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PREFACE

Medtronic is aware of recent difficulties with obtaining the proprietary disposable exhalation filter (p/n: 10043551) for the Puritan Bennett™ 980 ventilator (PB980). In order to help ensure that you are able to keep your PB980 ventilators in use during the COVID-19 pandemic, we have released a temporary-use exhalation filter adapter.

This temporary-use exhalation filter adapter allows the use of a non-proprietary filter that has a standard 22 mm tapered fitting as the PB980 ventilator expiratory filter. This solution is suggested only if inventory of the PB980 ventilator expiratory filter (p/n: 10043551) is unavailable during the COVID-19 pandemic and is only for use on pediatric or adult patients.

This temporary-use exhalation filter adapter solution is intended to address the COVID-19 emergency response in accordance to the US FDA “Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency” and is not 510(k) cleared.

THIS GUIDE WILL PROVIDE INFORMATION FOR:

1. Installing the PB980 Exhalation Filter Adapter Plate and Adapter
   ▪ Preparing the PB980 Exhalation Filter Adapter Plate (p/n: PT00121648) and Exhalation Filter Adapter (p/n: PT00121650) for installation
   ▪ Attaching the Exhalation Filter Adapter Plate to the PB980 Ventilator
   ▪ Connecting the Exhalation Filter Adapter to the Exhalation Filter Adapter Plate

2. Use of the PB980 Ventilator with the Exhalation Filter Adapter
   ▪ Filter installation with the PB980 Exhalation Filter Adapter
   ▪ Cleaning the PB980 Exhalation Filter Adapter

3. Instructions of Flow Sensor Calibration and Short Self-Test (SST) on the PB980
   ▪ Refer to Appendix A to complete the Flow Sensor Calibration and SST process after the Exhalation Filter Adapter Plate and Adapter are installed

HOW TO USE THIS GUIDE

This guide consists of two main sections: installation of PB980 Exhalation Filter Adapter onto the ventilator and use of PB980 Ventilator with an installed PB980 Exhalation Filter Adapter.

1. BIOMEDICAL ENGINEERS – INSTALLING THE PB980 VENTILATOR EXHALATION FILTER ADAPTER PLATE AND ADAPTER:
   ▪ To perform the Installation of PB980 Exhalation Filter Adapter Plate and Adapter, please refer to ‘INSTALLING THE PB980 EXHALATION FILTER ADAPTER PLATE AND ADAPTER’ on Page 5 of this guide.
   ▪ Complete all steps in Appendix A (page 13) prior to returning PB980 for patient use.

2. CLINICAL USERS – USING THE PB980 VENTILATOR WITH THE PB980 EXHALATION FILTER ADAPTER:
   ▪ Once the PB980 Exhalation Filter Adapter is installed, please refer to ‘USING PB980 VENTILATOR WITH THE PB980 EXHALATION FILTER ADAPTER’ on Page 10 of this guide.
EXHALATION FILTER ADAPTER SOLUTION RISKS

1. More frequent inspections of the filters are needed to check for condensate and increased filter resistance.
   a. This is also mitigated by the safety valve relief pressure, Low Exhaled Volume Alarms, and the High P\text{PEAK} Alarm.

2. Use of the PB980 Exhalation Filter Adapter and filters other than the PB980 expiratory filter may influence delivered tidal volume and monitored tidal volume accuracy.
   a. This is mitigated by Flow Sensor Calibration for volume accuracy as part of the system, and Short Self-Test (SST) that is performed after installation of the adapter/filter.

RECOMMENDED PERIOD OF USE

• This feature may only be used in the event of a PB980 Pediatric-Adult Exhalation Filter not being available due to the unforeseen demand caused by COVID-19 pandemic.
INSTALLING THE PB980 EXHALATION FILTER ADAPTER PLATE AND ADAPTER
PREPARING THE PB980 EXHALATION FILTER ADAPTER PLATE AND ADAPTER FOR INSTALLATION

Prior to the installation of the PB980 Exhalation Filter Adapter Plate and Adapter, either disinfect both parts with high-level disinfection liquid chemicals or sterilize by Autoclave:

1. Disinfect with high-level disinfection liquid chemicals:
   a. Presoak the PB980 Exhalation Filter Adapter Plate and Adapter in EMpower™* Dual Enzymatic Solution (Metrex Inc.).
   b. Follow the manufacturer's instructions to perform high-level disinfection using liquid chemical disinfectant with any of the following agents:
      i. Cidex™* (2.5%) (ASP1)
      ii. Cidex™* OPA (0.55%) ASP1

2. Autoclave:
   a. Clean and Inspect Adapter Plate and Adapter per current site Sterilization Procedures.
   b. Autoclave Adapter Plate and Adapter per current site Sterilization Procedures.
   c. Dry Adapter Plate and Adapter per current site Sterilization Procedures.
INSTALLING THE PB980 EXHALATION FILTER ADAPTER PLATE AND ADAPTER FOR USE

The PB980 Exhalation Filter Adapter Plate and Adapter will be placed inside the PB980 Ventilator for Adult and Pediatric ventilatory support.

1. Lift the exhalation filter latch to unlock. This raises the exhalation valve assembly and allows the filter door to swing away from the ventilator.

2. Open the exhalation filter door.

Note: Do not install the PB980 Exhalation Filter Adapter Plate and Adapter during patient ventilation.

Attaching the PB980 Exhalation Filter Adapter Plate:

1. Remove the screw from the outside corner of the exhalation filter door using a 5/64 Hex Driver.

2. Place the screw aside for use during Steps 6 and 7.

3. Remove the aluminum piece from the outside corner of the exhalation filter door, revealing the threaded hole on the exhalation filter door.

4. Save and store the aluminum piece in a safe place for future use, once the PB980 Adapter Plate and Adapter are uninstalled.
5. Place the PB980 Exhalation Filter Adapter Plate, with the slotted side up, aligning the Exhalation Filter Adapter Plate hole and the threaded hole on the exhalation filter door.

6. Place the screw through the PB980 Exhalation Filter Adapter Plate and into the exhalation filter door.

7. Tighten the screw using a 5/64 Hex Driver.

Note: Do not overtighten the screw/over torque the screw when installing the PB980 Exhalation Adapter Plate. Recommended hand-tightening with 5/64 Hex Driver.
Attaching the PB980 Exhalation Filter Adapter to the Adapter Plate:

1. Insert the PB980 Exhalation Filter Adapter into the center hole of the PB980 Exhalation Filter Adapter Plate.

2. Align the notch with the peg on the adapter plate.

3. Attach a new filter to the assembled PB980 Exhalation Filter Adapter.

4. Close the exhalation filter door.

5. Lower the exhalation filter latch to the lock position.

Note: Due to the design of other filters, the exhalation filter may not align with the cutout in the exhalation filter door. This does not impact performance.

Preparing the PB980 Ventilator for use:

1. Perform Flow Sensor Calibration and SST on the PB980 Ventilator, following instructions provided in Appendix A (page 13).

APPENDIX A.
PERFORMING FLOW SENSOR CALIBRATION, AND SST ON THE PB980
USING PB980 VENTILATOR WITH THE PB980 EXHALATION FILTER ADAPTER
FILTER INSTALLATION WITH PB980 EXHALATION FILTER ADAPTER

To install the Pediatric-Adult Exhalation Filter with the adapter in place the same overall workflow is followed, and the warnings noted in the Puritan Bennett™ 980 Series Ventilator Operator’s Manual are still applicable.

Steps to install the Pediatric-Adult Exhalation Filter:

1. If necessary, remove the expiratory limb of the patient circuit from the exhalation filter.

2. Raise the exhalation filter latch to unlock. This raises the exhalation valve assembly and allows the filter door to swing away from the ventilator.

3. Open the exhalation filter door.

4. Remove the existing filter.

5. Insert the new filter by connecting it to the PB980 Exhalation Filter Adapter that is installed on the exhalation filter door.

   Note: Due to the design of other filters, the exhalation filter may not align with the cutout in the exhalation filter door. This does not impact performance.

6. Close the exhalation filter door.

7. Lower the exhalation filter latch.

Note: More frequent inspections of the filters are needed to check for condensate and increased filter resistance.
CLEANING THE PB980 EXHALATION FILTER ADAPTER

When the gas pathway surfaces are visibly soiled or per institutional guidelines:

1. Remove the PB980 Expiratory Filter Adapter.

2. Either disinfect the PB980 Expiratory Filter Adapter with high-level disinfection liquid chemicals or sterilize by Autoclave:
   a. Disinfect with high-level disinfection liquid chemicals:
      i. Presoak the PB980 Expiratory Filter Adapter in EMpower™* Dual Enzymatic Solution (Metrex Inc.).
      ii. Follow the manufacturer’s instructions to perform high-level disinfection using liquid chemical disinfectant with any of the following agents:
         1. Cidex™* (2.5%) (ASP1)
         2. Cidex™* OPA (0.55%) ASP1
   b. Autoclave:
      i. Clean and inspect the Adapter per current site Sterilization Procedures.
      ii. Autoclave the Adapter per current site Sterilization Procedures.
      iii. Dry Adapter per current site Sterilization Procedures.

Note: Perform SST after cleaning/sterilization and reassembly.

FOR MORE INFORMATION & SUPPORT

Local support can be obtained by Medtronic staff through your normal communication channels.
APPENDIX A.

PERFORMING FLOW SENSOR CALIBRATION, AND SST ON THE PB980
APPENDIX A. PERFORMING FLOW SENSOR CALIBRATION, AND SST

FLOW SENSOR CALIBRATION

1. Put the PB980 into Service Mode by following the guidance in the Puritan Bennett™ 980 Series Ventilator Operator’s Manual below:

3.7.4 Service Mode

WARNING:
Before entering Service mode, ensure a patient is not connected to the ventilator. Ventilatory support is not available in Service mode.

Service mode is used for extended self test (EST), ventilator calibration, configuration, software upgrades, option installation (all of which must be performed by qualified service personnel), and for making adjustments to institutional settings. All information stored in the individual logs is available in Service mode. Service mode logs include:

- System Diagnostic
- System Comm.
- EST/SST Diagnostic
- Settings
- Alarms
- General Event
- Service
- Patient Data

See the Puritan Bennett™ 980 Series Ventilator Service Manual for details about Service mode logs. A patient must not be attached to the ventilator when entering Service mode. Specific actions must be performed to enter this mode, prior to PST completion.
To access Service mode

1. Remove the ventilator from patient usage.
2. Turn the ventilator’s power switch on.
3. Press and release the Service mode button (TEST) at the back of the ventilator, when the Cowdren splash screen appears on the status display after powering on the ventilator. See Figure 3-17, on page 3-31. See Table 2-9, on page 2-27 for an image of the splash screen. The ventilator prompts to confirm no patient is attached.

Figure 3-17. Service Mode Button (TEST)

4. Wait to enter Service mode.
5. Confirm that a patient is not connected to the ventilator by touching the corresponding button. The message SERVICE MODE VENTILATION SUPPORT IS NOT AVAILABLE appears on the graphical user interface.
2. Next, perform Flow Sensor Calibration as defined below:

Flow Sensor Calibration

The flow sensor calibration function builds a table of flow sensor offsets. The calibration requires a gold standard test circuit. A system leak is a common source of failure, particularly exhalation valve leaks.

Note:
If the ventilation has not reached operating temperature from recent usage, allow ventilator to warm up for at least 15 minutes in Service mode before performing flow sensor calibration.

To calibrate the flow sensors
1. Connect air and oxygen to the appropriate inlets.
2. Ensure external gas sources can supply 200 L/min.
3. Confirm secure attachment of the exhalation filter collector via components.
4. Securely attach the gold standard test circuit to both the in and from patient ports.
6. Touch the Calibration tab (Figure 1-10).

4. Touch Start Cal.
5. Touch Accept.
8. Follow all on-screen prompts.
11. If the calibration fails, verify firm attachment of the test circuit, secure connection of the exhalation filter, and ensure the system is free of leaks. Then run the test. Call Covidien Technical Services if the calibration continues to fail.
**SHORT SELF-TEST (SST)**

3. Perform SST as defined below:

- SST results are recorded in the SST results log, viewable in Service mode and in Normal mode using the configuration (wrench) icon.

**Required Equipment**
- Proprietary circuit for patient ventilation
- Accessories (water traps, etc.)
- Exhalation filter and condensate vial
- Humidifiers, if applicable
- A number 1 stopper to block the patient airway at the patient yoke
- Two gas sources (air and oxygen) connected to the ventilator at a pressure between 241.3 kPa and 599.9 kPa (35 psi and 87 psi)

**To run SST**
1. Ensure a patient is not connected to the ventilator.
2. So that the ventilator does not detect a patient connection, ensure that the breathing circuit yoke is not attached to a test lung or covered in any way that would cause an increase in pressure at the yoke.
3. Turn the ventilator on using the power switch located at the front of the ECU, below the status display. The ventilator runs POST when the power switch is turned on. Ensure the ventilator is operating on full AC power. Otherwise, SST test failures may result.
4. Wait at least 15 minutes to allow the ventilator to warm up and stabilize to ensure accurate results.
5. At the ventilator startup screen, touch SST or the configure icon (wrench) displayed in the lower right area of the GUI. The SST history log appears along with 'Patient Setup, Run Leak Test, and Run All SST buttons.'
6. Connect the patient circuit filters/condensate vial and all accessories to be used in patient ventilation. Ensure the patient yoke is not blocked.
7. Touch Run All SST to perform all SST tests or touch Run Leak Test to perform the SST Leak test of the ventilator breathing circuit.
8. Touch Accept to continue or Cancel to go back to the previous screen.
9. After accepting, touch the Circuit Type button, corresponding to the patient circuit type used to perform SST and to ventilate the patient (adult, pediatric, or neonatal).
10. Touch the Humidification Type button corresponding to the humidification type used for patient ventilation. If no humidifier is used, touch NONE. If a humidifier is used, touch Humidification Volume and turn the knob to enter the volume. See Table 3.4, for adult and pediatric patients and Table 3.5, for neonatal patients, to determine the correct volume to enter.
11. Touch Accept to start SST.
12. Follow the prompts. Certain SST tests require operator intervention, and will pause indefinitely for a response. See Table 3.3, and Table 3.6, for a summary of the SST tests and test step results, respectively.
13. After each test, the ventilator displays the results. If a particular test fails, the test result appears on the screen and a choice to repeat the test or perform the next test is given. When all of the SST tests are complete, the SST status screen displays the individual test results.
14. To proceed to patient setup, if SST did not detect an Alert or failure) touch Exit SST, then touch Accept or cycle the ventilator's power.

**SST Results**

SST reports results for each individual test. Three status indicators identify the SST results and actions to take for each:
- **Pass** — The individual SST test has met its requirements.
- **Alert** — Alerts occur when the ventilator detects one or more non-critical faults.
- **Failed** — The individual SST test did not meet its requirements.
# SST Outcomes

When SST completes all of the tests, analyze the results.

<table>
<thead>
<tr>
<th>Final outcome</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>PASS</td>
<td>All SST tests passed.</td>
<td>Touch Patient Setup to set up the patient for ventilation.</td>
</tr>
<tr>
<td>OVERERVICE</td>
<td>The ventilator detected one or more faults. Choose to override the ALERT status and authorize ventilation only when absolutely certain the circuit cannot cause a patient hazard or add to risks arising from other hazards.</td>
<td>Check the patient circuit to determine the problem or restart SST with a different patient circuit.</td>
</tr>
<tr>
<td>FAIL</td>
<td>One or more critical faults were detected. The ventilator enters the 990 state and cannot be used for normal ventilation until SST passes.</td>
<td>Check the patient circuit to determine the problem or restart SST with a different patient circuit.</td>
</tr>
</tbody>
</table>

NOTE: All screenshots taken for Appendix A were from either (P/N: PT00102829A00) or (P/N: PT00101843A00)