



P/N: 10039030
 REV: M
 TITLE: PB560 FINAL TEST PROCEDURE

INSTRUCTIONS

Page 1 of 12

DOCUMENTATION ASSOCIATED TO THIS PROCEDURE:

- [1] PB560 Product Requirements Doc (PRD) P/N 10035480
- [2] PB560 Device History Record (DHR) P/N 10038461
- [3] PB540 O₂ Valve Leak Tester Setup, P/N 10023391
- [4] PB500 Series System Calibration / Final Test Verification Log, P/N 10039304
- [5] PB560 Pediatric Volume and Pressure Test Script, P/N 10039032
- [6] PB560 Adult Volume and Pressure Test Script, P/N 10039033
- [7] PB560 Volume and Pressure Tests, Manuf Test Spec, P/N 10040465
- [8] Test Lung, Volume Determination Project Files # 3297 / M1288 / M1322
- [9] OpenVent Software Specification Doc, P/N 10026043
- [10] PB540 System Test Criteria Project File, # 3364
- [11] PB540 Patient Circuit/Exhalation Valve Usage Log Sheet, P/N 10029922
- [12] WEB SPC SYSTEM USER INSTRUCTION 10039404

REV	ECO	PREPARED BY	APPROVED BY	DATE	SUMMARY
N/A	N/A	N/A	N/A	N/A	Refer to 10039030 rev G for earlier revision history
H	ECO-R245059	██████████	See Agile	See Agile	Updating instructions to clarify on the steps required under the "Test Note" of the Volume and Pressure Tests' section. Also, removal of the Process monitoring as no longer required.
J	ECO-R254053	██████████	See Agile	See Agile	Update to clarify instruction following review of procedures versus practice
K	EC045533	██████████	See Agile	See Agile	Updates as per QAP056 redlines, no change to process.
L	EC075186	██████████	Refer to Agile	Refer to Agile	Added instruction to complete final test equipment verification log P/N 10039304. Move instruction on alarm test daily check, sound level meter (PN 10039030, pg.9) to front of procedure. Move O ₂ valve leak test (pg.3) and O ₂ valve functional test box (pg.8) to front (pg.3 & 7 of P/N 10036007).
M	EC102789	██████████	Refer to Agile	Refer to Agile	Updated following G-QAP056 FY18 review



P/N: 10039030
REV: M
TITLE: PB560 FINAL TEST PROCEDURE

INSTRUCTIONS

Page 2 of 12

TOOLING REQUIRED

Pentium Based PC with the OpenVent software P/N 10060473 loaded
Dual-limb Adult Patient Circuit with Exhalation Valve, DAR P/N 5094000 or approved equivalent
Dual-limb Pediatric Patient Circuit with Exhalation Valve, DAR P/N 5093900 or approved equivalent
Patient Hose, 22mm, 40cm length, P/N G-061440-00
██████████, Pneuflo Resistor, Rp50, P/N 13394-03
██████████, Pneuflo Resistor, Rp5, P/N 13394-05
Test Lung, 50 Litre bottle, See Doc Ref [8]
Test Lung, 3 Litre bottle, See Doc Ref [8]
PTS 2000 Performance Test Instrument with RS232 serial comm. cable
Sprint LC Multi Air Tester with 8mm tubing and PB540/PB560 O₂ Inlet connector
FiO₂ Sensor Kit, Airox P/N 3814199
Sound Level Calibrator Type 4231

TEST NOTES

1. If the ventilator fails any test step, describe the parameter out of spec in the Discrepancy Log of the DHR and notify line technician or Manufacturing Engineer before switching off. Refer to procedure TBD.
2. The Alarm Silence Reset button may be used to suppress alarms as needed.
3. If at any time you notice an abnormality of any kind then notify the line Engineer/Technician for clarification before continuing.
4. For each test section on the DHR, indicate Pass or Fail by signing initials in the appropriate Pass or Fail column on the DHR.
5. Leave the PTS2000 switched ON. If the PTS2000 power switch is turned off and on, the pressure transducers are automatically zeroed. Do not apply pressure to low or high pressure ports during power-up. Wait approximately 10 minutes for the PTS2000 to warm-up.
6. **Daily Check;** Daily log checks to be completed at the start of each shift.

PRIOR TO COMMENCING TESTING ENSURE PB500 SERIES SYSTEM CALIBRATION / FINAL TEST VERIFICATION LOG P/N 10039304 IS COMPLETED AS FOLLOWS:

ALARM TEST [REF [1] PRD174, PRD350, 193]

Daily Check: Sound Level Meter Check using the Breul & Kjaer meter and sound box

Prior to using the sound level meter for testing each day, check the sound level meter calibration by performing the following steps:

1. Fit the Sound Level Calibrator Type 4231 carefully onto the sound level meter and rest the assembly on a table or other flat surface.
2. Switch ON the sound level meter and ensure the L_{AF} (L_A Fast) parameter is displayed.
3. Switch ON the Sound Level Calibrator Type 4231, wait for the reading to settle and then check that the sound level meter displays 93.6 to 94.2 dB (93.9 dB ± 0.3 dB). If not, do not continue testing and contact Test Engineering.
4. Record the Cal ID and the sound level meter value on the PB500 Series System Final Test Equipment Verification Log P/N 10039304.



P/N: 10039030
REV: M
TITLE: PB560 FINAL TEST PROCEDURE

INSTRUCTIONS

Page 3 of 12

O₂ VALVE LEAK TEST [REF [1] PRD38, REF [10] SEC 4.6]

Daily Check: Air Pressure Gauge Check

This check is to be performed once before testing each day. Verify that the air supply pressure gauge is set to 100-120psi and record the setting on the PB500 Series System Final Test Equipment Verification Log, P/N 10039304. If this check fails, stop testing and notify the Line Supervisor or Manufacturing Engineer.

O₂ VALVE FUNCTIONAL TEST [REF [10] SEC 4.4]

Daily Check: O₂ Source Pressure Gauge Check

These checks are to be performed once before testing each day. Verify that the O₂ source pressure gauge is set to 1.5-2.0 bar and record the setting on the PB500 Series System Final Test Equipment Verification Log, P/N 10039304. Also check that the flow-meter valve is fully open (CCW) and check the appropriate box on the PB560 System Test Equipment Verification Log. If any of these checks fail, stop testing and notify the Line Supervisor or Manufacturing Engineer.

VENTILATOR PRELIMINARY CHECKS

1. Check that the ventilator's serial number agrees with the attached paperwork.
2. Ensure the device history package contains all the required sub-assembly testing.
3. Ensure the calibration documentation is complete.
4. Examine the ventilator for the following cosmetic deformities:
 - 4.1 Ensure that there are no scratches, dents or other physical damage on the Ventilator housing.
 - 4.2 Ensure that the 5 screws that secure the Housing are fitted to the lower side of the Ventilator.
 - 4.3 Ensure that the battery housing screws and ventilator handle is fitted.
5. If any of the Checks fail in this section, then the result is Fail. Indicate the Pass or Fail test result by signing initials in the appropriate column on the DHR.



P/N: 10039030
REV: M
TITLE: PB560 FINAL TEST PROCEDURE

INSTRUCTIONS

Page 4 of 12

REAL TIME CLOCK TEST [REF [1] PRD203]

1. Connect the AC mains cable to the Ventilator and verify that the AC Power LED is illuminated.
2. Switch the AC Power Switch at the rear of the Ventilator OFF and then ON.
3. Press and hold the Alarm Silence button to enter the **Setup Mode**. Release button when the setup menu is displayed on Ventilator screen.

NOTE: If a BUZZER FAULT1 alarm event occurs, contact the line technician.

LINE TECH NOTE: The BUZZER FAULT1 alarm can be triggered if the alarm inhibition button is pressed (during the initialization buzzer test) on vent power-up. If the vent passes the Involuntary Stop Alarm Test, Buzzer Sound Level Check in the 10036007 procedure and this alarm event is cleared when the vent is power cycled, then this alarm event is not considered a failure.

4. Check that the vent Date is current and that the vent Time is equivalent to the plant clock \pm 1 minute.
5. Switch the AC Power Switch at the rear of the Ventilator OFF.

O₂ VALVE LEAK TEST [REF [1] PRD38, REF [10] SEC 4.6]

Test Procedure:

1. Connect the tubing from the Sprint LC Multi Air Tester #1 test port to the O₂ Inlet at the rear of the ventilator.
2. Turn the ventilator power ON and ensure the ventilator is not ventilating.
3. On the Sprint LC Multi Air Tester press the square white button to start the test.
4. When the test has finished, record the Sprint LC Multi Air Tester leak measurement value (Leak Tester Reading) on the DHR.

NOTE:

This measurement is indicated to the right of 'Ch 1' on the Sprint leak tester screen. Limit: <0.073 psig.

5. .Disconnect the tubing from the O₂ Inlet at the rear of the ventilator.

FiO₂ SENSOR DETECTION TEST [REF [1] PRD288a]

TEST NOTE:

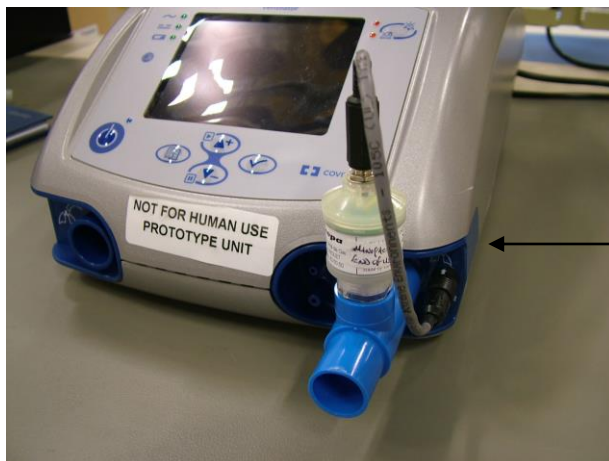
Maximum service life of the FiO₂ Sensor is 12 months starting from date of manufacture.

For initial use of an FiO₂ Sensor attach a label showing the Manufacture Date as indicated on the sensor packaging then add 12 months to this date to obtain the End-Use date and record this on the label also.

NOTE: The FiO₂ sensor needs to be calibrated for each vent used for testing the FiO₂.

FiO₂ Sensor Calibration

- 1) Connect the FiO₂ Sensor and cable to the PB560 ventilator as shown the picture below. Do not connect the Inspiratory Cap Test Assembly at this time.



FiO₂ Sensor Unit

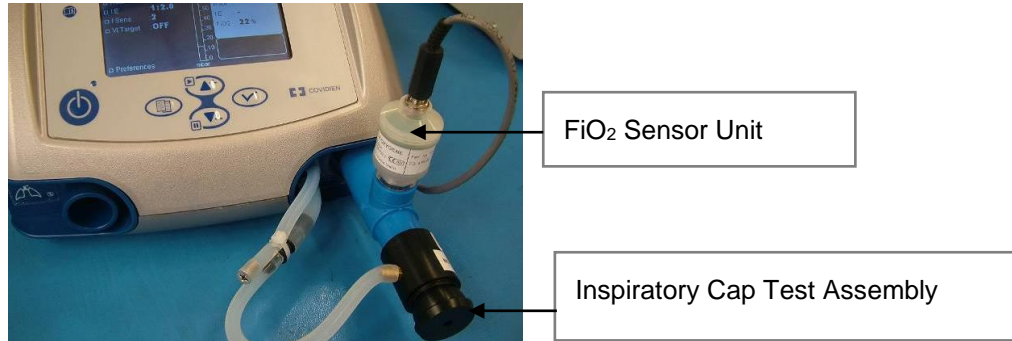
- 2) Turn ON the ventilator if not already on, and press the Menu key to enter the Alarm menu.
- 3) Move the cursor to the FiO₂ % row, and then press the Accept key twice to move to the 'Current' column.
- 4) Press the up arrow key to select YES and then the Accept key to perform the calibration operation.
- 5) If no calibration errors are displayed, then the calibration is successful.
- 6) Indicate the Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR.
- 7) Exit the Alarm menu to return to the ventilation menu.

INSTRUCTIONS

Page 6 of 12

FiO₂ Sensor Detection Test

- 1) Connect the Inspiratory Cap Test Assembly to the FiO₂ Sensor as shown in the picture below.



- 2) Press on the ventilation ϕ key to start ventilation
- 3) Check that the vent FiO₂ reading is 19-23 % ($21 \% \pm 2$), and **Record** the reading on the DHR.
- 4) Disconnect the FiO₂ cable from the vent Inspiratory block, and **Check** for a 'FiO₂ Sensor Missing' message is displayed on the vent.
- 5) Indicate the Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR.
- 6) Turn off the ventilation from the set-up menu.
 - To turn off ventilation press and hold the VENTILATION ON/OFF key for three seconds. see fig 1 & 2.
 - A double 'beep' sounds, then release the VENTILATION ON/OFF key. A second screen appears to confirm 'stop ventilation' (see fig 3).
 - Press the VENTILATION ON/OFF key within 5 seconds to confirm STOP (otherwise ventilation will continue).
 - Ventilation stops & the LED located to the upper-right of the VENTILATION ON/OFF key illuminates to indicate ventilation is on standby.

Fig 1

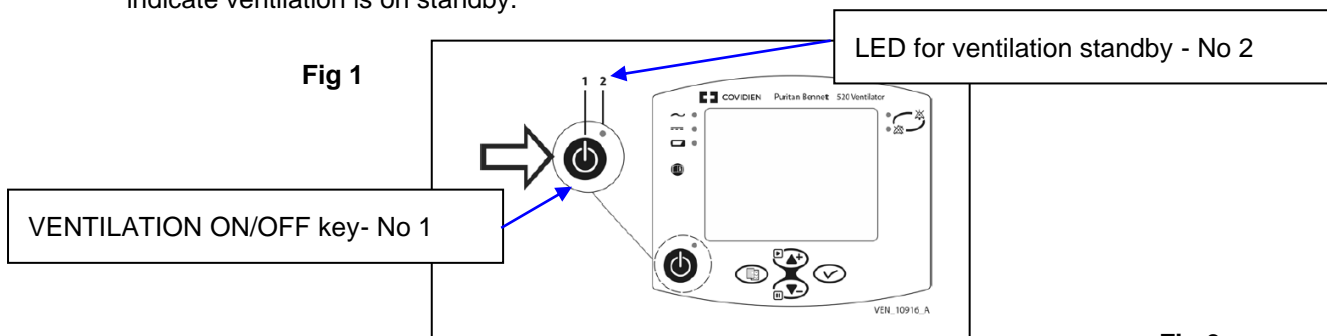


Fig 2

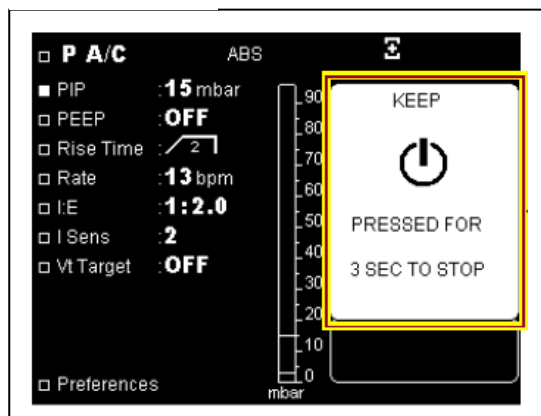
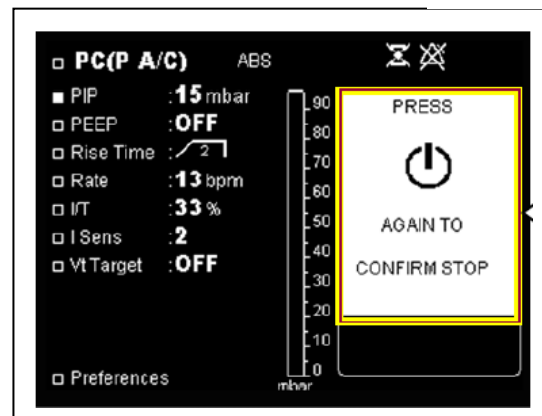


Fig 3



- 7) Press the Alarm Silence button to silence the Intentional Vent Stop alarm.
- 8) Disconnect the Inspiratory assembly and FiO₂ Sensor from the vent.

VOLUME AND PRESSURE TESTS [Ref Doc 7]



Fig.1 Connection of the patient circuit for the volume and pressure test



Fig.2 Connection of Patient hose to 3L Test Lung

Test Note: During the Paediatric and Adult Volume and Pressure Testing, the PB560 will display the Intentional Vent Stop Alarm when ventilation is switched OFF and the alarm will cease when ventilation is resumed. This is normal behaviour for the PB560.

Paediatric Volume and Pressure Tests

1. Connect the mini-USB cable from the PC to the vent.
2. Connect the **PAEDIATRIC** patient circuit tubing 'Y' end to the PTS2000 high flow inlet as shown in Figure.1 with the exhalation valve connected on the side of the vent with the arrow on the valve pointing out.
3. Connect the patient hose from the 3L test lung, to the high flow exhaust port at the back of the PTS2000, as in Fig.2.
4. Connect the patient tubing proximal pressure tubing to the PTS2000 Low Pressure (+) and the patient pressure vent port using a 'T' connection, connect the two remaining tubes to vent as per figure 1.
5. Ensure the PTS2000 is set for Remote Operation using the PTS2000 ▼▲ buttons.
6. Switch the ventilator power ON (if not already ON) and then select and enter the Preferences menu.
7. Confirm that 'Paediatric Circuit' option is **YES**, and then return to the Ventilation menu. Confirm on DHR.
8. Press the Menu button to enter the alarm limits menu.
9. Place the cursor on the VTE row, and press ✓ Accept twice.
10. Press the ▲ up arrow to select **yes** and press ✓ Accept to perform the Exp Flow Calibration.
11. Check that no CAL FAULT messages are displayed on the vent LCD.
12. Press the Menu button to return to the main menu.
13. Click on the PC desktop **PB560 PAEDIATRIC Test Script** icon to run the tests.
14. When the tests are finished, press the Alarm Silence button to silence the Intentional Vent Stop Alarm.
15. Check the test report test result and indicate the Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR.



P/N: 10039030
REV: M
TITLE: PB560 FINAL TEST PROCEDURE

INSTRUCTIONS

Page 8 of 12

16. From the *Ventilation* menu, select and enter the *Preferences* menu.
17. Set the 'Paediatric Circuit' option to **OFF**, and then return to the *Ventilation* menu.
18. Print the Test Report, Sign and Date the Test Report Title Page at the bottom and attach to the DHR.
19. Disconnect the paediatric patient circuit tubing from the vent and the 3 L test lung from the PTS2000.

Adult Volume and Pressure Tests

1. Connect the mini-USB cable from the PC to the vent, if not already connected.
2. Connect the **ADULT** patient circuit tubing 'Y' end to the PTS2000 high flow inlet as shown in Fig. 1 with the exhalation valve connected on the side of the vent with the arrow on the valve pointing out.
3. Connect the patient hose from the 50L test lung, to the high flow exhaust at the back of the PTS2000.
4. Connect the patient tubing proximal pressure tubing to the PTS2000 Low Pressure (+) and the patient pressure vent port using a 'T' connection. Connect the two remaining tubes to the Vent as per Fig.1 on previous page.
5. Ensure the PTS2000 is set for Remote Operation using the PTS2000 ▼▲ buttons.
6. On DHR confirm that Paediatric Circuit is set to NO.
7. Press the *Menu* button to enter the alarm limits menu.
8. Place the cursor on the VTE row, and press √ Accept twice.
9. Press the ▲ up arrow to select **yes** and press √ Accept to perform the Exp Flow Calibration.
10. Check that no CAL FAULT messages are displayed on the vent LCD.
11. Press the *Menu* button to return to the MAIN MENU.
12. Click on the PC desktop **PB560 ADULT Test Script** icon to run the tests.
13. When the tests are finished, press the Alarm Silence button to silence the Intentional Vent Stop Alarm.
14. Check the test report test result and indicate the Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR.
15. Print the Test Report, Sign and Date the Test Report Title Page at the bottom and attach to the DHR.
16. Do NOT remove the adult patient circuit tubing and the 50L test lung from the PTS2000.

O₂ VALVE FUNCTIONAL TEST [REF [10] SEC 4.4]

1. Using the PTS2000 ▼▲ buttons, select and display the Oxygen measurement on the PTS 2000.
2. Ensure the Oxygen supply valve located in the flexible hose is turned OFF.
3. Connect the Oxygen supply hose to the Oxygen inlet at the rear of the ventilator.
4. Set the ventilation mode to P A/C.
5. Set the vent PIP to 30 mbar.
6. Set the vent Rate to 15.
7. On DHR confirm settings, (Mode = A/C, Pi = 30 mbar & Rate = 15).
8. Press on the ventilation ϕ key to start ventilation.
9. Check that the PTS2000 Oxygen reading is 18-24% (21% \pm 3%). **Record** the Oxygen reading on the DHR.
10. Turn ON the Oxygen supply valve.
11. Check that the PTS2000 reading is **greater** than 30 % after 10 breath cycles of ventilation.
12. **Record** the PTS2000 % Oxygen reading on the DHR.
13. Check that the Ventilation Led is OFF.
14. Check that air escapes at the exhalation block during the exhale phase.
15. Indicate the Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR.
16. Turn OFF the Oxygen supply valve and then disconnect the Oxygen supply hose from the ventilator.

Turn off the ventilation from the set-up menu.

- To turn off ventilation press and hold the VENTILATION ON/OFF key for three seconds. See fig 1 & 2.
- A double 'beep' sounds, then release the VENTILATION ON/OFF key. A second screen appears to confirm 'stop ventilation' see fig 3.
- Press the VENTILATION ON/OFF key within 5 seconds to confirm STOP (otherwise ventilation will continue).
- Ventilation stops & the LED located to the upper-right of the VENTILATION ON/OFF key illuminates to indicate ventilation is on standby.

Fig 1

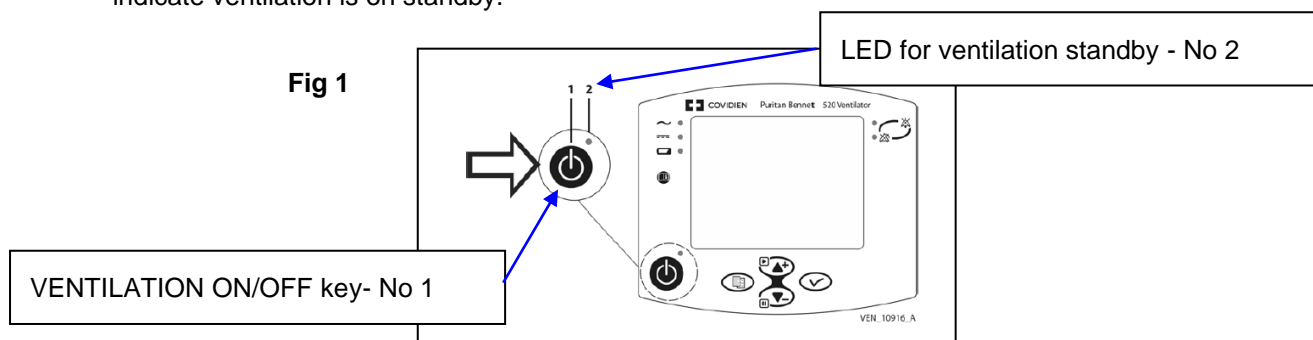


Fig 2

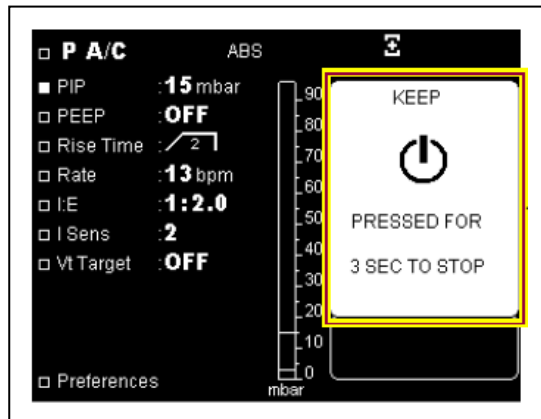
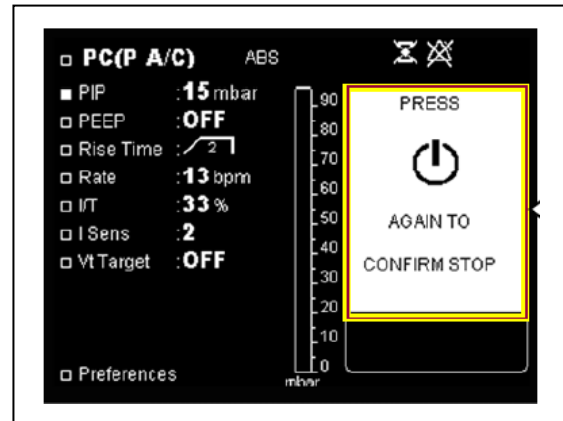


Fig 3



17. Press the Alarm Silence button to silence the Intentional Vent Stop alarm.
18. Disconnect the adult patient circuit tubing from the vent and the 50 L test lung from the PTS2000.

DEFAULT PARAMETER SETTING

1. Ensure the following default parameters are set on the Ventilator:
 - Ventilation Mode = P A/C
 - P = 15mbar
 - PEEP = OFF
 - Rise Time = 2
 - Rate = 13 breaths/min
 - I:E = 1:2.0 (Insp Time = 1.5 sec)
 - Insp Sens = 2
 - Vt Target = OFF
2. Enter the Preferences menu and ensure the **Alarm Level is set to 100 % (maximum)**.
3. In the Preferences menu ensure the LCD Backlight setting is set to OFF.
4. Indicate the Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR



P/N: 10039030
REV: M
TITLE: PB560 FINAL TEST PROCEDURE

INSTRUCTIONS

Page 11 of 12

CLEAR VENTILATOR LOGS [REF [1] PRD208, 209]

1. Check the Alarm History Log for any events during the test that are not related to normal operation activities.
2. Switch ventilator power OFF then ON and press Alarm Reset to enter Setup Mode.
3. Place cursor on **Maintenance** option and accept.
4. Place the cursor on **Faults Check** and press the accept button.
5. Check the Faults Checklist to be empty. If the list is not empty, check the events listed and record on the DHR any faults not being triggered by normal operation activities.
Refer to Appendix A for a listing of potential causes of the fault.
6. Place the cursor on **Back** and press the accept button to exit
7. **If the vent has failed any test step in system calibration or final testing that has not been fixed, then do not perform the next step which clears the vent logs and skip to Step 9 below.**
8. With the cursor at **Faults Check**, reset the alarm history by pressing and holding the Alarm Reset button until a long beep sounds. The alarm history is now cleared.
9. Record a Fail result if an unexpected fault was listed, otherwise record Pass result on the DHR.

DHR Section Signoff: Sign and Date the DHR.



P/N: 10039030
REV: M
TITLE: PB560 FINAL TEST PROCEDURE

INSTRUCTIONS

Page 12 of 12

APPENDIX A: Error Listing

Error Number	Fault	Fault Resolution
N°1	Inspiratory flow measurement fault	Calibrate the flow sensor
N°2	Calibration of the inspiratory flow sensor is not compliant	Calibrate the inspiratory flow sensor
N°3	Calibration of the expiratory flow sensor is not compliant	Calibrate the expiratory flow sensor
N°4	Calibration of the valve pressure sensor is not compliant	Calibrate the valve pressure sensor
N°5	Calibration of the patient pressure sensor is not compliant	Calibrate the patient pressure sensor
N°6	Abnormal Turbine speed	Change the Turbine or CPU card
N°7	Loss of the clock parameters	Update the date and time again or change the battery on the CPU card or change the CPU card
N°8	Calibration of the proximal pressure sensor is not compliant	Calibrate the proximal pressure sensor
N°9	Low Proximal Pressure	Change the CPU card
N°10	Low Internal Pressure	Change the CPU card
N°11	Low Valve Pressure	Change the CPU card
N°12	Event Log Error	Change the CPU card