debris may be removed, but do not scrape kapseal's Teflon off cylinder wall unless the kapseal is being replaced.

Power drivers may be used to remove screws.

Gearbox removal

1. Set the right end assembly on the right end plate.
2. Push the piston all the way down into the cylinder.
3. Use 9/64-in hex driver to remove the screw that secures the crankarm to the output shaft.
4. Use a 7/64-in hex driver to remove the 4 screws that secure the motor/gearbox assembly to the cylinder.

Be careful not to damage wires or EOT sensor when handling the motor/gearbox.

Caution

5. Pull up on motor/gearbox assembly until the dowel pins are clear of the cylinder. Remove it from the crankarm.

Gearbox installation

1. Position the right end assembly on the right end plate with motor/gearbox mounting holes on the cylinder away from you.
2. Push the piston assembly approximately half way into cylinder.

Caution

Be careful not to damage wires or EOT sensor when handling the motor/gearbox.

3. Apply Loctite Primer N7649 (P/N L-002697-000) to the shaft hole in the crankarm, and allow it to dry for a minute or two.
4. Apply a drop of Loctite 648 adhesive (P/N L-002696-000) on each of the two flats on the gearbox output shaft.
5. Slide the output shaft into the crankarm until it is flush with the underside of the crankarm. Rest motor/gearbox assembly on left side of cylinder so the right side of crankarm faces up.
6. Apply a drop of Loctite 242 adhesive (P/N L-002688-000) on the crankarm 8-32 x 5/8-in (15.875 mm) Nylok patch screw (P/N L-002600-305). Install the screw with the output shaft flush to the underside of the crankarm. Torque screw using torque driver set at 35 in-lbs (3.96 N-m) and 9/64-in hex bit. Verify output shaft is still flush with crankarm. Wipe off any excess adhesive.
7. Hold wires out of the way and push the piston into the cylinder. Align and insert motor/gearbox dowel pins into the cylinder mounting holes.
8. Secure the motor/gearbox to the cylinder with 4, 6-32 x 1/2-in (12.7 mm) screws (P/N L-002600-204). Torque the screws in a cross pattern, using a torque driver set at 22 in-lb. (2.49 N-m) with a 7/64-in hex bit.

9. Verify the following:

    - The motor wires are not damaged or pinched.
    - The rotor is able to turn, and the piston glides tightly and smoothly.

Left end plate repairs

Equipment required

- Side cutters
- Delrin screwdriver (P/N L-003075-000)
- Small wire brush

Perform only steps needed for repair.

Notes

Inspect each part for damage before use.

Clean assembly as needed throughout process.

Alarm removal

1. From the inside of the left end plate, unscrew the alarm (counterclockwise) from the end plate.
2. If the alarm will be reused, verify it is not damaged. Use a small wire brush to clean Loctite from alarm threads.
3. Clean Loctite from alarm hole threads if the end plate will be reused.

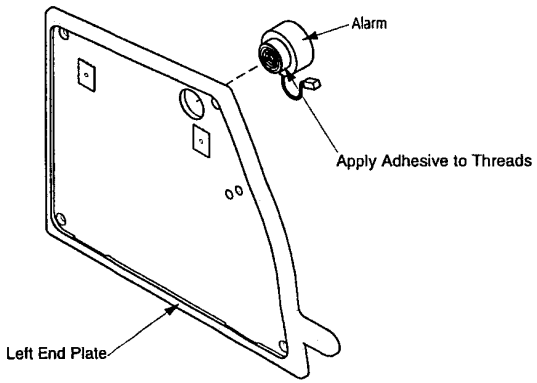

FIGURE 4-14.

Applying the Nurse Call Label

1. Apply the nurse/call alarm label (P/N Y-102707-00A) onto the outside of the left end plate so that the holes in the label are aligned with the holes in the end plate.

EMI gasket installation

Note

A damaged section of EMI gasket can be removed and replaced without replacing the whole gasket. If a section is replaced, verify that no gap is larger than 1/4-in (6.35 mm) between any gasket sections.

1. Install EMI Gasket (P/N L-007033-000) into the groove around outer edge of the inside of the left end plate. Do not stretch the gasket.
2. Cut the gasket so that the two ends meet.

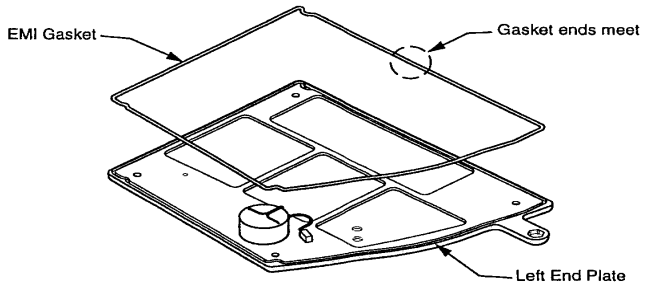

FIGURE 4-15.

Alarm installation

1. Remove and discard the mounting nut, if present, from the alarm (P/N L-006170-001).
2. Apply a small amount of Loctite 425 (P/N L-004448-000) to threads of alarm.

3. Screw the alarm threads (clockwise) into the inside of the large hole of the end plate until the outer threads of the alarm are flush with the outside surface of the end plate.

Right end/manifold repairs

Equipment required

- X-ACTO knife (or equivalent)
- Phillips bit
- Torque driver, 8 in-lbs (.904 N-m)
- Torque driver, 4 in-lbs (.452 N-m)
- Torque driver, 35 in-lbs (3.96 N-m)
- Torque driver, 22 in-lbs (2.49 N-m)
- Torque driver, 20 in-lbs (2.26 N-m)
- Torque driver, 5 in-lbs (.565 N-m)
- Hex bit, 3/32-in
- Hex bit, 1/16-in
- Hex bit, 9/64-in
- Hex driver, 3/32-in
- Hex driver, 9/64-in
- Hex driver, 7/64-in
- Hex driver, 1/16-in
- Milwaukee battery-powered screwdriver (or equivalent)
- Delrin screwdriver (P/N L-003075-000)
- Small flat-blade screwdriver
- High pressure relief adjustment tool (P/N L-003071-000)
- Alignment pins (5)
- Right end assembly test stand, Model No. Y-101573-01, 115V; and Y-101573-02, 230V
- Low pressure ionized air

Notes

Clean the assembly as needed throughout the process. Loose kapseal debris may be removed, but do not scrape the kapseal's Teflon coating off of the cylinder wall, unless you are replacing the kapseal.

Perform only the steps needed for the repair.

Notes (cont'd)

Inspect each part for damage before use.

Power drivers may be used to remove screws.

Warning

To avoid damage to wires, do not set the right end on the primary transducer.

Right end disassembly

1. Set the right end assembly on the right end plate.
2. *Unique to the Base and PS units,* use a Phillips screwdriver to remove the filler block grounding cable screw from the end plate.
3. Push the piston down all the way into the cylinder.
4. Use a 9/64-in hex driver to remove the screw that secures the crankarm to the output shaft.
5. Use a 7/64-in hex driver to remove the 4 screws that secure the motor/gearbox assembly to the cylinder.

Caution

Be careful not to damage wires or EOT sensor when handling the motor/gearbox.

6. Pull up on the motor/gearbox assembly until the dowel pins are clear of the cylinder. Remove the motor/gearbox from the crankarm. Set the motor/gearbox aside.
7. Remove the piston assembly from the cylinder and set it aside. Be careful not to damage the kapseal. A rubber band may be used to retain the piston guides in the angle brackets.
8. Turn the right end assembly over and place it on the cylinder. Use a 7/64-in hex driver to remove 9 screws that secure the right end plate to the manifold; and remove the 6 screws that secure the right end plate and manifold to the cylinder.

9. Remove the right end plate and manifold gasket. Discard the manifold gasket.
10. Carefully remove the manifold and cylinder gasket from the cylinder. Discard the cylinder gasket.

Manifold disassembly

1. Use a 3/32-in hex driver to remove the 2 screws and retainer bracket securing the PEEP valve to the manifold.
2. Use a 7/64-in hex driver to remove the 2 screws securing the O_2 blender, or the blender filler block, to the manifold.
3. Remove the PEEP valve and the O_2 blender, or the blender filler block, carefully from the manifold. Remove the O-rings.
4. Use a 1/16-in hex driver to remove the 2 screws that secure the O_2 flow sensor, or the flow sensor filler plate, to the manifold. Remove the O-rings.
5. Use a 1/16-in hex driver to remove the 2 screws securing the primary flow sensor to the manifold. Remove the O-rings.
6. Use a 3/32-in hex driver to remove the 2 screws securing the primary pressure transducer to the manifold.
7. Hold the body of the auxiliary pressure transducer and carefully turn the transducer counter-clockwise to remove it from the manifold. Be sure to hold and turn the wire harness, with the flow sensors and the primary pressure transducer, to avoid getting the wires tangled. Set the sensors and transducers aside.
8. Turn the manifold over and use a small screwdriver to remove the retainer ring, internal filter screen, and 3-in diameter O-ring from the manifold.
9. Use the high pressure relief (HPR) adjustment tool (P/N L-003071-000) to remove the HPR adjustment screw. Remove the HPR adjustment spring and HPR valve.
10. Remove the silicone valves, if necessary, by holding onto the valve and pulling the stem out of

the valve body.

11. Remove the outlet gasket.

Silicone valve installation

1. Install silicone valve #1 from the underside of the manifold. See Figure 4-16.
2. Insert the stem into the center hole of the valve body and pull the stem, until the silicone valve is fully seated against the inner ring.
3. Trim the stem flush with the valve body.
4. Install silicone valve #2 from the topside of the manifold. See Figure 4-16.
5. Trim the stem flush with the valve body.
6. Install silicone valve #3 from the inside of the air inlet chamber. See Figure 4-16. A flat metal ruler may be used as a guide to ease installation.
7. Insert the stem into the center hole of the valve body and pull the stem until the silicone valve is fully seated against the inner ring. The valve may need to have the stem trimmed slightly to ease installation.
8. Trim the stem flush with the valve body.

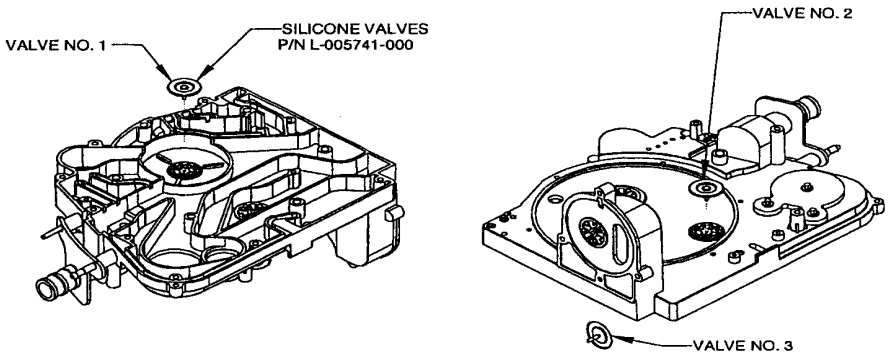

FIGURE 4-16.

Filter screen installation

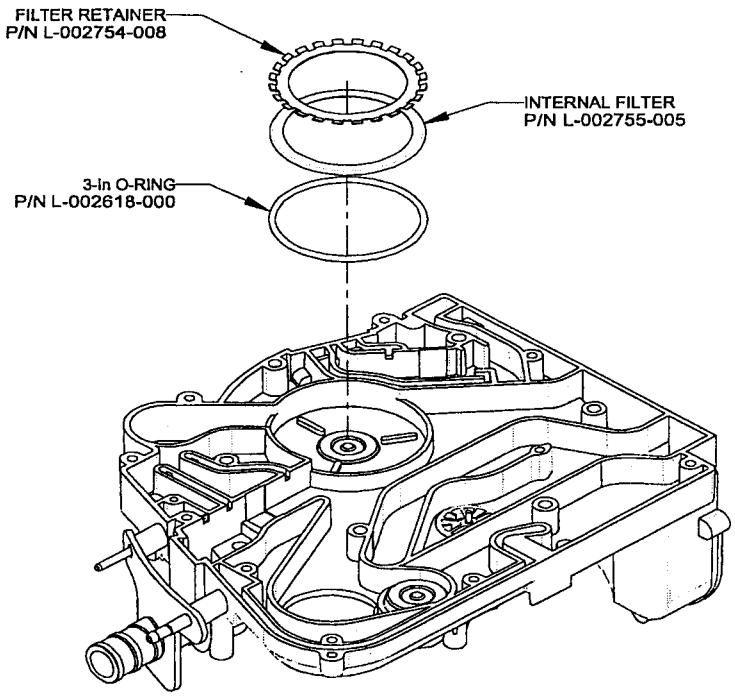

FIGURE 4-17.

1. On the new manifold, install the 3-in O-ring (P/N L-002618-000) and the internal filter screen (P/N L-002755-005). See Figure 4-17.
2. Install the retainer (P/N L-002754-008) with the bent tabs facing up away from the manifold (manifold may be set on the cylinder for support to ease installation of retainer).
3. Press the filter retainer down until it is tight against the internal filter screen. Verify that the tabs are secure.

Auxiliary pressure transducer installation

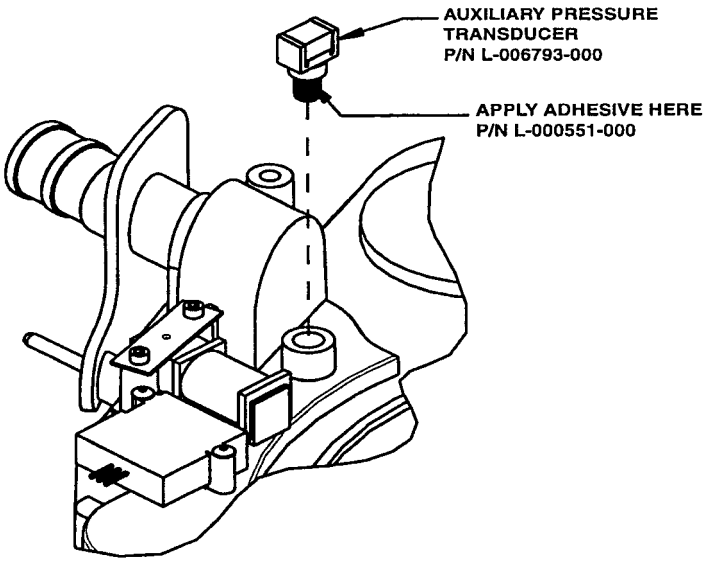

FIGURE 4-18.

1. Clean off the Room Temperature Vulcanizing silicone adhesive (RTV) from the threads of the auxiliary pressure transducer (P/N L-006793-000) and the manifold.
2. Apply a small bead of G.E. White RTV 162 adhesive (P/N L-000551-000) around the shoulder of the shaft of the transducer.
3. Hold the body of the transducer and carefully screw the transducer into place (threaded manifold hole behind the patient air tube). See Figure 4-18. Avoid getting the wires tangled. Hand-tighten until snug.

Primary pressure transducer installation

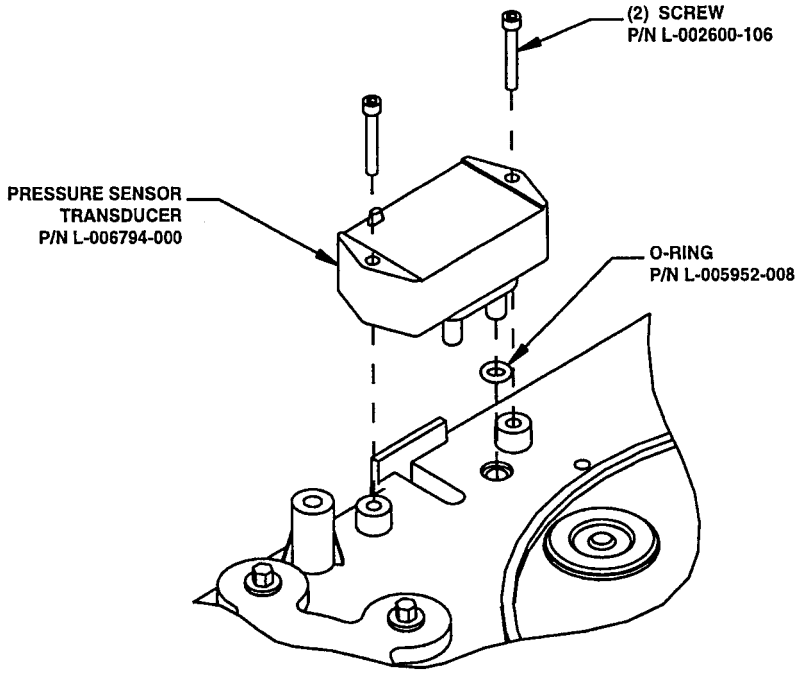

FIGURE 4-19.

1. Remove the O-ring from the primary pressure transducer (P/N L-006794-000), port P2.
2. Install an O-ring (P/N L-005952-008) into the manifold hole in which port P2 of the transducer will be installed. See Figure 4-19.
3. Set the transducer into position with the wires towards the bottom of the manifold. Install the transducer into the port holes provided in the manifold. Be sure the wires are not twisted or tangled with the wires for the other sensors.
4. Secure the transducer by starting 2 screws (P/N L-002600-106), 4-40 x 3/4-in (19.05 mm).

Use a 3/32-in hex driver to install the screws until they just make contact with the transducer. Alternately tighten each screw using a torque driver set at 5 in-lbs (.565 N-m) with a 3/32-in hex bit.

Install flow sensor transducer(s)/filler plate on manifold

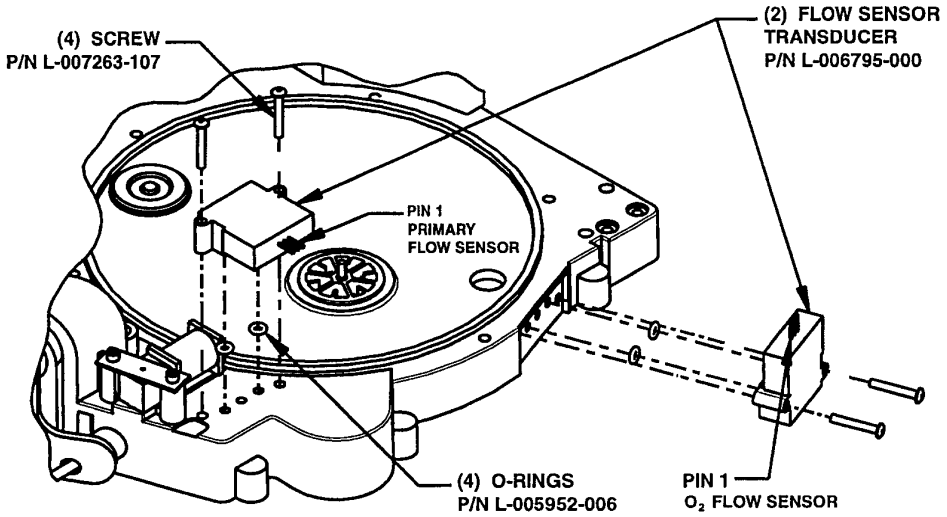

FIGURE 4-20.

For Achieva-PSO_2,

Notes

1. Install each of 4 O-rings (P/N L-005952-006) so that 1 fits into each port of the 2-flow sensor transducers (P/N L-006795-000). See Figure 4-20.
2. Orient and install both flow sensor transducers. See Figure 4-20.
3. Secure each flow sensor transducer with 2 screws (P/N L-007263-107) by applying a small drop of Loctite 242 adhesive (P/N L-002688-000) to the bottom threads of each screw prior to installing. Alternately tighten each screw with a 1/16-in hex driver until the screw head

makes contact with the sensor.

4. Torque each screw with a torque driver set at 4 in-lbs (.452 N-m) and a 1/16-in hex bit.

5. Install the flow sensor cables onto the flow sensors, if necessary. The primary flow sensor cable (P/N L-007819-000) will have a white lead wire that denotes pin . The O_2 flow sensor cable will have either a white lead wire (P/N L-007819-000) or an orange lead wire (cable P/N Y-103010-00A) that denotes pin 1. For matching pin 1 on the flow sensors, see Figure 4-20.

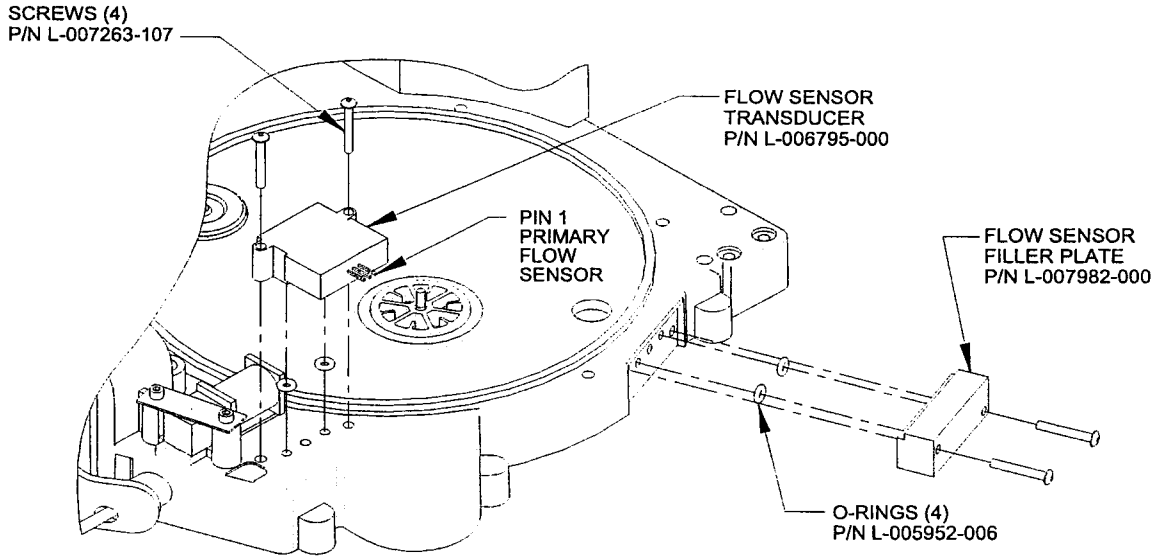

FIGURE 4-21.

For Achieva PS and Base Achieva,

1. Install each of 2 O-rings (P/N L-005952-006) into each port of a flow sensor transducer (P/N L-006795-000).

2. Orient and install the flow sensor transducer near the PEEP valve. See Figure 4-21.

3. Secure the flow sensor transducer with 2 screws (P/N L-007263-107) by applying a small drop of Loctite 242 adhesive (P/N L-002688-000) to the bottom threads of each screw prior to

installation. Alternately tighten each screw with a 1/16-in hex driver until the screw head makes contact with the sensor.

4. Torque each screw with a torque driver set at 4 in-lbs (.452 N-m) and 1/16-in hex bit.
5. Install the flow sensor cable (P/N L-007819-000) onto the flow sensor, if necessary. The white lead wire on the 3-pin connector denotes pin 1. For matching pin 1 on the flow sensor, see Figure 4-21.
6. Install each of 2 O-rings (P/N L-005952-006) in each port of the flow sensor filler plate (P/N L-007982-000), and install the plate. See Figure 4-21.
7. Use 2 screws (P/N L-007263-107) to secure the plate in the same manner as the flow sensor, according to steps 3 and 4 above.

Install oxygen blender/filler block onto manifold

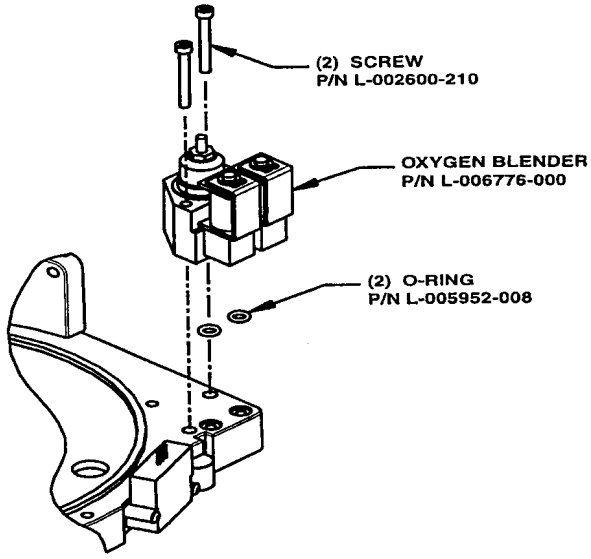

FIGURE 4-22.

For Achieva PSO_2,

1. Install and seat each of 2 O-rings (P/N L-005952-008) into the 2 manifold blender ports. See Figure 4-22.
2. Orient and install the oxygen blender (P/N L-006776-000) onto the manifold. See Figure 4-22.
3. Secure the oxygen blender to the manifold with 2 screws (P/N L-002600-210) 6-32 x 1 1/2-in (38.1 mm). Use a Milwaukee battery-powered screwdriver set at “2” (or equivalent) and a 7/64 -in hex bit to install the screws until the screw heads just make contact with the blender. Alternately tighten each screw with a torque driver set at 8 in-lbs (.904 N-m) with a 7/64-in hex bit.

For Achieva PS and Base Achieva,

1. Install and seat each of 2 O-rings (P/N L-005952-008) into 2 manifold blender ports. See Figure 4-23.
2. Orient and install the blender filler block (P/N L-007981-000) onto the manifold. See Figure 4-23.

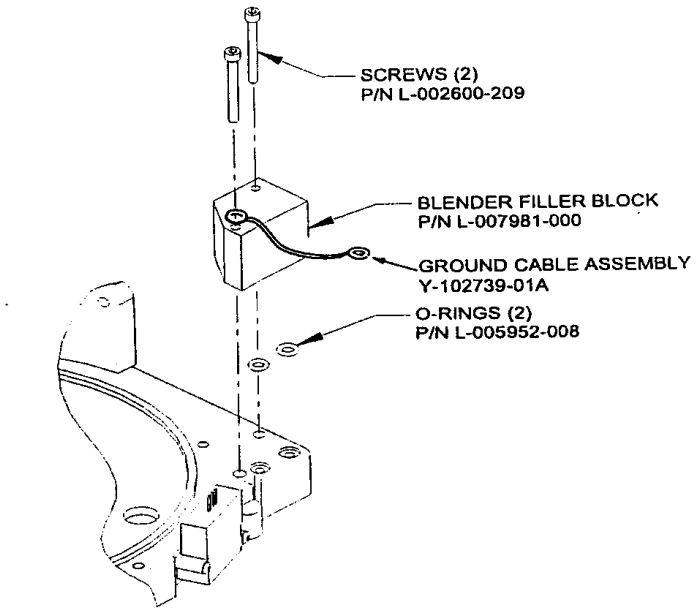

FIGURE 4-23.

3. Insert 1 screw (P/N L-002600-209) 6-32 x 1 1/4-in (31.75mm) through ground cable assembly (P/N Y-102739-01A) and blender filler block as shown in Figre 4.23. Secure the blender filler block to the manifold, using a Milwaukee battery-powered screwdriver set at “2” (or equivalent) with a 7/64-in hex bit to install screws until the screw heads just make contact with the blender filler block. Alternately tighten each screw with a torque driver set at 8 in-lbs (.904 N-m) with a 7/64-in hex bit.

PEEP valve installation

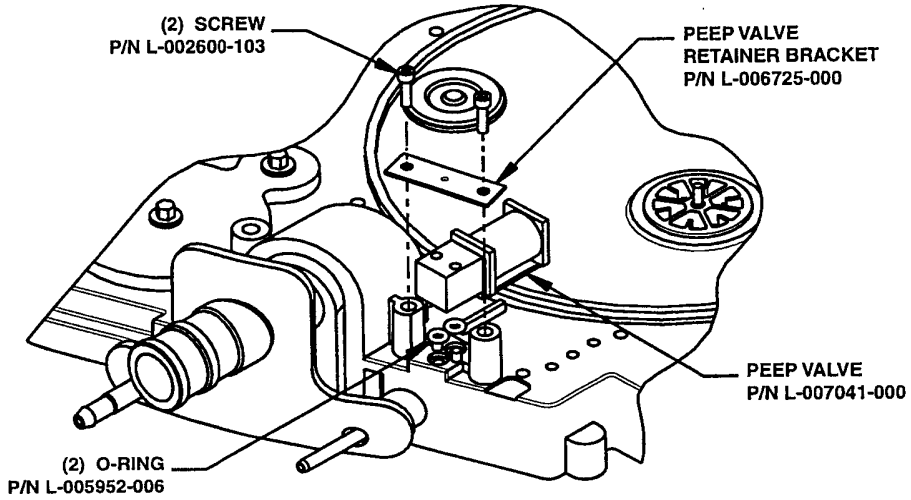

FIGURE 4-24.

1. Install each of 2 O-rings into each corresponding manifold port used for the PEEP valve. See Figure 4-24.
2. Rotate the brass housing on the PEEP valve (P/N L-007041-000), if necessary, so that the side with 2 holes is facing up along with the lead wires.
3. Slide the valve under the wire assemblies of the pressure transducers and flow sensors already installed on the manifold. Be sure the wires are not tangled with the other wire assemblies. Set the valve into position with the 2 countersunk holes positioned over the O-rings and the end with the wires towards the back of the manifold.
4. Secure valve with 2 screws (P/N L-002600-103) 4-40 x 3/8-in (9.525 mm) and a retainer (P/N L-006725-000). The dimple on the retainer must protrude down into the valve housing. Use a 3/32-in hex driver to install the screws until the screw heads make contact with the retainer Use a torque driver set at 5 in-lbs (.565 N-m) to tighten the screws with a 3/32-in hex bit.

Cylinder manifold assembly

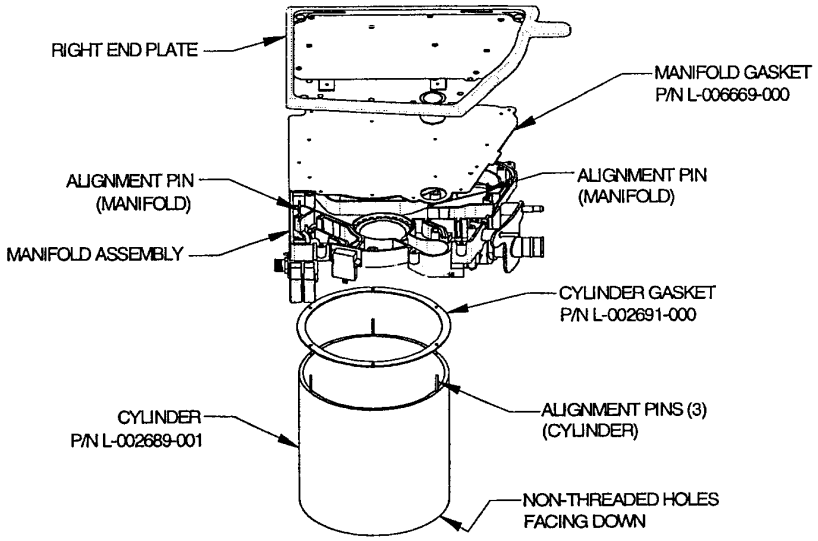

FIGURE 4-25.

1. Set the cylinder on the work surface with the motor/gearbox mounting holes closest to you and facing down.
2. Insert 3 alignment pins in the top of the cylinder, 1 into every other hole. See Figure 4-25.
3. Inspect the new cylinder gasket for damage and cleanliness. Install the gasket over the alignment pins and adjust to fit the cylinder.
4. Install the manifold assembly over the alignment pins and onto the cylinder gasket. Make sure no wires are pinched.
5. Verify the cylinder gasket is properly aligned inside and outside of the cylinder.
6. Insert 2 more alignment pins into the manifold. See Figure 4-25.

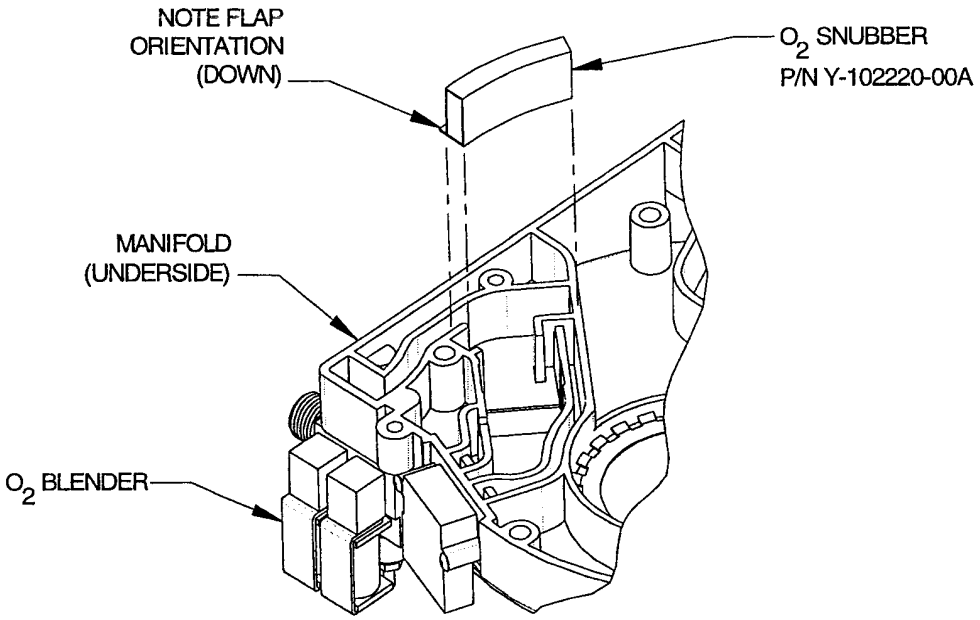

FIGURE 4-26.
For Achieva PSO_2

1. Verify the O_2 snubber is properly in place. See Figure 4-26. Note the flap orientation. The snubber is held in place by friction; *do not* apply any adhesives.

Note

For the Achieva PS and Base Achieva, the O_2 snubber is optional; it serves no purpose.

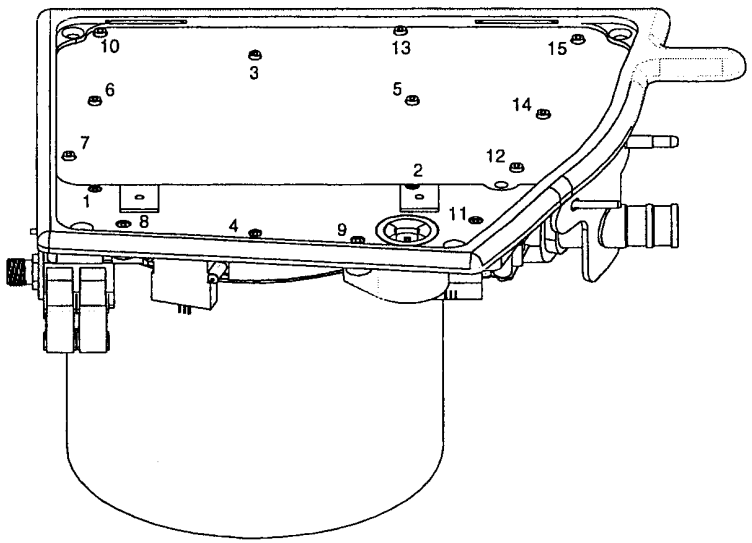

FIGURE 4-27.

1. Inspect a new manifold gasket for damage and cleanliness. Make sure all holes are completely punched out with the gasket material removed.
2. Blow out the manifold thoroughly with low pressure ionized air to remove any dust particles.
3. Install the manifold gasket over the alignment pins onto the manifold.
4. Verify the right end panel is clean of any gasket material from the old manifold gasket. Install the end panel over the alignment pins and onto the manifold gasket.

Note

An electric torque driver may be used to start the cylinder and manifold screws, and to compress the gaskets. The electric torque driver must be set at 20 in-lbs (2.26 N-m) or less.

5. Use a 7/64-in hex driver to start 3 screws (P/N L-002600-209), size 6-32 x 1-in (25.399 mm), 1 into each of the 3 cylinder holes without an alignment pin (cylinder screws are numbered 1-6). See Figure 4-27.

6. Remove the 3 alignment pins from the cylinder and start 3 more screws, 1 into each of the 3 remaining cylinder holes.
7. Remove the remaining 2 alignment pins from the manifold.
8. Use a 7/64-in hex driver to start 9 screws (P/N L-002600-203), 6-32 x 3/8-in (9.525 mm), 1 into each of the 9 manifold holes in the right end panel.
9. Verify the manifold gasket is visible all the way around the outside edge of the manifold.
10. Verify the cylinder gasket is visible all the way around the outside edge and the inside edge of the cylinder.
11. Starting with the cylinder screws, tighten the screws in a cross pattern. Use a torque driver set at 20 in-lbs (2.26 N-m) to tighten the screws with a 7/64-in hex bit. For proper sequence, refer to Figure 4-27.

High pressure relief (HPR) valve installation

1. Install the HPR valve (P/N Y-100323-00A), HPR spring (P/N L-100866-00A), and HPR screw (P/N L-002745-001) in the housing in the right end plate.
2. Tighten the HPR adjustment screw with your fingers, until the nylon rod makes contact with the housing threads.
3. Use the HPR adjustment tool (P/N L-003071-000) to tighten the screw approximately 1 1/2 complete revolutions clockwise. See Figure 4-28.

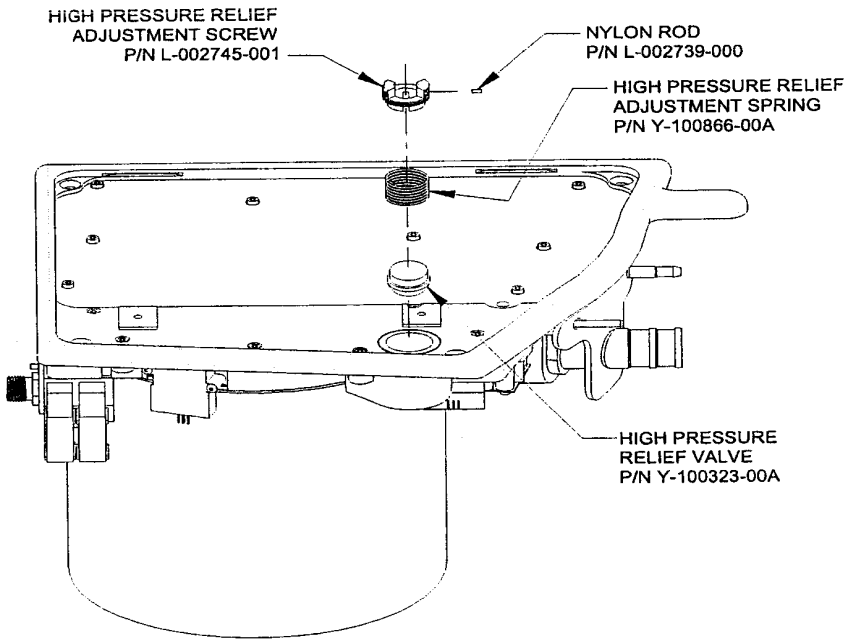

FIGURE 4-28.

Leak/piston set test

1. Perform set-up and leak test sections of Chapter 4, Kapseal replacement.
2. Perform piston set test section of Chapter 4, Kapseal replacement, if kapseal, seal ring, and piston guides were replaced.
3. Perform right end test completion section of Chapter 4, *Kapseal replacement*.
4. Apply Loctite 242 adhesive (P/N L-002688-000) on each piston angle bracket set screw (8), if the kapseal, seal ring, and piston guides were replaced, allowing Loctite to flow onto threads.

Motor/gearbox installation

1. Position the right end assembly on its right end panel with the motor/gearbox mounting holes on the cylinder away from you.
2. Push the piston assembly into the cylinder approximately halfway.

Caution

Be careful not to damage wires or the EOT sensor when handling the motor/gearbox.

3. Apply Loctite Primer N7649 (P/N L-002697-000) to the shaft hole in the crankarm, and allow it to dry for a minute or two.
4. Apply a drop of Loctite 648 adhesive (P/N L-002696-000) on each of the two flats on the gearbox output shaft.
5. Slide the output shaft into the crankarm until it is flush with the underside of the crankarm. Rest motor/gearbox assembly on left side of cylinder so the right side of the crankarm is facing up.
6. Apply a drop of Loctite 242 adhesive (P/N L-002688-000) on the crankarm Nylok patch screw (P/N L-002600-305) 8-32 x 5/8-in (15.88 mm). Install the screw with the bottom of the output shaft flush with the underside of the crankarm. Torque the screw using a torque driver set at 35 in-lbs (3.96 N-m) with a 9/64-in hex bit. Verify output shaft is still flush with the crankarm. Wipe off any excess adhesive.
7. Hold the wires out of the way and push the piston into the cylinder. Align and insert the motor/gearbox dowel pins into the cylinder mounting holes.
8. Start 4, 6-32 x 1/2-in (12.7 mm) Nylok patch screws (P/N L-002600-204) to secure the motor/gearbox to the cylinder. Torque screws in a cross pattern, using a torque driver set at 22 in-lbs (2.49 N-m) with a 7/64-in hex bit.
9. Use an 8 in-lbs Torque driver with a Phillips bit to secure the filler block grounding cable, P/N Y-102739-01A, to the end plate, using a 6-32 x 1/4-in (6.35 mm) Phillips head screw, P/N

L-001439-404.

10. Verify the following:
    - The motor wires are not damaged or pinched.
    - The rotor is able to turn and the piston glides tightly and smoothly.

Wire Routing

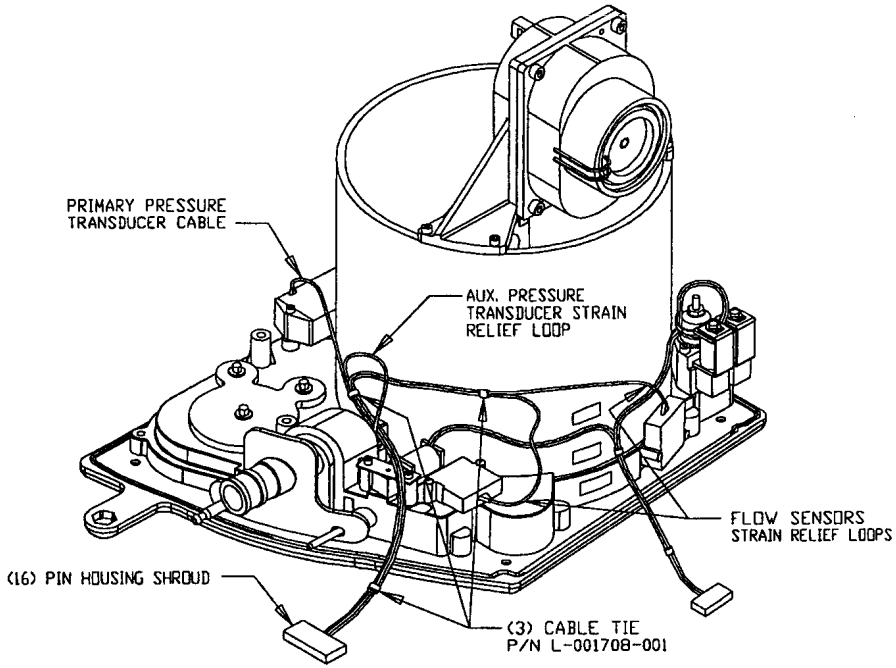

FIGURE 4-29.

Route and secure the wires with cable ties, as shown in Figure 4-29.

Gasket installation

1. Apply an Intake Gasket onto the manifold inlet. See Figure 4-30.

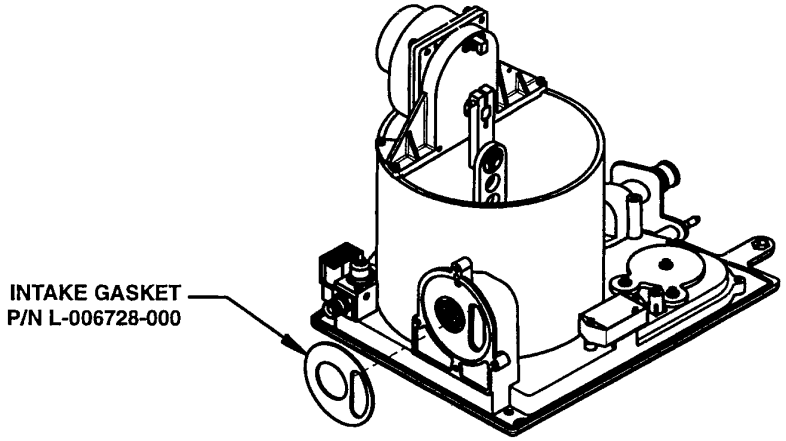

FIGURE 4-30.

2. Install the Outlet Gasket over the Patient Air Port, the Proximal Tube, and the Exhalation Tube. See Figure 4-31.

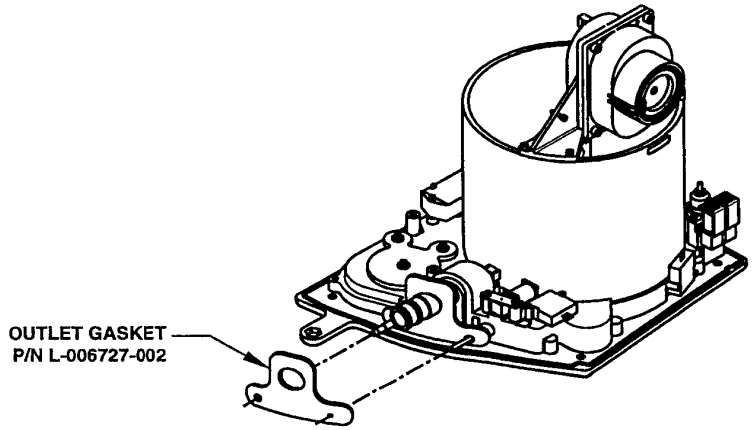

FIGURE 4-31.

Rear panel repairs

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- 1/2-in nut driver
- 1/4-in nut driver
- 11/32-in nut driver
- Small flat-blade screwdriver
- Phillips screwdriver
- 15/16-in deep socket with ratchet
- 1/8-in hex bit
- Makita battery-powered torque driver (or equivalent)
- Milwaukee battery-powered screwdriver (or equivalent)
- Small needle nose pliers
- Pin removal tool
- Pliers
- 5/64-in hex bit
- 15/16-in wrench
- Side cutters
- X-ACTO knife (or equivalent)
- 5/64-in hex driver
- 1/8-in hex driver
- 3/32-in hex driver
- 3/32-in hex bit
- Small Phillips screwdriver
- Phillips bit
- Torque driver, 5 in-lbs (.565 N-m)
- Torque driver, 5.5 in-lbs (0.62 N-m)

- 3/4-in crowfoot
- 1/4-in hex bit to 1/4-in drive bit adapter
- Torque driver, 8 in-lbs (0.904 N-m)
- 1/4-in socket

Perform only those steps that are needed for the repair.

Inspect each part for damage before use.

Clean the assembly as needed throughout the process.

Power drivers may be used to remove screws.

Notes

Rear panel assembly removal

Warning

The bottom plate has sharp edges. Handle with care to avoid injury.

1. Remove and discard the 2 cable ties that secure the cables routed across the battery bracket.
2. Disconnect the wires from the battery terminals.
3. Stand the rear panel and bottom plate assemblies on their right sides.
4. Use a Phillips screwdriver to remove the 4 screws that secure the bottom plate assembly to the rear panel assembly.
5. Disconnect the following:
    - 3-socket, 2-wire connector of the DC connector cable from the 3-pin connector on the power supply.
    - 5-socket, 3-wire AC inlet power connector from the 3-pin (normally 5-pin) connector on the power supply.

AC cord/AC inlet receptacle removal

1. Use a 1/8-in hex driver to remove the 10-32 x 3/8-in (9.525 mm) screw that secures the cable clamp to the rear extrusion.
2. Disconnect the AC power cord from the AC inlet receptacle.
3. Disconnect the AC power internal cable wires from the AC inlet receptacle terminals.
4. Disconnect the terminal lug of the hook-up cable from the ground terminal of the AC inlet receptacle.
5. Use a small Phillips screwdriver to remove the 2 screws that secure the AC inlet receptacle to the rear extrusion.
6. Remove the AC inlet receptacle from the rear extrusion.

Hook-up cable removal

1. Use an 11/32-in nut driver to remove the keps nut that secures the ring terminal of the hook-up cable.
2. Remove the hook-up cable.

DC power cable removal

1. Disassemble the connector of the DC power cable assembly by turning the small screw on the housing counterclockwise with a small screwdriver until the receptacle body and cable assembly slide out of the housing.
2. Use a 15/16-in deep socket with ratchet or wrench to remove the locking nut and the washer from the connector housing. Remove the connector housing from the rear extrusion.

Removal of the shield grounds

1. For units with an internal modem,

- Use a 1/4-in nut driver to remove the keps nut that secures the ring terminal of the internal modem cable to the threaded ground stud of the rear extrusion.

2. Use a 1/4-in nut driver to remove the keps nut that secures the ring terminals of the shield grounds to the threaded ground stud of the rear extrusion.
3. Remove the following from the threaded ground stud:
   - The ring terminal of the shield ground wire from the nurse call cable.
   - An external toothlock washer.
   - The ring terminal of the shield ground wire from the remote alarm cable.
   - A second external toothlock washer.
   - The solder lug from the surge arrestor assembly
   - A third external toothlock washer.

Nurse call cable removal

1. Use a 1/2-in nut driver to remove the locking nut.
2. Remove the metal washer and the insulating washer.
3. Remove the phone jack from the rear extrusion.

Remote alarm cable/RS232 connector removal

1. Use a Hypertronics pin removal tool to remove the pins from the remote alarm connector.
2. Use a pair of pliers to remove the locking nut. Remove the remote alarm connector from the rear extrusion.
3. Use a small Phillips screwdriver to remove 2 screws that secure the RS232 connector to the rear extrusion and remove the cable.

Power cord wrap feet/HSQ vent/modem port cover or internal modem cable

assembly removal

1. Use a 5/64-in hex driver to remove the 3 screws that secure the HSQ vent to the rear extrusion. See Figure 4-32.
2. Use a 1/8-in hex driver to remove the 4 screws that secure the 4 power cord wrap feet to the rear extrusion. See Figure 4-32.
3. Use a 5/64-in hex driver to remove the 2 screws that secure the modem port cover, or internal modem cable assembly and cover, to the rear extrusion. Remove the cover and modem cable assembly, if present.

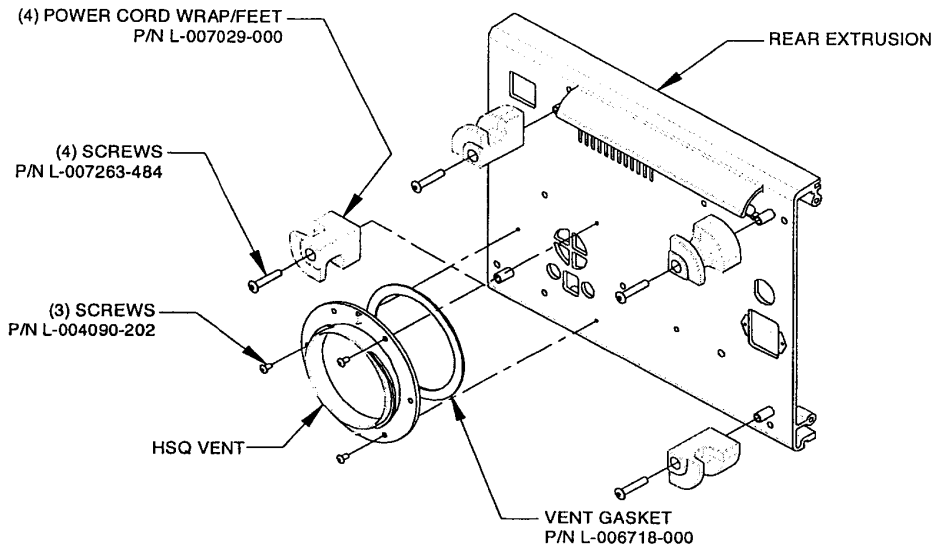

FIGURE 4-32.

Air vent screen removal

Note

Perform screen removal only if the screen needs to be replaced and the rear extrusion is to be reused.

1. Remove the screen from the rear extrusion.
2. Clean away the adhesive (RTV) from the rear extrusion.

Air vent screen installation

1. Apply a small bead of RTV adhesive (GE translucent, 108; P/N L-004213-000) around the edge of the rectangular countersunk area surrounding the air vent slots in the rear extrusion. See Figure 4-33.
2. Install a mesh screen (P/N L-007649-000) into the rectangular countersunk area. Verify the edges of the screen are secured by the RTV adhesive. Remove any excess adhesive. See Figure 4-33.

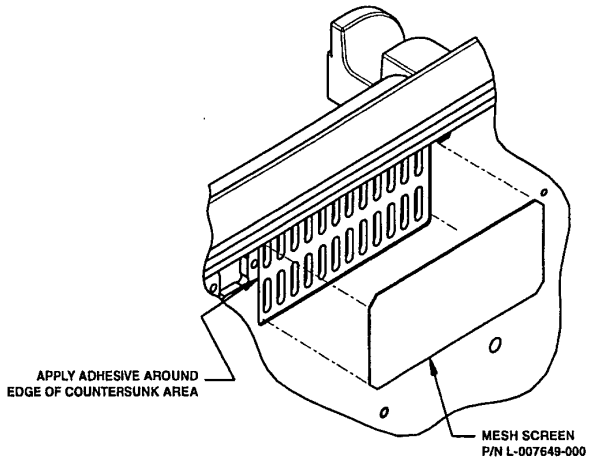

FIGURE 4-33.

Note

Allow the RTV to cure for a minimum of 2 hours before assembling the rear extrusion assembly into the vent assembly.

Power cord wrap feet/HSQ vent installation

1. Use a Makita battery-powered torque driver set at 4 with the speed range set at “L” (or equivalent) with an 1/8-in hex bit to secure the 4 power cord wrap feet (P/N L-007029-000). Secure the cord wrap feet onto the threaded spacers on the rear extrusion with 4, 10-32 x 1-in (25.4 mm) screws (P/N L-007263-484). See Figure 4-32.
2. Remove the backing from the adhesive of a vent gasket (P/N L-006718-000) and adhere the gasket to the recessed groove on the back of the vent housing.
3. Align the holes on the vent housing to the holes on the rear extrusion. Position the tabs on the vent housing at the top and the bottom. See Figure 4-32.
4. Use a torque driver set at 5 in-lbs with a 5/64-in hex bit to secure the HSQ vent to the rear extrusion with 3, 6-32 x 1/4-in (6.35 mm) screws (P/N L-004090-202). See Figure 4-32.

Application of serial number label

1. Apply the serial number label if the the rear extrusion was replaced.

Modem port cover/internal modem cable installation

For Achieva models *without* an internal modem,

1. From inside the rear extrusion, install the modem port cover (P/N L-007641-000) over the modem hole.
2. Secure the cover with 2 screws (P/N L-004090-252). Tighten with a 5 in-lb torque driver and a 5/64-in hex bit.

For Achieva models *with* an internal modem,

1. Install the internal modem cable assembly (P/N L-007076-000) into the modem hole inside the rear extrusion, as shown in Figure 4-34.

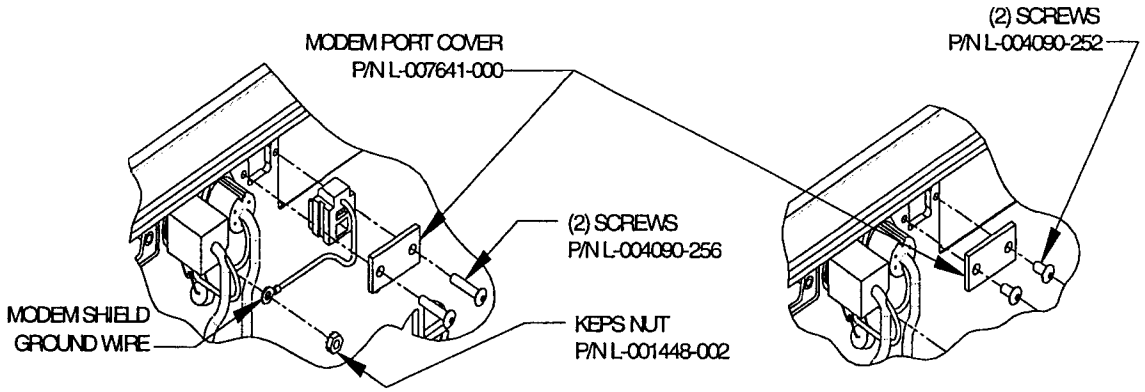

FIGURE 4-34.

2. Place the modem port cover (P/N L-007641-000) onto the modem connector housing.
3. Secure the cover over the modem connector with 2 screws (P/N L-004090-256). Drive the screws into the holes located on the sides of the modem housing and tighten with a 5 in-lb torque drive and a 5/64 -in hex bit.
4. Verify that a phone plug can be inserted easily and removed easily from the modem jack. If necessary, loosen the screws, readjust the modem jack, and retorque the screws until the plug can be inserted and removed easily.

Remote alarm cable/RS232 connector installation

1. Go to step 7 if you are installing a new remote alarm cable. Reinstall the old remote alarm cable according to the following instructions.
2. Remove the locking nut (P/N L-004553-003), if present, from the remote alarm connector. Insert the connector into the remote alarm hole from the outside of the rear extrusion noting orientation of the connector key. See Figure 4-35.

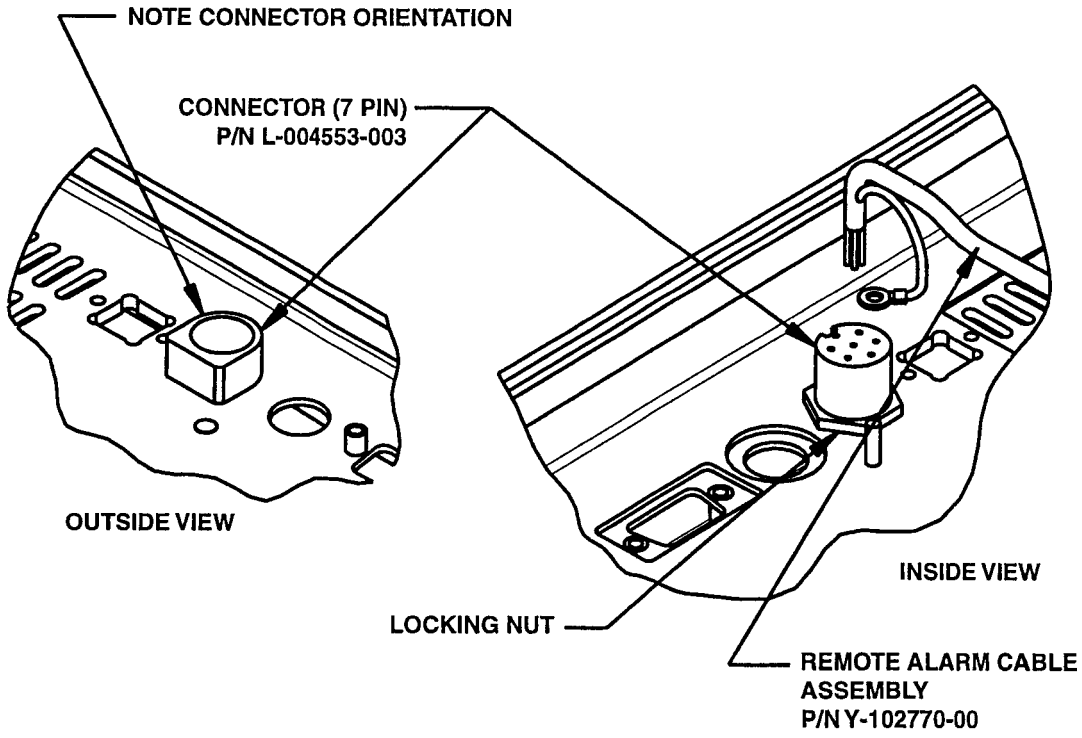

FIGURE 4-35.

3. Apply a drop of adhesive (P/N L-002665-000) to the threads of the remote alarm connector (P/N L-004553-003) towards the rear extrusion. Use pliers to install the locking nut. Do not overtighten the nut. Verify the connector orientation is still correct. See Figure 4-35.

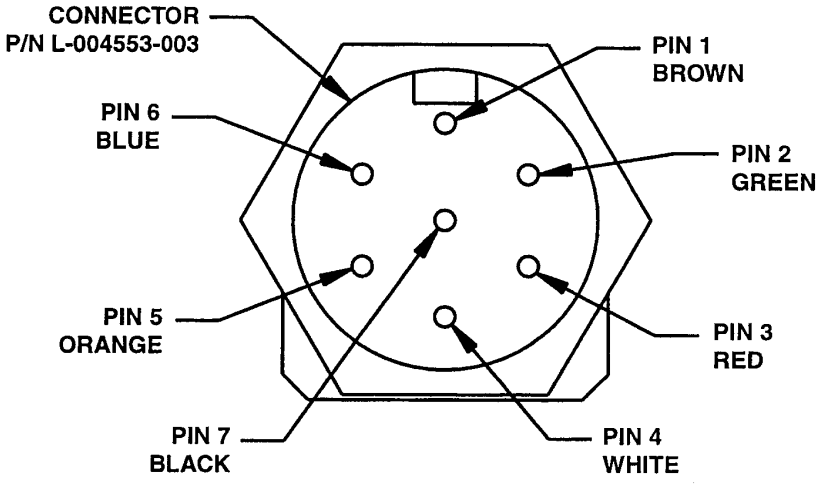

FIGURE 4-36.

4. Inspect the remote alarm cable (P/N Y-102770-00) and verify the wires are secure in the connector pins.
5. Insert the pins into the the remote alarm connector until they lock into place. For proper pin location, see Figure 4-36. This view is from the inside of the unit.
6. Turn the rear extrusion over and verify the pins are fully inserted by viewing the pins from the outside of the remote alarm connector. Go to step 12.
7. Remove the locking nut, if present, from the remote alarm connector.
8. Insert the remote alarm cable into the remote alarm hole from the outside of the rear extrusion, noting the orientation of the connector key. See Figure 4-35.
9. Apply a drop of adhesive, P/N L-002665-000, to the threads of the remote alarm connector

towards the rear extrusion.

10. Slide the locking nut up the remote alarm cable and onto the connector. Torque the locking nut, using a 5.5 in-lb Torque driver with a 3/4 -in crowfoot and 1/4-in hex bit to a 1/4-in drive bit adapter. Verify the connetor's orientation is till correct. See Figure 4-35.

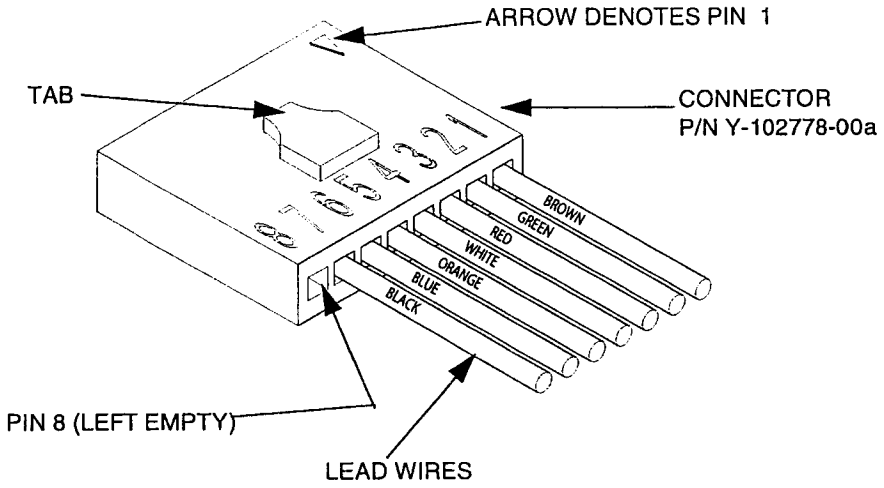

FIGURE 4-37.

Table 1: Connector pin locations

Pin	**Lead Wire Color**
1	Brown
2	Green
3	Red
4	White
5	Orange
6	Blue
7	Black
8	Left Empty

11. Insert the pins into the remote alarm conector, until they lock into place. For proper pin location , see Figure 4-37. The arrow on the connector denotes pin 1.
12. Use a small Phillips screwdriver to secure the RS232 connector to the rear extrusion by hand-tightening 2 screws (P/N L-001442-203).

Nurse call cable installation

1. Remove the locking nut and the washer from the nurse call phone jack, if present. Install the 3/8-in solder lug terminal of the surge arrestor assembly (P/N Y-102249-00A) over the phone jack. See Figure 4-38.

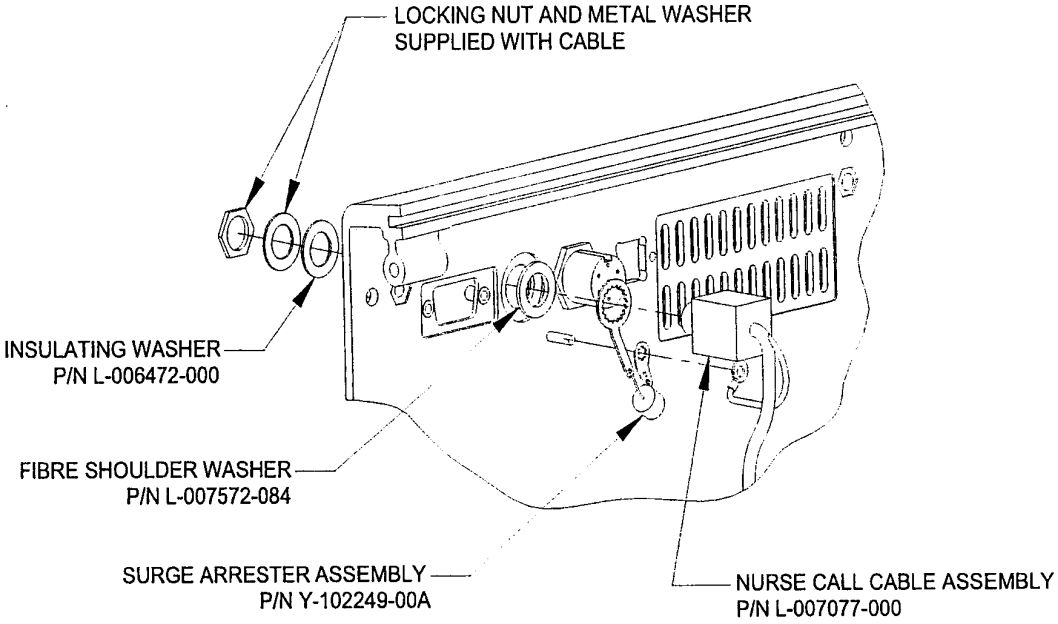

FIGURE 4-38.

2. Install a fibre shoulder washer (P/N L-007572-084) on the phone jack stem with the shoulder up. Insert the phone jack into the nurse call hole from the inside of the rear extrusion. See Figure 4-38.
3. Install an insulating washer (P/N L-006472-000) on the phone jack stem, followed by the metal washer removed earlier.
4. Apply a drop of Loctite 242 adhesive (P/N L-002688-000) to the threads of the connector

towards the rear extrusion. Use a 1/2-in nut driver to install the locking nut. Do not overtighten the nut.

Installation of the shield grounds

Ensure the large terminal lug of the surge arrestor assembly (installed under the nurse call phone jack) does not make contact with the rear extrusion. If necessary, carefuly bend up the terminal lug slightly, away from the rear extrusion.

Note

Install all ring terminals with the crimp side up.

1. Install the following, in the order listed, over the threaded ground stud located below the remote alarm jack. See Figure 4-39.

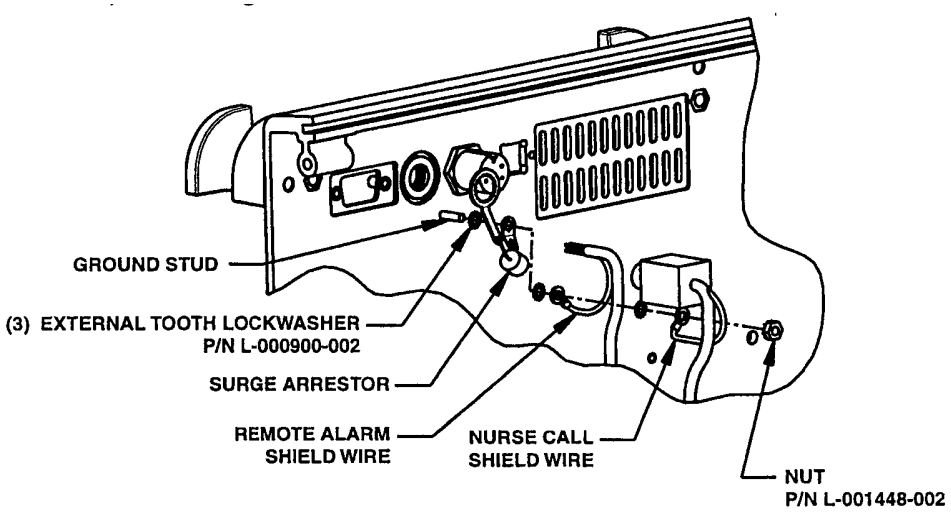

FIGURE 4-39.

- External toothlock washer (P/N L-000900-002).
- Solder lug from the surge arrestor assembly.
- Second external toothlock washer.

- Ring terminal of the shield ground wire from the remote alarm cable.
- Third external toothlock washer.
- Ring terminal of the shield ground wire from the nurse call cable.
- 4-40 keps nut (P/N L-001448-002). Secure with an 8 in-lb torque driver and a 1/4-in socket.
- Ring terminal of the shield ground wire from the modem cable assembly, if present.
- 4-40 keps nut (P/N L-001448-002), if modem cable is present.

DC power cable installation

1. Disassemble the connector of the DC power cable assembly (P/N L-007080-000), if necessary, by turning the small screw on the housing counterclockwise with a small screwdriver until the receptacle body and cable assembly slide out of the housing.
2. Remove the locking nut and the washer from the connector housing, if present. Insert the connector housing into the DC power hole from the outside of the rear extrusion, noting the connector's orientation. See Figure 4-40. Reinstall the washer.

3. Apply a drop of Loctite 425 adhesive (P/N L-004448-000) to the threads of the connector towards the rear extrusion. Use a 15/16-in deep socket with ratchet or wrench to secure the housing with the locking nut removed earlier. Figure 4-40.

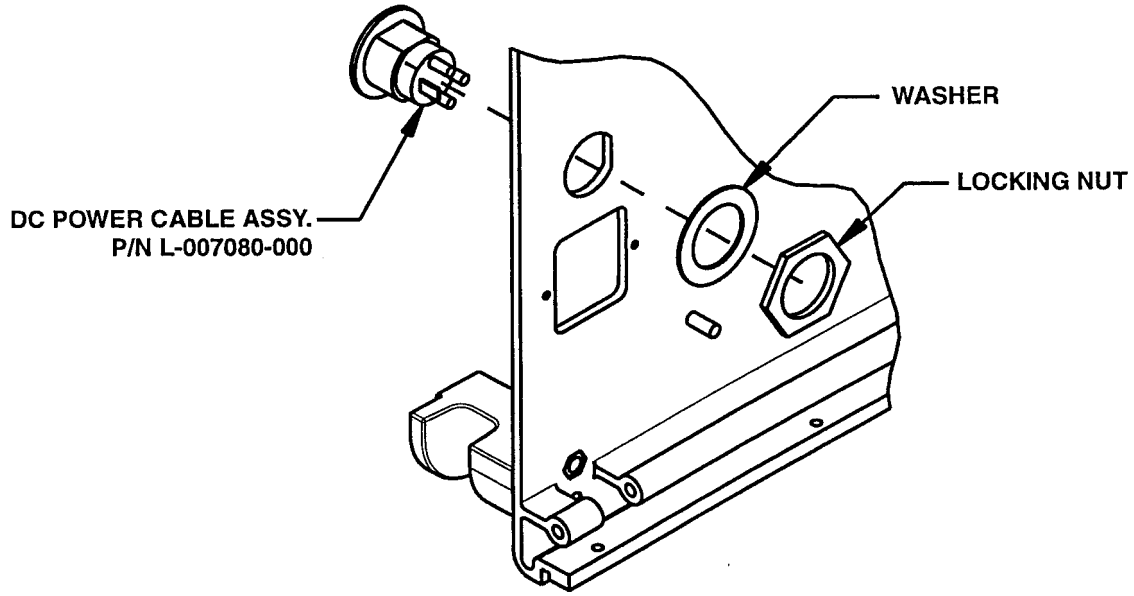

FIGURE 4-40.

4. Reinstall the receptacle body and cable assembly into the connector housing. Secure them by tightening the small screw on the housing clockwise with a small screwdriver.

Hook up cable installation

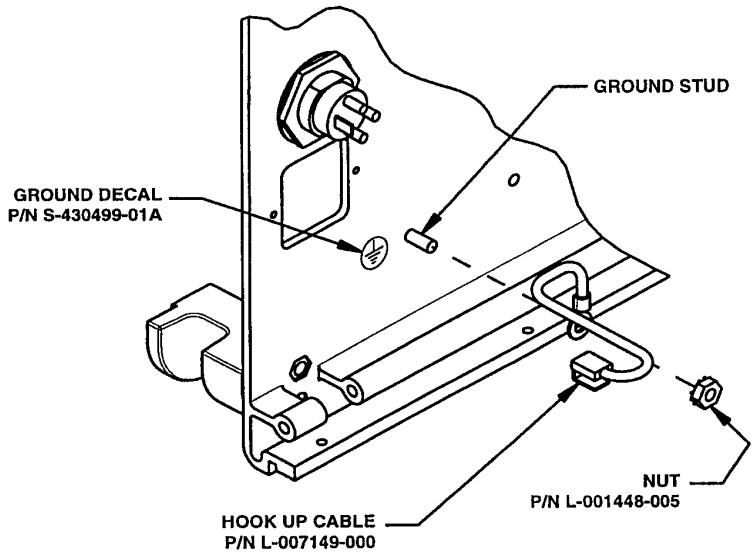

FIGURE 4-41.

1. Install the ring terminal (crimp side up) of the hookup cable (P/N L-007149-000) over the threaded ground stud located next to the AC inlet receptacle hole in the rear extrusion. Use an 8 in-lb torque driver with a 11/32-in socket to secure the ring terminal with a kep nut (P/N L-001448-005). See Figure 4-41.
2. Apply ground decal (P/N S-430499-01A) to the rear extrusion, noting its location and orientation. Figure 4-41.

AC cord/AC inlet receptacle installation

1. Insert the AC inlet receptacle (P/N Y-100054-000) into the designated hole from the outside of the rear extrusion, noting the receptacle's orientation. Figure 4-42.

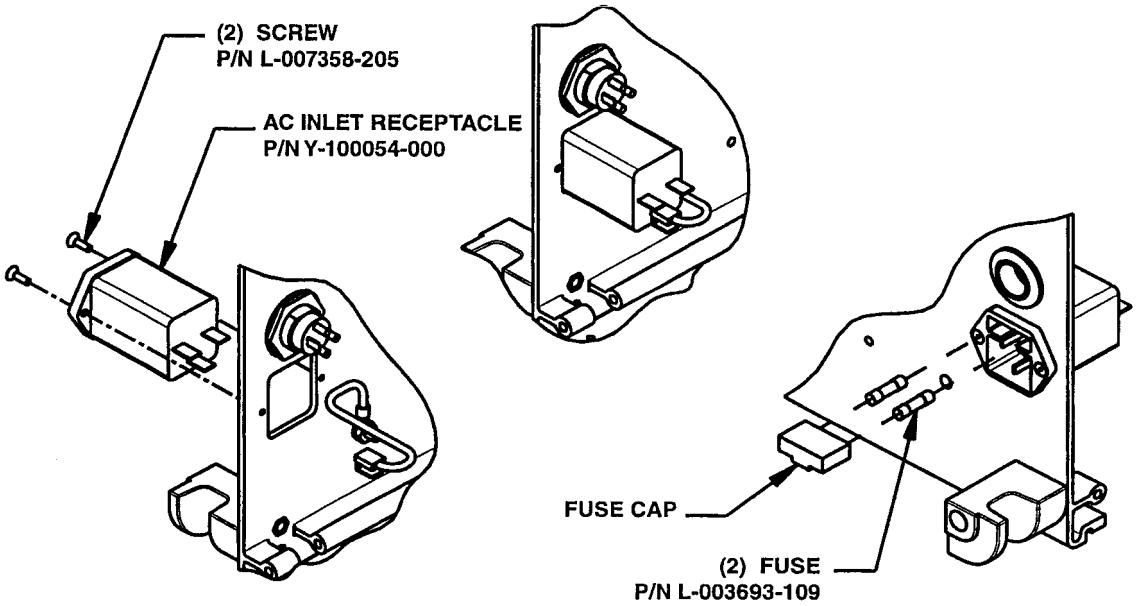

FIGURE 4-42.

2. Apply a drop of Loctite 425 adhesive (P/N L-004448-000) to 2, 4-40 x 3/8-in (9.525 mm) screws (P/N L-007358-205). Use a Phillips screwdriver to secure the AC inlet receptacle to the rear extrusion with 2 screws. Tighten until snug.
3. Remove the fuse cap from the receptacle, if necessary, and insert 2 fuses (P/N L-003693-109) into the cap. Reinstall the fuse cap.
4. Install the terminal lug of the hook-up cable onto the ground terminal of the AC inlet receptacle, noting its orientation.

5. Install the AC power internal cable (P/N L-007075-000) onto the AC inlet receptable terminals. For the wire color orientation, see Figure 4-43.

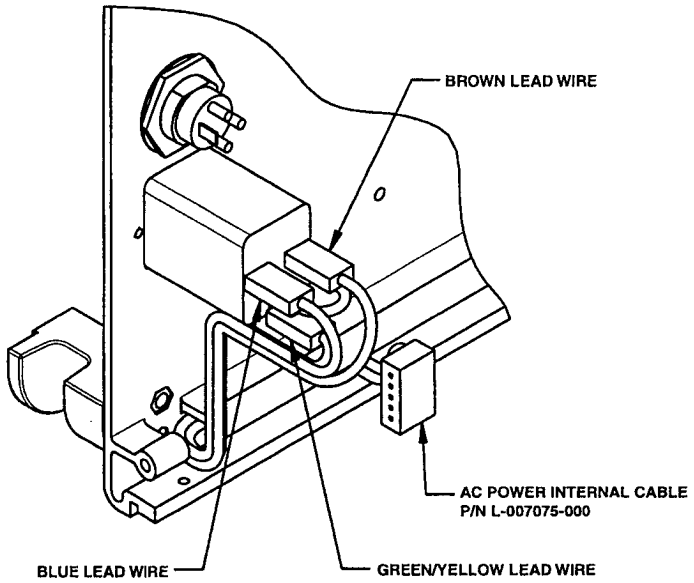

FIGURE 4-43.

6. Connect the AC power cord to the AC inlet receptable. Install the cable clamp over the AC power cord.
7. Use a Milwaukee screwdriver set at 1 (or equivalent) with an 1/8-in hex bit to secure the cable clamp (P/N L-004396-011) to the rear extrusion with a 10-32 x 1/8-in (3.175 mm) screw (P/N L-004090-429), so that the AC power cord is below the screw.

Rear panel assembly installation

1. Install an EMI gasket (P/N L-007033-000) into the bottom groove of the rear extrusion. Verify the gasket is flush with both ends of the extrusion. See Figure 4-44.

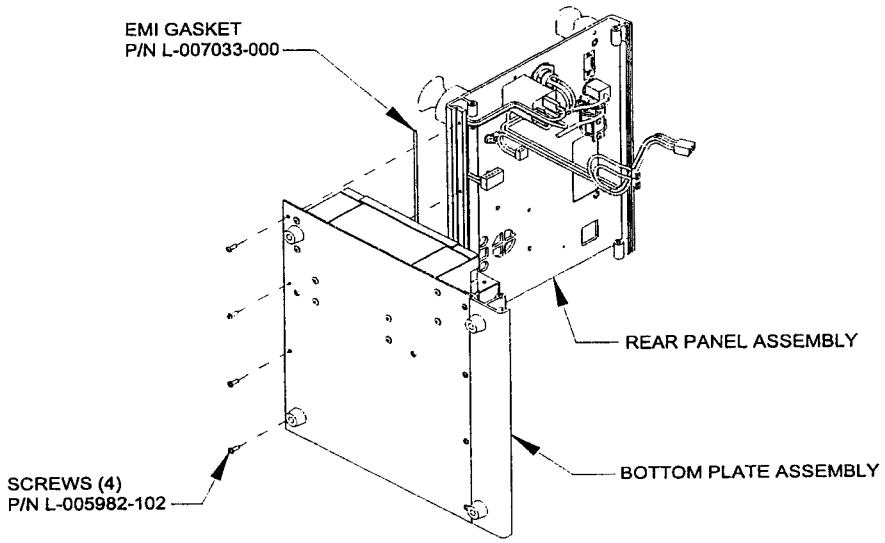

FIGURE 4-44.

2. Stand the rear panel and bottom plate assemblies on their right sides and connect the following:

   - The 3-socket, 2-wire connector of the DC connector cable to the 3-pin connector on the power supply.
   - The 5-socket, 3-wire AC inlet power connector to the 3-pin (normally 5-pin) connector on the power supply. Route the cable into the large bottom groove of the rear extrusion. Verify the connectors are properly seated.

3. Use a Milwaukee screwdriver set at 6 (or equivalent) with a Phillips bit to secure the bottom plate assembly to the rear panel assembly with 4, 6/32 by 3/8-in screws (P/N L-005982-102).
4. Stand the assembly on its bottom feet.
5. Thread each of 2 cable ties (P/N L-001708-001) through each of the 2 cable tie mounts located on the top of the battery bracket.

6. Route the RS232 cable down the rear panel and across the top of the battery bracket and cable ties.
7. Route the nurse call cable and the remote alarm cable down the rear panel and across the top of the battery bracket and cable ties.
8. Route the DC power cables across the top of the battery bracket and cable ties. Connect the wires to the battery terminals, the red wire to the positive terminal (terminal marked “+” or red).
9. Bundle and secure the cables that are routed across the battery bracket. Cinch cable tie around all cables. Do not overstress the cables. Cut off excess cable ties.

Bottom plate repairs

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- Milwaukee battery-powered screwdriver (or equivalent)
- Side cutters
- 3/32-in hex driver
- 3/32-in hex bit
- Phillips screwdriver
- Phillips bit
- 5/64-in hex driver
- Makita battery-powered torque driver (or equivalent)
- Torque driver, 22 in-lbs (2.49 N-m)

Notes

Perform only those steps needed for repair.

Inspect each part for damage before use.

Clean assembly as needed throughout process.

Power drivers may be used to remove screws.

Bottom plate removal

Warning

The bottom plate has sharp edges. Handle with care to avoid injury.

1. Remove and discard the 2 cable ties that secure the cables routed across battery bracket.
2. Disconnect wires and the jumper wire from the battery terminals.
3. Stand the rear panel and bottom plate assemblies on their right sides.
4. Use a Phillips screwdriver to remove the 4 screws that secure the bottom plate assembly to the rear panel assembly.
5. Disconnect the following:
   - 3-socket, 2-wire connector of the DC connector cable from the 3-pin connector on the power supply.
   - 5-socket, 3-wire AC inlet power connector from the 3-pin (normally 5-pin) connector on the power supply.

Battery removal

1. Use a 3/32-in hex driver to remove the 4 screws that secure the battery bracket to the bottom plate. Remove the battery support bracket from the battery pack.
2. Remove battery pack from battery pad.
3. Remove battery pad from bottom plate.

Power supply removal

1. Use 3/32-in hex driver to remove 4 screws securing power supply to bottom plate.
2. Remove power supply from bottom plate.

Power supply disassembly

1. Use a 3/32-in hex driver to remove the 4 screws that secure the power supply cover to the power supply base. Remove the power supply cover.
2. Use a 5/64-in hex driver to remove the 5 screws that secure the power supply to the power

supply base. Remove the power supply.

3. Remove the insulator from the power supply base.

Bottom plate disassembly

1. Use a Phillips screwdriver to remove 4 screws securing bottom plate to front extrusion. Remove the front extrusion.
2. Use a Phillips screwdriver to remove 2 screws securing 2 bottom feet to front extrusion. Remove the 2 bottom feet.
3. Use a Phillips screwdriver to remove 2 screws securing 2 bottom feet to bottom cover. Remove the 2 bottom feet.

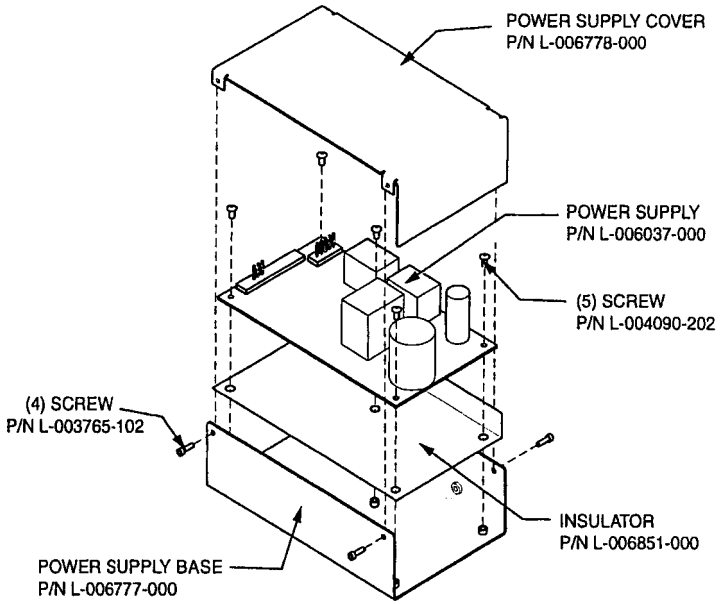

FIGURE 4-45.

Power supply assembly

1. Fold the insulator (P/N L-006851-000) upward 90° along the bead line. See Figure 4-45.
2. Align the holes in insulator over the 5 pem nuts in the power supply base, P/N L-006777-000.
3. Install the power supply (P/N L-006037-000) over the insulator into the base, keeping the transformers towards the side of the base with 4 pem nuts.
4. Use a 5/64-in hex driver to secure the power supply with 5, 6-32 x 1/4-in (6.35 mm) screws (P/N L-004090-202) from the inside of the base.
5. Install the power supply cover (P/N L-006778-000) onto the base with the open end towards the power supply connectors. Align the screw tabs of the cover to the inside of the screw holes in the base. Use a Milwaukee screwdriver set at 4 (or equivalent) with a 3/32-in hex bit to secure the cover to the base with 4, 4-40 x 1/4-in (6.35 mm) screws (P/N L-003765-102).

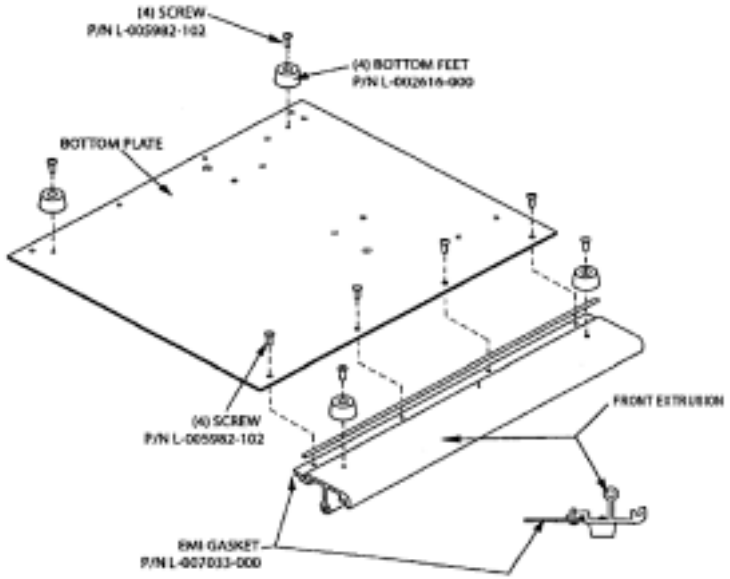

FIGURE 4-46.

Bottom plate assembly

1. Use a Makita torque driver set at 1 with the speed range set at “L” (or equivalent) with a Phillips bit to install the 2 bottom feet (P/N L-002616-000). Use 2, 6-32 x 3/8-in (9.525 mm) screws (P/N L-005982-102) to secure the feet to the underside (painted side) of the bottom cover.
2. Use a Makita torque driver set at 1 with the speed range set at “L” (or equivalent) with a Phillips bit to install the 2 bottom feet (P/N 002616-000). Use 2, 6-32 x 3/8-in (9.525 mm) screws (P/N L-005982-102) to secure feet to the underside (painted side) of the front extrusion.
3. Install the EMI gasket (P/N L-007033-000) into the groove in the front extrusion. See Figure 4-46. Verify the gasket is flush with both ends of extrusion.
4. Use a Makita torque driver set at 2 with the speed range set at “L” (or equivalent) with a Phillips bit to secure bottom plate to the front extrusion with 4, 6-32 x 3/8-in (9.525 mm) screws (P/N L-005982-102). Verify that the EMI gasket has been set in place properly.

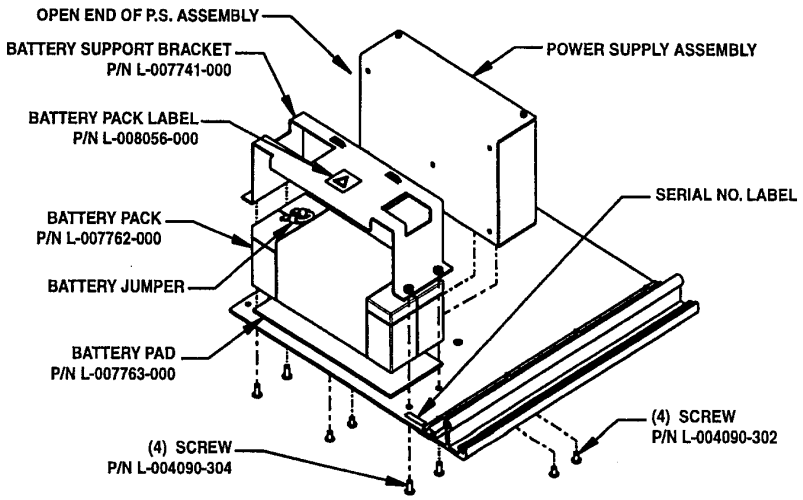

FIGURE 4-47.

Power supply installation

1. Position the power supply on top of the bottom plate with the open end of the power supply "cage" facing away from the front extrusion. See Figure 4-47. Use a Milwaukee screwdriver set at 4 (or equivalent) with a 3/32-in hex bit to secure the power supply to the bottom plate with 4, 8-32 x 1/4-in (6.35 mm) screws (P/N L-004090-302).

Battery installation

1. Position the battery pad (P/N L-007763-000) on top of the bottom plate. See Figure 4-47.
2. Position the battery pack (P/N L-007762-000) on top of the battery pad (with the connector tabs facing up). Remove the jumper between the terminals, if it is present.
3. Position the battery support bracket (P/N L-007741-000) over the battery pack (with 2 cable tie mounts towards the power supply). Align the mounting holes in the bracket with mounting holes in the bottom plate. Verify that the bracket does not rest on the battery pad.
4. Use a Milwaukee screwdriver set at 4 (or equivalent) with a 3/32-in hex bit to secure the battery bracket. Use 4, 8-32 x 3/8-in (9.525 mm) screws (P/N L-004090-304) to secure the battery bracket to the bottom plate.
5. Verify the battery pack label (P/N L-008056-000) is located on top of the battery bracket.
6. Reconnect the jumper to the battery terminals, making sure the fast-on connectors are fully seated.

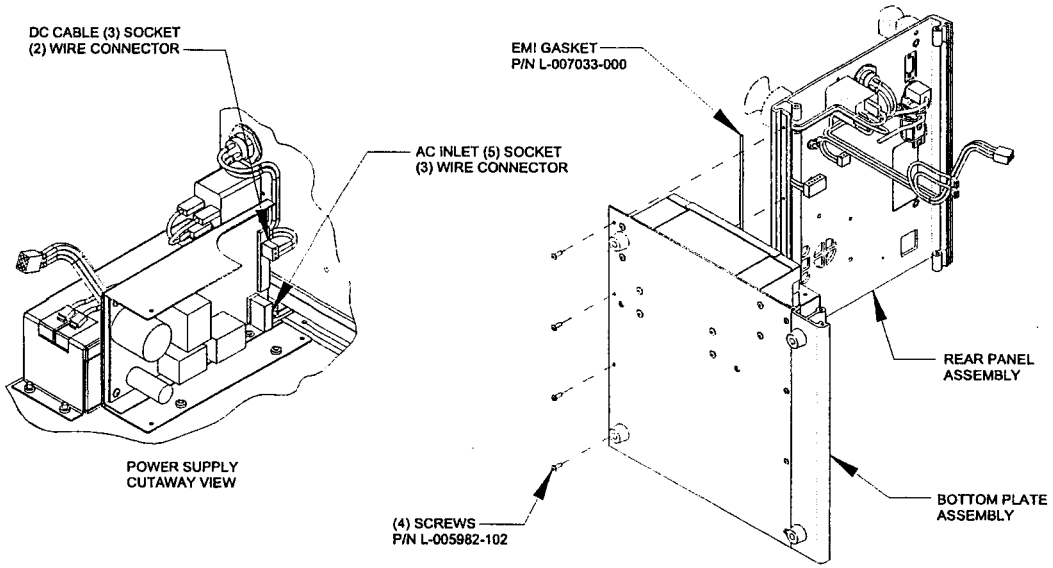

FIGURE 4-48.

Bottom plate installation

1. Install the EMI gasket (P/N L-007033-000) into the bottom groove of the rear extrusion. See Figure 4-48. Verify that the gasket is flush with both ends of the extrusion.
2. Place the rear panel and bottom plate assemblies on their right sides and connect the following:
   - A 3-socket, 2-wire connector of DC connector cable to the 3-pin connector on power supply.
   - A 5-socket, 3-wire AC inlet power connector to the 3-pin (normally 5-pin) connector on the power supply. Route the cable into the large bottom groove of the rear extrusion. Verify the connectors are properly seated.

3. Use a torque driver set at 22 in-lbs with a Phillips bit to secure the bottom plate assembly. Use 4, 6-32 x 3/8-in (9.525 mm) screws (P/N L-005982-102) to secure the bottom plate assembly to the rear panel assembly.
4. Stand the assembly on its bottom feet.
5. Thread each of 2 cable ties (P/N L-001708-001) through each of the 2 cable tie mounts located on top of the battery bracket.
6. Route the RS232 cable down the rear panel and across the top of the battery bracket and cable ties.
7. Route the nurse call cable and the remote alarm cable down the rear panel and across the top of the battery bracket and cable ties.
8. Route the DC power cables across the top of the battery bracket and cable ties. Connect the wires to the battery terminals, attaching the red wire to the positive “+” terminal.
9. Bundle and secure the cables routed across the battery bracket. Cinch cable tie around all cables. Do not overstress the cables. Cut off excess cable ties.

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Chapter 5: Pre-calibration assembly

Warning

All repair, calibration, and testing must be done in a static controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- 5/64-in hex bit
- 1/8-in hex bit
- 1/8-in hex driver
- Small, nonconductive, flat-blade screwdriver
- Milwaukee battery-powered screwdriver (or equivalent)
- Makita torque driver (or equivalent)
- Sealant

Caution

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and top cover. Finger prints will damage the coating.

Notes

Perform only the steps needed for the repair.

Inspect each part for damage before use.

Clean the assembly as needed throughout the process.

Attach right end assembly

Caution

Do not set the right end assembly on the primary pressure transducer or damage to the wires may occur.

1. Verify the EMI gasket, P/N L-007033-000, is installed in the groove around the outer edge of the right end plate. See Figure 5-1.

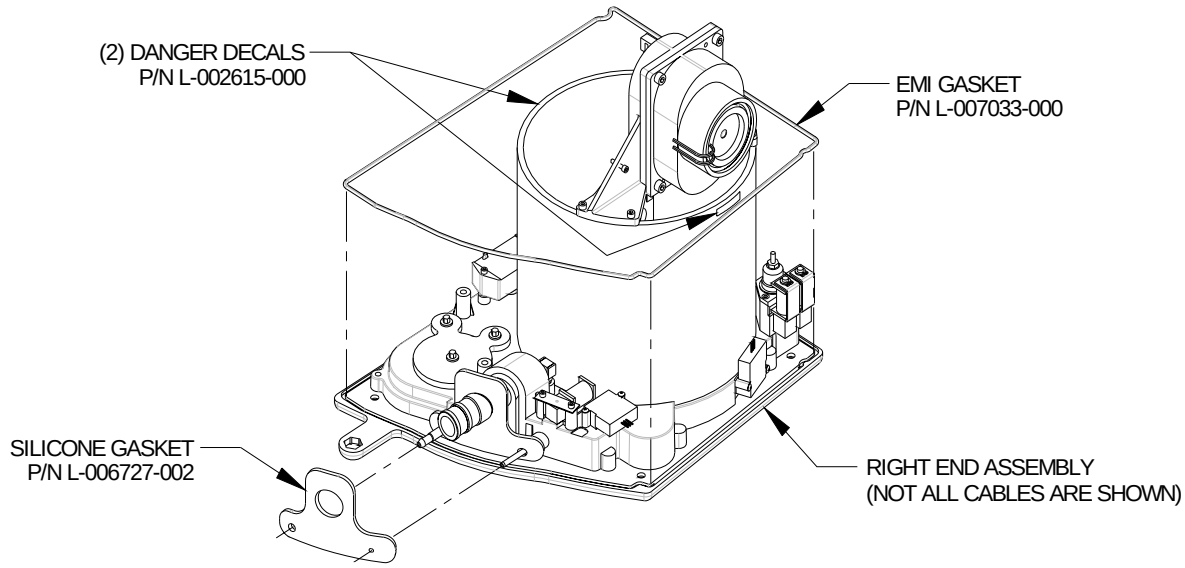

FIGURE 5-1.

2. Verify the silicone gasket, P/N L-006727-002, is installed over the patient air port, patient pressure tube and exhalation tube. See Figure 5-1.

3. Install the square ESD gasket, P/N L-007497-000, over the O_2 inlet port and onto the square seat of the O_2 blender; or, onto the square seat of the blender filler block. See Figure 5-2.

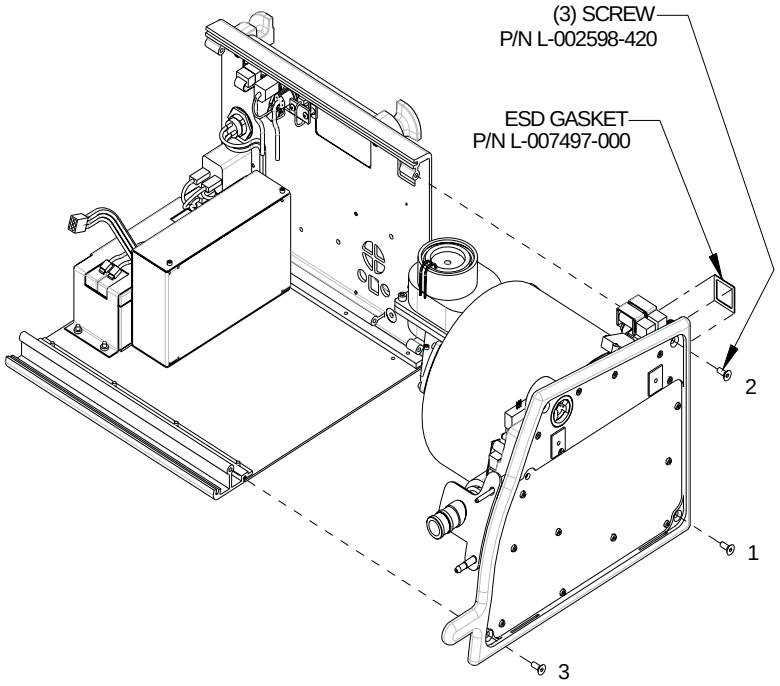

FIGURE 5-2.

4. Being careful not to pinch any wires, set the right end assembly into position. Verify the square ESD gasket installed in step 3 is still in place. See Figure 5-2.

5. Use an 1/8-in hex driver to attach the right end assembly by starting 3 screws, 10-32 x 1/2-in (P/N L-002598-420), in the order shown in Figure 5-2.

6. Use an 1/8-in hex bit and a Makita torque driver set at “5” with the speed range set at “L” (or equivalent) to secure the right end assembly by tightening the 3 screws in the same order. See Figure 5-2.

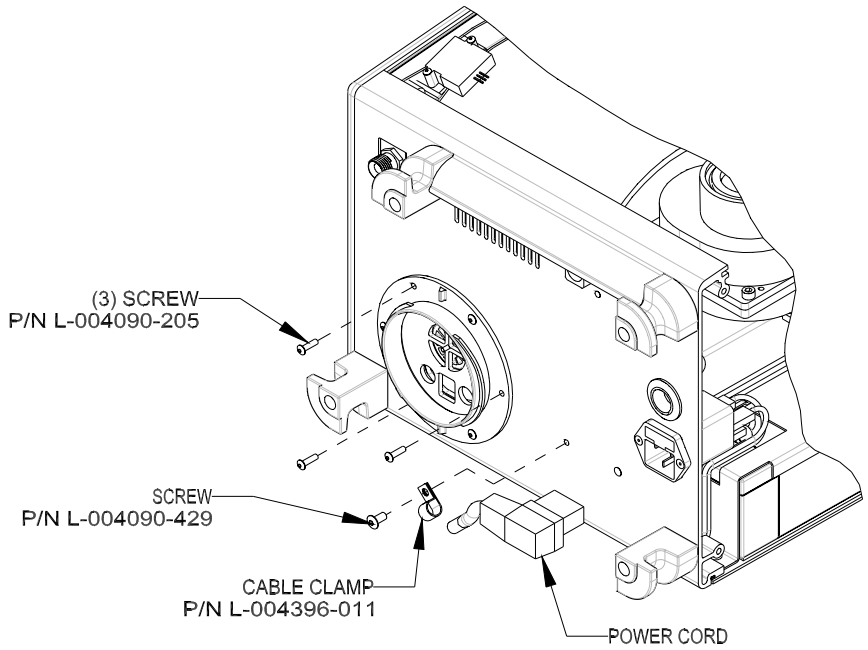

FIGURE 5-3.

7. Use a torque driver set at 5 in-lbs with a 5/64-in hex bit to secure the manifold to the rear panel assembly with 3 screws, 6-32 x 1/2-in (P/N L-004090-205). See Figure 5-3.

Warning

The O_2 inlet grounding spring has tension when installed. Be careful when removing and installing the O_2 inlet grounding spring. Safety glasses are recommended.

1. Bring the spring legs together to enlarge the opening and place the spring on the O_2 inlet

port, beyond the threaded area.

2. Rotate one leg of the spring below the foot adjacent to the O_2 inlet port. Orient the spring so that the end loops are pointing upward.
3. Insert the O_2 inlet cap chain retaining screw (P/N L-003765-104), 4-40 x 3/8-in (9.525 mm), through the chain eyelet.
4. Bring both spring legs together to tighten the spring around the O_2 inlet port and align the spring leg end loops with one another.
5. Insert the O_2 inlet cap chain retaining screw with the chain eyelet through both leg end loops of the spring.
6. Use a 10 in-lb torque driver and a 3/32-in hex bit to secure the screw to the rear extrusion.

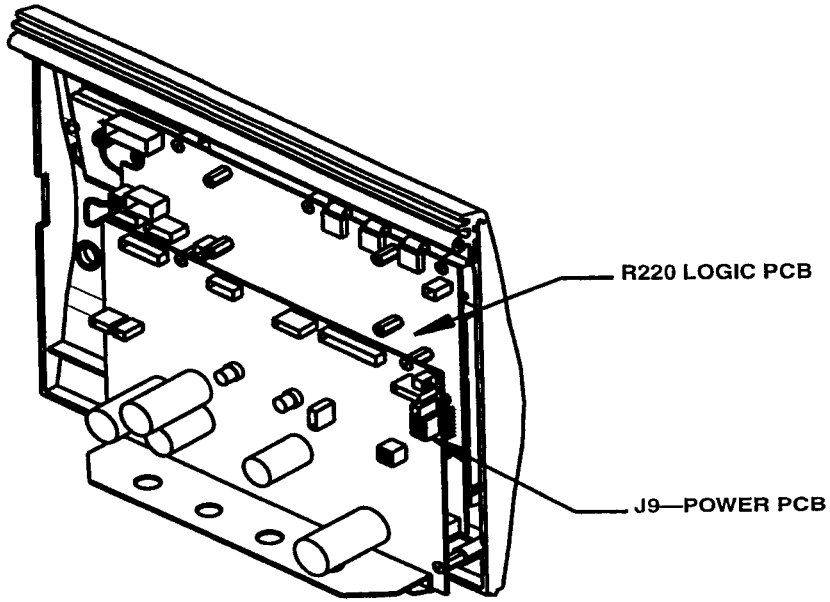

FIGURE 5-4.

Adjustment of LCD flutter rate

Note

The flutter rate adjustment of the LCD is only needed to be performed if a new LCD or a new logic circuit assembly was installed.

1. Use a small Phillips screwdriver to remove 4 screws securing the modem circuit assembly to the logic board, if applied.
2. Remove the modem circuit assembly from the hex spacers, making sure not to damage any connector pins, if applied.
3. Connect the internal battery connector to J9 on the power circuit assembly.

4. Press ENTER to display the ventilator's parameters.
5. Press MENU/ESC and verify the LCD displays "Press ENTER to begin User Self Test."
6. Adjust R220 on the logic circuit assembly with a small, non-conductive screwdriver until the display is at its brightest and the "flutter" is at a minimum. See Figure 5-4.
7. Disconnect the internal battery connector from J9 on the power circuit assembly.
8. Apply a small drop of varnish or nail polish to the top of the R220 to prevent movement.
9. Install a modem circuit assembly (P/N L-006120-000) onto the hex spacers, if it was removed, making sure that all connector pins properly insert into the connectors.
10. Use a small Phillips screwdriver to secure the modem circuit assembly, if applicable, by starting 4, 4-40 x 3/16-in screws (P/N L-001442-203). Hand-tighten until snug.

Front panel connection

1. Verify the EMI gasket, P/N L-007033-000, is installed in the groove of the front extrusion on the bottom plate assembly.
2. Lay the front panel assembly down next to the front extrusion as shown in Figure 5-5.

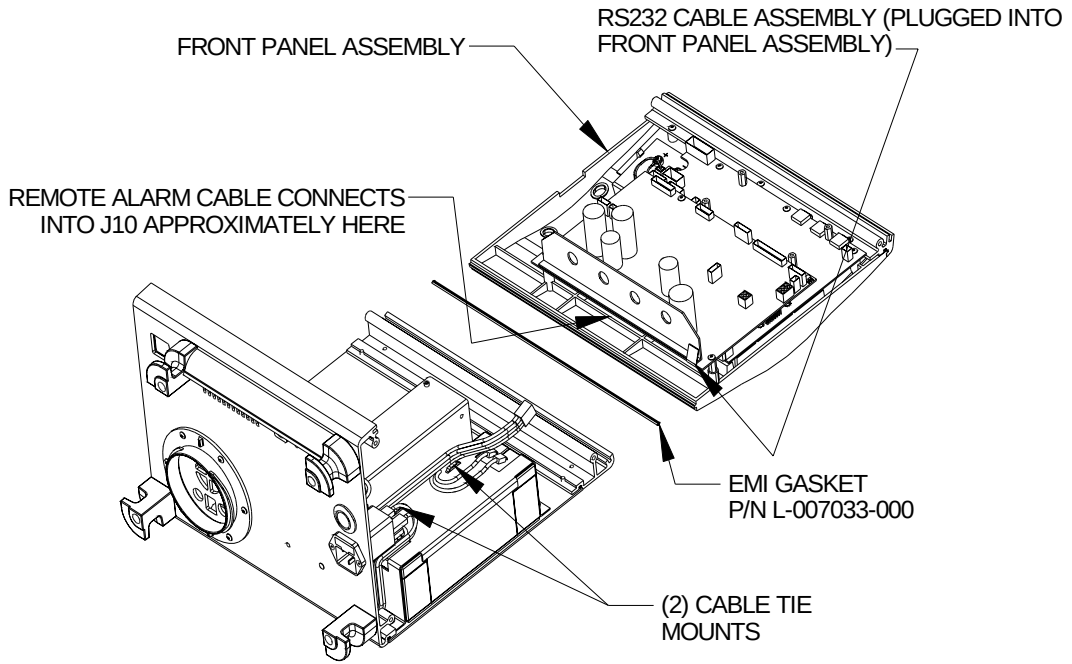

FIGURE 5-5.

3. Connect the remote alarm cable to J10, located towards the middle of the bottom edge of the logic board. See Figure 5-5.
4. Connect the RS232 ribbon cable to J31, located on the right side of the bottom edge of the logic board. See Figure 5-5.
5. Stand the front panel in an upright position with the bottom of the panel in the groove of the front extrusion on the bottom plate assembly.

Caution

Make sure the cables are routed away from the cylinder opening and the full movement of the crank arm.

6. In the order listed, connect the following cables to their connectors on the circuit boards.

    - Connect the motor power cable (red, green and black wires) to J1 on the power circuit assembly.
    - Connect the Hall sensor cable (yellow, brown, blue, orange, and gray wires) to J3 on the power circuit assembly.
    - Connect the EOT (end of travel) sensor cable to J4 on the logic circuit assembly.
    - Connect the PEEP valve/O_2 blender cable (8-pin connector with 2 or 6 black wires, depending on the model) to J14 on the logic circuit assembly.
    - Connect the nurse call cable to J7 on the power circuit assembly.
    - Connect the external power cable (square 4-pin with 2 red and 2 black wires) to J2 on the power circuit assembly.
    - Connect the flow and pressure sensor cable (16-pin connector with 10 or 13 wires, depending on the model) to J30 on the logic circuit assembly.
    - For models with an internal modem, connect the modem cable to J2 on the modem circuit assembly.

Warning

The ventilator may cycle when connecting the internal battery cable to the power board. Keep fingers and objects clear of the crank arm's path.

- Carefully connect the internal battery to J9 on the power circuit assembly.

Ventilators that have passed pre-calibration are now ready for calibration.

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Chapter 6: Calibration

Base Achieva, Achieva PS calibration

Warning

All repair, calibration, and testing must be done in a static-controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- MaSSII software, Version 2.0a (or greater)
- Communications cable, Model Y-6490, or the equivalent RS232 null modem cable with gender changer
- High pressure relief adjustment tool, P/N L-003071-000
- Voltage calibration cable test fixture, P/N L-007887-000
- 18-in Flex hose, P/N L-002777-000 (or equivalent 18–24-in)
- 5-ft patient circuit, Model Y-6263 w/exhalation manifold, Model Y-6353
- Calibration analyzer, Mallinckrodt PTS2000
- Rp20 Resistor
- IBM compatible computer with Windows Operating System (95, 98 or NT)
- High pressure/flow source air or O_2 [up to 80 psi (5.52 bar) and 180 lpm]
- Power supply, capable of 3.5A / 35V
- Small flat blade screwdriver
- Miscellaneous patient circuit adapters

Warning

Keep hands and clothing clear of the ventilator. The unit cycles when powered and could cause injury when not completely encased.

Caution

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and the top cover. Finger prints will damage the coating.

Notes

A Calibration Data Sheet must be completed.

Mechanical or electrical rework requires that the entire calibration process be performed again.

If the ventilator fails a calibration step, record the failure in the comment section of the Calibration Data Sheet. Do not sign and date Calibration Data Sheet.

The Alarm Silence/Reset button may be used to reset alarms as needed.

The *slpm* mode on the PTS2000 should only be used for the Flow Calibration. Use the lpm mode for verifying the flow calibration.

Documentation

1. Record the following information on the Calibration Data Sheet:
   - Operator's name
   - Date
   - Power supply serial number
   - PTS2000 serial number
   - Ventilator serial number

Initialize date/time

1. Connect the ventilator to AC power and allow it to complete its Homing sequence.

Note

If there is a Setting Error when the unit is first connected to AC power, or if the unit does not perform a homing sequence, the ventilator Self-Test has determined that there are calibration parameters out of specification. If this happens, a MaSSII session should be initiated and the Error Log

should be checked. The Error Codes should be used to determine the problem. Once identified, the problem parameter may be calibrated first per this process. Completely power down the ventilator. When the ventilator is reconnected to AC power it should “home” correctly and the Setting Error Alarm should not be activated.

2. On the ventilator, press ENTER on the front panel display so that the Settings Entry Screen is active. Press the MENU/ESC button.
3. Press the UP or DOWN arrow key until the “Press ENTER to modify Date and Time” prompt is displayed. Press ENTER.

Note

For ventilators that display readings in English, the order will be the current Month, Day, Year, Hours, and Minutes. For ventilators that display a language other than English, the order will be the current Day, Month, Year, Hours, and Minutes.

4. For ventilators that display English,
   - Verify or set the current Month, using the Up/Down arrows.
   - Press ENTER.
   - Repeat to verify, or set the current Day, Year, Hours, and Minutes.

   For ventilators that display languages other than English,
   - Verify or set the current Day, using the Up/Down arrows.
   - Press ENTER.
   - Repeat to verify, or set the current Month, Year, Hours, and Minutes.
5. Press ENTER to skip the Seconds entry.
6. Press MENU/ESC to go to the Settings Entry screen.

Unit ID

1. Connect the computer to the ventilator using the communications cable.
2. Initiate a MaSSII session.
3. Enter your User ID and Password and select “OK.”

Caution

Using the MaSSII "Setup…Initialize NVRAM…" command will reset all calibration parameters and unit information to defaults. This will also reset the Operating Hours to zero. A complete re-calibration will be required and the operating hours will have to be re-entered.

4. On the MaSSII screen, select “Parameters... Miscellaneous....”
5. Identify the model and serial number of the ventilator and verify they are all displayed correctly in the Ventilator Information section on the screen. (If the serial number is not displayed correctly, enter it in the space provided. Select “Download Serial Number.”)
6. Record the software version on the Calibration Data Sheet.
7. Select “Done” to clear the screen.
8. If the serial number was changed, select “Parameters... Miscellaneous....” on the MaSSII screen.
9. Verify the serial number is correct and select “Done.”

Homing calibration

1. Verify or set the following parameters:
   - MODE A/C
   - VOLUME 200 ml
   - INSPIRATORY TIME 0.7 second
   - SENSITIVITY 5 lpm
   - BREATH RATE 16 bpm
   - PRESSURE SETTING 0 cmH_2O
   - PEEP 0 cmH_2O
   - LOW PRESSURE 1 cmH_2O
   - HIGH PRESSURE 80 cmH_2O
   - OPERATING ALTITUDE set for the local elevation.
2. Connect the PTS2000 high flow inlet to the ventilator using an Rp20 resistor and a 5-ft

patient circuit with exhalation manifold.

Note

The PTS2000 must be on at least 15 minutes prior to use.

3. Select and zero screen 2 on the PTS2000.

Note

See Appendix A, “PTS2000 Menu Structure,” for PTS2000 screen setup.

4. On the MaSSII screen select “Parameters...Calibration….”
5. Record the Homing Position reading on the first “Cal. Point” line on the Calibration Data Sheet.
6. Start ventilation by pressing ENTER, and then VENTILATE.

Note

Left/Right side is defined by looking down the cylinder from the motor/gearbox end of the unit. The ventilator’s crankarm continues to operate on the side of the cylinder it started on, until it has been placed into Standby mode. Once it re-enters Ventilate mode, it will operate from the opposite side of the cylinder.

7. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first line under the heading of “L. Side” or “R. Side,” whichever is correct.
8. Set the ventilator to Standby.
9. Press ENTER and then VENTILATE. The Ventilator will be operating from the opposite side of the cylinder.
10. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first line under the heading of “L. Side” or “R. Side,” whichever is correct.
11. If the Volume readings are within .010 of each other and within .010 of .200 L, additional Homing Calibration is not required. Select “Done” to clear the screen. Set the ventilator to

STANDBY and proceed to *Internal volts calibration*. If adjustment is needed, set the calibration parameter using the MaSSII software as outlined in the following steps.

Notes

Decrease the Homing Position setting to decrease the volume on the Left side of the cylinder and/or increase the volume on the Right side of the cylinder.

Increase the Homing Position setting to increase the volume on the Left side of the cylinder and/or decrease the volume on the Right side of the cylinder.

An increase or decrease of approximately 4 counts usually is sufficient.

a. Enter the new Homing Position setting and select “Update” to transfer the new data to the ventilator.
b. Record the new Homing Position on the first available “Cal. Point” line on the Calibration Data Sheet.
c. Set the ventilator to Standby.
d. Start ventilation by pressing ENTER and then VENTILATE.
e. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first available line under the heading of “L. Side” or “R. Side,” whichever is correct.
f. Set the ventilator to Standby.
g. Press ENTER and then VENTILATE. The ventilator will be operating from the opposite side of the cylinder.
h. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first available line under the heading of “L. Side” or “R. Side,” whichever is correct.
i. Verify volume accuracy. If the volume accuracy on each side of the stroke is not within specification, repeat the “Homing Calibration Adjustment” section until it is.
j. If no further adjustments are required, select “Done” to clear the screen. Set the ventilator to STANDBY.

Internal volts calibration

1. Remove AC power from the ventilator and allow the ventilator to shut down. Disconnect all tubing from the ventilator.
2. Set the power supply voltage to 24.00 volts and the current limit to 3.5 Amps. Verify that the power supply output is OFF.
3. Disconnect the internal battery from the ventilator's power circuit assembly, J9.
4. Connect the power supply to the ventilator's power circuit assembly, J9, using the voltage calibration cable.

The ventilator may cycle when turning on the power supply output. Warning

5. Turn ON the power supply output.
6. Connect the ventilator to AC power.
7. The voltage reading on the power supply may read up to 30 volts. (The power supply may be displaying the battery charger voltage.)
8. On the MaSSII screen, select "Parameters...Calibration…."
9. In the Internal Battery Voltage section, select "Prepare for Cal." The power supply output will read approximately 24.00 volts. (The ventilator's battery charger has been disabled.)
10. Set the power supply to 30.00 volts.
11. On the MaSSII screen in the Internal Battery Voltage section, select "Point 1."
12. Set the power supply to 20.00 volts.
13. Select "Point 2" in the Internal Battery Voltage section.
14. Set the power supply to 27.00 volts.
15. In the Internal Battery Voltage section, select "Read Voltage." The acceptable range is 27.00

+/- 0.2 volts. Select “OK” to clear the DB (Dialog Box).

Note

When selecting the “Read Voltage” button, the DB displayed will say “Battery voltage = ”. When the charger is disabled, the battery voltage will be displayed. When the charger is not disabled, the charger voltage will be displayed, even though the DB display says “Battery voltage = ”.

16. In the Internal Battery Voltage section, select “Cal Complete.” The power supply may read up to 30 volts.
17. Turn off the power supply output.
18. Remove AC power from the ventilator and allow the ventilator to shut down.
19. Disconnect the power supply from the ventilator’s power circuit assembly, J9.

Warning

The ventilator may cycle when connecting the internal battery.

20. Reconnect the internal battery to J9.
21. Reconnect AC power to the ventilator.
22. In the Internal Battery Voltage section, select “Read Voltage” while the Battery Charging LED is lit. Record the battery charger voltage on the Calibration Data Sheet. If the charger voltage is not above 28 volts, the battery will need to be charged before the ventilator goes into Run-in.
23. Record on the Calibration Data Sheet whether the internal battery needs additional charging prior to Run-in. Circle Y if less than 28 volts or N if greater than 28 volts. Select “OK” to clear the DB.

Pressure sensors and front panel meter calibration

Warning

High pressure compressed gas is used during calibration. Pressurized gas lines can cause injury. DO NOT disturb tubing unless the high pressure source has been turned off and the lines have been purged.

Note

The pressure/flow source is required to maintain a constant pressure in the circuits. A circuit with a small leak is used to allow the flow rate/pressure to be adjusted manually without damaging the pressure sensors. See Figure 6-1.

Caution

DO NOT apply more than 150 cmH_2O to the ventilator's patient ports or the PTS2000 low pressure ports.

1. Use the high pressure relief adjustment tool to tighten the high pressure relief 1 complete revolution clockwise.

Caution

DO NOT tighten the high pressure relief all the way or damage to the high pressure relief valve may occur.

2. Select and zero screen 1 on the PTS2000.
3. With no tubing connected to the ventilator, select "Zero" in the Pressure Calibration section on the MaSSII screen.
4. With no tubing connected to the ventilator, verify that the patient pressure meter reads "0". If not, remove the overlay covering the meter adjustment hole, located below the meter, and use a small flat blade screwdriver to center the needle on the "0" mark of the meter.
5. Connect the "Leaky" circuit to the pressure source, the PTS2000 low pressure "+" port, the

ventilator's patient air port, and the ventilator's patient pressure port, per Figure 6-1. Make sure that the connections are secure. Ensure that the "leak" is located in the section of the circuit prior to any in-line T, and the "leak" is not blocked.

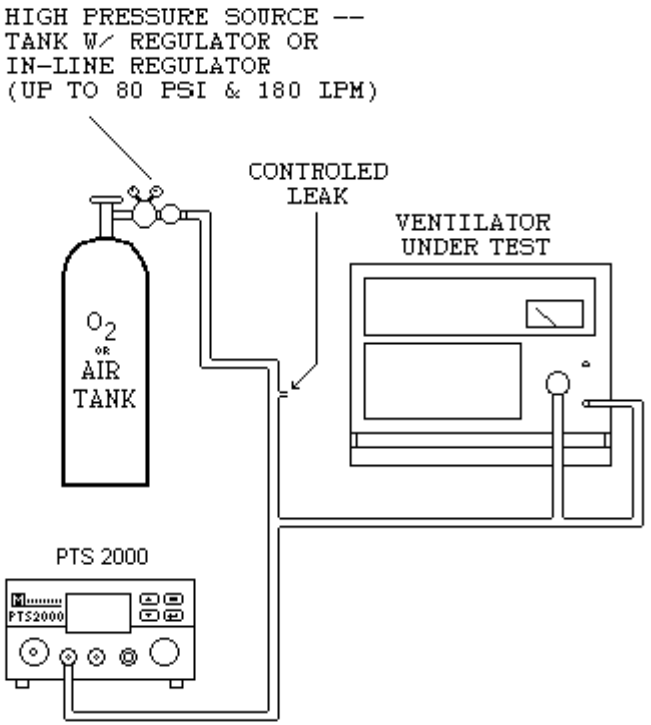


FIGURE 6-1.

6. Slowly adjust the flow so that the pressure on the PTS2000 display is 50.00 +/- 0.10 cmH_2O.
7. Ensure that the pressure stabilizes and does not vary by more than 0.10 cmH_2O over several seconds.
8. In the Pressure Calibration section, select "Scale."

9. Meter Calibration.

   - Verify that the pressure on the PTS2000 display is 50.00 +/- 0.10 cmH_2O (adjust if necessary).
   - Check the pressure indicated on the front panel meter (FPM). Verify that the meter indicates within 1/2 needle's width of 50. If correct, select "Done" to clear the screen and proceed to "Pressure Accuracy Verification." If not, continue.
   - In the Meter section, type the FPM value displayed into the field labeled Reading. Select "Calibrate."

Note — The value entered must be a whole number. For example, if the PTS2000 display is 50.00 cmH_2O and the FPM is reading 53.5, enter 53 or 54.

   - Verify that the FPM adjusts to within 1/2 needle's width of the pressure reading on the PTS2000. If necessary, repeat until the FPM matches the PTS2000 reading. Select "Done" to clear the screen.

10. Pressure Accuracy Verification – at calibrated pressure

Note — The flow source can be turned off to conserve compressed air or O_2 when doing the comparisons called out in the following steps.

   - Verify the PTS2000 reading is 50.00 +/- 0.10 cmH_2O, and select "Parameters...Measurements…" on the MaSSII screen.

Note — Select "Refresh" to update the readings of the MaSSII measurements as needed.

   - Record the PTS2000 value displayed on the Calibration Data Sheet, Pressure Verification – Line A.
   - Record the FPM value displayed to the nearest 1 cmH_2O on the Calibration Data Sheet, Pressure Verification – Line B.

- Record the Calculated Pressure Reading (Primary) on the Calibration Data Sheet, Pressure Verification – Line C.
- Record the Calculated Secondary Pressure Reading (Secondary) on the Calibration Data Sheet, Pressure Verification – Line D.
- Compare the 4 pressure readings on the Calibration Data Sheet. The pressure transducers must be within 0.50 cmH_2O and FPM must be within 1 cmH_2O of the PTS2000 reading. If not within range, repeat the pressure calibration portion of this process. If within range, proceed to the next step.

11. Pressure Accuracy Verification – at noncalibrated pressures

- Increase the flow rate until the PTS2000 reads 90.00 +/- 0.10 cmH_2O. Select “Refresh” to update readings. Record the PTS2000, FPM, Primary, and Secondary pressure readings on Lines E–H on the Calibration Data Sheet.
- Compare the 4 pressure readings. The pressure transducers must be within 1.00 cmH_2O and the FPM must be within 2 cmH_2O of the PTS2000 reading. If not within range, repeat the pressure calibration portion of the process. If within range, proceed to the next step.
- Decrease the flow rate until the PTS2000 reads 10.00 +/- 0.10 cmH_2O. Select “Refresh” to update readings. Record the PTS2000, FPM, Primary, and Secondary pressure readings on Lines I–L on the Calibration Data Sheet.
- Compare the 4 pressure readings. The pressure transducers and the FPM must be within 1.00 cmH_2O of the PTS2000 reading. If not within range, repeat the pressure calibration portion of this process. If within range, proceed to the next step.

12. Turn off the flow source and disconnect the “leaky” circuit from the ventilator, flow source, and PTS2000.
13. Verify the ventilator’s FPM again reads “0”, within 1/2 needle’s width. If necessary, install a new label over the meter adjustment hole.

High pressure relief valve calibration

1. Using the high pressure relief adjustment tool, loosen the high pressure relief by turning it counter-clockwise until the high pressure relief screw is even with the outer edge of the housing. Set the initial high pressure relief setting by turning it clockwise 1 revolution.
2. Zero the PTS2000.
3. Connect the 5-ft patient circuit with exhalation manifold to the ventilator, with the small striped/colored tubing going to both the ventilator and PTS2000 low pressure "+" port.
4. Initiate a Self-Test as follows:
   - Set the right side panel in place on the ventilator. Seal the mounting holes with tape or use your fingers to seal the holes.
   - With the LCD display activated (press ENTER if necessary), press MENU/ESC. The display will read "Press ENTER to begin User Self-Test."
   - On the ventilator, press ENTER. The display will momentarily read "Occlude the patient's end of breathing circuit" and "Press ENTER when ready to begin Test."
   - Block the open end of the exhalation manifold, hold the right side panel firmly against the ventilator, and press ENTER. The ventilator will begin a Self-Test.

Notes

The first part of the Self-Test is a high pressure relief valve test. If the unit fails this test, the "high pressure alarm" will activate.

During the second part of the Self-Test, the unit checks for leaks by pressurizing the cylinder and reading the pressure transducers over time. If the unit fails the test, the "Low Pressure/Apnea Alarm" will activate. Correct any leaks and restart the Self-Test.

5. During the high pressure portion of the Self-Test, watch the display on the PTS2000. Verify the highest reading displayed is 88.00 +/- 3.00 cmH_2O. If not in the correct range, reset any alarms and make slight adjustments to the HPR setting (clockwise to increase and counter-clockwise to decrease the peak pressure). Repeat the Self-Test.

6. When adjustments are finalized and there are no alarms, the PTS2000 displays 88.00 +/- 3.00 cmH_2O, and the Self-Test passes, record the HPR peak pressure from the PTS2000 on the Calibration Data Sheet – PTS2000 Setting.
7. Repeat the Self-Test while watching the FPM. Verify that the FPM on the ventilator peaks in the 90 +/- 10 cmH_2O range. Record the FPM displayed peak pressure on the Calibration Data Sheet – FPM Verification.
8. Verify that the ventilator passed both the Leak and HPR tests and no alarms occurred.
9. Remove the right side panel from the ventilator.
10. Disconnect all tubing from the ventilator and the PTS2000.

Flow sensor calibration

Warning

High pressure compressed gas is used during calibration. Pressurized gas lines can cause injury. DO NOT disturb tubing unless the high pressure source has been turned off and the lines have been purged.

Notes

Disregard any Setting Error Alarms that occur during the flow rate calibration.

For pneumatic configurations, see Figure 6-2.

1. Select and zero the PTS2000 screen:
   - Screen 4 if using Air source.
   - Screen 6 if using Oxygen source.
2. Record whether you are using Air or O_2 on the Calibration Data Sheet.

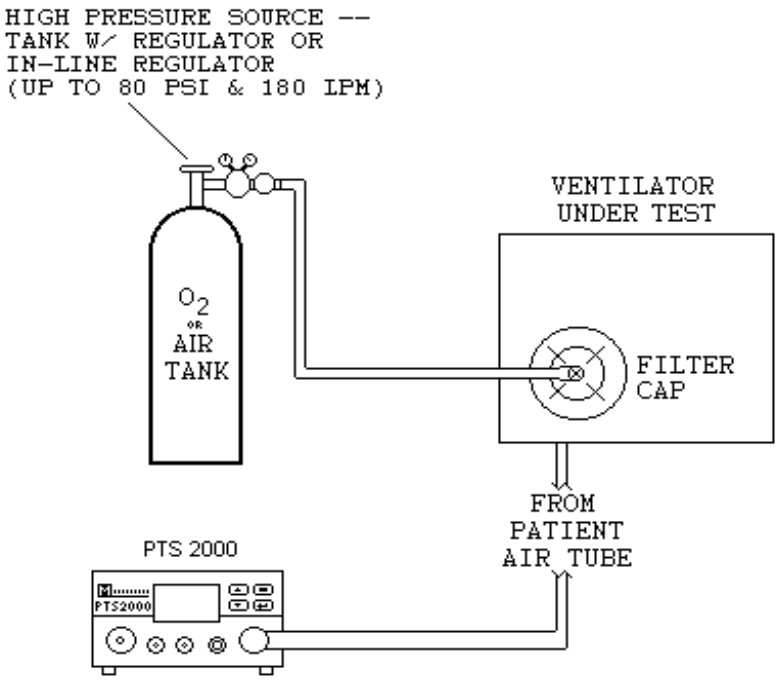


FIGURE 6-2.

3. Connect the ventilator's patient air port to the PTS2000 high flow inlet with an 18–24-in flex hose.
4. Plug the ventilator's exhalation valve port.
5. Connect the high pressure/flow source to the air intake on the back of the ventilator. Set the high pressure/flow source regulator to approximately 80 psi (5.52 bar) when the output is turned off.

The high pressure source valves may be closed between readings to conserve compressed air or O_2.

Notes

If unable to get stable readings, +/- 0.1 lpm, use the PTS2000HF averaging software as follows:

- Set the PTS2000 to “REMOTE OPERATION.”
- Connect, or verify the “RS232 TO COMPUTER” port on the back of the PTS2000 is connected to a serial port on the computer.
- Initiate a PTS2000HF session by selecting “Start . . . Programs . . . Mallinckrodt . . . PTS2000HF” from the taskbar. The PTS2000HF window will stay on top of the MaSSII window and both can be used at the same time.
- Select *slmp* for collecting Raw Readings. Select “LPM” (lpm) for collecting Adjusted Readings.
- Select “START SAMPLING DATA” to start taking readings.
- Once you get the reading you need, select “Refresh” on the MaSSII screen, as usual.
- To end a PTS2000HF session, select “STOP SAMPLING DATA” then select “EXIT.” Select the PTS2000 Menu screen as needed.

6. Adjust the flow control valves as needed to increase the flow through the ventilator to 180 +/- 0.10 lpm.
7. Select “Refresh” to update the readings of the MaSSII Measurements.
8. Record the raw flow reading on the Calibration Data Sheet in the location specified for the 180 lpm flow rate.

All flow settings for this section, *Flow sensor calibration*, are +/- 0.10 lpm.

Note

9. Working your way down the chart, repeat the flow source adjustments for all flow rates shown on the Calibration Data Sheet except for the 5–0 lpm readings. When the flow is reduced to 30 lpm and less, record the raw amplified flow readings on the Calibration Data Sheet.

10. Once the entire flow sensor calibration section is complete (except for 5–0 lpm), turn off the flow control valves.
11. Disconnect the 18–24-in flex hose from the ventilator. Using an adapter with tubing, connect the ventilator's patient air port to the PTS2000 low flow inlet port.
12. Zero the PTS2000:
13. Starting with 5 lpm and working down the chart to 0 lpm, repeat the flow source adjustments for the 5–0 lpm readings for the primary and amplified flow readings. Record the raw readings.
14. Once the 5–0 lpm calibration is complete, turn off the flow control valves and select "Done" to clear the screen.
15. Primary Flow Table Data Entry:
    - On the MaSSII screen, select "Parameters...Flow Tables…" and then select "Read Tables from Ventilator." The screen will display the current tables set in the ventilator.

Note

After a value is entered, use the "TAB" key or the "ENTER" key to highlight the next value to be changed.

- In the Primary Flow A/D Value column, enter the raw readings for the primary flow sensor for each flow rate corresponding to the flow rates on the Calibration Data Sheet.
- Once all of the raw readings are entered, verify the flow rate entries match those on the Calibration Data Sheet. If necessary, change the flow rate entries to match those on the Calibration Data Sheet.
- Once all of the raw readings and flow rates are entered per the Calibration Data Sheet, select "Calibrate" (in the Primary Flow section) to send the table to the ventilator.

16. Amplified Flow Table Entry
    - In the Amplified Flow A/D Value column, enter the raw readings for the amplified primary flow sensor.

- Once all the raw readings are entered, verify the flow rate entries match those on the Calibration Data Sheet. If necessary, change the flow rate entries to match those on the Calibration Data Sheet.
- Once all of the raw readings and flow rates are entered per the Calibration Data Sheet, select “Calibrate” (in the Amplified Flow section) to send the table to the ventilator.

17. Select “Done” to clear the screen.
18. On the MaSSII screen, select “Parameters...Flow Tables…” and then select “Read Tables from Ventilator.” The screen will display the current tables set in the ventilator.
19. Verify the tables are correct by comparing them to the Calibration Data Sheet. If the data points are correct, select “Done” to clear the screen. If any values are incorrect, correct them by re-entering the data and selecting “Calibrate” in the section where the change occurred.

Note

After each time that the tables are changed, you must close the Flow Tables window and then reopen it to verify the changes downloaded to the ventilator correctly.

20. Flow Calibration Verification
    - Select and zero the PTS2000 screen:

      Screen 3 if using Air source.

      Screen 5 if using Oxygen source.
    - Adjust the flow through the ventilator to 5.00 +/- 0.10 lpm.
    - On the MaSSII screen, select “Parameters...Measurements….”
    - Verify the Calculated readings for the flow and amplified flow are both 5.00 +/- 0.50 lpm. If acceptable, continue with the next step. If not acceptable, check all connections and retry.
    - Turn off the flow control valves.

- Disconnect the adapter with tubing from the ventilator's patient air port.
- Connect the 18–24-in flex hose from the PTS2000 high flow inlet port to the ventilator's patient air port.
- Zero the PTS2000.
- Adjust the flow through the ventilator to 25.00 +/- 0.10 lpm.
- Select "Refresh" to update the readings of the MaSSII measurements.
- Verify the calculated readings for the flow and amplified flow are both 25.00 +/- 1.50 lpm. If acceptable, continue with the next step. If not acceptable, check all connections and retry.
- Adjust the flow through the ventilator to 70.00 +/- 0.10 lpm.
- Select "Refresh" to update the readings of the MaSSII measurements.

Note

The amplified flow is out of range and will not read the correct flow rate.

- Verify the calculated reading for the flow is 70.00 +/- 2.00. If acceptable, continue with the next step. If not acceptable, check all connections and retry.
- Turn off the flow control valves.

21. Flow Calibration Completion

- Select "Done" to clear the screen.
- Turn off the high pressure/flow source.
- Completely power down the ventilator by disconnecting it from AC power.
- Disconnect all tubing from the PTS2000 and the ventilator.
- Remove the plug from the exhalation valve port.
- Disconnect the high pressure/flow source from the ventilator's O_2 inlet.

- Carefully purge high pressure from the air lines.

Initialize repair history

Caution

IMPORTANT! Only perform the ”Initialize repair history” section if a PM was performed.

1. Connect the ventilator to AC power.
2. On the MaSSII screen, select “Parameters... Miscellaneous....”
3. In the Repair History section, enter the number zero in both fields. Select “Download” in the Repair History section.
4. Select “Done” to clear the screen.
5. On the MaSSII screen, select “Parameters... Miscellaneous....”
6. In the Repair History section, verify that both data fields are zeroed. If the fields do not show zero hours, try to zero it a second time.
7. Select “Done” to clear the screen.

Initialize data logs

1. On the MaSSII screen, select “Parameters... Data Logs....”
2. Select “Initialize Event, Compliance and Trended.” A dialog box will display “Are you sure you want to initialize all Data Logs?” Select “Yes.”
3. A dialog box will display “Data Logs Have Been Initialized.” Select “OK.”
4. Select “Done” to clear the screen.

Generate report

1. On the MaSSII screen, select “Report... Report...,” then select the following:
   - Event Log
   - Compliance Data
   - Trended Data
   - Flow Tables
   - Unit ID
   - Cumulative Data
   - Repair History
   - Calibration Parameters
   - Error Log
2. On the MaSSII screen, select “Generate Report.” Save the file in the folder designated for Calibration.
3. A dialog box will appear to confirm the file was saved. Select “OK.”
4. On the Report Generator screen, select “Quit.”
5. Close out the MaSSII software.

Completion

1. Completely power down the ventilator by disconnecting it from AC power.
2. Disconnect the communications cable from the ventilator.
3. Wrap the AC cord on the cord wraps and secure with the attached Velcro strap.
4. Start a WORDPAD session and open the report file saved in the “Generate Report” section above. Print out the report (to be used for file comparison at Run-in Data Retrieval).
5. Close out WORDPAD.
6. Sign and date the Calibration Data Sheet.
7. Passed units are now ready for Reassembly.

Base Achieva, Achieva PS Calibration Data Sheet

Documentation Section

Operator: _____ Date: _____

PS S/N: _____ PTS2000 S/N: _____

Unit ID Section

Ventilator Serial Number:_____

Software Version Level: _____

Homing Calibration Section

	L. Side	Cal. Point	R. Side
Vol.:	_____	_____	Vol.: _____
Vol.:	_____	_____	Vol.: _____
Vol.:	_____	_____	Vol.: _____

Internal Volts Calibration Section

Charger Voltage:_____

Charge Req'd? Y N

Pressure Sensor & Front Panel Meter Calibration Section

	50 cmH_2O	90 cmH_2O	10 cmH_2O
PTS2000	A_____	E_____	I_____
FP Meter	B_____	F_____	J_____
Primary	C_____	G_____	K_____
Secondary	D_____	H_____	L_____

High Pressure Relief Valve Calibration Section

PTS2000 Setting: _____

FPM Verification: _____

Comments

Flow Sensor Calibration Section Air _____ O_2_____

Set Flow	*Flow*	*Amplified*	*O_2 Intake*	*Set Flow*
180	*			
170	*			
160	*			
150	*			
140	*			
130	*			
125	*			
120	*			
110	*	MAX	N/A	_____
100	*	INT2	N/A	_____
90	*	INT1	N/A	_____
80	*			80
70	*		N/A	70
60	*		N/A	60
50	*		N/A	50
40	*			40
30	*	*	N/A	30
27		*		27
25		*		25
22		*		22
20	*	*	N/A	20
17		*		17
15		*	N/A	15
12		*		12
10	*	*	N/A	10
7		*		7
5	*	*	N/A	5
4		*	N/A	4
3		*	N/A	3
2		*	N/A	2
1		*	N/A	1
0	*	*	N/A	0

Completion Section

This unit has passed all steps as specified in this process.

Date: _____/_____/_____

Signed:_____

Achieva PSO_2 calibration

All repair, calibration, and testing must be done in a static-controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Warning

Equipment required

- MaSSII software, Version 2.0a (or greater)
- Communications cable, Model Y-6490, or the equivalent RS232 null modem cable with gender changer
- High pressure relief adjustment tool, P/N L-003071-000
- Voltage calibration cable test fixture, P/N L-007887-000
- Blender/power supply adapter test fixture, P/N L-007899-000
- 18-in flex hose, P/N L-002777-000 (or equivalent 18–24-in)
- 5-ft patient circuit, Model Y-6263 with exhalation manifold, Model Y-6353
- Calibration analyzer, Mallinckrodt PTS2000
- Rp20 Resistor
- IBM-compatible computer w/ Windows Operating System (95, 98, or NT)
- High pressure/flow source air or O_2 [up to 80 psi (5.52 bar) and 180 lpm]
- Power supply, capable of 3.5A / 35V
- Small flat blade screwdriver
- Miscellaneous patient circuit adapters

Keep hands and clothing clear of the ventilator. The unit cycles when powered and could cause injury when not completely encased.

Warning

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and the top cover. Finger prints will damage

Caution

the coating.

A Calibration Data Sheet must be completed.

Notes

Calibration because of mechanical or electrical rework will require that the entire calibration process be performed again.

If the ventilator fails a calibration step, record the failure in the comment section of the Calibration Data Sheet. Do not sign and date Calibration Data Sheet.

The Alarm Silence/Reset button may be used to reset alarms as needed.

The *slpm* mode on the PTS2000 should only be used for the Flow Calibration. Use the lpm mode for verifying the flow calibration.

Documentation

1. Record the following information on the Calibration Data Sheet:
   - Operator's name
   - Date
   - Power supply serial number
   - PTS2000 serial number
   - Ventilator serial number

Initialize date/time

1. Connect the ventilator to AC power and allow it to complete its homing sequence.

If there is a Setting Error when the unit is first connected to AC power, or if the unit does not perform a homing sequence, the ventilator Self Test has determined that there are calibration parameters out of specification. If this happens, a MaSSII session should be initiated and the Error Log should be checked. The Error Codes should be used to determine the problem. Once identified, the problem parameter may be calibrated first per this process. Completely power down the venti-

Note

lator. When the ventilator is reconnected to AC power it should “home” correctly and the Setting Error Alarm should not be activated.

2. On the ventilator, press ENTER on the front panel display so that the Settings Entry Screen is active. Press the MENU/ESC button.
3. Press the UP or DOWN arrow key until the “Press ENTER to modify Date and Time” prompt is displayed. Press ENTER.

Note

For ventilators that display readings in English, the order will be the current Month, Day, Year, Hours, and Minutes. For ventilators that display a language other than English, the order will be the current Day, Month, Year, Hours, and Minutes.

4. For ventilators that display English,
   - Verify or set the current Month, using the Up/Down arrows.
   - Press ENTER.
   - Repeat to verify, or set the current Day, Year, Hours, and Minutes.

   For ventilators that display languages other than English,
   - Verify or set the current Day, using the Up/Down arrows.
   - Press ENTER.
   - Repeat to verify, or set the current Month, Year, Hours, and Minutes.
5. Press ENTER to skip the Seconds entry.
6. Press MENU/ESC to go to the Settings Entry screen.

Unit ID

1. Connect the computer to the ventilator using the communications cable.
2. Initiate a MaSSII session.
3. Enter your User ID and Password and select “OK.”

Caution

Using the MaSSII "Setup…Initialize NVRAM…" command will reset all calibration parameters and unit information to defaults. This will also reset the Operating Hours to zero. A complete re-calibration will be required and the operating hours will have to be re-entered.

4. On the MaSSII screen, select “Parameters... Miscellaneous....”
5. Identify the model and serial number of the ventilator and verify they are displayed correctly in the Ventilator Information section on the screen. (If the serial number is not displayed correctly, enter it in the space provided. Select “Download Serial Number.”)
6. Record the software version on the Calibration Data Sheet.
7. Select “Done” to clear the screen.
8. Select “Parameters... Miscellaneous....” on the MaSSII screen if the serial number was changed.
9. Verify the serial number is correct and select “Done.”

Blender leak test

Warning

High pressure compressed gas is used during calibration. Pressurized gas lines can cause injury. DO NOT disturb tubing unless the high pressure source has been turned off and the lines have been purged.

Notes

The PTS2000 must be on for at least 15 minutes prior to use.

Zero the PTS2000 as needed throughout the process.

1. Remove the cap over the O_2 inlet port. Connect the flow source to the O_2 inlet. Do not apply any inlet pressure.

2. Select and zero the PTS2000 screen:
   - Screen 3 if using Air source.
   - Screen 5 if using Oxygen source.

Note

See *PTS2000 Menu Structure* for PTS2000 screen setup.

3. Using an adapter with tubing, connect the ventilator's patient air port to the PTS2000 low flow inlet port.
4. Verify the PTS2000 reading is 0.000 lpm. Set the O_2 inlet pressure to 60 psi +/- 5 psi (3.79–4.48 bar). Allow the PTS2000 10 seconds to stabilize. Verify the PTS2000 reading is still 0.000 lpm.
5. Turn OFF the O_2 inlet pressure and slowly disconnect the flow source from the ventilator's O_2 inlet, allowing any pressure to escape.
6. Disconnect the adapter with tubing from the ventilator's patient air port.

Homing calibration

1. Verify or set the following parameters:
   - MODE A/C
   - VOLUME 200 ml
   - INSPIRATORY TIME 0.7 second
   - SENSITIVITY 5 lpm
   - BREATH RATE 16 bpm
   - PRESSURE SETTING 0 cmH_2O
   - PEEP 0 cmH_2O
   - LOW PRESSURE 1 cmH_2O
   - HIGH PRESSURE 80 cmH_2O
   - F_IO_2 21%
   - OPERATING ALTITUDE Set for the local elevation.

2. Connect the PTS2000 high flow inlet to the ventilator using an Rp20 resistor and a 5-ft patient circuit with exhalation manifold.
3. Select and zero screen 2 on the PTS2000.
4. On the MaSSII screen, select “Parameters...Calibration….”
5. Record the Homing Position reading on the first “Cal. Point” line on the Calibration Data Sheet.
6. Start ventilation by pressing ENTER, and then VENTILATE.

Note

Left/Right side is defined by looking down the cylinder from the motor/gearbox end of the unit. The ventilator’s crankarm continues to operate on the side of the cylinder it started on, until it has been placed into Standby mode. Once it re-enters Ventilate mode, it will operate from the opposite side of the cylinder.

7. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first line under the heading of “L. Side” or “R. Side,” whichever is correct.
8. Set the ventilator to Standby.
9. Press ENTER and then VENTILATE. The Ventilator will be operating from the opposite side of the cylinder.
10. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first line under the heading of “L. Side” or “R. Side,” whichever is correct.
11. If the Volume readings are within .010 of each other and within .010 of .200 L, additional Homing Calibration is not required. Select “Done” to clear the screen. Set the ventilator to STANDBY and proceed to *Internal volts calibration*. If adjustment is needed, set the calibration parameter using the MaSSII software as outlined in the following steps.

Notes

Decrease the Homing Position setting to decrease the volume on the Left side of the cylinder and/or increase the volume on the Right side of the cylinder.

Increase the Homing Position setting to increase the volume on the Left side of the cylinder and/or decrease the volume on the Right side of the cylinder.

An increase or decrease of approximately 4 counts usually is sufficient.

a. Enter the new Homing Position setting and select “Update” to transfer the new data to the ventilator.
b. Record the new Homing Position on the first available “Cal. Point” line on the Calibration Data Sheet.
c. Set the ventilator to Standby.
d. Start ventilation by pressing ENTER and then VENTILATE.
e. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first available line under the heading of “L. Side” or “R. Side,” whichever is correct.
f. Set the ventilator to Standby.
g. Press ENTER and then VENTILATE. The ventilator will be operating from the opposite side of the cylinder.
h. Allow 3–5 breaths for the PTS2000 reading to stabilize. Record the average volume on the Calibration Data Sheet on the first available line under the heading of “L. Side” or “R. Side,” whichever is correct.
i. Verify volume accuracy. If the volume accuracy on each side of the stroke is not within specification, repeat the “Homing Calibration Adjustment” section until it is.
j. If no further adjustments are required, select “Done” to clear the screen. Set the ventilator to STANDBY.

Internal volts calibration

1. Remove AC power from the ventilator and allow the ventilator to shut down. Disconnect all tubing from the ventilator.
2. Set the power supply voltage to 24.00 volts and the current limit to 3.5 Amps. Verify that the

power supply output is OFF.

3. Disconnect the internal battery from the ventilator's power circuit assembly, J9.
4. Connect the power supply to the ventilator's power circuit assembly, J9, using the voltage calibration cable.

The ventilator may cycle when turning on the power supply output. Warning

5. Turn ON the power supply output.
6. Connect the ventilator to AC power.
7. The voltage reading on the power supply may read up to 30 volts. (The power supply may be displaying the battery charger voltage.)
8. On the MaSSII screen, select "Parameters...Calibration…."
9. In the Internal Battery Voltage section, select "Prepare for Cal." The power supply output will read approximately 24.00 volts. (The ventilator's battery charger has been disabled.)
10. Set the power supply to 30.00 volts.
11. On the MaSSII screen, in the Internal Battery Voltage section, select "Point 1."
12. Set the power supply to 20.00 volts.
13. Select "Point 2" in the Internal Battery Voltage section.
14. Set the power supply to 27.00 volts.
15. In the Internal Battery Voltage section, select "Read Voltage." The acceptable range is 27.00 +/- 0.2 volts. Select "OK" to clear the DB (Dialog Box).

Note

When selecting the "Read Voltage" button, the DB displayed will say "Battery voltage = ." When the charger is disabled, the battery voltage will be displayed. When the charger is not disabled, the charger voltage will be displayed, even though the DB display says "Battery voltage = ."

16. In the Internal Battery Voltage section, select “Cal Complete.” The power supply may read up to 30 volts.
17. Turn off the power supply output.
18. Remove AC power from the ventilator and allow the ventilator to shut down.
19. Disconnect the power supply from the ventilator's power circuit assembly, J9.

The ventilator may cycle when connecting the internal battery. Warning

20. Reconnect the internal battery to J9.
21. Reconnect AC power to the ventilator.
22. In the Internal Battery Voltage section, select “Read Voltage” while the Battery Charging LED is lit. Record the battery charger voltage on the Calibration Data Sheet. If the charger voltage is not above 28 volts, the battery will need to be charged before the ventilator goes into Run-in.
23. Record on the Calibration Data Sheet whether the internal battery needs additional charging prior to Run-in. Circle Y if less than 28 volts or N if greater than 28 volts. Select “OK” to clear the DB.

Pressure sensors and front panel meter calibration

High pressure compressed gas is used during calibration. Pressurized gas lines can cause injury. DO NOT disturb tubing unless the high pressure source has been turned off and the lines have been purged. Warning

Note

The pressure/flow source is required to maintain a constant pressure in the circuits. A circuit with a small leak is used to allow the flow rate/pressure to be adjusted manually without damaging the pressure sensors. See Figure 6-3.

Caution

DO NOT apply more than 150 cmH_2O to the ventilator's patient ports or the PTS2000 low pressure ports.

1. Using the high pressure relief adjustment tool, tighten the high pressure relief 1 complete revolution clockwise.

Caution

DO NOT tighten the high pressure relief all the way, or damage to the high pressure relief valve may occur.

2. Select and zero screen 1 on the PTS2000.
3. With no tubing connected to the ventilator, select "Zero" in the Pressure Calibration section on the MaSSII screen.
4. With no tubing connected to the ventilator, verify that the patient pressure meter reads "0". If not, remove the overlay covering the meter adjustment hole, located below the meter, and use a small flat blade screwdriver to center the needle on the "0" mark of the meter.
5. Connect the "Leaky" circuit to the pressure source, the PTS2000 low pressure "+" port, the ventilator's patient air port, and the ventilator's patient pressure port, as shown in Figure 6-3. Make sure that the connections are secure. Ensure that the "leak" is located in the section of the circuit prior to any in-line "T", and the "leak" is not blocked.

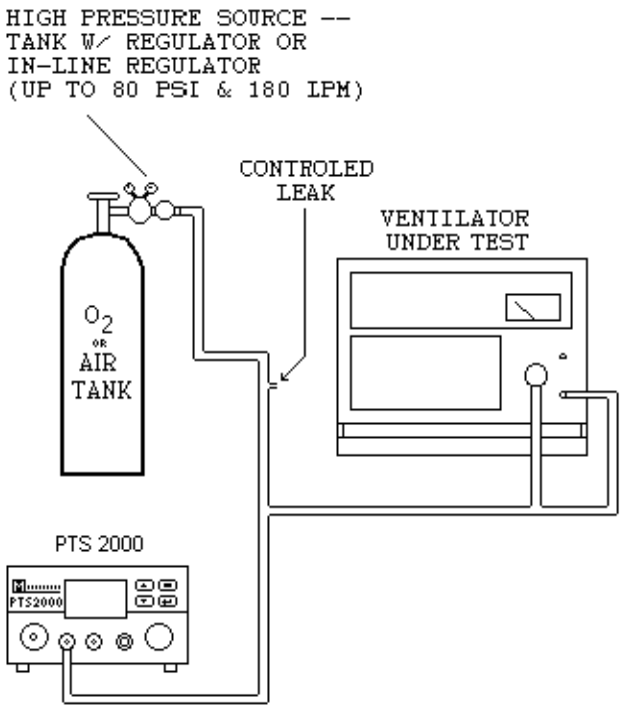


FIGURE 6-3.

6. Slowly adjust the flow so that the pressure on the PTS2000 display is 50.00 +/- 0.10.
7. Ensure that the pressure stabilizes and does not vary by more than 0.10 cmH_2O over several seconds.
8. In the Pressure Calibration section, select “Scale.”
9. Meter Calibration

    - Verify that the pressure on the PTS2000 display is 50.00 +/- 0.10 (adjust if necessary).

- Check the pressure indicated on the front panel meter (FPM). Verify that the meter indicates within 1/2 needle's width of 50. If correct, select "Done" to clear the screen and proceed to "Pressure Accuracy Verification." If not, continue.
- In the Meter section, type the FPM value displayed into the field labeled Reading. Select "Calibrate."

Note

The value entered must be a whole number. For example, if the PTS2000 display is 50.00 cmH_2O and the FPM is reading 53.5, enter 53 or 54.

- Verify that the FPM adjusts to within 1/2 needle's width of the pressure reading on the PTS2000. If necessary, repeat until the FPM matches the PTS2000. Select "Done" to clear the screen.

10. Pressure Accuracy Verification – at calibrated pressure

Note

The flow source can be turned off to conserve compressed air or O_2 when doing the comparisons called out in the following steps.

- Verify the PTS2000 reading is 50.00 +/- 0.10, and select "Parameters...Measurements…" on the MaSSII screen.

Note

Select "Refresh" to update the readings of the MaSSII measurements as needed.

- Record the PTS2000 value displayed on the Calibration Data Sheet, Pressure Verification – Line A.
- Record the FPM value displayed to the nearest 1 cmH_2O on the Calibration Data Sheet, Pressure Verification – Line B.
- Record the Calculated Pressure Reading (Primary) on the Calibration Data Sheet, Pressure Verification – Line C.
- Record the Calculated Secondary Pressure Reading (Secondary) on the Calibration Data

Sheet, Pressure Verification – Line D.

- Compare the 4 pressure readings on the Calibration Data Sheet. The pressure transducers must be within 0.50 cmH_2O and FPM must be within 1 cmH_2O of the PTS2000 reading. If not within range, repeat the pressure calibration portion of this process. If within range, proceed to the next step.

11. Pressure Accuracy Verification – at noncalibrated pressures

- Increase the flow rate until the PTS2000 reads 90.00 +/- 0.10 cmH_2O. Select "Refresh" to update readings. Record the PTS2000, FPM, Primary, and Secondary pressure readings on Lines E – H on the Calibration Data Sheet.
- Compare the 4 pressure readings. The pressure transducers must be within 1.00 cmH_2O and the FPM must be within 2 cmH_2O of the PTS2000 reading. If not within range, repeat the pressure calibration portion of the process. If within range, proceed to the next step.
- Decrease the flow rate until the PTS2000 reads 10.00 +/- 0.10 cmH_2O. Select "Refresh" to update readings. Record the PTS2000, FPM, Primary, and Secondary pressure readings on Lines I – L on the Calibration Data Sheet.
- Compare the 4 pressure readings. The pressure transducers and the FPM must all be within 1.00 cmH_2O of the PTS2000 reading. If not within range, repeat the pressure calibration portion of this process. If within range, proceed to the next step.
- Turn off the flow source and disconnect the "leaky" circuit from the ventilator, flow source, and PTS2000.
- Verify the ventilator's FPM again reads "0", within 1/2 needle's width. If necessary, install a new label over the meter adjustment hole.

High pressure relief valve calibration

1. Using the high pressure relief adjustment tool, loosen the high pressure relief by turning it counter-clockwise, until the high pressure relief screw is even with the outer edge of the

housing. Set the initial high pressure relief setting by turning it clockwise 1 revolution.

2. Zero the PTS2000.
3. Connect the 5-ft patient circuit with exhalation manifold to the ventilator, with the small striped/colored tubing going to both the ventilator and PTS2000 low pressure "+" port.
4. Initiate a Self-Test as follows:
   - Set the right side panel in place on the ventilator. Seal the mounting holes with tape or use your fingers to seal the holes.
   - With the LCD display activated (press ENTER if necessary), press MENU/ESC. The display will read "Press ENTER to begin User Self-Test."
   - Press ENTER on the ventilator. The display will momentarily read "Occlude the patients end of breathing circuit" and "Press ENTER when ready to begin Test."
   - Block the open end of the exhalation manifold, hold the right side panel firmly against the ventilator, and press ENTER. The ventilator will begin a Self-Test.

Notes

The first part of the Self-Test is a High Pressure Relief Valve Test. If the unit fails this test, the "High Pressure Alarm" will activate.

During the second part of the Self-Test, the unit checks for leaks by pressurizing the cylinder and reading the pressure transducers over time. If the unit fails the test, the "Low Pressure/Apnea Alarm" will activate. Correct any leaks and repeat the Self-Test.

5. During the high pressure portion of the Self-Test, watch the display on the PTS2000. Verify the highest reading displayed is 88.00 +/- 3.00 cmH_2O. If not in the correct range, reset any alarms and make slight adjustments to the HPR setting (clockwise to increase and counter-clockwise to decrease the peak pressure). Repeat the Self-Test.
6. When adjustments are finalized and there are no alarms, the PTS2000 displays 88.00 +/- 3.00 cmH_2O, and the Self-Test passes, record the HPR peak pressure from the PTS2000 on the Calibration Data Sheet – PTS2000 Setting.

7. Repeat the Self-Test while watching the FPM. Verify that the FPM on the ventilator peaks in the 90 +/- 10 cmH_2O range. Record the FPM displayed peak pressure on the Calibration Data Sheet – FPM Verification.
8. Verify that the ventilator passed both the Leak and HPR tests and no alarms occurred.
9. Remove the right side panel from the ventilator.
10. Disconnect all tubing from the ventilator and the PTS2000.

Flow sensor calibration

Warning

High pressure compressed gas is used during calibration. Pressurized gas lines can cause injury. DO NOT disturb tubing unless the high pressure source has been turned off and the lines have been purged.

Notes

Disregard any Setting Error Alarms that occur during the flow rate calibration.

For pneumatic configurations, see Figure 6-4.

1. Disconnect the ventilator from AC power. Make sure the ventilator is completely powered down.
2. Disconnect the blender cable connector from the ventilator's logic circuit assembly, J14. (The blender cable consists of 6 coupled black wires and an 8-pin connector.)
3. With the output off, set the power supply to 8 volts and the current limit to 1 Amp.
4. Connect the blender – power supply adapter to the blender cable. Connect one wire to the power supply positive and the other wire to the power supply negative. (No polarity is required.)
5. Connect the ventilator to AC power.

6. Select and zero the PTS2000 screen:
   - Screen 4 if using Air source.
   - Screen 6 if using Oxygen source.
7. Record whether you are using Air or O_2 on the Calibration Data Sheet.

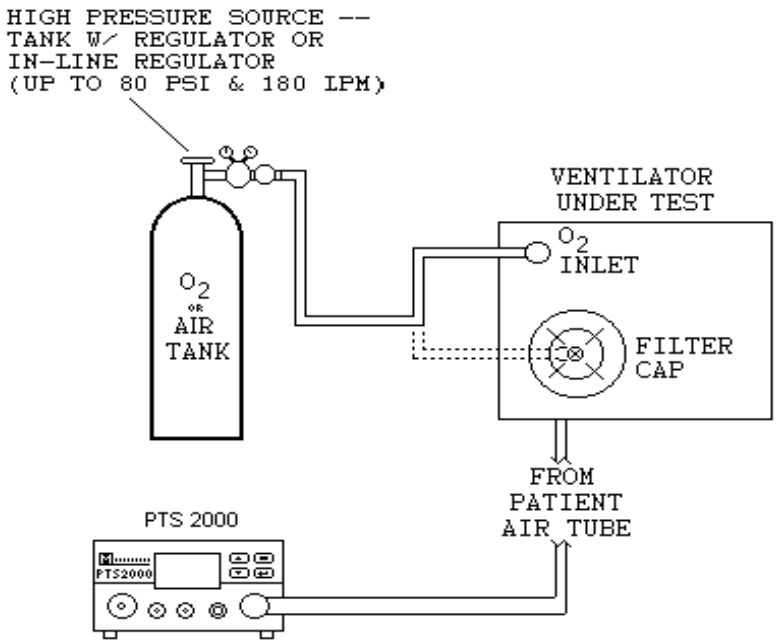


FIGURE 6-4.

8. Connect the ventilator's patient air port to the PTS2000 high flow inlet with an 18–24-in flex hose.
9. Plug the ventilator's exhalation valve port.
10. If necessary, remove the O_2 inlet cap from the ventilator.
11. Connect the high pressure/flow source to the ventilator's O_2 inlet. Set the high pressure/flow

source regulator to approximately 80 psi (5.52 bar) when the output is turned off.

12. Turn on the power supply output. The current draw should be between 250–400 mAmps.

DO NOT apply more than 20 volts to the blender cables. Caution

The power supply output may be turned off and the high pressure source valves may be closed between readings to conserve compressed air or O_2. Note

Do not leave the power supply on longer than 3 minutes at a time when it is set higher than 10v. Caution

If unable to get stable readings, +/- 0.1 lpm, use the PTS2000HF averaging software as follows: Note

- Set the PTS2000 to “REMOTE OPERATION.”
- Connect, or verify the “RS232 TO COMPUTER” port on the back of the PTS2000 is connected to a serial port on the computer.
- Initiate a PTS2000HF session by selecting “Start . . . Programs . . . Mallinckrodt . . . PTS2000HF” from the taskbar. The PTS2000HF window will stay on top of the MaSSII window and both can be used at the same time.
- Select *slpm* for collecting Raw Readings. Select lpm for collecting Adjusted Readings.
- Select “START SAMPLING DATA” to start taking readings.
- Once you get the reading you need, select “Refresh” on the MaSSII software as usual.
- To end a PTS2000HF session, select “STOP SAMPLING DATA” then select “EXIT.” Select the PTS2000 Menu screen as needed.

13. Open the flow control valve. Increase the power supply voltage to 20 volts and adjust the flow control valves to increase the flow through the ventilator to the maximum amount possible without applying more than 80 psi (5.52 bar) to the input. Adjust the flow rate to within 0.10 lpm of a whole number as displayed on the PTS2000. Verify the maximum rate is greater than 80 lpm.
14. Select “Refresh” to update the readings of the MaSSII measurements.
15. Record the maximum flow rate PTS2000 value displayed (rounded off to the nearest whole number) and the raw O_2 intake flow reading on the Calibration Data Sheet, in the location specified for the maximum flow rate.
16. Calculate the INT1 and INT2 flow rates as follows:
    X=(max - 70) / 3 INT1 = 70 + X (round off to nearest 1 lpm)
    INT2 = 70 + (2 x X) (round off to nearest 1 lpm)
17. Record INT1 and INT2 on the Calibration Data Sheet in the locations specified.

Note

All flow settings for this section are +/- 0.10 lpm.

18. Reduce the power supply voltage or adjust the flow valves to reduce the flow to INT2 lpm.
19. Select “Refresh” to update the readings of the MaSSII measurements.
20. Record the raw O_2 intake flow reading on the Calibration Data Sheet in the location specified for the INT2 lpm flow rate.
21. Reduce the power supply voltage or adjust the flow valves to reduce the flow to INT1 lpm.
22. Select “Refresh” to update the readings of the MaSSII measurements.
23. Record the raw O_2 intake flow reading on the Calibration Data Sheet in the location specified for the INT1 lpm flow rate.

Note

Once the power supply voltage is reduced to approximately 8 volts, discontinue the power supply adjustments and use the flow valves to set the desired flow rates.

24. Reduce the power supply voltage to reduce the flow to 70 lpm. (Adjust the flow valves if necessary.)
25. Select “Refresh” to update the readings of the MaSSII measurements.
26. Record the raw flow and raw O_2 intake flow readings on the Calibration Data Sheet in the locations specified for the 70 lpm flow rate.
27. Repeat the power supply and flow source adjustments for all flow rates shown on the Calibration Data Sheet, except for the 180–80 lpm readings for the primary flow sensor and the 5–0 lpm readings for the primary, amplified and O_2 flow sensors. When the flow is reduced to 30 lpm and less, record the raw amplified flow readings in the center column of the Calibration Data Sheet.
28. Once the entire flow sensor calibration section is completed (except for the primary flow sensor at 180–80 lpm and the primary, amplified and O_2 flow sensors at 5–0 lpm), turn off the flow control valves and the power supply output.
29. Disconnect the 18–24-in flex hose from the ventilator. Using the adapter with tubing, connect the ventilator’s patient air port to the PTS2000 low flow inlet port.
30. Zero the PTS2000.
31. Repeat the power supply and flow source adjustments for the 5–0 lpm readings for the primary, amplified and O_2 flow sensors and record the raw flow readings, starting with 5 lpm and working down the chart to 0 lpm.
32. Once the 5–0 lpm calibration is complete, turn off the flow control valves and the power supply.
33. Disconnect the adapter with tubing from the ventilator’s patient air port.
34. Connect the 18–24-in flex hose from the PTS2000 high flow inlet port to the ventilator’s patient air port.
35. Zero the PTS2000.

36. Disconnect the high pressure/flow source from the ventilator's O_2 inlet. Connect the high pressure/flow source to the air intake port on back of the ventilator.
37. Complete the flow sensor calibration section by adjusting the flow rate and recording the raw flow readings for the 180–80 lpm settings, starting with 180 lpm and working down the chart to 80 lpm.
38. Once all data is collected, turn off all pressure/flow control valves and select "Done" to clear the screen.
39. Primary Flow Table Data Entry:
    - On the MaSSII screen, select "Parameters...Flow Tables…" and then select "Read Tables from Ventilator." The screen will display the current tables set in the ventilator.

Note

After a value is entered, use the "TAB" key or the "ENTER" key to highlight the next value to be changed.

- In the Primary Flow A/D Value column, enter the raw readings for the primary flow sensor for each flow rate corresponding to the flow rates on the Calibration Data Sheet.
- Once all the raw readings are entered, verify the flow rate entries match those on the Calibration Data Sheet. If necessary, change the flow rate entries to match those on the Calibration Data Sheet.
- Once all of the raw readings and flow rates are entered per the Calibration Data Sheet, select "Calibrate" (in the Primary Flow section) to send the table to the ventilator.

40. Amplified Flow Table Entry
    - In the Amplified Flow A/D Value column, enter the raw readings for the Amplified Primary Flow Sensor.
    - Once all the raw readings are entered, verify the flow rate entries match those on the Calibration Data Sheet. If necessary, change the flow rate entries to match those on the Calibration Data Sheet.

- Once all of the raw readings and flow rates are entered per the Calibration Data Sheet, select “Calibrate” (in the Amplified Flow section) to send the table to the ventilator.

41. O_2 Intake Flow Table Entry

    - In the O_2 Flow A/D Value column, enter the raw readings for the O_2 flow sensor.
    - Once all the raw readings are entered, verify the flow rate entries match those on the Calibration Data Sheet. If necessary, change the flow rate entries to match those on the Calibration Data Sheet.
    - Once all of the raw readings and flow rates are entered per the Calibration Data Sheet, select “Calibrate” (in the O_2 Flow section) to send the table to the ventilator.

42. Select “Done” to clear the screen.
43. On the MaSSII screen, select “Parameters...Flow Tables…” and then select “Read Tables from Ventilator.” The screen will display the current tables set in the ventilator.
44. Verify the tables are correct by comparing them to the Calibration Data Sheet. If the data points are correct, select “Done” to clear the screen. If any values are incorrect, correct them by re-entering the data and selecting “Calibrate” in the section where the change occurred.

Note

After each time that the tables are changed, you must close the Flow Tables window and then reopen it to verify the changes downloaded to the ventilator correctly.

45. Flow Calibration Verification

    - Select and zero the PTS2000 screen:

      Screen 3 if using Air source.

      Screen 5 if using Oxygen source.

    - Disconnect the 18–24-in flex hose from the ventilator. Using an adapter with tubing, connect the ventilator’s patient air port to the PTS2000 low flow inlet port.

- Disconnect the high pressure/flow source from the air intake port on the back of the ventilator and reconnect it to the O_2 inlet port.
- Set the power supply output to 10 volts. Turn on the power supply output.
- Adjust the flow through the ventilator to 5.00 +/- 0.10 lpm.
- On the MaSSII screen, select “Parameters...Measurements…”
- Verify the Calculated readings for the flow, amplified flow and O_2 intake flow are all 5.00 +/- 0.50 lpm. If acceptable, continue with the next step. If not acceptable, check all connections and retry.

- Turn off the flow control valves.
- Disconnect the adapter with tubing from the ventilator’s patient air port.
- Connect the 18–24-in flex hose from the PTS2000 high flow inlet port to the ventilator’s patient air port.
- Zero the PTS2000.
- Adjust the flow through the ventilator to 25.00 +/- 0.10 lpm.
- Select “Refresh” to update the readings of the MaSSII measurements.
- Verify the Calculated readings for the flow, amplified flow and O_2 intake flow are all 25.00 +/- 1.50 lpm. If acceptable, continue with the next step. If not acceptable, check all connections and retry.
- Adjust the flow through the ventilator to 70.00 +/- 0.10 lpm.
- Select “Refresh” to update the readings of the MaSSII measurements.

Note

The amplified flow is out of range and will not read the correct flow rate.

- Verify the calculated readings for the flow and O_2 intake flow are both 70.00 +/- 2.00. If acceptable, continue with the next step. If not acceptable, check all connections and retry.
- Turn off the flow control valves.
- Turn off the power supply output.

46. Flow Calibration Completion

- Select “Done” to clear the screen.
- Turn off the high pressure/flow source.
- Completely power down the ventilator by disconnecting it from AC power.
- Disconnect all tubing from the PTS2000 and the ventilator.
- Remove the plug from the exhalation valve port.
- Disconnect the high pressure/flow source from the ventilator’s O_2 inlet.
- Carefully purge high pressure from the air lines.
- Finger-tighten the O_2 inlet port cap onto the O_2 inlet port.
- Disconnect the blender/power supply adapter from the blender/PEEP valve cable connector.
- Reconnect the blender/PEEP valve cable connector to J14 on the ventilator’s logic circuit assembly and reposition the front panel on the ventilator.

Initialize repair history

Caution

IMPORTANT! Only perform the ”Initialize repair history” section if a PM was performed.

1. Connect the ventilator to AC power.

2. On the MaSSII screen, select “Parameters... Miscellaneous....”
3. In the Repair History section, enter the number zero in both fields. Select “Download” in the Repair History section.
4. Select “Done” to clear the screen.
5. On the MaSSII screen, select “Parameters... Miscellaneous.....”
6. In the Repair History section, verify that both data fields are zeroed. If the fields do not show zero hours, try to zero it a second time.
7. Select “Done” to clear the screen.

Initialize data logs

1. On the MaSSII screen, select “Parameters... Data Logs....”
2. Select “Initialize Event, Compliance and Trended.” A dialog box will display “Are you sure you want to initialize all Data Logs?” Select “Yes.”
3. A dialog box will display “Data Logs Have Been Initialized.” Select “OK.”
4. Select “Done” to clear the screen.

Generate report

1. On the MaSSII screen select “Report...Report...,” then select the following:
   - Event Log
   - Compliance Data
   - Trended Data
   - Flow Tables
   - Unit ID
   - Cumulative Data
   - Repair History
   - Calibration Parameters
   - Error Log

2. On the MaSSII screen, select “Generate Report.” Save the file in the folder designated for Calibration.
3. A dialog box will appear to confirm the file was saved. Select “OK.”
4. On the Report Generator screen, select “Quit.”
5. Close out the MaSSII Software.

Completion

1. Completely power down the ventilator by disconnecting it from AC power.
2. Disconnect the communications cable from the ventilator.
3. Wrap the AC cord on the cord wraps and secure with the attached Velcro strap.
4. Start a WORDPAD session and open the report file saved in the “Generate Report” section above. Print out the report (to be used for file comparison at Run-in Data Retrieval).
5. Close out WORDPAD.
6. Sign and Date the Calibration Data Sheet.
7. Passed units are now ready for Reassembly.

Achieva PSO$_2$ Calibration Data Sheet

Documentation Section

Operator: _____ Date: _____

PS S/N: _____ PTS2000 S/N: _____

Unit ID Section

Ventilator Serial Number:_____

Software Version Level:_____

Homing Calibration Section

	L. Side	Cal. Point	R. Side
Vol.:	_____	_____	Vol.: _____
Vol.:	_____	_____	Vol.: _____
Vol.:	_____	_____	Vol.: _____

Internal Volts Calibration Section

Charger Voltage:_____

Charge Req'd? Y N

Pressure Sensor & Front Panel Meter Calibration Section

	50 cmH$_2$O	90 cmH$_2$O	10 cmH$_2$O
PTS2000	A_____	E_____	I_____
FP Meter	B_____	F_____	J_____
Primary	C_____	G_____	K_____
Secondary	D_____	H_____	L_____

High Pressure Relief Valve Calibration Section

PTS2000 Setting: _____

FPM Verification: _____

Comments

Flow Sensor Calibration Section Air _____ O$_2$_____

Set Flow	Flow	Amplified	O$_2$ Intake	Set Flow
180	*			
170	*			
160	*			
150	*			
140	*			
130	*			
125	*			
120	*			
110	*	MAX	*	_____
100	*	INT2	*	_____
90	*	INT1	*	_____
80	*			80
70	*		*	70
60	*		*	60
50	*		*	50
40	*			40
30	*	*	*	30
27		*		27
25		*		25
22		*		22
20	*	*	*	20
17		*		17
15		*	*	15
12		*		12
10	*	*	*	10
7		*		7
5	*	*	*	5
4		*	*	4
3		*	*	3
2		*	*	2
1		*	*	1
0	*	*	*	0

Completion Section

This unit has passed all steps as specified in this process.

Date: _____/_____/_____

Signed:_____

Chapter 7: Reassembly

Warning

All repair, calibration, and testing must be done in a static-controlled area. Repair personnel should follow Electro-Static Discharge (ESD) precautions.

Equipment required

- 1/8-in hex bit
- 1/8-in hex driver
- Makita battery-powered torque driver (or equivalent)
- Rubber mallet

Caution

Anti-static gloves or finger cots must be worn when handling the EMI coating on the front panel and the top cover. Finger prints will damage the coating.

Notes

Perform only the steps needed for the repair.

Inspect each part for damage before use.

Clean the assembly as needed throughout the process.

Top cover installation

1. Verify the EMI gasket, P/N L-007033-000, is installed in the top groove of the rear extrusion.
2. Verify the EMI gasket, P/N L-007033-000, is installed in the top groove of the top extrusion on the front panel assembly.
3. Slide the top cover into the grooves where the rear extrusion and right end assembly meet. If

necessary, gently tap the cover into position using a rubber mallet.

4. Verify the bottom of the front panel is in the groove of the front extrusion on the bottom plate assembly.

5. Pivot the front panel into place until the top cover is inserted into the top groove of the top extrusion on the front panel.

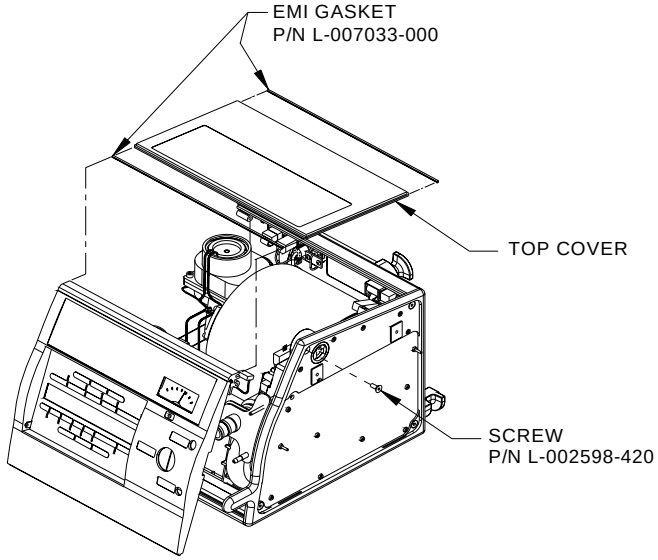


FIGURE 7-1.

6. Use an 1/8-in hex bit and a Makita torque driver set at “5” with the speed range set at “L” (or equivalent) to secure the front panel to the right end assembly using 1, 10-32 x 1/2-in screw (P/N L-002598-420). See Figure 7-1.

Attach left end plate

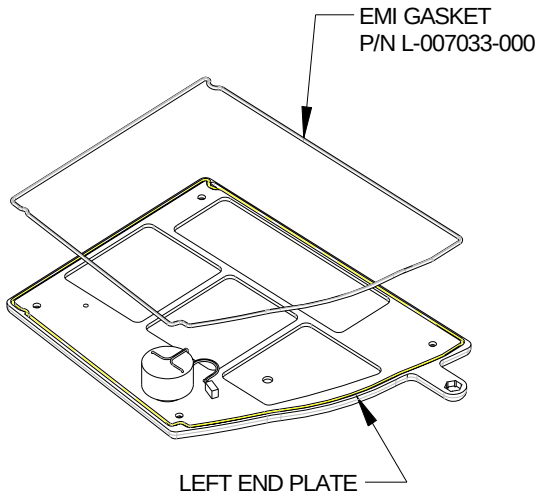


FIGURE 7-2.

1. Verify the EMI gasket, P/N L-007033-000, is installed in the groove around the outer edge of the left end plate. See Figure 7-2.
2. Holding the left end plate next to the left side of the ventilator, connect the alarm cable to J9 on the logic circuit assembly.
3. Insert one end of the handle into the right end plate with the curve of the handle facing away from the ventilator and the mold mark facing down. Insert the other end of the handle into the left end plate.

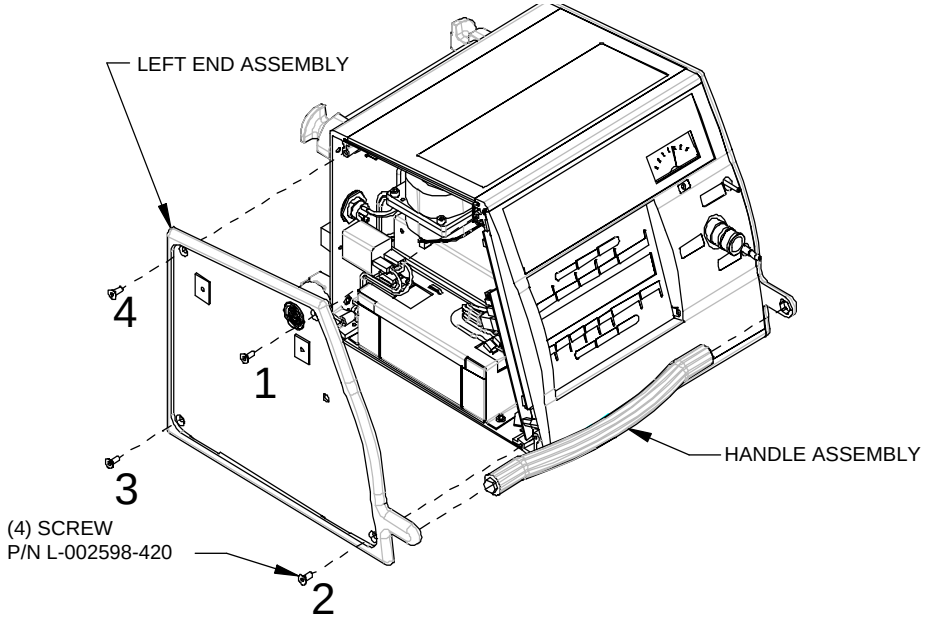


FIGURE 7-3.

4. Set the left end plate into position. Use an 1/8-in hex driver to attach the left end plate by starting 4 screws, 10-32 x 1/2-in (P/N L-002598-420), in the order shown in Figure 7-3.
5. Use an 1/8-in hex bit and a Makita torque driver set at “5” with the speed range set at “L” (or equivalent) to secure the left end plate by tightening the 4 screws in the same order. See Figure 7-3.
6. Verify the handle is secure.

Side panel installation

1. Insert the bottom tabs of the left side panel into the bottom slots of the left end plate. Position the side panel into the recessed area of the end plate.
2. Position a side rail onto the left side panel. Use an 1/8-in hex bit and a Makita torque driver

set at “5” with the speed range set at “L” (or equivalent) to secure the side rail to the end plate with 2 screws, 10-32 x 3/4-in (P/N L-002599-422).

3. Insert the bottom tabs of the right side panel into the bottom slots of the right end plate. Position the side panel into the recessed area of the end plate.

4. Position a side rail onto the right side panel. Use an 1/8-in hex bit and a Makita torque driver set at “5” with the speed range set at “L” (or equivalent) to secure the side rail to the end plate with 2 screws, 10-32 x 3/4-in (P/N L-002599-422).

Intake filter assembly installation

1. Perform the following in the order listed and refer to Figure 7-4.
    - Install the 3-in diameter O-ring (P/N L-002618-000);
    - Install the FlatPak filter, Model Y-6109
    - Install the retainer ring, Model Y-6109-ACH

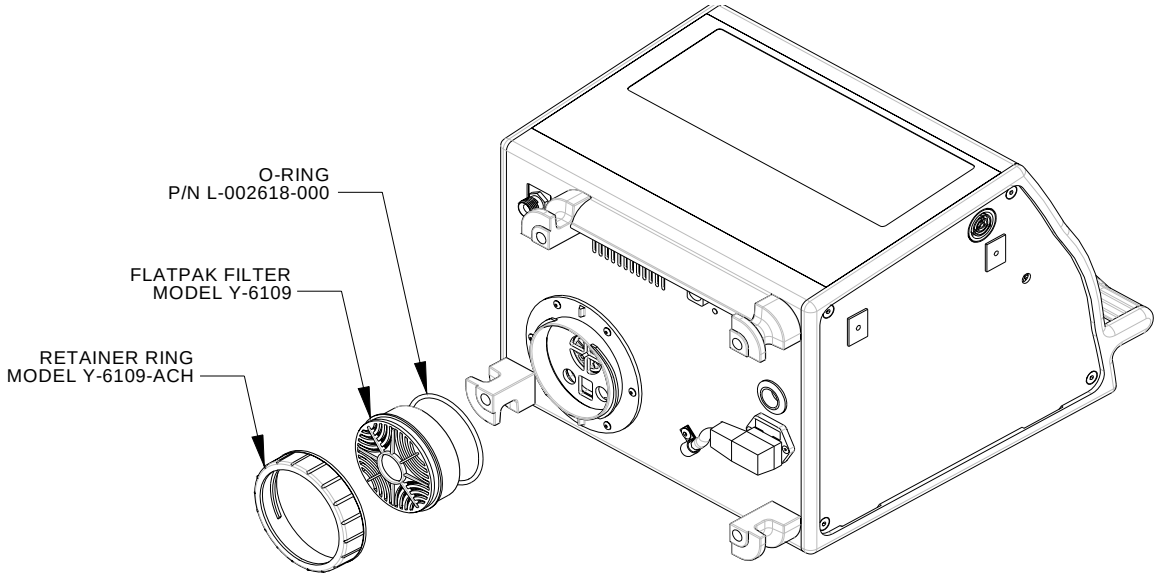


FIGURE 7-4.

2. Refer to the Calibration Data Sheet to determine whether to charge the internal battery. If charging is required, connect the ventilator to AC power for a minimum of 12 hours.
3. Passed ventilators are now ready for Run-in.

Chapter 8: Run-in

Equipment required

- Red Run-in plug (P/N L-003068-000)
- Silicone adapter (P/N L-004100-000)
- Communications cable, Model Y-6490, or the equivalent RS232 null modem cable with gender changer
- Computer, IBM compatible with Windows 95, 98, or NT operating systems
- MaSSII software, Version 2.0a (or greater)
- 5-ft patient circuit, Model Y-6263 with exhalation manifold, Model Y-6353
- SMS test lung, Model SMS0015001 or SMS0015201 (resistance set to 20 and compliance set to 20 ml/cmH_2O)

Ventilator preliminary checks

1. On the Achieva Run-in Data Sheet, record the ventilator's serial number.
2. Connect the ventilator to AC power.
3. Verify or set the following parameters:
   - MODE = A/C
   - VOLUME = 2200 ml
   - SENSITIVITY = 5 lpm
   - BREATH RATE = 10 bpm
   - INSPIRATORY TIME = 2.5 seconds
   - PRESSURE = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 50 cmH_2O
   - HIGH PRESSURE = 80 cmH_2O
   - F_IO_2 = 21% (only for PSO_2 units)
   - Pressure Trigger = 2 cmH_2O

4. Attach a red Run-in plug to the ventilator using a silicone adapter.
5. Set the ventilator to VENTILATE.
6. Record the Run-in start date, time, and hours on the Run-in Data Sheet.

Notes

If the parameter screen is active, check “Ventilating Hours” by selecting the MENU/ESC button, and then using the arrow keys to scroll through the menu items, until the “Ventilating hours since last maintenance” message is displayed.

Allow the ventilator to run a minimum of 30 minutes before performing battery rundown.

8-2

Battery rundown

Note

Battery rundown time requirements are stated on the Achieva Run-in Data Sheet.

1. Disconnect the ventilator from AC power. Verify the POWER SWITCHOVER LED flashes and an audible alarm sounds. Verify the ventilator displays a “WARNING: Power source is now the internal battery” message. Press the Alarm Silence/Reset button to reset the alarm.
2. Allow the ventilator to ventilate for 5–10 breaths on battery power. Press and hold the ventilator’s “Test Battery” button. Verify that the Front Panel Meter indicates a value greater than 65.
3. When the next alarm sounds, verify the following:
   - The Low Power LED flashes.
   - No other alarm LED is lit or flashing.
   - The ventilator displays a “WARNING: Low Internal Battery Power.”
   - The ventilator is functioning properly.

Note

The initial Low Power audible alarm will be a single, extended beep with a latched and flashing Low Power LED. Every 5 minutes thereafter a single extended beep will sound.

4. When the next alarm stage sounds, verify the following:
   - The Low Power LED flashes.
   - No other alarm LED is lit or flashing.
   - The ventilator displays a “WARNING: Extremely Low Internal Battery Power.”
   - The ventilator is functioning properly.
   - An ongoing three-pulse audible alarm sounds.
5. Reset the audible alarm.

Note

The “Extremely Low Internal Battery Power” audible alarm is an ongoing three-pulse alarm that sounds every 5 minutes when reset by the operator. The operator may silence the alarm as needed.

6. Allow the ventilator to run on internal battery until it displays the “WARNING: Battery charge depleted.” There should be an ongoing five-pulse alarm, and the Low Power LED should be flashing.
7. Set the ventilator to Standby.
8. DO NOT touch any front panel buttons for 30 seconds; it will take that long for the ventilator to shut down and for the audible alarm to stop.
9. Reconnect the ventilator to AC power. Allow the ventilator to complete its Homing cycle.
10. Record on the Run-in Data Sheet that the rundown was performed.

Run-in completion

1. Set the ventilator to VENTILATE.
2. Run the ventilator on AC power for approximately 5 minutes, then disconnect the ventilator from AC power. Verify the ventilator switched to internal battery and is operating normally.
3. Press Alarm Silence/Reset and connect the ventilator to AC power.
4. Allow the unit to run a minimum of 20 hours total for Run-in, with at least 12 hours of run time after the battery rundown.

5. Disconnect the ventilator from AC power. Verify the ventilator switched to the internal battery and is operating normally. Press Alarm Silence/Reset and connect the ventilator to AC power.
6. Disconnect the ventilator from AC power again. Verify the ventilator switched to the internal battery and is operating normally. Press Alarm Silence/Reset and connect the ventilator to AC power.
7. Record the ventilating hours for the end of the Run-in.
8. Set the ventilator to Standby.
9. Remove the red Run-in plug and the silicone adapter from the ventilator.

Assist/Spontaneous Check

Note

The Assist/Spontaneous Check needs to be performed while the ventilator is at operation temperature. Do not allow the unit to cool down before performing the test.

1. Connect a 5-ft patient circuit with exhalation manifold and SMS test lung (Set at: Resistance 20 cmH_2O/litre/sec., Compliance 20 ml/cmH_2O) to the ventilator.
2. Verify or set the following parameters:
   - MODE = A/C
   - VOLUME = 800 ml
   - BREATH RATE = 12 bpm
   - INSPIRATORY TIME = 1 second
   - SENSITIVITY = 5 lpm
   - PRESSURE SUPPORT = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O
   - HIGH PRESSURE = 80 cmH_2O
   - F_IO_2 = 21%

3. Set the ventilator to VENTILATE, allow 3 breaths for it to stabilize. Observe the ventilator for 5 breaths and verify the ASSIST/SPONTANEOUS LED does not flash.
4. Set the ventilator to Standby.
5. Remove the patient circuit with exhalation manifold and SMS test lung.
6. Disconnect the ventilator from AC power.

Data retrieval

Data screens on the computer can be cleared when convenient for the operator.

Note

8-5

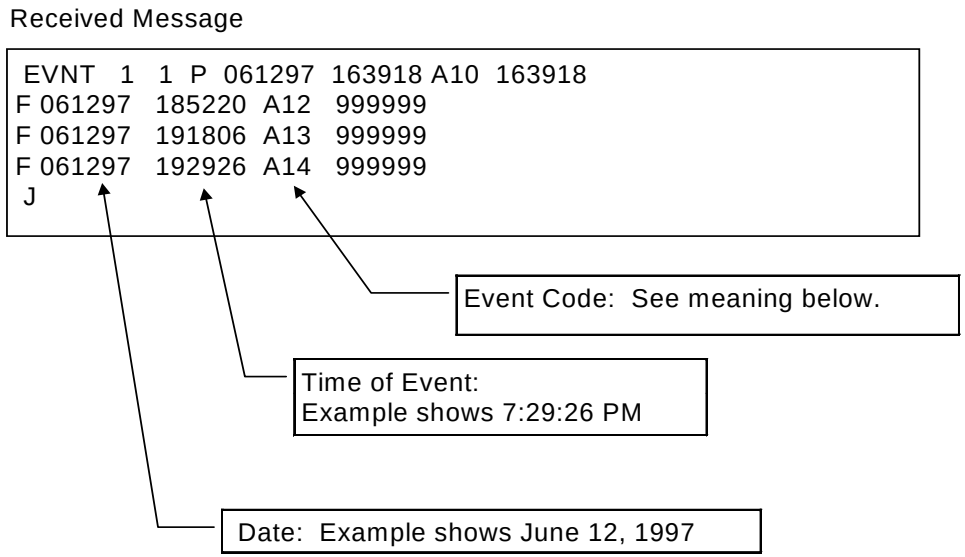
Cautions

DO NOT select any “calibrate” buttons on the MaSSII screen during this process.

DO NOT use the MaSSII “Setup...Initialize NVRAM” command. This command will reset all calibration parameters and unit information to defaults. This will also reset the Operating Hours to zero. A complete re-calibration will be required and the operating hours will have to be re-entered.

1. From the Run-in Data Sheet, compute the “Total Run-in Hours” by subtracting the “Run-in Start Hours” from the “Run-in End Hours” and record it on the Data Sheet. Verify the “Total Run-in Hours” are greater than or equal to 20.
2. Connect the ventilator to AC power.
3. Connect the ventilator to the computer using a communications cable.
4. Initiate a MaSSII session.
5. Enter your user ID and password and select “OK.”

6. On the MaSSII screen, select “Parameters...Miscellaneous....” Compare the on-screen model and serial number to the model and serial number on the calibration printout accompanying the ventilator. Verify it is correct.
7. Select “Done” to clear the screen.
8. On the MaSSII screen, select “Parameters...Data Logs.”
9. On the Data Logs screen, select “Event Log.” Verify the event log; for example:



10. Perform the following battery rundown time verification for the battery rundown performed during Run-in.
    - Review the data on the screen and note the times of the following event codes which correlate to the date and time of the rundown being analyzed:
      A10 (Switched to Internal Battery)

A12 (Low Battery)
A13 (Extremely Low Battery)
A14 (Depleted Battery)

- Record the times of all 4 event codes on the Run-in Data Sheet. Compute and record the Elapsed Times on the Run-in Data Sheet.

- Battery rundown requirements are listed on the Run-in Data Sheet. If the ventilator has successfully completed a phase of the battery rundown, record it on the Run-in Data Sheet as "P".

  If the ventilator fails any part of the battery rundown time requirements, repeat the rundown once. Repeat the battery rundown verification and record the results in the Comment Section of the Data Sheet. If the ventilator passes this battery rundown, continue with the normal Run-in. If the ventilator fails the battery rundown a second time, disposition the ventilator as "FAIL."

- Select "Done" on the Data Logs screen.

11. Select "Report...Report...," and then the following:
    - Event Log
    - Compliance Data
    - Flow Tables
    - Unit ID
    - Cumulative Data
    - Repair History
    - Calibration Parameters

12. Select "Generate Report."

13. Save the file as follows:
    a. Ventilators that passed Run-in:
       Save the file in a folder designated for ventilators that passed Run-in.
    b. Ventilators that failed Run-in:

Save the file in a folder designated for ventilators that failed Run-in.

14. A dialog box will appear to confirm the file was saved. Select “OK.”

15. On the Report Generator screen, select “Quit.”

16. Record the File Save activity by checking the “Report Saved” line on the Run-in Data Sheet.

Disposition

1. If the ventilator failed any step of this process, perform the following:

    - Power down the ventilator completely by disconnecting it from AC power.
    - Disconnect the communications cable from the ventilator.
    - Record the “operational hours at reject,” the “reason” for reject, and your name on the Run-in Data Sheet. Do not reset any of the reports. Do not sign the Run-in Data Sheet for “Successful Completion.”
    - Forward the unit to the proper rework station.

2. For ventilators that passed all previous steps of this process, perform the following:

Note

“Total Hours of Operation” cannot be changed.

- On the MaSSII screen, select “Parameters...Cumulative Data.” Replace any numbers with a zero, except for “Total Hours of Operation.” Select “Download Changes” to send the data to the ventilator. Select “Done.”

Note

After making corrections, always verify the data by calling up the screen after it has been cleared.

- On the MaSSII screen, select “Parameters...Cumulative Data.” Verify that all the data fields (except for “Total Hours of Operation”) are zeroed. If all fields do not display zero, try to zero it a second time. Select “Done.”

Note

"Ampere-Minutes of Internal Battery Charge" may or may not read zero when verifying the entered data, due to charging of the internal battery.

- On the MaSSII screen, select "Parameters...Data Logs...." Select "Initialize Event, Compliance and Trended." A dialog box will display "Are you sure you want to initialize all Data Logs?" Select "Yes."
- A dialog box will display "Data Logs Have Been Initialized." Select "OK."
- On the Data Logs screen select "Done." Close the MaSSII session.
- Completely power down the ventilator by disconnecting from AC power.
- Disconnect the communications cable from the ventilator.
- Date and sign the Run-in Data Sheet.
- Passed units are now ready for Safety Testing.

Achieva Run-in Data Sheet

ACHIEVA RUN-IN DATA SHEET

Ventilator Serial Number: _____

Run-in Start:	Date:_____	Time:_____	Hours:_____
Rundown Performed:	(Check)_____	End of Run-in Hours _____	
Flow Tables Comparison: (P or F) _____		Total Run-in Hours: _____	
Parameters Comparison: (P or F) _____		Report Saved: (Check) _____	
Event Code Times:	Elapsed Times:	Required	P or F
A10 Time _____			
A12 Time _____	A14-A10_____	1:30:00	_____
A13 Time _____	A13-A12_____	00:10:00	_____
A14 Time _____	A14-A13_____	00:05:00	_____

For Rejected Units: Operational Hours at Reject _____

Reason:_____

_____

_____Operator:_____

Comments:_____

_____

_____

_____

_____

Run-in Successfully Completed: Date:____/____/____ Operator: _____

Chapter 9: Safety test

Equipment required

- Hi-Pot Tester, Slaughter 106-2.5W (or equivalent)
- Bio-Tek 601 Pro Series Safety Analyzer with Test Probe (or equivalent)

Ground resistance

1. Test the ground resistance between the following locations using a minimum current source of 10 Amps. Be sure to make good contact by firmly holding the test probe in place.

    - Ground prong on the AC power cord plug to a screw head on the left side rail.
    - Ground prong on the AC power cord plug to a screw head on the right side rail.
    - Ground prong on the AC power cord plug to the head of the AC power cord clamp screw.

2. Each of the three readings for ground resistance cannot exceed 0.2 ohms.

Chassis leakage current

1. Test the chassis leakage current between the AC power cord plug and one of the side rail screw heads. Be sure to make good contact by firmly holding the test probe in place. Test for each of the following conditions at the applicable voltage(s) for your location:

    - Normal, no fault conditions.
    - Open ground condition (single fault condition).
    - Reversed hot/neutral condition (single fault condition).

2. Each of the three readings for chassis leakage current cannot exceed

    - 300 uAmps at 115 VAC (normal and single fault condition).
    - 100 uAmps at 240 VAC (normal condition).
    - 500 uAmps at 240 VAC (single fault condition).

Hi-Pot

Warning

SHOCK HAZARD! DO NOT touch the end of the probe or the ventilator during any Hi-Pot testing. DO NOT touch the probe to any points other than those explicitly called out in the test process.

1. Plug the ventilator AC power cord into the Hi-Pot tester. Use power cord adapters as needed.
2. Turn on the Hi-Pot tester. If the voltage is not already at zero, reduce the voltage to zero.
3. Press the Hi-Pot test probe against the ventilator AC power cord clamp screw head on the back of the ventilator.
4. Steadily increase the voltage on the Hi-Pot tester until it reads 1800 VAC. Hold there for one second then reduce the voltage to zero and remove the probe from the ventilator.
5. If the Hi-Pot Tester has an indicator light to indicate that current is flowing through the filter components on the ventilator, it is expected the light may glow slightly. However, there should not be a failure indicating a breakdown of insulation.
6. Turn off the Hi-Pot tester.
7. Disconnect the ventilator AC power cord from the Hi-Pot tester.

Chapter 10: Final inspection

Base Achieva final inspection

Equipment required

- IBM-compatible computer with Windows Operating System (95, 98, or NT)
- MaSSII software, Version 2.0a (or greater)
- Communications cable, Model Y-6490, or the equivalent RS232 null modem cable with gender changer
- Calibration analyzer, Mallinckrodt PTS2000
- 5-ft patient circuit, Model Y-6263 with exhalation manifold, Model Y-6353
- Calibrated stop watch
- Syringe, Ametek Model T-810, Ralston Model DPOV0000 (or equivalent)
- SMS test lung, Model SMS0015001 or SMS0015201 with resistance set to 20 and compliance set to 20 ml/cmH_2O
- Rp50 resistor
- Alarm tester, P/N Y-100864-00A
- Digital multimeter, Fluke 77 (or equivalent)
- 18-in flex hose, P/N L-002777-000 (or equivalent, 18–24-in)
- High pressure / flow source, O_2 [up to 80 psi (5.52 bar) and 180 lpm]
- Pediatric patient circuit, Model Y-6464
- Rp200 resistor (or adjustable valve)
- 12-V battery with external battery cable
- 24-V battery with external battery cable
- Miscellaneous patient circuit adapters

Notes

If the ventilator fails any step and is to be rejected, describe the parameter that is not in compliance with the specification in the comments section of the Achieva Final Inspection Data Sheet (Data Sheet).

The Alarm Silence Reset button may be used to reset alarms as needed.

Ventilator preliminary checks

1. Verify the ventilator's serial number agrees with the attached paperwork. Verify all necessary operations needed prior to FINAL INSPECTION have been completed.
2. Record on the Data Sheet the date, the serial number of the ventilator under test, and the inspector's name. Record the serial number of the PTS2000 that will be used for this process.
3. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Self-test

1. Connect the ventilator to AC power. All LEDs should light and turn off except for the AC and BATTERY CHARGING LEDs which should remain on. The audible alarm will sound momentarily and the unit will cycle. Initiate a SELF-TEST as follows:
   - Connect a 5-ft patient circuit with exhalation manifold to the ventilator.
   - Press ENTER, then press MENU/ESC. The unit will display “Press ENTER to begin User Self Test.”
   - Press ENTER and wait for the unit to display “Press ENTER when ready to begin test.”
   - Block the open end of the exhalation manifold and press ENTER. If the SELF-TEST passes, only the AC and BATTERY CHARGING LEDs will remain lit, and the ventilator's display will show “Test PASSED.” Any LED flashing at the end of the test means that a failure has occurred.
   - Remove the 5-ft patient circuit with exhalation manifold.
2. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Pressure accuracy test

Note

The PTS2000 must be on at least 15 minutes prior to use.

1. Verify the PATIENT PRESSURE meter needle is within 1/2 needle’s width of “0”.
2. Select and zero screen 1 on the PTS2000.

Note

See Appendix A, “PTS2000 Menu Structure,” for PTS2000 screen setup.

3. Connect the syringe to both the Low Pressure “+” port on the PTS2000 and the PATIENT PRESSURE port on the ventilator.
4. Observe the PTS2000 and apply a pressure of 6.00 (+/- 0.50) cmH_2O. Verify the pressure value on the PATIENT PRESSURE meter is within 2 cmH_2O of the value displayed on the PTS2000.
5. Increase the pressure slowly until the Setting Error LED lights and an audible alarm sounds. Verify the PTS2000 displays 15.00 cmH_2O (+/- 2.00) cmH_2O.
6. Observe the PTS2000 and apply a pressure of 80.00 (+/-0.50) cmH_2O. Verify the pressure value on the PATIENT PRESSURE meter is within 2 cmH_2O of the value displayed on the PTS2000.
7. Use the syringe to decrease the pressure to approximately “0”. If necessary, press ALARM SILENCE/RESET.
8. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Pressure trigger test

1. Remove the tubing from the Low Pressure “+” port on the PTS2000 and connect it to the Low Pressure “-” port on the PTS2000.
2. Set the following parameters:
   - MODE = A/C
   - VOLUME = 1000ml
   - BREATH RATE = 6 bpm
   - INSPIRATORY TIME = 2.0 seconds
   - SENSITIVITY = 5 lpm
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O

- HIGH PRESSURE = 80 cmH_2O
- PRESSURE TRIGGER = 5 cmH_2O
- OPERATING ALTITUDE = Set for the local elevation
- ALARM LATCHING STATUS = LATCHING

3. Set the unit to VENTILATE. Alarms may occur during this test. Press ALARM SILENCE/RESET to silence the alarms.

Note

When using the Low Pressure "-" port, the PTS2000 does not display the negative sign "-" when the pressure is negative.

4. Between cycles, slowly decrease the pressure until the ASSIST/SPONTANEOUS LED lights and the ventilator autocycles. Verify the pressure displayed on the PTS2000 is at negative 5.00 (+/- 2.00) cmH_2O. Record the pressure reading on the Data Sheet.
5. Set the pressure trigger level to 10 cmH_2O.
6. Between cycles, slowly decrease the pressure until the ASSIST/SPONTANEOUS LED lights and the ventilator autocycles. Verify the pressure displayed on the PTS2000 is at negative 10.00 (+/- 2.00) cmH_2O. Record the pressure reading on the Data Sheet.
7. Use the syringe to increase the pressure to approximately "0". Disconnect the syringe from the ventilator, and set the ventilator to STANDBY.
8. Press the ALARM SILENCE/RESET button if necessary.
9. Set the pressure trigger level to 2 cmH_2O.
10. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Volume accuracy test

1. Verify an Rp50 resistor is connected to the High Flow Inlet port of the PTS2000 with a 5-ft patient circuit and exhalation manifold attached. Attach the other end of the patient circuit to the ventilator.

2. Select and zero screen 2 on the PTS2000.
3. Set following parameters:
   - VOLUME 1000 ml
   - BREATH RATE 10 bpm
   - INSPIRATORY TIME 2.0 seconds
4. Set the unit to VENTILATE and allow the PTS2000 reading to stabilize.
5. The average volume reading must be 1.000 +/- 0.050 (0.950 to 1.050) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.
6. Set the unit to STANDBY, then back to VENTILATE. Allow the PTS2000 reading to stabilize. The average volume reading must be 1.000 +/- 0.050 (0.950 to 1.050) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.
7. Verify the two recorded readings for 1000 ml do not differ by more than 0.030 liters.
8. Set the unit to STANDBY.
9. Set the following parameters:
   - VOLUME 2000 ml
   - BREATH RATE 6 bpm
   - INSPIRATORY TIME 3.5 seconds
10. Set the unit to VENTILATE and allow the PTS2000 reading to stabilize.
11. The average volume reading must be 2.000 +/- 0.070 (1.930 to 2.070) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.
12. Set the unit to STANDBY, then back to VENTILATE. Allow the PTS2000 reading to stabilize. The average volume reading must be 2.000 +/- 0.070 (1.930 to 2.070) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.

13. Verify the two recorded readings for 2000 ml do not differ by more than 0.030 liters.
14. Set the unit to STANDBY and disconnect the patient circuit from the ventilator and the PTS2000.
15. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Operational test

1. Set the following parameters:
   - VOLUME 1000 ml
   - INSPIRATORY TIME 1.2 seconds
   - BREATH RATE 10 bpm
2. Select and zero screen 1 on the PTS2000.
3. Connect a test lung to the High Flow Exhaust of the PTS2000, using a 5-ft patient circuit with an exhalation manifold. Connect the ventilator's patient air port to the PTS2000 High Flow Inlet using an 18–24-in flex hose. The small striped/colored tubing on the patient circuit should be connected to both the ventilator and the PTS2000 Low Pressure "+" port. The other small tube on the patient circuit should be connected between the ventilator and the exhalation valve.
4. Set the unit to VENTILATE.
5. Press MENU/ESC, then press the up or down arrow key to select "VENTILATING HOURS." Verify the "Ventilating hours since last maintenance" is correct. Press the up or down arrow key to select "DATE AND TIME," then press ENTER. Verify the date and the time are correct. If the date and time are correct, press MENU/ESC twice. If the date and time are not correct, set the correct date and time and shut down the ventilator for at least 5 seconds. Turn the ventilator back on and check the date and time. If the date and time cannot be held correctly, reject the unit.
6. Check the peak pressure on the PTS2000. Verify the ventilator's front panel meter peaks within 8 cmH_2O of the peak pressure value, then returns to "0".
7. Set the Inspiratory Time to 2.0 seconds.

8. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Power switchover test

Note

The BATTERY CHARGING LED will periodically turn off, then turn back on. This is normal operation.

1. Connect a 24-V battery to the ventilator's external battery jack using an external battery cable.
2. Disconnect the ventilator from AC power. The POWER SWITCHOVER LED will flash and an alarm will sound. The EXTERNAL BATTERY LED will come on and the BATTERY CHARGING LED will stay on. The AC LED will turn off.
3. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
4. Set the unit to STANDBY. The BATTERY CHARGING LED will turn off.
5. Set the unit to VENTILATE. The BATTERY CHARGING LED will turn on.
6. Disconnect the 24-V battery. The POWER SWITCHOVER LED will flash, the INTERNAL BATTERY LED will light, and an alarm will sound. The EXTERNAL BATTERY and BATTERY CHARGING LEDs will turn off.
7. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
8. Connect the 24-V battery. Verify the EXTERNAL BATTERY and BATTERY CHARGING LEDs light and the INTERNAL BATTERY LED turns off. The ventilator should not alarm POWER SWITCHOVER.
9. Connect the ventilator to AC power. Verify the AC LED lights and the EXTERNAL BATTERY LED turns off. The ventilator should not alarm POWER SWITCHOVER.
10. Disconnect the 24-V battery.
11. Set the ventilator to STANDBY, then back to VENTILATE.

12. Connect a 12-V battery to the ventilator's external battery jack using an external battery cable.
13. Disconnect the ventilator from AC power. The POWER SWITCHOVER LED will flash and an alarm will sound. The EXTERNAL BATTERY LED will come on and the AC LED will turn off.
14. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
15. Disconnect the 12-V battery. The POWER SWITCHOVER LED will flash, the INTERNAL BATTERY LED will light and an alarm will sound. The EXTERNAL BATTERY and BATTERY CHARGING LEDs will turn off.

16. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
17. Press and hold the TEST BATTERY button. The front panel meter needle must display a value greater than 65.
18. Connect the 12-V battery. Verify the EXTERNAL BATTERY and BATTERY CHARGING LEDs light and the INTERNAL BATTERY LED turns off. The ventilator should not alarm POWER SWITCHOVER.
19. Connect the ventilator to AC power. Verify the AC LED lights and the EXTERNAL BATTERY LED goes out. The ventilator should not alarm POWER SWITCHOVER.
20. Disconnect the 12-V battery from the ventilator.
21. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Remote jack test

1. Connect the alarm tester to the REMOTE ALARM output on the ventilator. Connect a digital multimeter to the tester (red wire to “+” black wire to “-”). Set the multimeter to VDC.
2. Set the selection knob to SUPPLY. Verify the displayed voltage is 8.0 +/- 0.4 VDC.
3. Set the knob to the VISUAL position. Verify the displayed voltage is 4.5 +/- 0.4 VDC.

4. Set the knob to the AUDIBLE position. Verify the displayed voltage is 4.5 +/- 0.4 VDC.
5. Set the HIGH PRESSURE to 25 cmH_2O.
6. Within 2 cycles verify:
   - The alarm sounds.
   - The High Pressure LED flashes.
7. Verify the displayed voltage is 0.0 +/- 0.4 VDC.
8. Set the knob to the VISUAL position. Verify the displayed voltage is 0.0 +/- 0.4 VDC.
9. Press the RESET button on the alarm tester. The voltage displayed should remain at 0.0 +/- 0.4 VDC.
10. Set the knob to the AUDIBLE position. Verify the displayed voltage is 4.5 +/- 0.4 VDC.
11. Verify the Peak Pressure displayed on the PTS2000 is less than 35 cmH_2O.
12. Set the HIGH PRESSURE to 80 cmH_2O. Verify the HIGH PRESSURE LED stops flashing. If necessary, press ALARM SILENCE/RESET to reset the SETTING ERROR LED if it occurs.
13. Disconnect the patient pressure tubing from the ventilator. Within 2 cycles verify the SETTING ERROR LED flashes and the alarm sounds. Within 3 cycles verify:
    - An audible 5-pulse alarm sounds.
    - The LOW PRESSURE/APNEA LED flashes.
14. Verify the displayed voltage is pulsing.
15. Set the knob to the VISUAL position. Verify the displayed voltage is 0.0 +/- 0.4 VDC.
16. Press the RESET button on the alarm tester.
17. Reconnect the patient pressure tubing. If necessary, after the LOW PRESSURE/APNEA LED goes out, press ALARM SILENCE/RESET to reset the SETTING ERROR LED.
18. Set the unit to STANDBY and verify the displayed voltage is 0.0 +/- 0.4 VDC.
19. Set the knob to the AUDIBLE position. Verify the displayed voltage is 0.0 +/- 0.4 VDC.

20. Press the ALARM SILENCE/RESET button on the ventilator and verify the displayed voltage is 4.5 +/- 0.4 VDC.
21. Disconnect the tester from the ventilator.
22. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Nurse call output test

1. Connect the alarm tester to the NURSE CALL output jack of the ventilator.
2. Set the alarm tester selection knob to BATTERY CHECK. Verify the voltage is greater than 8 VDC.

3. Set the selection knob to NURSE CALL. Set the multimeter to ohms.
   - If the Digital Multimeter reads greater than 1.0 MΩ (1 megaohm), go to step 4.
   - If the Digital Multimeter reads less than 1.0 ohm, go to step 12.
4. Turn off the multimeter and set the selection knob to Alarm Test.
5. Set the unit to VENTILATE. After the ventilator completes its start up sequence verify the LED on the test fixture is not lit.
6. Set the HIGH PRESSURE to 40. Within 2 cycles, verify the LED on the test fixture is lit continuously as the HIGH PRESSURE LED flashes and an audible alarm sounds.
7. Set the HIGH PRESSURE to 80 and press ALARM SILENCE/RESET. Verify the LED on the test fixture turns off, the HIGH PRESSURE LED stops flashing, and the audible alarm resets. If necessary, press ALARM SILENCE/RESET to reset the SETTING ERROR LED if it occurs.
8. Disconnect the patient pressure tubing from the ventilator.
9. Within 2 breaths, verify the SETTING ERROR LED flashes and the alarm sounds. Within 3 breaths, verify the LOW PRESSURE LED lights and a 5-pulse alarm is generated along with a corresponding flashing of the test fixture LED.
10. Reconnect the patient pressure tubing and press ALARM SILENCE/RESET. Verify the LED on the test fixture stops flashing, the LOW PRESSURE and SETTING ERROR LEDs stop

flashing, and the audible alarm resets.

11. Go to step 19.
12. Turn off the multimeter and set the knob to ALARM TEST.
13. Set the unit to VENTILATE. After the ventilator completes its start-up sequence, verify that the LED on the test fixture is lit.
14. Set the HIGH PRESSURE to 40. Within 2 cycles, verify the LED on the test fixture turns off as the HIGH PRESSURE LED flashes and an audible alarm sounds.
15. Set the HIGH PRESSURE to 80 and press ALARM SILENCE/RESET. Verify the LED on the test fixture turns on, the HIGH PRESSURE LED stops flashing, and the audible alarm resets. If necessary, press ALARM SILENCE/RESET to reset the SETTING ERROR LED if it occurs.
16. Disconnect the patient pressure tubing from the ventilator.
17. Within 2 breaths, verify the SETTING ERROR LED flashes and the alarm sounds. The test fixture LED will turn off while the alarm sounds. Within 3 breaths, verify the LOW PRESSURE LED lights and a 5-pulse alarm is generated, along with a corresponding flashing of the test fixture LED.
18. Reconnect the patient pressure tubing and press ALARM SILENCE/RESET. Verify the LED on the test fixture stops flashing and is lit continuously, the LOW PRESSURE and SETTING ERROR LEDs stop flashing, and the audible alarm resets.
19. Disconnect the alarm tester from the ventilator and set the selection knob of the tester to Supply.
20. Set the ventilator to STANDBY.
21. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Pressure cycle test

Note

A VOLUME cannot be set if the ventilator is in the PRESSURE mode.

1. Remove the 18–24-in flex hose connecting the ventilator to the PTS2000 High Flow Inlet port. Disconnect the test lung from the PTS2000 High Flow Exhaust port and connect the test lung to the ventilator's Patient Air port.

2. Set the ventilator to VENTILATE, then set the following parameters:
   - PRESSURE SETTING = 10 cmH_2O
   - PEEP = 5 cmH_2O
   - LOW PRESSURE = 13 cmH_2O

3. Allow the ventilator to cycle for a minimum of 1 minute. Observe the continuous pressure readings on the PTS2000. Verify the readings alternate between a low of 5.00 cmH_2O (+/-2.50 cmH_2O), and a high of 15.00 cmH_2O (+/-2.50 cmH_2O). Disregard any readings between the low and the high readings.

4. Set the following parameters:
   - PEEP = 10 cmH_2O
   - PRESSURE SETTING = 20 cmH_2O

5. Allow the ventilator to cycle for a minimum of 1 minute. Observe the continuous pressure readings on the PTS2000. Verify the readings alternate between a low of 10.00 cmH_2O (+/-2.50 cmH_2O), and a high of 30.00 cmH_2O (+/-2.50 cmH_2O). Disregard any readings between the low and the high readings.

6. Set the unit to STANDBY, then set the following parameters:
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O

7. Disconnect the patient circuit with test lung from the ventilator.

8. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Flow sensitivity test

Note

The PTS2000 must be on at least 15 minutes prior to use.

1. Set or verify the following parameters:
   - POWER = AC
   - MODE = A/C
   - VOLUME = 1000 ml
   - INSPIRATORY TIME = 2.0 seconds
   - SENSITIVITY = 5 lpm
   - BREATH RATE = 6 bpm
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O
   - HIGH PRESSURE = 80 cmH_2O
2. Connect the high pressure/flow source to the ventilator's air inlet port. Verify that an 18–24-in flex hose is connected from the ventilator's patient air port to the PTS2000 high flow inlet port.
3. Select and zero the screen on the PTS2000:
   - Screen 3 if using Air source.
   - Screen 5 if using Oxygen source.

Note

Alarms will occur. Disregard any alarms during this section. ALARM SILENCE/RESET may be used to reset the audible alarm.

4. Set the unit to VENTILATE.
5. Allow the ventilator 3 cycles to stabilize. Verify the ASSIST/SPONTANEOUS LED does not light or blink.
6. Between cycles, as the flow readings stabilize, increase the flow slow enough to be able to see each digit change on the PTS 2000 until the ventilator autocycles. Verify the

ASSIST/SPONTANEOUS LED lights between cycles.

7. Set the ventilator to STANDBY. Verify the flow is set at 5.00 (+/- 1.00) lpm. (The reading should be within 0.1 lpm of the reading oberved in step 6 when the unit started to autocycle. If it is not, repeat steps 6 and 7.) Record the flow reading on the Data Sheet.
8. Set the SENSITIVITY to 15 lpm.
9. Set the ventilator to VENTILATE.
10. Allow the ventilator 3 cycles to stabilize. Verify the ASSIST/SPONTANEOUS LED does not light or blink.
11. Between cycles, as the flow readings stabilize, increase the flow slow enough to be able to see each digit change on the PTS 2000 until the ventilator autocycles. Verify the ASSIST/SPONTANEOUS LED lights between cycles.
12. Set the ventilator to STANDBY. Verify the flow reading is 15.00 (+/- 1.00) lpm. (The reading should be within 0.1 lpm of the reading oberved in step 11 when the unit started to autocycle. If it is not, repeat steps 11 and 12.) Record t6he flow reading on the Data Sheet.
13. Turn off the flow source.
14. Disconnect the High Pressure/Flow Source and remove the 18–24-in flex hose.
15. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Completion

1. Set, or verify, the following parameters:
   - MODE = A/C
   - VOLUME = 1000 ml
   - INSPIRATORY TIME = 1.5 seconds
   - SENSITIVITY = 5 lpm
   - BREATH RATE = 10 BPM
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O

- LOW PRESSURE = 25 cmH_2O
- HIGH PRESSURE = 30 cmH_2O
- Pressure Trigger = 2 cmH_2O
- EXPIRATORY SENSITIVITY = 15 %
- FLOW ACCELERATION = Off

2. Connect the computer to the ventilator, using the communications cable.
3. Initiate a MaSSII session.
4. Enter your User ID and Password; then select "OK."

Caution

DO NOT use the MaSSII "Setup...Initialize NVRAM" command. This command will reset all calibration parameters and unit information to defaults. This will also reset the Operating Hours to zero. A complete re-calibration will be required and the operating hours will have to be re-entered.

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5. On the MaSSII, select "Parameters. . . Data Logs. . .".
6. Select "Initialize Event, Compliance and Trended." A dialog box will display "Are you sure you want to initialize all Data Logs?" Select "Yes."
7. A dialog box will display "Data Logs Have Been Initialized." Select "OK."
8. Disconnect the communications cable.
9. Select "Done" to clear the screen.
10. Close out the MaSSII Software.
11. Disconnect the ventilator from AC power. It will take up to 30 seconds for the ventilator to shut down.
12. Wrap the ventilator's power cord around the cord wrap feet and secure it in place.

13. Record on the Data Sheet if the ventilator passed or failed this section of the process.
14. If the ventilator passed the entire final inspection, sign and date the Data Sheet.

Base Achieva Final Inspection Data Sheet

BASE ACHIEVA FINAL INSPECTION DATA SHEET

PTS2000 #: _____ Definitions: Date: _____/_____/_____

P=PASS

F=FAIL Unit Serial #: _____

Inspected by: _____

PRELIMINARY CHECKS _____ NURSE CALL OUTPUT TEST_____

SELF-TEST _____ PRESSURE CYCLE TEST_____

PRESSURE ACCURACY TEST _____

PRESSURE TRIGGER TEST _____

-5 cmH_2O_____ -10 cmH_2O _____

(-3.0 to -7.0) (-8.0 to -12.0)

VOLUME ACCURACY TEST _____

Vol. @ 1.0 L = _____ _____

(0.950 - 1.050)

Vol. @ 2.0 L = _____ _____ FLOW SENSITIVITY _____

(1.930 - 2.070)

OPERATIONAL TEST _____ 5 lpm _____ 15 lpm _____

(4.0 - 6.0) (14.0 - 16.0)

POWER SWITCHOVER TEST _____ COMPLETION _____

REMOTE JACK TEST _____

This ventilator has passed all tests specified in this process.

SIGNATURE: _____ DATE: _____

COMMENTS:

Achieva PS and PSO_2 final inspection

Equipment required

- Modem, Hayes compatible, 9600 BAUD minimum
- 2 telephone lines, analog (or phone line simulator, Viking DLE-200B)
- IBM-compatible computer with Windows operating system (95, 98, or NT)
- MaSSII software, Version 2.0a (or greater)
- Communications cable, Model Y-6490, or the equivalent RS232 null modem cable with gender changer
- Calibration analyzer, Mallinckrodt PTS2000
- 5-ft patient circuit, Model Y-6263 with exhalation manifold, Model Y-6353
- Calibrated stop watch
- Syringe, Ametek Model T-810, Ralston Model DPOV0000 (or equivalent)
- SMS test lung, Model SMS0015001 or SMS0015201 with resistance set to 20 and compliance set to 20 ml/cmH_2O
- Rp50 resistor
- Alarm tester, P/N Y-100864-00A
- Digital multimeter, Fluke 77 (or equivalent)
- 18-in flex hose, P/N L-002777-000 (or equivalent, 18–24-in)
- High pressure / flow source, O_2 [up to 80 psi (5.52 bar) and 180 lpm]
- Pediatric patient circuit, Model Y-6464
- Rp200 resistor (or adjustable valve)
- 12-V battery with external battery cable
- 24-V battery with external battery cable
- Miscellaneous patient circuit adapters

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Notes

If the ventilator fails any step and is to be rejected, describe the parameter that is not in compliance with the specification in the comments section of the Achieva Final Inspection Data Sheet (Data Sheet).

The Alarm Silence Reset button may be used to reset alarms as needed.

The LEAK, OXYGEN BLENDING, and FLOW SENSITIVITY TESTS may be performed at any time throughout this process, as long as they are performed before the Completion section.

Ventilator preliminary checks

1. Verify the ventilator's serial number agrees with the attached paperwork. Verify all necessary operations needed prior to FINAL INSPECTION have been completed.
2. Record on the Data Sheet the date, the serial number of the ventilator under test, and the inspector's name. Record the serial number of the PTS2000 that will be used for this process.
3. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Self-test

1. Connect the ventilator to AC power. All LEDs should light and turn off except for the AC and BATTERY CHARGING LEDs which should remain on. The audible alarm will sound momentarily and the unit will cycle. Initiate a SELF- TEST as follows:
   - Connect a 5- ft patient circuit with an exhalation manifold to the ventilator.
   - Press ENTER, then press MENU/ ESC. The unit will display "Press ENTER to begin User Self Test."
   - Press ENTER and wait for the unit to display "Press ENTER when ready to begin test."
   - Block the open end of the exhalation manifold and press ENTER. If the SELF-TEST passes, only the AC and BATTERY CHARGING LEDs will remain lit, and the ventilator's display will show "Test PASSED." Any LED flashing at the end of the test means that a failure has occurred.
   - Remove the 5- ft patient circuit with exhalation manifold.
2. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Pressure accuracy test

Note

The PTS2000 must be on at least 15 minutes prior to use.

1. Verify the PATIENT PRESSURE meter needle is within 1/2 needle's width of "0".
2. Select and zero screen 1 on the PTS2000.

Note

See Appendix A, "PTS2000 Menu structure," for PTS2000 screen setup.

3. Connect the syringe to both the Low Pressure "+" port on the PTS2000 and the PATIENT PRESSURE port on the ventilator.
4. Observe the PTS2000 and apply a pressure of 6.00 (+/- 0.50) cmH_2O. Verify the pressure value on the PATIENT PRESSURE meter is within 2 cmH_2O of the value displayed on the PTS2000.

5. Increase the pressure slowly until the Setting Error LED lights and an audible alarm sounds. Verify the PTS2000 displays 15.00 cmH_2O (+/- 2.00) cmH_2O.
6. Observe the PTS2000 and apply a pressure of 80.00 (+/-0.50) cmH_2O. Verify the pressure value on the PATIENT PRESSURE meter is within 2 cmH_2O of the value displayed on the PTS2000.
7. Use the syringe to decrease the pressure to approximately "0". If necessary, press ALARM SILENCE/RESET.
8. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Pressure trigger test

1. Remove the tubing from the Low Pressure "+" port on the PTS2000 and connect it to the Low Pressure "-" port on the PTS2000.

Note

All F_IO_2 settings in this process are only for PSO_2 units.

2. Set the following parameters:
   - MODE = SPON (10 bpm backup rate “N”)
   - SENSITIVITY = 5 lpm
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O
   - HIGH PRESSURE = 80 cmH_2O
   - F_IO_2 = 21%
   - Pressure Trigger = 5 cmH_2O
   - OPERATING ALTITUDE = Set for the local elevation
   - ALARM LATCHING STATUS = LATCHING

3. Set the unit to VENTILATE. Alarms may occur during this test. Press ALARM SILENCE/RESET to silence the alarms.

Note

When using the Low Pressure “-” port, the PTS2000 does not display the negative sign “-” when the pressure is negative.

4. Decrease the pressure slowly until the ASSIST/SPONTANEOUS LED lights and the ventilator cycles. Verify the pressure displayed on the PTS2000 is at negative 5.00 (+/- 2.00) cmH_2O. Record the pressure reading on the Data Sheet.

5. Set the pressure trigger level to 10 cmH_2O.

6. Decrease the pressure slowly until the ASSIST/SPONTANEOUS LED lights and the ventilator cycles. Verify the pressure displayed on the PTS2000 is at negative 10.00 (+/- 2.00) cmH_2O. Record the pressure reading on the Data Sheet.

7. Use the syringe to increase the pressure to approximately “0”. Disconnect the syringe from the ventilator, and set the ventilator to STANDBY.

8. Press ALARM SILENCE/RESET, if necessary.

9. Set the Pressure Trigger level to 2 cmH_2O.

10. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Volume accuracy test

1. Verify an Rp50 resistor is connected to the High Flow Inlet port of the PTS2000 with a 5-ft patient circuit and exhalation manifold attached. Attach the other end of the patient circuit to the ventilator.
2. Select and zero screen 2 on the PTS2000.
3. Set following parameters:
   - MODE = A/C
   - VOLUME = 1000 ml
   - BREATH RATE = 10 bpm
   - INSPIRATORY TIME = 2.0 seconds
   - SENSITIVITY = 5 lpm
   - PRESSURE SUPPORT = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O
   - HIGH PRESSURE = 80 cmH_2O
   - F_IO_2 = 21%
4. Set the unit to VENTILATE and allow the PTS2000 reading to stabilize.
5. The average volume reading must be 1.000 +/- 0.050 (0.950 to 1.050) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.
6. Set the unit to STANDBY, then back to VENTILATE. Allow the PTS2000 reading to stabilize. The average volume reading must be 1.000 +/- 0.050 (0.950 to 1.050) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.
7. Verify the two recorded readings for 1000 ml do not differ by more than 0.030 liters.
8. Set the unit to STANDBY.

9. Set the following parameters:
   - VOLUME 2000 ml
   - BREATH RATE 6 bpm
   - INSPIRATORY TIME 3.5 seconds
10. Set the unit to VENTILATE and allow the PTS2000 reading to stabilize.
11. The average volume reading must be 2.000 +/- 0.070 (1.930 to 2.070) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.
12. Set the unit to STANDBY, then back to VENTILATE. Allow the PTS2000 reading to stabilize. The average volume reading must be 2.000 +/- 0.070 (1.930 to 2.070) liters and must not vary by more than 0.010 liters between 2 consecutive cycles. Record the average volume on the Data Sheet.
13. Verify the two recorded readings for 2000 ml do not differ by more than 0.030 liters.
14. Set the unit to STANDBY and disconnect the patient circuit from the ventilator and the PTS2000.
15. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Operational test

1. Set the following parameters:
   - VOLUME 1000 ml
   - INSPIRATORY TIME 1.2 seconds
   - BREATH RATE 10 bpm
   - SENSITIVITY 25 lpm
2. Select and zero screen 1 on the PTS2000.
3. Connect a test lung to the High Flow Exhaust of the PTS2000, using a 5-ft patient circuit with an exhalation manifold. Connect the ventilator's patient air port to the PTS2000 High Flow Inlet using an 18–24-in flex hose. The small striped/colored tubing on the patient circuit should be connected to both the ventilator and the PTS2000 Low Pressure "+" port.

The other small tube on the patient circuit should be connected between the ventilator and the exhalation valve.

4. Set the unit to VENTILATE.
5. Press MENU/ESC, then press the up or down arrow key to select “VENTILATING HOURS.” Verify the “Ventilating hours since last maintenance” is correct. Press the up or down arrow key to select “DATE AND TIME,” then press ENTER. Verify the date and the time are correct. If the date and time are correct, press MENU/ESC twice. If the date and time are not correct, set the correct date and time and shut down the ventilator for at least 5 seconds. Turn the ventilator back on and check the date and time. If the date and time cannot be held correctly, reject the unit.

6. Check the peak pressure on the PTS2000. Verify the ventilator's front panel meter peaks within 8 cmH_2O of the peak pressure value, then returns to “0”.
7. At the start of a breath, set the MODE to SPON. Using a stopwatch, start timing immediately when the expiratory cycle of the breath ends. Press the up or down arrow key to select “Y” for the “10BPM Back Up Rate” and then press ENTER.
8. Stop the stopwatch when the audible alarm sounds. Verify that the stopwatch displays 20.0 (+/- 1.0) seconds, the LOW PRESSURE/APNEA LED flashes, and the ventilator starts ventilating.
9. Press ALARM SILENCE/RESET and set the MODE to A/C.
10. Verify or set the following parameters:
    - SENSITIVITY 5 lpm
    - INSPIRATORY TIME 2.0 seconds
11. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Power switchover test

Note

The BATTERY CHARGING LED will periodically turn off, then turn back on. This is normal operation.

1. Connect a 24-V Battery to the ventilator's external battery jack using an external battery cable.
2. Disconnect the ventilator from AC power. The POWER SWITCHOVER LED will flash and an alarm will sound. The EXTERNAL BATTERY LED will come on and the BATTERY CHARGING LED will stay on. The AC LED will turn off.
3. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
4. Set the unit to STANDBY. The BATTERY CHARGING LED will turn off.
5. Set the unit to VENTILATE. The BATTERY CHARGING LED will turn on.
6. Disconnect the 24-V Battery. The POWER SWITCHOVER LED will flash, the INTERNAL BATTERY LED will light, and an alarm will sound. The EXTERNAL BATTERY and BATTERY CHARGING LEDs will turn off.
7. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
8. Connect the 24-V Battery. Verify the EXTERNAL BATTERY and BATTERY CHARGING LEDs light and the INTERNAL BATTERY LED turns off. The ventilator should not alarm POWER SWITCHOVER.
9. Connect the ventilator to AC power. Verify the AC LED lights and the EXTERNAL BATTERY LED turns off. The ventilator should not alarm POWER SWITCHOVER.
10. Disconnect the 24-V battery.
11. Set the ventilator to STANDBY, then back to VENTILATE.

12. Connect a 12-V battery to the ventilator's external battery jack using an external battery cable.
13. Disconnect the ventilator from AC power. The POWER SWITCHOVER LED will flash and an alarm will sound. The EXTERNAL BATTERY LED will come on and the AC LED will turn off.
14. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
15. Disconnect the 12-V battery. The POWER SWITCHOVER LED will flash, the INTERNAL BATTERY LED will light and an alarm will sound. The EXTERNAL BATTERY and BATTERY CHARGING LEDs will turn off.

16. Press the ALARM SILENCE/RESET button to reset the alarm and the POWER SWITCHOVER LED.
17. Press and hold the TEST BATTERY button. The front panel meter needle must display a value greater than 65.
18. Connect the 12-V battery. Verify the EXTERNAL BATTERY and BATTERY CHARGING LEDs light and the INTERNAL BATTERY LED turns off. The ventilator should not alarm POWER SWITCHOVER.
19. Connect the ventilator to AC power. Verify the AC LED lights and the EXTERNAL BATTERY LED goes out. The ventilator should not alarm POWER SWITCHOVER.
20. Disconnect the 12-V battery from the ventilator.
21. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Remote jack test

1. Connect the alarm tester to the REMOTE ALARM output on the ventilator. Connect a digital multimeter to the tester (red wire to “+” black wire to “-”). Set the multimeter to VDC.
2. Set the selection knob to SUPPLY. Verify the displayed voltage is 8.0 +/- 0.4 VDC.
3. Set the knob to the VISUAL position. Verify the displayed voltage is 4.5 +/- 0.4 VDC.

4. Set the knob to the AUDIBLE position. Verify the displayed voltage is 4.5 +/- 0.4 VDC.
5. Set the HIGH PRESSURE to 25 cmH_2O.
6. Within 2 cycles verify:
   - The alarm sounds.
   - The High Pressure LED flashes.
7. Verify the displayed voltage is 0.0 +/- 0.4 VDC.
8. Set the knob to the VISUAL position. Verify the displayed voltage is 0.0 +/- 0.4 VDC.
9. Press the RESET button on the alarm tester. The voltage displayed should remain at 0.0 +/- 0.4 VDC.
10. Set the knob to the AUDIBLE position. Verify the displayed voltage is 4.5 +/- 0.4 VDC.
11. Verify the Peak Pressure displayed on the PTS2000 is less than 35 cmH_2O.
12. Set the HIGH PRESSURE to 80 cmH_2O. Verify the HIGH PRESSURE LED stops flashing. If necessary, press ALARM SILENCE/RESET to reset the SETTING ERROR LED if it occurs.
13. Disconnect the patient pressure tubing from the ventilator. Within 2 cycles verify the SETTING ERROR LED flashes and the alarm sounds. Within 3 cycles verify:
    - An audible 5-pulse alarm sounds.
    - The LOW PRESSURE/APNEA LED flashes.
14. Verify the displayed voltage is pulsing.
15. Set the knob to the VISUAL position. Verify the displayed voltage is 0.0 +/- 0.4 VDC.
16. Press the RESET button on the alarm tester.
17. Reconnect the patient pressure tubing. If necessary, after the LOW PRESSURE/APNEA LED goes out, press ALARM SILENCE/RESET to reset the SETTING ERROR LED.
18. Set the unit to STANDBY and verify the displayed voltage is 0.0 +/- 0.4 VDC.
19. Set the knob to the AUDIBLE position. Verify the displayed voltage is 0.0 +/- 0.4 VDC.

20. Press the ALARM SILENCE/RESET button on the ventilator and verify the displayed voltage is 4.5 +/- 0.4 VDC.
21. Disconnect the tester from the ventilator.
22. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Nurse call output test

1. Connect the alarm tester to the NURSE CALL output jack of the ventilator.
2. Set the alarm tester knob to BATTERY CHECK. Verify the voltage is greater than 8 VDC.
3. Set the knob to NURSE CALL. Set the multimeter to ohms.
   - If the Digital Multimeter reads greater than 1.0 M Ω (1 megaohm), go to step 4.
   - If the Digital Multimeter reads less than 1.0 ohm, go to step 12.
4. Turn off the multimeter and set the knob to ALARM TEST.
5. Set the unit to VENTILATE. After the ventilator completes it's start up sequence verify the LED on the test fixture is not lit.
6. Set the HIGH PRESSURE to 40. Within 2 cycles, verify the LED on the test fixture is lit continuously as the HIGH PRESSURE LED flashes and an audible alarm sounds.
7. Set the HIGH PRESSURE to 80 and press ALARM SILENCE/RESET. Verify the LED on the test fixture turns off, the HIGH PRESSURE LED stops flashing, and the audible alarm resets. If necessary, press ALARM SILENCE/RESET to reset the SETTING ERROR LED if it occurs.
8. Disconnect the patient pressure tubing from the ventilator.
9. Within 2 breaths, verify the SETTING ERROR LED flashes and the alarm sounds. Within 3 breaths, verify the LOW PRESSURE LED lights and a 5-pulse alarm is generated along with a corresponding flashing of the test fixture LED.
10. Reconnect the patient pressure tubing and press ALARM SILENCE/RESET. Verify the LED on the test fixture stops flashing, the LOW PRESSURE and SETTING ERROR LEDs stop flashing, and the audible alarm resets.

11. Go to step 19.
12. Turn off the multimeter and set the knob to ALARM TEST.
13. Set the unit to VENTILATE. After the ventilator completes it's start up sequence verify the LED on the test fixture is lit.
14. Set the HIGH PRESSURE to 40. Within 2 cycles, verify the LED on the test fixture turns off as the HIGH PRESSURE LED flashes and an audible alarm sounds.
15. Set the HIGH PRESSURE to 80 and press ALARM SILENCE/RESET. Verify the LED on the test fixture turns on, the HIGH PRESSURE LED stops flashing, and the audible alarm resets. If necessary, press ALARM SILENCE/RESET to reset the SETTING ERROR LED if it occurs.
16. Disconnect the patient pressure tubing from the ventilator.
17. Within 2 breaths, verify the SETTING ERROR LED flashes and the alarm sounds. The test fixture LED will turn off while the alarm sounds. Within 3 breaths, verify the LOW PRESSURE LED lights and a 5-pulse alarm is generated, along with a corresponding flashing of the test fixture LED.
18. Reconnect the patient pressure tubing and press ALARM SILENCE/RESET. Verify the LED on the test fixture stops flashing and is lit continuously, the LOW PRESSURE and SETTING ERROR LEDs stop flashing, and the audible alarm resets.
19. Disconnect the alarm tester from the ventilator and set the selection knob of the tester to Supply.
20. Set the ventilator to STANDBY.
21. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Pressure cycle test

Note

A VOLUME cannot be set if the ventilator is in the PRESSURE mode or the SPONTANEOUS mode.

1. Remove the 18–24-in flex hose connecting the ventilator to the PTS2000 High Flow Inlet port. Disconnect the test lung from the PTS2000 High Flow Exhaust port and connect the test lung to the ventilator's Patient Air port.

2. Set the ventilator to VENTILATE, then set the following parameters:
   - PRESSURE SETTING = 10 cmH_2O
   - PEEP = 5 cmH_2O
   - Low Pressure = 13 cmH_2O

3. Allow the ventilator to cycle for a minimum of 1 minute. Observe the continuous pressure readings on the PTS2000. Verify the readings alternate between a low of 5.00 cmH_2O (+/-2.50 cmH_2O), and a high of 15.00 cmH_2O (+/-2.50 cmH_2O). Disregard any readings between the low and the high readings.

4. Set the following parameters:
   - PEEP = 10 cmH_2O
   - PRESSURE SETTING = 20 cmH_2O

5. Allow the ventilator to cycle for a minimum of 1 minute. Observe the continuous pressure readings on the PTS2000. Verify the readings alternate between a low of 10.00 cmH_2O (+/-2.50 cmH_2O), and a high of 30.00 cmH_2O (+/-2.50 cmH_2O). Disregard any readings between the low and the high readings.

6. Set the unit to STANDBY, then set the following parameters:
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O

7. Disconnect the patient circuit with test lung from the ventilator.

8. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Leak test (only PSO_2 units)

The PTS2000 must be on at least 15 minutes prior to use.

Notes

The PTS2000 must be calibrated to 21% and 100% O_2 within 1 hour before each use. Refer to the PTS2000 manual for oxygen calibration instructions. After calibrating the PTS2000 at 100% O_2, flush the oxygen out of the analyzer.

1. Select screen 7 on the PTS2000.
2. Connect an 18–24-in flex hose from the ventilator's Patient Air port to the High Flow Inlet of the PTS2000. Connect a pediatric patient circuit to the High Flow Exhaust port of the PTS2000. The small striped/colored tubing on the patient circuit should be connected to the ventilator's Patient Pressure port. The other small tube on the patient circuit should be connected to the ventilator's Exhalation Valve port.
3. Verify that an Rp200 resistor, or adjustable valve, is connected to the patient end of the patient circuit.
4. Set or verify the following parameters:
   - POWER AC
   - MODE A/C
   - VOLUME 50 ml
   - SENSITIVITY 5 lpm
   - INSPIRATORY TIME 0.5 second
   - BREATH RATE 40 bpm
   - PRESSURE SETTING 0 cmH_2O
   - PEEP 0 cmH_2O
   - LOW PRESSURE 1 cmH_2O
   - HIGH PRESSURE 80 cmH_2O
   - F_IO_2 21%

Note

It is important that nothing is connected to the O_2 inlet port of the ventilator, except the O_2 inlet cap.

5. Set the ventilator to VENTILATE. If using an adjustable valve, adjust the valve so that the patient pressure meter on the ventilator peaks at 10 (+/-2) cmH_2O.
6. Allow the ventilator to run until the PTS2000 reading is stabilized. Record the reading on the Data Sheet.
7. Set the ventilator to STANDBY.
8. Remove the cap over the O_2 inlet port. Connect the oxygen source to the O_2 Inlet.
9. Set the O_2 Inlet Pressure to 60 psi +/- 5 psi (3.79–4.48 bar) . Verify there are no leaks in the oxygen line or in any of the connections.

Note

If there is even a very small leak in the oxygen line or the O_2 adapter, the ventilator may fail this section due to taking oxygen in through the Air Inlet Port.

10. Set the ventilator to VENTILATE. If using an adjustable valve, verify the valve is still adjusted so that the patient pressure meter on the ventilator peaks at 10 (+/-2) cmH_2O.
11. Allow the ventilator to run a minimum of 15 minutes. Verify the PTS2000 reading is less than 1.0% greater than the reading in step 6. If the difference is 1% or greater, fail the ventilator for the blender leak rate being too high.

    EXAMPLE: If the reading in step 6 was 21.3%, the reading in step 11 must be less than 22.3%.
12. Record the PTS2000 reading on the Data Sheet.
13. Set the ventilator to STANDBY.
14. Disconnect the pediatric patient circuit.
15. Turn off the O_2 inlet pressure and slowly disconnect the O_2 inlet adapter from the ventilator,

allowing any pressure to escape.

16. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Oxygen blending test (only PSO_2 units)

Notes

The PTS2000 must be on at least 15 minutes prior to use.

The PTS2000 must be calibrated to 21% and 100% O_2 within 1 hour before each use. After calibrating the PTS2000 at 100% O_2, flush the oxygen out of the analyzer.

1. Select screen 7 on the PTS2000.
2. If necessary, remove the cap over the ventilator O_2 inlet port. Connect the oxygen source to the O_2 Inlet.
3. Verify or connect the ventilator's Patient Air port to the PTS2000 High Flow Inlet with an 18–24-in flex hose.
4. Set or verify the following parameters on the ventilator:
   - POWER = AC
   - MODE = A/C
   - VOLUME = 1000 ml
   - BREATH RATE = 12 bpm
   - INSPIRATORY TIME = 2.0 seconds
   - SENSITIVITY = 5 lpm
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 1 cmH_2O
   - HIGH PRESSURE = 80 cmH_2O
   - F_IO_2 = 70%
   - O_2 INLET PRESSURE = 45–50 psi (3.10–3.45 bar)

5. Set the unit to VENTILATE. Low Pressure alarms will occur during this section. Use the Alarm Silence/Reset button as needed to silence the alarm.
6. Allow the PTS2000 to stabilize.
7. The reading on the PTS2000 should be 70.0 +/- 5.0 (65.0–75.0). Record the reading on the Data Sheet.
8. Set the following parameteres:
   - F_IO_2 100%
   - O_2 INLET PRESSURE 75–80 psi (5.17–5.52 bar)
9. Verify the reading on the PTS2000 is 100.0, +0 / -10.0 (90.0–100.0). Record the reading on the Data Sheet.
10. Set the F_IO_2 to 21%.
11. Set the ventilator to STANDBY and turn off the O_2 inlet pressure.
12. Disconnect the O_2 inlet adapter slowly from the ventilator allowing any pressure to escape. Reinstall the cap over the O_2 inlet port.
13. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Flow sensitivity test

Note

The PTS2000 must be on at least 15 minutes prior to use.

1. Set or verify the following parameters:
   - POWER = AC
   - MODE = SPON (10 bpm backup rate “N”)
   - SENSITIVITY = 5 lpm
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O

- LOW PRESSURE = 1 cmH_2O
- HIGH PRESSURE = 80 cmH_2O

2. Connect the high pressure/flow source to the ventilator's Air Inlet port. Verify that an 18–24-in flex hose is connected from the ventilator's Patient Air port to the PTS2000 High Flow Inlet port.
3. Select and zero the screen on the PTS2000:
   - Screen 3 if using air source.
   - Screen 5 if using oxygen source.

Note

Alarms will occur. Disregard any alarms during this section. ALARM SILENCE/RESET may be used to reset the audible alarm.

4. Set the unit to VENTILATE.
5. Increase the flow slow enough to be able to see each digit change on the PTS 2000 until the ventilator autocycles. Verify the ASSIST/SPONTANEOUS LED lights between cycles.
6. Set the ventilator to STANDBY. Verify the flow reading is 5.00 (+/- 1.00) lpm. (The reading should be within 0.1 lpm of the reading observed in step 5 when the unit started to autocycle. If it is not, repeat steps 5 and 6.) Record the flow reading on the Data Sheet.
7. Set the SENSITIVITY to 15 lpm.
8. Increase the flow slow enough to be able to see each digit change on the PTS2000 until the ventilator autocycles. Verify the ASSIST/SPONTANEOUS LED lights between cycles.
9. Set the ventilator to STANDBY. Verify the flow reading is 15.00 (+/- 1.00) lpm. (The reading should be within 0.1 lpm of the reading observed in step 8 when the unit started to autocycle. If it is not, repeat steps 8 and 9.) Record the flow reading on the Data Sheet.
10. Turn off the flow source.
11. Disconnect the High Pressure/Flow Source and remove the 18–24-in flex hose.
12. Record on the Data Sheet whether the ventilator passed or failed this section of the process.

Modem test (only for units with an internal modem)

1. Connect the test phone line to the ventilator's MODEM jack and turn on the modem.
2. Initiate a MaSSII session by double-clicking its icon or selecting it from the Start Menu.
3. Enter your User ID and Password, then select "OK".

Caution

DO NOT use the MaSSII "Setup...Initialize NVRAM" command. This command will reset all calibration parameters and unit information to defaults. This will also reset the Operating Hours to zero. A complete re-calibration will be required and the operating hours will have to be re-entered.

4. On the MaSSII, select "Setup . . .Modem Test. . .". The Setup Menu will clear, and the MaSSII will be in the modem test mode.
5. On the ventilator press ENTER, MENU/ESC, then the "up arrow" key twice. The ventilator will display "Press ENTER for remote data transfer."
6. On the ventilator press ENTER. The unit will display "Sending Data."
7. If "Failed to Connect" displays on the ventilator, check all connections and retry.
8. When the ventilator is done transferring the data, it should display "Transfer Successful."
9. Verify the following data transferred to the computer:
   - Unit ID
   - Events Log
   - Compliance Data
   - Trend Data
10. Verify the following on the Unit ID block is correct:

- Model
- Serial Number
- Date and Time

11. Turn off the modem.
12. Disconnect the test phone line from the ventilator's MODEM jack.
13. Close out the MaSSII Software.
14. Record on the Data Sheet if the ventilator passed or failed this section of the process.

Completion

1. Set, or verify, the following parameters:
   - MODE = A/C
   - VOLUME = 1000 ml
   - INSPIRATORY TIME = 1.5 seconds
   - SENSITIVITY = 5 lpm
   - BREATH RATE = 10 bpm
   - PRESSURE SETTING = 0 cmH_2O
   - PEEP = 0 cmH_2O
   - LOW PRESSURE = 25 cmH_2O
   - HIGH PRESSURE = 30 cmH_2O
   - F_IO_2 = 21%
   - Pressure Trigger = 2 cmH_2O
   - EXPIRATORY TRIGGER = 15 %
   - FLOW ACCELERATION = Off
2. Connect the computer to the ventilator, using the communications cable.
3. Initiate a MaSSII session.
4. Enter your User ID and Password; then select "OK."

Caution

DO NOT use the MaSSII “Setup...Initialize NVRAM” command. This command will reset all calibration parameters and unit information to defaults. This will also reset the Operating Hours to zero. A complete re-calibration will be required and the operating hours will have to be re-entered.

5. On the MaSSII, select “Parameters... Data Logs...”.
6. Select “Initialize Event, Compliance and Trended.” A dialog box will display “Are you sure you want to initialize all Data Logs?” Select “Yes.”
7. A dialog box will display “Data Logs Have Been Initialized.” Select “OK.”
8. Disconnect the communications cable.
9. Select “Done” to clear the screen.
10. Close out the MaSSII Software.
11. Disconnect the ventilator from AC power. It will take up to 30 seconds for the ventilator to shut down.
12. Wrap the ventilator's power cord around the cord wrap feet and secure it in place.
13. Record on the Data Sheet whether the ventilator passed or failed this section of the process.
14. If the ventilator passed the entire final inspection, sign and date the Data Sheet.

Achieva PS, PSO_2 Final Inspection Data Sheet

ACHIEVA PS, PSO_2 FINAL INSPECTION DATA SHEET

PTS2000 #: _____ Definitions: Date: _____/_____/_____

P=PASS

F=FAIL Unit Serial #: _____

Inspected by: _____

PRELIMINARY CHECKS _____ NURSE CALL OUTPUT TEST_____

SELF-TEST _____ PRESSURE CYCLE TEST_____

PRESSURE ACCURACY TEST _____ LEAK TEST _____% _____% _____

PRESSURE TRIGGER TEST _____

-5 cmH_2O_____ -10 cmH_2O _____ OXYGEN BLENDING _____

(-3.0 to -7.0) (-8.0 to -12.0)

70% @ 45-50 psi _____

(65.0 - 75.0)

VOLUME ACCURACY TEST _____ 100%@75-80 psi _____

(90.0 - 100.0)

Vol. @ 1.0 L = _____ _____

(0.950 - 1.050)

Vol. @ 2.0 L = _____ _____ FLOW SENSITIVITY _____

(1.930 - 2.070)

OPERATIONAL TEST _____ 5 lpm _____ 15 lpm _____

(4.0 - 6.0) (14.0 - 16.0)

POWER SWITCHOVER TEST _____ MODEM TEST _____

COMPLETION _____

REMOTE JACK TEST _____

This ventilator has passed all tests specified in this process.

SIGNATURE: _____ DATE: _____

COMMENTS:

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Chapter 11: Language conversion

This chapter gives instructions on how to change the language of the software in the series of Achieva ventilators with flow acceleration and apnea back-up.

Equipment required

- IBM-compatible computer with Windows Operating System (95, 98, or NT)
- MaSSII software, Version 2.0a (or greater)
- Communications cable, Model Y-6490, or the equivalent RS232 null modem cable with gender changer

Language selection

1. Connect the ventilator to AC power. All LEDs should light and turn off except for the AC and BATTERY CHARGING LEDs, which should remain on. The audible alarm will sound momentarily, and the unit will cycle.
2. Connect the computer to the ventilator, using a communications cable.
3. Initiate a MaSSII session.
4. Enter your User ID and Password, then select “OK.”
5. On the MaSSII, select “Parameters... Settings...”.
6. Select the proper language for the ventilator from the language drop-down box.
7. Select “Download Changes.”
8. Disconnect the communications cable.
9. Select “Done” to clear the screen.
10. Close out the MaSSII software.
11. On the ventilator, press Enter and then disconnect it from AC power. Press Alarm Silence/Reset, the ventilator will display “Powering off.” Verify the ventilator is displaying the

proper language according to the following list:

Dutch:	Bezig met Uitschakelen ...
English:	Powering off ...
French:	Mise hors tension ...
German:	Abschalten ...
Italian:	Spegnimento ...
Spanish:	Apagando ...
Japanese:	"ﾃﾞﾝｹﾞﾝヲｷｯﾃｲﾏｽ...

12. It will take up to 30 seconds for the ventilator to shut down.
13. Wrap the ventilator's power cord around the cord wrap feet and secure it in place.

Appendix A: PTS2000 Menu Structure

PTS2000 Menu Structure*	
Choose this menu item	**to see...**
1a Low pressure	cmH_2O
1b Peak low pressure	1slpm cmH_2O
2a Breath rate	1slpm bpm
2b Volume	Air 1slpm LATP
3a Low flow	Air lpm
3b High flow	Air lpm
4a Low flow	Air slpm
4b High flow	Air slpm
5a Low flow	O_2 lpm
5b High flow	O_2 lpm
6a Low flow	O_2 slpm
6b High flow	O_2 slpm
7a % Oxygen	%
7b – **10b** (spare)	
*Refer to the *PTS2000 Manual* for screen set-up instructions.	

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Appendix B: Torque Reference

Torque Reference for the Achieva Ventilator

Hand Drivers +/- 10%	
in-lb	*N-M*
4	0.45
5	0.56
8	0.90
16	1.81
20	2.26
22	2.49
28	3.16

Battery Powered +/- 25%		
Makita	*Mean in-lb*	*Mean N-M*
1L	13.8	1.56
2L	21.66	2.45
3L	26.26	2.97
4L	32.33	3.65
5L	37.66	4.26
1H	9.70	1.10
2H	15.59	1.76
3H	16.53	1.87
4H	22.65	2.56
5H	25.22	2.85
6H	64.66	7.31

Battery Powered +/- 20%		
Milwaukee	*in-lb*	*N-M*
1	5	0.56
2	5	0.56
3	12	1.36
4	14	1.58
5	14	1.58
6	22	2.49

Note: The information in these tables should only be used for reference purposes. It is based on limited empirical data.

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Appendix C: Service

This appendix provides service information and the limited warranty.

Service information

Achieva model ventilators are warranted against defects in workmanship and materials. The full text of the warranty provides the details. Do not make any service repairs on this equipment during the stated warranty period. Any unauthorized work immediately voids the warranty. If you need information or assistance, or if the information in this manual is insufficient, contact Puritan Bennett Technical Support at this number:

800.255.6774

Puritan Bennett does not recognize the owner of a ventilator as an authorized service representative. Puritan Bennett will not be liable for any repairs attempted by the owner. Any such attempted repairs other than specified nonwarranty repairs void the warranty. Parts and labor costs incurred by the owner will not be reimbursed by Puritan Bennett. Puritan Bennett will make available on request: diagrams, component parts lists, descriptions, calibration procedures and instructions to assist in the repair of parts classified by Puritan Bennett as repairable.
Before returning any device to Puritan Bennett you must get a Return Authorization Number by calling Puritan Bennett at the number listed above.

Limited Warranty

For warranty information, refer to the *Achieva Ventilators Clinician's Manual*.

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CE 0123

This device complies with the requirements of Medical Device Directive 93/42/EEC.

Partnumber Y-102923-00A Rev C

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