



**P/N:** 10036007  
**Rev:** Z  
**Title:** PB560, System Calibration and Test Procedure

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### DOCUMENTATION ASSOCIATED TO THIS PROCEDURE:

- [1] PB560-520 Product Requirements Document (PRD) P/N 10035480
- [2] PB560 Device History Record (DHR) P/N 10038461
- [3] Product Software Download/Control Procedure P/N 10016627
- [4] PB540 System Test Criteria Project File, # 3364
- [6] CPU Board Hardware Specification, P/N 10024980
- [7] PB500 Series System Calibration / Final Test Verification Log, P/N 10039304
- [8] Turbine Box Specification, P/N 10025027
- [9] Battery Hardware Specification, P/N 10025023
- [10] Power Supply Board Hardware Requirements Specification, P/N 10025029
- [11] Power Supply Board SRS, P/N 10025031
- [12] CPU SRS, P/N 10025034
- [13] COSMETIC CRITERIA, MONITORS / PB540 G-AMFG-1814-00
- [14] WEB SPC SYSTEM USER INSTRUCTION 10039404
- 10021500 PB560 Rework Procedure

REV	ECO	PREPARED BY	APPROVED BY	DATE	SUMMARY
N/A	N/A	N/A	N/A	N/A	For previous revision history refer to AGILE
U	ECO-R254053	██████████	Refer to Agile	Refer to Agile	Update to clarify instruction following review of procedures versus practice
V	EC054912	██████████	Refer to Agile	Refer to Agile	Update to clarify that seconds are not required to be recorded on PHR when calculating Discharge/ Charge Cycle Event times. In System Measurement check clarify that the Barometric Pressure reading is taken from the display on the Vent.
W	EC075186	██████████	Refer to Agile	Refer to Agile	Added instruction to complete final test equipment verification log P/N 10039304. Move O <sub>2</sub> valve leak test (pg.3) and O <sub>2</sub> valve functional test box (pg.8) to front. Also include instruction on alarm test daily check, sound level meter (PN 10039030, pg.9) here.
Y	EC117821	██████████	Refer to Agile	Refer to Agile	Update to PB560 power management board software from AL020002 to AL020003.  Update to reflect CPU software upgrade from LX010104 to LX010105. LX010105 will no longer be downloaded at pack and will be replacing redundant software LX010024 at software download.
Z	EC125483	██████████	Refer to Agile	Refer to Agile	Update PB560 Power board software from AL020003 to AL020004.  Update PB560 CPU board software from LX010105 to LX010106.



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### EQUIPMENT REQUIRED

- Pentium Based PC with the software download applications ST10Flasher (P/N 10060477), PICFlasher (P/N 3832600) and PB PVTS (P/N 10060476) software applications installed.
- USB memory device formatted in the FAT32 file format (no specific memory size needed).
- Remote Alarm Test Box, P/N **10003746** or approved equivalent.
- USB Cable, Type A/Mini B for software download.
- DC Power Supply, 4-digit meters for voltage and current, adjustable, 0-36VDC with Voltage Setting Accuracy of  $\pm$  (0.1% + 10mV) or better, 0-5 Amps.
- DC Power Cable, p/n 10022945.
- PTS 2000 Performance Test Instrument.
- Sound Level Meter, Breul & Kjaer, Model 2240 or CEL model 231.
- Sound Level Calibrator Breul & Kjaer, Type 4231 or CEL model 282.
- Sound Reducing Box, p/n 10029106.
- Calibrated Stop Watch.
- 22mm pneumatic tubing, p/n G-061439-00.
- Outlet Port Connector Assembly #1, see Diagram 1.
- Outlet Port Connector Assembly #2, see Diagram 2.
- Setra Digital Pressure Gauge, Model 370.
- DVM (Digital Volt Meter).

To Patient Pressure Port, 5-6mm to  
3.24mm ID tubing adapter,  
(0.25" X 0.125" reducing coupling)

To Exhalation Valve Port: tubing (3.2-  
4mm ID) p/n 4-008578-00 plugged with  
screw p/n  
4-076100-00. Length 3.5" ( $\pm$  0.5")

Tubing (3.2-4mm ID) p/n 4-008578-00.  
Length 5.5" ( $\pm$  0.5")

Male barbed fitting, p/n 4-009724-00

Patient Outlet Cap, p/n 10023946

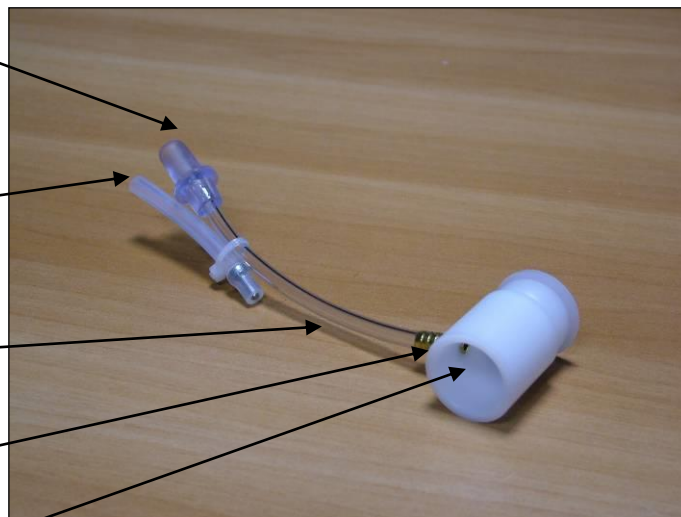
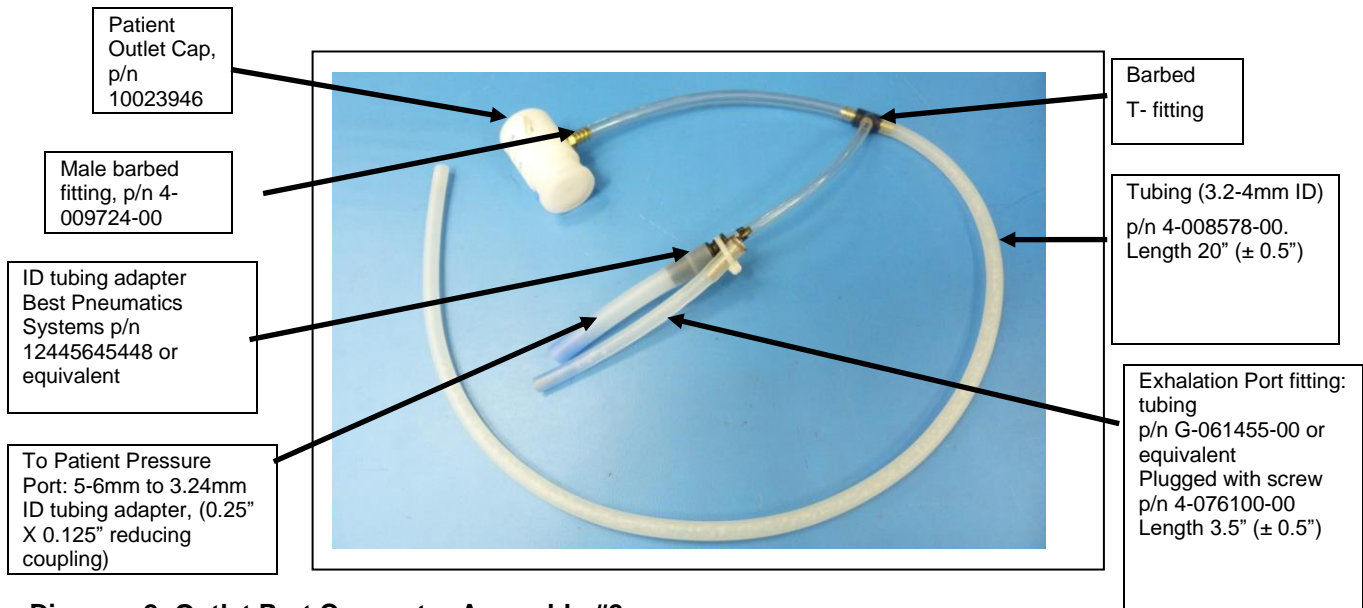


Diagram 1: Outlet Port Connector Assembly #1

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**Diagram 2: Outlet Port Connector Assembly #2**

## Testing Notes

1. For each test section on the DHR, indicate Pass or Fail by signing initials in the appropriate Pass or Fail column on the DHR.
2. If the ventilator fails any test step, describe the parameter out of spec in the Discrepancy Log section of the DHR and notify line technician or Manufacturing Engineer before switching off. Refer to the PB560 Rework Procedure p/n 10021500.
3. The Alarm Pause/ Silence button may be used to suppress alarms as needed.
4. If at any time you notice an abnormality of any kind, then notify the line Engineer/Technician for clarification before continuing.
5. **Leave PTS2000 switched ON.** If the PTS2000 power 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.



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**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 (93.9dB  $\pm$  0.3dB). 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.

### **O<sub>2</sub> 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.

### **O<sub>2</sub> VALVE FUNCTIONAL TEST** [REF [10] SEC 4.4]

#### **Daily Check: O<sub>2</sub> Source Pressure Gauge Check**

These checks are to be performed once before testing each day. Verify that the O<sub>2</sub> 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.



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### LCD DISPLAY CHECK

1. With the vent power switched ON, check that there are no visual defects on the vent LCD display according to COSMETIC CRITERIA, MONITORS / PB540 PN G-AMFG-1814-00.
2. Indicate the overall Pass or Fail test result for the LCD Display Check by signing initials in the appropriate Pass or Fail column on the DHR.

### SOFTWARE DOWNLOAD

#### PIC Software Download

1. Connect the ventilator AC power cord and ensure the Ventilator power is switched **OFF**.
2. Connect the PC USB download cable to the ventilator PC port.
3. Click on **PICFlasher\_BE** program on the PC desktop to start the PIC download program if it is not running.
4. Select **Port COM** for the correct com port number. **NOTE:** This port number can be found in the PC Control Panel under 'System', 'HW tab', 'Device Manager', 'Ports (COM & LPT)'. The Com Port number to be used is the **first** of the two "USB Serial Ports" listed.
5. Click on **Fichier a Telecharger** button to open the C:\PB560\10086985\AL020004.hex.
6. Click on **Programmer** to start the download.
7. When programming is successfully complete **Programmation terminee avec succes** will be shown in the lower left corner (See Appendix 1). Otherwise the download fails, and testing cannot continue.
8. Indicate the overall Pass or Fail test result for the PIC SW Download by signing initials in the appropriate Pass or Fail column on the DHR.

#### ST10 CPU Software Download

1. Connect the ventilator AC power cord and ensure the ventilator power is switched **OFF**.
2. Click on **ST10Flasher\_BE** program on the PC desktop to start the ST10 download program if it is not running.
3. Select **COM Port** for the correct com port number. **NOTE:** This port number can be found in the Control Panel under 'System', 'HW tab', 'Device Manager', 'Ports (COM & LPT)'. The Com Port number to be used is the second of the two "USB Serial Ports" listed.
4. Set the **COM Speed** (baud rate) to **256000**.
5. Ensure the **Sequence** radio button is clicked.
6. Click on **File download** button to open the C:\PB560\10096556\LX010106.H86.
7. Click on the **Bootstrap** button.
8. Switch the ventilator power **ON**.
9. Click on the **Programmer** to start the download.
10. When programming is successfully complete '**Program download successful**' message will be shown in the lower left corner, otherwise, the download fails, and testing cannot continue.
11. Switch the ventilator power **OFF**.
12. Indicate the overall Pass or Fail test result for the ST10 CPU download by signing initials in the appropriate Pass or Fail column on the DHR.



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### BATTERY

#### BATTERY CAPACITY CHECK [REF [10] HWSBAT11]

1. Switch the ventilator power OFF and then ON and press and hold the Alarm Reset button to enter the Setup Menu.

**NOTE:** If a BUZZER FAULT1 alarm event occurs in this step, contact the line technician.

**Line Technician:** Refer to APPENDIX 5

2. Place the cursor on Maintenance and then √ Accept.
3. Place the cursor on MEASUREMENT CHECK and √ Accept.
4. Place the cursor on INTERNAL BATTERY MENU and √ Accept.
5. Check that Theoretical Capacity value displayed is **4800 mAh**.
6. Check that Capacity value displayed is **4800 mAh**. Record the Capacity value on the DHR.
7. If the Battery Capacity **is not** 4800mAh perform the steps in the Battery Patch Download section, otherwise indicate the overall Pass/Fail test result for the DHR test section by signing initials in the appropriate column on the DHR.

#### BATTERY PATCH DOWNLOAD

**NOTE:** Perform these steps to download the Battery\_Patch hex file p/n 3840900 **if** the Battery Capacity **is not** 4800mAh from the Battery Capacity Check.

1. Ensure the Ventilator power is switched **OFF**.
2. Disconnect the AC cord from the vent unit, wait approx 10 seconds then re-connect the AC cord and wait approx 10 seconds.
3. Connect the PC USB download cable to the ventilator PC port.
4. Click on **PICFlasher\_BE** program on the PC desktop to start the PIC download program if it is not running.
5. Select **Port COM** for the correct com port number. **NOTE:** This port number can be found in the PC Control Panel in the Device Manager section. The Com Port number to be used is the **first** of the two "USB Serial Ports" listed.
6. Click on **Fichier a Telecharger** button to open the C:\PB500\3840900\Battery\_\*.hex (where \* is the latest revision).
7. Click on **Programmation** to start the download.
8. When programming is successfully complete **Programmation terminee avec success** will be shown in the lower left corner (See Appendix 1). Otherwise, the download fails and testing cannot continue.
9. Switch the ventilator power ON and wait for the unit to fully boot up.
10. Disconnect the AC cord from the vent unit, wait approx 10 seconds, then re-connect the AC cord and wait approx 10 seconds.
11. **Perform the steps in the PIC Software download section.**
12. **Perform the steps in the Battery Capacity Check**, and complete DHR.

**Note:** if the test fails again then the overall test result is **Fail**.



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### CHECK POWER UP INDICATORS [REF [1] PRD50]

1. Switch the ventilator power OFF and then ON and check that Puritan Bennett 560 is displayed on the vent LCD after power ON.
2. Check that the Red and Yellow Alarm LEDs illuminate briefly and that the 2 buzzers sound briefly.
3. Check that the Blue Ventilation LED is ON.
4. Check that the AC LED is ON.
5. Complete DHR for checks. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR.

### CLEAR VENT LOGS

1. In the Maintenance Menu, place the cursor at Faults Check.
2. Reset the alarm history by pressing and holding the Alarm Reset button until a long beep sounds. The alarm history is now cleared.

### SET VENT S/N [REF [1] PRD274]

1. Select **PB560** model in the ST10 download program.
2. Enter the product serial number.
3. Click **Download S/N** to store the product serial number to the ventilator.
4. Disconnect the USB cord from the ventilator.

**Test Note:** To prevent the LCD screen going into the power save mode (dimmed screen), enter the PB560 Preferences Menu and change the Backlight setting to YES.

### SETUP TIME/DATE & CHECK S/W REVISION [REF [1] PRD203, 276]

1. Switch the ventilator power OFF and then ON and press and hold the Alarm Reset button to enter the Setup Menu.

**NOTE:** If a BUZZER FAULT1 alarm event occurs in this step, contact the line technician.  
Line Technician: Refer to APPENDIX 5

2. Ensure the Language is set to **English**.
3. Move the cursor with the + and – buttons to Date, and then √ Accept.
4. Set current date.
5. Move the cursor to Time and then √ Accept.
6. Set the current time using the plant clock.
7. Move the cursor to Maintenance and then √ Accept, then **Record** the two Software Versions on the DHR and check that they match the versions indicated.

### CHECK VENT S/N [REF [1], PRD274]

1. Check that the Vent S/N in the Maintenance Menu matches the S/N on the bottom of the unit and the DHR.




## REMOTE ALARM TESTS [REF [1], PRD41, 42, 43, 197]

### Setup

1. Fit the connector assembly #1 to the ventilator Patient Outlet Port as shown in the pictures below.



2. Fit the unplugged tubing line of the connector assy to the Patient Pressure Port of the ventilator.
3. Fit the plugged tubing line of the connector assy to the Exhalation Valve Port of the ventilator.
4. Switch the external DC power supply **ON**.
5. Set the external DC power supply voltage to **22.50 V** (press the  button on the keypad of the power supply to adjust the voltage) & the, current limit to **2.00 A** and check on the DHR that these values have been set.
6. Connect the DC Power Cable to the ventilator.
7. Enable the Ext DC power supply output.
8. Connect the Remote Alarm Test Box to the ventilator Remote Alarm jack on the rear panel of the ventilator.

### Procedure:

1. Switch the ventilator power OFF and then ON and wait for the vent to power up to the ventilation menu.
2. Disconnect the AC mains cord from the ventilator.
3. Check that the AC LED is **OFF** and the DC LED is **ON**.
4. Check that the Yellow Alarm LED is **flashing ON**.
5. Using DVM in the Resistance-Buzzer mode put the DVM probes into the **COM** and **N.O.** (normally open contacts) terminals of the Remote Alarm Test Box and Check that the DVM buzzer is **ON** for continuity.
6. Using DVM in the Resistance-Buzzer mode put the DVM probes into the **COM** and **N.C.** (normally closed) terminals of the Remote Alarm Test Box and Check that the DVM buzzer is **OFF** for no continuity.
7. Check that the ventilator indicates the message "AC POWER DISCONNECTION".
8. Press the Alarm Reset button.
9. Check that the ventilator alarm buzzer is silenced.





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10. Using DVM in the Resistance-Buzzer mode put the DVM probes into the **COM** and **N.O.** (normally open contacts) terminals of the Remote Alarm Test Box and Check that the DVM buzzer is **OFF** for no continuity.
11. Using DVM in the Resistance-Buzzer mode put the DVM probes into the **COM** and **N.C.** (normally closed) terminals of the Remote Alarm Test Box and Check that the DVM buzzer is **ON** for continuity.
12. Switch the ventilator power **OFF**.
13. Disconnect the DVM and the Remote Alarm Test Box.
14. If **any Checks** in this test section fail then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.

## POWER SOURCE SWITCHING TESTS [REF [1] PRD211, 212, 158, REF [11] HWSSUB10, REF [12] PSFSYST6.7]

1. Set the external DC power supply voltage to **10.00V**, current limit to **2.00A** and check on the DHR that these values have been set.
2. Switch the ventilator power **ON**.
3. Check that the BATTERY led is lit.
4. **Battery to DC** - Increase the external DC power supply voltage by 0.10V. Stop, and check if the vent DC led is ON. Repeat this step until the vent DC led is ON, and then record the power supply reading on DHR.  
**Limit:** 10.20V to 10.80V (10.50 ± 0.30V).
5. Check that the BATTERY led is OFF and the DC led is ON.
6. **DC to Battery** - Decrease the external DC power supply voltage by 0.10 V. Stop, and check if the vent BATTERY led is ON. Repeat this step until the vent BATTERY led is ON, then record the power supply reading on the DHR. **Limit:** 9.50 V to 10.10 V (9.80 ± 0.30 V).
7. Check that the DC led is OFF and the BATTERY led is ON and that the ventilator indicates the message "DC Power Disconnection".
8. Press the Alarm Reset twice to suppress the alarm.
9. **Battery to DC - Slowly** Increase the power supply by 0.10 V. Stop, and check if the vent External DC led is ON. Repeat the step until the vent External DC led is ON, then record the power supply reading on the DHR. **Limit:** 12.50 V to 13.10 V (12.80 V ± 0.30 V).
10. Check that the BATTERY led is OFF and the DC led is ON.
11. Re-connect the AC mains cord to the ventilator.
12. Check that the DC led is OFF and the AC led is ON.
13. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column on the DHR.

**DHR Section Signoff:** Sign and Date the DHR.



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### PATIENT DISCONNECT ALARM TEST

1. Start ventilation by pressing on the `Ventilation` button.
2. Check that the Ventilation Led is OFF.
3. Remove the connector assembly from the Patient Outlet Port and using the calibrated stopwatch Check that the ventilator alarm sounds within 15 seconds wait. Record the time elapsed on the DHR.
4. Check that the Red Alarm LED is flashing ON.
5. Check for the 'Patient Disconnection' message on the ventilator LCD.
6. Replace the connector assembly and Check that the alarm stops.
7. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column on the DHR.



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### EXHALATION VALVE ALARM

1. Stop ventilation. Reference Appendix 6 for stop ventilation procedure.
2. Check that the vent indicates an Intentional Vent Stop Alarm and press the Alarm Silence button to silence the alarm.
3. Ensure the vent is set to the following settings in the P A/C mode:

PIP	20
PEEP	OFF

4. Remove the tubing from the ventilator Exhalation Valve port.
5. Start ventilation by pressing on the Ventilation button.
6. Check that the ventilator alarm sounds immediately and the 'Connect Valve OR /Change Press' message is displayed.
7. Replace the tubing to the ventilator Exhalation Valve port and cancel any active alarms.
8. If **any Checks** in this test section fail, then the test result is Fail. Indicate the Pass or Fail test result by signing initials in the appropriate Pass or Fail column on the DHR.

### INVOLUNTARY STOP ALARM

**TEST NOTE:** Insure the vent has been switched ON (no ventilation) for at least 15 minutes to permit ample charging time of the buzzer board battery before performing this test.

1. Place the Sound Reducing Box, p/n 10029106, over the PB560 vent.
2. Remove the sponge cover from the sound-level meter and fully insert into the centre front hole of the Sound Reducing Box.
3. When Using the Breul & Kjaer sound-level meter **with the range selected to 30-110 dB**, record the **lowest** sound level seen on the sound level meter (to exclude turbine noise) and Check that the background noise level is **less than 85.0 dB** and record the value on the DHR. When using the CEL sound level meter select range A LO record the **lowest** sound level seen on the sound level meter (to exclude turbine noise) and Check that the background noise level is **less than 85.0 dB** and record the value on the DHR.
4. Switch the ventilator power **OFF**.
5. Using the stopwatch, check that the alarm sounds for at least 120 seconds, and record this on the DHR along with the time waited. If the buzzer does not sound for at least 120 seconds, then the test fails and should be recorded on the DHR.
6. While the buzzer is sounding, when using the Breul & Kjaer sound-level meter **with the range selected to 60-140 dB**, Check that the sound level is **greater than 95.0 dB** and **record** level on the DHR / when using the CEL sound-level meter **with the range selected to A HI**, Check that the sound level is **greater than 95.0 dB** and **record** level on the DHR.
7. Remove the Sound Level Meter and then the Sound Reducing Box and press the Alarm Silence button.
8. Check that the ventilator alarm buzzer is now silenced.
9. Switch ventilator power **ON** and then stop ventilation reference appendix 6 for stop ventilation procedure.
10. Press the Alarm Silence button to silence the Intentional Vent Stop alarm.
11. Switch OFF the sound level meter.
12. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column on the DHR.



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### USB PORTS TEST [REF [1] Section 5.3]

1. Cancel any active alarms before starting the USB Ports test using the Alarm Inhibit button.
2. Connect the USB memory device (formatted in the FAT32 file format) to each of the two USB-A ports at the rear of the ventilator.
3. For each of the two USB-A ports, check that the vent screen displays the "**USB MEMORY DEVICE**" menu. Do not remove the USB key until the **WAIT** message has disappeared.
4. Remove USB memory device from the USB port.
5. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column on the DHR.
6. Switch the ventilator power **OFF** and then **ON** then press and hold the **Alarm Reset** button to enter the **Setup Menu**.

**NOTE:** If a BUZZER FAULT1 alarm event occurs in this step, contact the line technician.

Line Technician: Refer to APPENDIX 5

### CALIBRATE PATIENT PRESSURE SENSOR [REF [7], HWSCP101]

#### PTS2000 Settings

High Flow	Low Pressure
air	cmH <sub>2</sub> O
slpm	

#### Setup

1. Disable the external DC power supply output and disconnect the DC Power Cable from the ventilator.
2. Fit connector assembly #2 to the Patient Outlet Port as shown in the pictures below.



3. Ensure the PTS2000 is set to display Menu #1 with Low Pressure in cmH<sub>2</sub>O.
4. Connect the PTS2000 (+) Low Pressure input, ventilator Patient Pressure Port and Outlet Port Connector Assy to the T connection as shown.
5. Check and record on the DHR that the PTS2000 pressure reading is -0.10 cmH<sub>2</sub>O to +0.10 cmH<sub>2</sub>O (0.00 cmH<sub>2</sub>O  $\pm$  0.10 cmH<sub>2</sub>O).



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### Procedure

1. Enter the ventilator Maintenance Menu.
2. Place the cursor on Sensors Calibration and press  $\checkmark$  Accept.
3. Place the cursor on Patient Pressure and press  $\checkmark$  Accept.
4.  $\checkmark$  Accept the 0 reading by a **long button press**.
5. Decrease or increase the Turbine speed using the  $\blacktriangledown$   $\blacktriangle$  buttons to set 39.80 to 40.20 cmH<sub>2</sub>O (40.00 cmH<sub>2</sub>O  $\pm$  0.20) on the PTS2000 pressure measurement.
6.  $\checkmark$  Accept by a **long button press** and Check for Short Beep - PASS (Long Beep = FAIL).
7. Check the value by pressing twice on the **Menu** button to be 39.60 to 40.40 0 cmH<sub>2</sub>O (40.00 cmH<sub>2</sub>O  $\pm$  0.40) and **record** the PTS2000 pressure reading on DHR.
8. Press the **Menu** button to end test.
9. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column on the DHR.

## CALIBRATE EXHALATION VALVE SENSOR

1. Place the cursor on Int Valve Pressure and press  $\checkmark$  Accept.
2.  $\checkmark$  Accept the 0 reading by **pressing the accept button, Check for 3 Short Beeps during this calibration step:**
  - **If the beep response is 3 short beeps, the result = Pass**
  - **If the beep response contains a long beep, the result = FAIL.**
3. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column on the DHR.

## INSPIRATORY FLOW SENSOR CALIBRATION [REF [7] HWSCP98]

### Setup

1. Remove the connector assembly from the Patient Outlet Port
2. Connect the 22 mm patient tubing between the Patient Outlet Port and the PTS2000 High Flow Inlet as shown in the picture below.



3. Ensure the PTS2000 is set to display Menu #1, with the PTS200 set to display High Flow, air in slpm.
4. Check and record on the DHR that the PTS2000 flow reading is -0.10 to +0.10.Lpm (0.0.Lpm  $\pm$  0.10.Lpm).



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### Calibration Procedure

1. Place the cursor on **Inspiration Flow** and press  $\checkmark$  Accept.
2.  $\checkmark$  Accept the 0 measurement (long press).
3. Use the  $\blacktriangledown$   $\blacktriangle$  buttons to set the turbine flow to the following values using the 2% setting limits below on the PTS2000 and then press the  $\checkmark$  Accept button with a long button press to continue. After each  $\checkmark$  Accept button press, Check for Short Beep = PASS (Long Beep = FAIL)
  - Set 4.90 to **5.10** Lpm ( **$5.00 \pm 0.10$** ), then  $\checkmark$  Accept by a long button press
  - Set **11.76** to **12.24** Lpm ( **$12.00 \pm 0.24$** ), then  $\checkmark$  Accept by a long button press
  - Set **19.60** to **20.40** Lpm ( **$20.00 \pm 0.40$** ), then  $\checkmark$  Accept by a long button
  - Set **36.26** to **37.74** Lpm ( **$37.00 \pm 0.74$** ), then  $\checkmark$  Accept by a long button press
  - Set **58.80** to **61.20** Lpm ( **$60.00 \pm 1.20$** ), then  $\checkmark$  Accept by a long button press
  - Set **88.20** to **91.80** Lpm ( **$90.00 \pm 1.80$** ), then  $\checkmark$  Accept by a long button press
  - Set **127.40** to **132.60** Lpm ( **$130.00 \pm 2.60$** ), then  $\checkmark$  Accept by a long button press

*Note: These are setting limits only*

4. If **any** beep responses are not a short beep, the result is Fail.

### Check Inspiratory Flow Calibration

1. Press the **Menu** button twice.
2. Wait until the value **5** stabilizes on the PTS2000 and record the value on DHR. Limit: 4.50 to 5.50 Lpm ( $5.00 \pm 0.50$  Lpm).
3. Press the **Menu** button.
4. Wait until the value **12** stabilizes on the PTS2000 and record the value on DHR. Limit: 11.10 to 12.90 Lpm ( $12.00 \pm 0.90$  Lpm).
5. Press the **Menu** button.
6. Wait until the value **20** stabilizes on the PTS2000 and record the value on DHR. Limit: 19.00 to 21.00 Lpm ( $20.00 \pm 1.00$  Lpm).
7. Press the **Menu** button.
8. Wait until the value **37** stabilizes on the PTS2000 and record the value on DHR. Limit: 35.10 to 38.90 Lpm ( $37.00 \pm 1.90$  Lpm).
9. Press the **Menu** button.
10. Wait until the value **60** stabilizes on the PTS2000 and record the value on DHR. Limit: 57.00 to 63.00 Lpm ( $60.00 \pm 3.00$  Lpm).
11. Press the **Menu** button.
12. Wait until the value **90** stabilizes on the PTS2000 and record the value on DHR. Limit: 85.50 to 94.50 ( $90.00 \pm 4.50$  Lpm).
13. Press the **Menu** button.
14. Wait until the value **130** stabilizes on the PTS2000 and record the value on DHR. Limit 123.50 to 136.50 ( $130.00 \pm 6.50$  Lpm).
15. Press the **Menu** button to end test.

If any **Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column on the DHR.



## **PROCESS MONITORING**

Fill in appropriate Pareto chart.

### **Flow Sensor Capacity** [REF [7] HWSCPB98] **and Turbine performance tests** [REF [9], HWTUB5]

#### **Setup**

1. Connect the PTS2000 (+) Low Pressure input and the ventilator Patient Pressure Port to Outlet Port Connector Assy #2 as shown (see picture below).
2. Ensure the PTS2000 is set to display Menu #1, with Low Pressure in cmH<sub>2</sub>O.
3. **Do not fit** connector assembly to the Patient Outlet Port at this time (see picture below).



#### **Procedure**

1. Place the cursor on Turbine Speed and press the Menu **button**.
2. Check the value displayed by the ventilator on the Inspiratory Flow line is greater than 145.0 Lpm. Record value on the DHR. (Flow Sensor Capacity Test).
3. Fit the connector assembly to the Patient Outlet Port and **block** the hole of the connector with finger.



4. Check that the value displayed by the PTS 2000 is greater than 70.00 cmH<sub>2</sub>O. Record value on the DHR (Turbine Performance).
5. Check the value displayed by the ventilator on the Patient Pressure line is greater than 70.0 mbar. Record value on the DHR.
6. Remove finger blocking hole and remove tubing from the vent Patient Pressure port.



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7. Check that the pressure reading in the right column on the Patient Pressure line is -0.5 to +0.5 mbar. Record value on the DHR.
8. Stop the Turbine by pressing on the ▲ or ▼ button.
9. Remove all air tubing.
10. Indicate the overall Pass or Fail test result when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.

## BATTERY DISCHARGE-CHARGE CYCLE [REF [1] PRD212, 213, 220]

### Timer Setup

1. Check and ensure that the 24-hour AC timer on the Battery Discharge-Charge rack is set to the current time  $\pm \frac{1}{2}$  hour using plant wall clock as a reference.
2. The overnight timed discharge-charge cycle consists of 8.5 hours of battery discharge followed by 11 hours of battery charge in the active ventilation. The AC timer switches power to the vent as required.
3. Ensure that the AC power OFF time is set correctly for 8.5 hours on the timer.
4. Ensure that the AC power ON time is set correctly for 11 hours on the timer.
5. If the timers are not set as described above inform the Line Supervisor, Manufacturing Technician or Engineer.

### Battery-Cycle Pre-Test Checks

1. Switch the ventilator power ON with battery power only and Check that the Battery Capacity is **95-100 %** otherwise battery needs to be charged before performing the Battery Discharge-Charge Cycle to be in this charge range. Record the Battery Capacity on the DHR when the vent is ready to be placed on Battery Discharge-Charge Cycle rack to continue the test.
2. Indicate the Pass or Fail for the Battery Cycle Pre-Test Checks when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.

**DHR Section Signoff:** Sign and Date the DHR.



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### Vent Setup

1. Switch ventilator power **ON**.
2. Place the cursor on the Ventilation Mode line and √ Accept.
3. Select the **P A/C** mode and √ Accept.
4. Set and accept the following parameters:

PIP	30 cmH2O
PEEP	8 cmH2O
Rise Time	2
R-Rate	15 bpm
Insp Time	1.3 s
Insp Sens	5
Vt Target	OFF

5. Enter preference menu, set VTI ML min to off and VTE ML min to off.
6. Place the ventilator on the battery Discharge-Charge Cycle rack.
7. Connect the AC cord to the ventilator.
8. Connect the connector assembly #1 to the Patient Outlet Port as shown in the picture below.



### Procedure

**Note:** Do not disconnect the AC cord from the ventilator at any time while the unit is on the overnight timed discharge-charge cycle.

**Note:** Ensure battery LED is no longer flashing before taking off discharge/charge cycle.

1. Start ventilation by pressing the **Ventilation** button.
2. Suppress the 'AC Power Disconnection' alarm if present, by pressing the Alarm Silence Reset button twice.
3. When the overnight timed discharge-charge cycle has completed, stop ventilation reference appendix 6 for stop ventilation procedure.
4. Press the Alarm Silence button to silence the Intentional Vent Stop alarm.
5. Perform the 'System Measurements' Check and 'Check Battery Data' test sections immediately after this test section.
6. Disconnect the AC mains cord from the ventilator.
7. Check that the Battery Charged indicator on the ventilator is at **99-100 %** (charged). Record on the DHR.
8. Switch ventilator power **OFF**.
9. If **any Checks** in this test section fail, then the test result is Fail. Indicate the overall Pass or Fail when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.



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**Note:** Proceed immediately to the 'System Measurements Check' and 'Check Battery Data' sections below

### SYSTEM MEASUREMENTS CHECK [REF [1] PRD59, REF [11] HWSSUB30, REF [7] HWSCP104, HWSCP93, REF [4] SECT 4.1, 4.2]

**Note:** This test section must be performed directly after the Battery Discharge-Charge Cycle Test.

1. Switch the ventilator power **ON** then press and hold the **Alarm Reset** button to enter the **Setup Menu**  
**NOTE:** If a BUZZER FAULT1 alarm event occurs in this step, contact the line technician.

Line Technician: see APPENDIX 5

2. Enter the Maintenance Menu.
3. Place the cursor on MEASUREMENT CHECK and √ Accept.
4. Check that the **24 V Check** reads 23.5 to 24.5 V (24 V ± 0.5 V). Record value on the DHR.
5. Check that the **Watchdog** reads 23.5 to 24.5 V (24 V ± 0.5 V). Record value on the DHR.
6. Check and record **Barometric Pressure** (displayed on vent) on the DHR. Record the Setra Pressure gauge reading on the DHR. Compare this value to be within ± 11.0 mmHg of the Setra Pressure gauge reading. Record Result and PASS if within limits.
7. Check that the **Internal Temperature** reads between 30.0 to 55.0° C. Record value on the DHR.
8. Check that the **Blower Temperature** reads between 35.0 to 65.0° C. Record value on the DHR.
9. Indicate the overall Pass or Fail when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.

### CHECK BATTERY DATA [REF [10] HWSBAT11, REF [10] HWSBAT5, REF [12] PSFSYST1.6, REF [4] SECT 4.3]

**Note:** This test section must be performed directly after the Battery Discharge-Charge Cycle Test.

1. Place the cursor on INTERNAL BATTERY MENU and √ Accept.
2. Check that the Battery **Supplier** is either [REDACTED] or [REDACTED]. Record Pass or Fail on the DHR.
3. Check that the (actual) Battery **Capacity** is between 4320 to 5280 mAh (4800 mAh ±10%). Record value on the DHR.
4. Check that the **Battery Voltage** reads 28.5 to 29.5 V. Record value on the DHR.
5. Check that the **Battery Temperature** reads between 20.0 to 40.0° C. Record value on the DHR.
6. Place the cursor on Back and √ Accept to return to the MEASUREMENT CHECK MENU.
7. Indicate the overall Pass or Fail when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.



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### BUZZER SOUND LEVEL CHECK [REF [1] PRD31, REF [4] SECT 4.12]

**NOTE:** Ear protection is available to employees for use during the Buzzer Sound Level Check test, as required.

1. Perform the **Daily Check: Sound Level Meter Check** in the **ALARM TEST** section if not already done.
2. Switch ON the sound level meter and ensure the LAF (L<sub>A</sub> Fast) for Breul & Kjaer parameter is displayed and the **sound level range selected is 60-140dB** or for the CEL model set range to A HI and response to F (fast).
3. Place the sound level meter directly in the front center of the vent with the sponge cover touching the unit cover.
4. Using the sound-level meter, check that the background noise level is **less than 85.0 dB** and record reading on the DHR.
5. While in the MEASUREMENT CHECK place the cursor on BUZZER and √ Accept.
6. Check that the sound level is **greater than 95.0 dB** and record level on the DHR.
7. Indicate the overall Pass or Fail when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.

### BACK-UP BUZZER CHECK [REF [1] PRD34]

1. While in the MEASUREMENT CHECK **menu** place the cursor on Back-up Buzzer and √ Accept.
2. Check that the buzzer sounds, and record Pass or Fail on the DHR by signing initials in the appropriate Pass or Fail column.

### FAULTS CHECK LOG [REF [1] PRD209]

1. In the Maintenance MENU, place the cursor on Faults Check and √ Accept.
2. Check for any faults that are not associated with normal activities. Refer to Appendix 3 for listing of possible errors that are not associated with normal activities. Record Pass/Fail on the DHR.
3. Place the cursor on BACK and √ Accept.
4. Indicate the overall Pass or Fail when the DHR test section is finished by signing initials in the appropriate Pass or Fail column.



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### Battery Discharge-Charge Cycle Event Times [REF [1] PRD194, 195]

1. **Note: Seconds are not required to be recorded on PHR when calculating Discharge/Charge Cycle Event times.**
2. With the vent on the test bench, double-click on the PB PVTs Technical Software icon on the PC desktop to start the program.
3. Connect the vent AC cord and switch the power OFF then ON.
4. After the vent power-up, connect the PC mini-USB cable to the vent.
5. Click on the 'Read Data' icon after it turns grey to download the vent data.
6. When the download has completed, click on the Events tab.
7. Click on the Report button.
8. Click on File and then Print to print the report and on the cover page strike a line through the '00' appended to the vent serial number. Initial and date the change and also sign and date the bottom of the first page of the report.
9. After the report has printed, click on the X in the upper right-hand corner to exit.
10. Click on the X in the upper right-hand corner to exit the PB Technical Software.
11. Using the printed report, record the time (HH:MM) of the Low Battery, Empty Battery and the Ventilator Unvoluntary Stop events on the DHR.
12. Subtract the Low Battery Alarm event time from the Ventilator Unvoluntary Stop event time paying attention to the HH:MM format. Check that the time from Low Battery to Unvoluntary Stop is greater than 30 minutes and record on the DHR.
13. Subtract the Empty Battery Alarm event time from the Ventilator Unvoluntary Stop event time paying attention to the HH:MM format. Check that the time from Empty Battery to Unvoluntary Stop is greater than 10 minutes and record on the DHR.
14. Attach the report to the DHR.
15. Press the Menu button on the vent.
16. Place the cursor on Alarm Logs and Accept.
17. Check that there are no battery alarm events in the alarm log other than the Low Battery and Empty Battery events for the Battery Discharge-Cycle Test. Record Pass or Fail on DHR.

If unexpected alarm events occur contact the Line Technician to review the Events Logs. Indicate Pass/Fail according to the Line Technician review of the Event Log,

**Note:** Ensure LED is no longer flashing before taking off Discharge-Charge cycle.

**DHR Section Signoff:** Sign and Date the DHR.

## PROCESS MONITORING

Input the inspection data into Web SPC system for CTQ parameters.

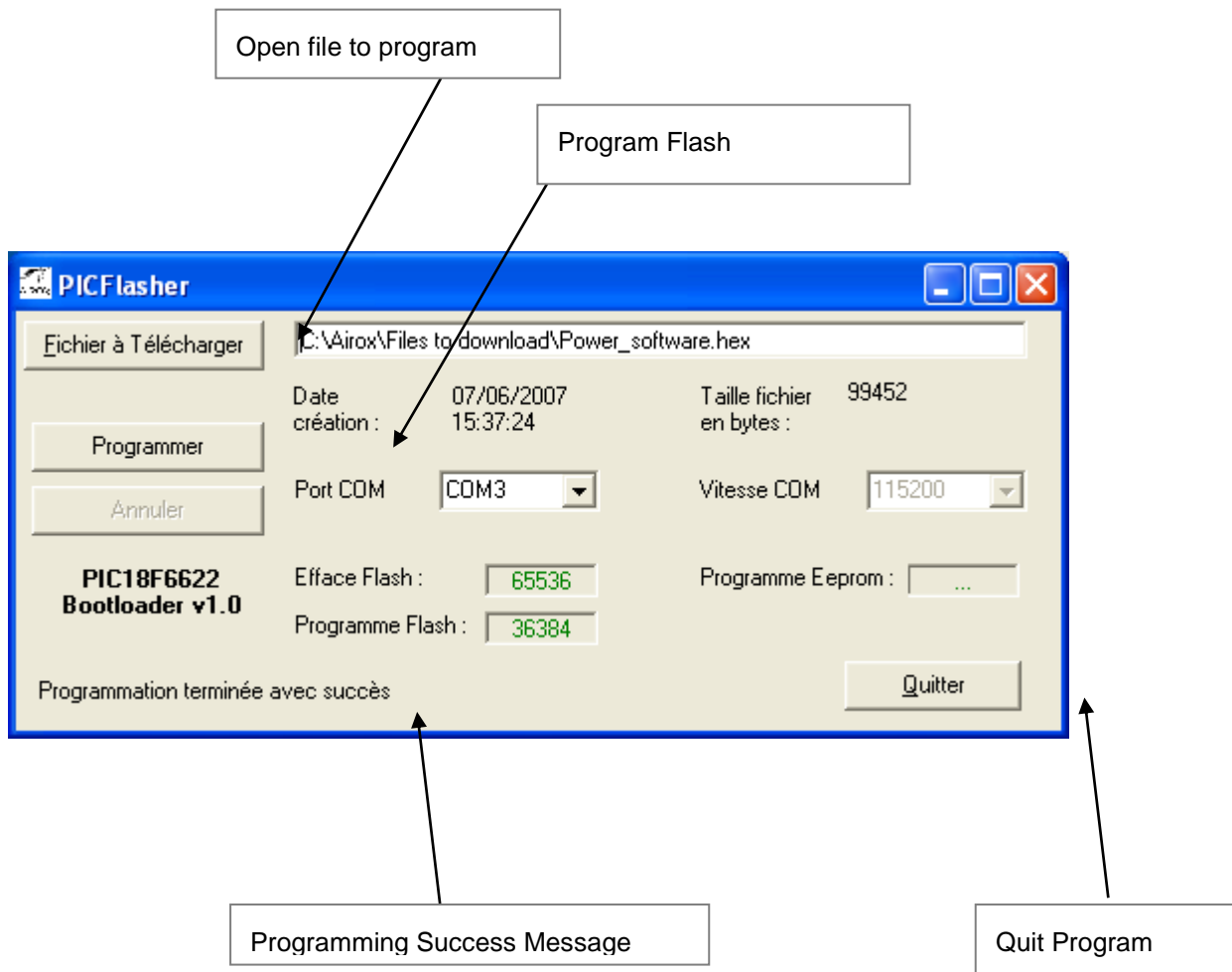
Reference Web SPC User process Instructions procedure (P/N: 10039404) to complete this step.

Fill in appropriate Pareto chart.

**LINE TECHNICIAN NOTE:** The BUZZER FAULT1 alarm event can occur after the Empty Battery Alarm event in the battery discharge-charge cycle but should terminate after the battery is fully charged and are not considered a failure for this test. Occurrences of these error codes in any other circumstance need to be debugged / investigated. Refer to APPENDIX 4 for the vent to PB PVTs log alarm event cross-reference listing.



## APPENDIX 1: PIC Download Screen





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### APPENDIX 3: 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



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### APPENDIX 4: Vent to PVTs Log Alarm Event Cross-Reference Listing

Vent LCD Screen	PB PVTs Event Log (Name Column)
PATIENT DISCONNECTION*	AL_DISC
HIGH PRESSURE	AL_HIGH_PRESS
APNEA	AL_APNEA
HIGH VtI	AL_HIGH_VTI
LOW VtI	AL_LOW_VTI
LOW VtE	AL_LOW_VTE
HIGH MINUTE VOLUME	AL_HIGH_VM
LOW MINUTE VOLUME	AL_LOW_VM
HIGH RATE	AL_HIGH_RATE
AC POWER DISCONNECTION	AL_AC_POW_FAIL
DC POWER DISCONNECTION	AL_DC_POW_FAIL
POWER FAULT RESTART/SRVC	AL_CHK_SUPPLY
LOW BATTERY	AL_LOW_BATT
EMPTY BATTERY	ALE_BATT
BATTERY FAULT1 RESTART/SRVC	AL_CHK_BATT
BATTERY FAULT2 RESTART/SRVC	AL_NO_BATT
BUZZER FAULT1 RESTART/SRVC	AL_CHK_BUZZ
BUZZER LOW BATTERY	AL_LOW_BUZZ_BATT
BUZZER FAULT3 RESTART/SRVC	AL_BUZZ_BATT_CHRG
BUZZER FAULT4 RESTART/SRVC	AL_BUZZ_BATT_FAIL
BUZZER FAULT2 RESTART/SRVC	AL_TECH_PB
INVERSE I:E RATIO	AL_REVERSED_IE
PRES SENS FLT1 RESTART/SRVC	AL_CHK_PRESS
PROX SENS FLT2 RESTART/SRVC	AL_CHK_PROXI
CHECK PROXIMAL LINE1*	AL_PROXI_DISC



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NO PROXIMAL LINE2*	AL_NO_PROXI
CHK EXH VALV RESTART VENT*	AL_NO_VALVDETECT
CHECK EXH VALVE	AL_CHK_VALVE
VtI NOT REACHED	AL_CHK_VOL
EXH VALVE LEAKAGE	AL_VALV_LEAK
CHECK REMOTE ALARM	AL_CHK_REMOTE
UNKNOWN BATTERY_	AL_UNKNOWN_BATT
CHECK BATTERY CHARGE_	AL_CHK_BATT_CHARG
HIGH VtE_	AL_HIGH_VTE
CALIBRATION FAIL_	AL_CALIBRATION
KEYPAD FAULT RESTART/SRVC	AL_KEYBOARD
HIGH INT TEMP COOL VENT*	AL_AMBIENT_TEMP
HIGH/LOW BATTERY TEMP	AL_BAT_TEMP
DEVICE FAULT3 RESTART/SRVC	AL_FAILUR24V
COOLING FAN RESTART/SRVC	AL_COOLING_FAN
DEVICE FAULT5 RESTART/SRVC	AL_SUPPLY_MEASE
TURB. OVERHEAT RESTART/SRVC	AL_TURBIN_HEAT
OCCLUSION CHECK CIRCUIT*	AL_OCCLUSION
DEVICE FAULT7 REPLACE VENT	AL_CPU_REF
EXHSENS FAULT OR CIRC LEAK	AL_BRTH_TIME_CYCL
DEVICE FAULT8 REPLACE VENT	AL_INSP_FLOW_FAIL

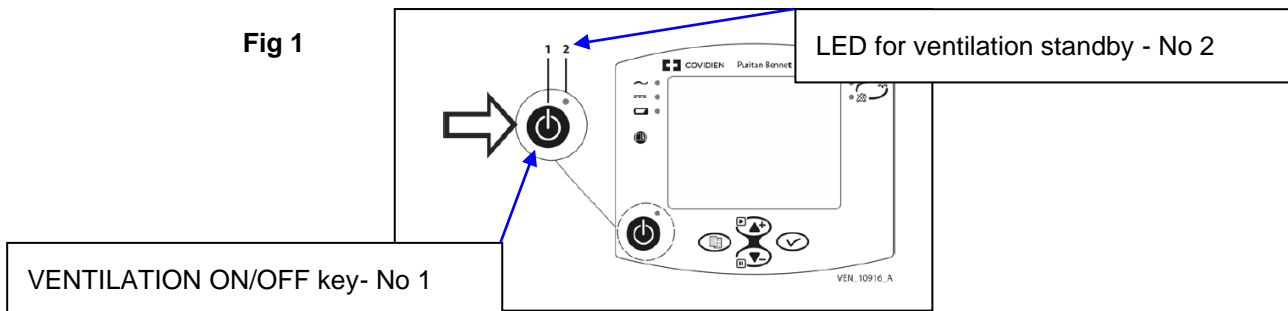
## APPENDIX 5: BUZZER FAULT1 LINE TECH NOTE

This 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 and this alarm event is cleared when the vent is power cycled, then this alarm event is not considered a failure.

## Appendix 6: Ventilation stop procedure.

- 1) 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**

