Puritan Bennett™

980 Series Ventilator

High Flow Oxygen Therapy Option
The ventilator should be operated and serviced only by trained professionals. Covidien’s sole responsibility with respect to the ventilator and software, and its use, is as stated in the limited warranty provided.

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### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Rx ONLY" /></td>
<td>This device is for sale by or on the order of a physician</td>
</tr>
<tr>
<td><img src="image" alt="CE Mark" /></td>
<td>CE Mark—Signifies compliance with Medical Device Directive 93/42/EEC</td>
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<td><img src="image" alt="European Community (EC) authorized representative" /></td>
<td>European Community (EC) authorized representative</td>
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<td><img src="image" alt="Manufacturer—Ventilator manufacturer" /></td>
<td>Manufacturer—Ventilator manufacturer</td>
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1. High Flow Oxygen Therapy (HFO₂T)

1.1. Overview
This addendum describes the operation of the Puritan Bennett™ 980 Series Ventilator High Flow Oxygen Therapy (HFO₂T) software option, which provides a continuous flow of inspiratory gas to spontaneously breathing patients.

1.2. Product Description
HFO₂T software adds an additional selection for ventilation type to the ventilator. When selected, HFO₂T will deliver and maintain the operator-set constant flow (V_CONST) and O₂% through a single limb circuit that is connected to an oxygen therapy interface. The vital patient data banner clearly indicates that HFO₂T is active and displays monitored V_CONST and O₂% (see Figure 1).

HFO₂T is used with a single-limb breathing circuit connected from the gas outlet (To patient port) of the ventilator, through the humidifier, to an HFO₂T patient interface. During HFO₂T, the ventilator's graphical user interface (GUI) settings area displays:

- Set constant flow rate (V_CONST)
- Set O₂%

During HFO₂T, the ventilator's GUI monitored patient data area displays:

- Monitored V_CONST

![Figure 1. PB980 HFO₂T](VEN_12713_A)
• Monitored O₂% (see Figure 2).

Figure 2. PB980 HFO₂T Vital Patient Data area and Settings area

1.3. Intended Use

The HFO₂T software option is intended to provide a constant flow of oxygen and air, which is ideally heated and humidified, to spontaneously breathing adult, pediatric, and neonatal patients using a single limb circuit.

1.4. Safety Terms

This section contains safety information for users who should always exercise appropriate caution while using the ventilator.

Table 1. Safety Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Warning</td>
<td>Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.</td>
</tr>
<tr>
<td>Caution</td>
<td>Cautions alert users to exercise appropriate care for safe and effective use of the product.</td>
</tr>
<tr>
<td>Note</td>
<td>Notes provide additional guidelines or information.</td>
</tr>
</tbody>
</table>

1.5. Safety Information

**Warning:** The ventilator offers a variety of breath delivery options. Throughout the patient’s treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the
benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

**Warning:** For proper delivery of HFO₂T to the patient, the HFO₂T interface must be connected directly to the inspiratory limb of the breathing circuit. The wye connector and expiratory limb are not used with HFO₂T.

**Warning:** Do not use HFO₂T with a dual-limb ventilator circuit that is connected to the ventilator's exhalation filter or HFO₂T will not be delivered properly to the patient.

**Warning:** Ensure that the circuit being used does not have a pressure relief valve anywhere between the ventilator and the patient as this may prevent the ventilator alarms from working properly.

**Warning:** To prevent impedance to patient exhalation and exposure to excess pressure, use only interfaces intended for HFO₂T such as a high flow nasal cannula, a tee piece, an aerosol mask, or a tracheal mask.

**Warning:** To prevent CO₂ rebreathing, ensure that the flow used during HFO₂T is adequate to clear the HFO₂T interface of exhaled CO₂.

### 1.6. Software Requirements

The HFO₂T software option must be installed and enabled by a Medtronic-trained service technician.

### 1.7. On-screen Symbols

Table 2. Symbols and Abbreviations

<table>
<thead>
<tr>
<th>Symbol or abbreviation</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Monitored $V_{\text{const}}$</td>
<td>Constant flow</td>
</tr>
<tr>
<td>$O_2%$</td>
<td>Oxygen percentage</td>
</tr>
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</table>

### 1.8. SST Requirements

Prior to the use of HFO₂T with a single-limb circuit, perform SST using a dual-limb circuit that is appropriately sized for the patient type. Although SST is not required for HFO₂T, Medtronic recommends that SST be performed, in the event that the patient requires switching to invasive or noninvasive ventilatory support.

### 1.9. Using the HFO₂T Function

Review and follow all warnings prior to patient ventilation with the HFO₂T feature. See [Safety Information, page 2](#).

**Configure the breathing circuit for HFO₂T:**

1. Remove the expiratory limb and patient wye connector from the conventional dual limb ventilator breathing circuit.
2. Connect one end of the inspiratory, single limb to the heated humidification system outlet.
3. Connect the other end of the inspiratory, single limb to an appropriately sized, HFO₂T patient interface.

**Set up the ventilator to deliver HFO₂T on a new patient prior to ventilation:**

1. Select HFO₂T as the Ventilation Type from the vent setup screen.
2. Adjust $V_{\text{CONST}}$ and $O₂\%$ settings as prescribed.
   
   **Note:** The ventilator emits an audible tone when the recommended high flow limit is reached. To continue beyond this point, the operator must acknowledge a visual prompt.
3. Touch ACCEPT ALL to begin HFO₂T.

**Set up the ventilator to deliver HFO₂T on a patient currently receiving ventilatory support:**

1. Enter Stand-By before using HFO₂T. Figure 3 shows that selecting HFO₂T without first entering Stand-By results in a prompt that reminds the operator to enter Stand-By.
2. Assemble and connect a single limb circuit configuration according to Step 1 through Step 3 under Configure the breathing circuit for HFO₂T.
3. Touch the vent setup button at the bottom left of the GUI display screen.
4. Touch HFO₂T as the Ventilation Type.
5. Adjust $V_{\text{CONST}}$ and $O₂\%$ settings as prescribed.
6. Touch ACCEPT ALL to begin HFO₂T.
   
   **Note:** If a SEVERE OCCLUSION alarm occurs while transitioning to HFO₂T, the ventilator will not transition to HFO₂T until the following steps are performed.
   a. Disconnect the inspiratory limb at the (To patient port).
   b. Touch the Alarm Reset key.
   c. Reconnect the inspiratory limb.
   d. Verify that (HFO₂T Active) is displayed at the top of the screen.
To monitor the patient on HFO₂T:
Observe the GUI vital patient data area for displays of monitored $V_{\text{const}}$ and $O_2\%$ (see Figure 4).

Figure 3. HFO₂T with current patient with Stand-By prompt

Figure 4. PB980 HFO₂T Vital Patient Data
To disable HFO\textsubscript{2}T and initiate conventional positive pressure ventilatory support:

1. Reconfigure the HFO\textsubscript{2}T breathing circuit to a dual-limb configuration by attaching the expiratory limb and patient wye connector to the inspiratory limb previously used for HFO\textsubscript{2}T.
2. Connect the free end of the expiratory limb to the ventilator’s expiratory filter.
3. Touch the vent setup button.
4. Touch either Invasive or NIV as the desired Ventilation Type.
5. Adjust mode, breath type, and settings as prescribed.
6. Touch ACCEPT ALL (see Figure 5).

Figure 5. Transitioning from HFO\textsubscript{2}T to Invasive Ventilation

1.10. Alarms

The following alarm events are associated with the HFO\textsubscript{2}T feature:

**Note:** No user-settable alarms are available.

- **HIGH DELIVERED O\textsubscript{2} %**—Alarm indicates the delivered O\textsubscript{2} percentage is at or above the error percentage above the O\textsubscript{2} % setting for at least 30 seconds.
  
  **Note:** The 30 second time delay is intended to eliminate nuisance alarms after changes to set O\textsubscript{2} % while delivering low flows.

- **LOW DELIVERED O\textsubscript{2} %**—Alarm indicates the measured O\textsubscript{2} % during any phase of a breath is at or below the error percentage below the O\textsubscript{2} % setting, or less than or equal to 18%, for at least 30 seconds.
• LOW DELIVERED $V_{\text{CONST}}$—Alarm indicates the measured $V_{\text{CONST}}$ value is less than the set $V_{\text{CONST}}$ value (see Figure 6).

• EXPIRATORY LIMB CONNECTED—Alarm indicates the ventilator has detected a conventional breathing circuit is being used for HFO$_2$T ventilation instead of an inspiratory limb, only (see Figure 7).

Figure 6. HFO$_2$T Low Measured Constant Flow alarm
1.11. Specifications

Table 3 lists the ventilator setting, range, and resolution.

<table>
<thead>
<tr>
<th>Setting</th>
<th>Range and resolution</th>
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</table>
| $V_{\text{CONST}}$ | Range:  
ADULT: 1 L/min to 80 L/min (softbound alert at 60 L/min)  
PEDIATRIC: 1.0 L/min to 50 L/min  
NEONATAL: 1.0 L/min to 50 L/min  
Resolution:  
0.5 L/min for values < 10 L/min  
1 L/min for values ≥ 10 L/min |
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