1.1 Overview

This addendum to the User’s Manual and Clinician’s Manual describes product enhancements in the LX010101, LX010102 and LX010103 software updates (for the Puritan Bennett 560 ventilator), and the LS010101, LS010102 and LS010103 software updates (for the Puritan Bennett 520 ventilator).

Enhancements in this update include:

- an additional inspiratory trigger sensitivity level for paediatric patients
- the ability to set respiratory rate from 1-60 bpm in Assist/Control ventilation mode
- the ability to configure inspiratory time directly in Assist/Control ventilation mode
- Circuit Check feature that checks the patient circuit for potential leaks
- the option to select a secondary alarm tone
- the ability to restore the ventilator’s default settings
- miscellaneous labelling updates.

Note:

Depending on the revision level of your User’s Manual and Clinician’s Manual, one or more features described in this addendum may differ from what is described in the manual. Refer to the back cover of the manual to find its revision level.

If your ventilator is running with the LX010101/LX010102/LX010103 or LS010101/LS010102/LS010103 update, the functionality descriptions in this addendum supercede the corresponding descriptions in previously released User’s Manuals and Clinician’s Manuals. Refer to individual feature descriptions for details on affected sections, figures and tables.

For further information and assistance, please contact Covidien or a local Covidien representative.
1.2 I Sens—Inspiratory Trigger Sensitivity

Previous versions of the Puritan Bennett 560 & Puritan Bennett 520 ventilator software offered five trigger sensitivity levels (1P, 2, 3, 4 and 5).

With this update, the existing five levels operate as before; however, a second level intended for paediatric use, 0P, is now available.

1.2.1 Detailed Description

I Sens allows users to set the level of inspiratory effort that the patient must provide to initiate a machine breath.

Lower I Sens setting numbers indicate greater trigger sensitivity. Sensitivity levels correspond to differences in flow compared to the bias flow (the turbine flow through the patient circuit during the exhalation phase that helps the patient avoid rebreathing exhaled carbon dioxide). The Time Delay is the time period between trigger initiations, during which another inspiration cannot be triggered.

<table>
<thead>
<tr>
<th>Name</th>
<th>Setting</th>
<th>Flow</th>
<th>Time Delay</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Sens 0 (P*)</td>
<td>0P</td>
<td>Bias flow + (0.4 to 0.6 lpm)</td>
<td>300 ms</td>
</tr>
<tr>
<td>I Sens 1 (P*)</td>
<td>1P</td>
<td>Bias flow + (0.4 to 0.8 lpm)</td>
<td>500 ms</td>
</tr>
<tr>
<td>I Sens 2</td>
<td>2</td>
<td>Bias flow + (0.7 to 1.3 lpm)</td>
<td>700 to 2000 ms**</td>
</tr>
<tr>
<td>I Sens 3</td>
<td>3</td>
<td>Bias flow + (0.9 to 1.5 lpm)</td>
<td>700 to 2000 ms**</td>
</tr>
<tr>
<td>I Sens 4</td>
<td>4</td>
<td>Bias flow + (1.0 to 1.6 lpm)</td>
<td>700 to 2000 ms**</td>
</tr>
<tr>
<td>I Sens 5</td>
<td>5</td>
<td>Bias flow + (1.2 to 1.8 lpm)</td>
<td>700 to 2000 ms**</td>
</tr>
</tbody>
</table>

* Levels for paediatric use.

** The time delay for inspiratory trigger initiation varies between these values, and depends on the preceding peak inspiratory flow.

1.2.2 Manual Sections Affected

This description affects the I Sens—Inspiratory Trigger Sensitivity subsections of the following Puritan Bennett 560 Clinician’s Manual and Puritan Bennett 520 Clinician’s Manual sections:

- 3.1: PSV Mode Parameters and Setting Ranges
- 3.3: P A/C Mode Parameters and Setting Ranges
- 3.4: V A/C Mode Parameters and Setting Ranges (PB560 only)
1.3 Respiratory Rate

Previous versions of the Puritan Bennett 560 & Puritan Bennett 520 ventilator software allowed users to set the respiratory rate (Rate) to 5-60 bpm in P A/C mode on either ventilator, and in V A/C mode on the Puritan Bennett 560.

With this update, users may set the Rate to 1-60 bpm in P A/C mode on either ventilator, and also in V A/C mode on the Puritan Bennett 560.

(The Rate range in P SIMV and V SIMV modes is unchanged from the previous release.)

1.3.1 Detailed Description

The Rate parameter adjustable in P A/C and V A/C modes is shown below:

<table>
<thead>
<tr>
<th>Name</th>
<th>Units</th>
<th>Min. Value</th>
<th>Max. Value</th>
<th>Adjustment Resolution</th>
<th>Default Value</th>
<th>Linked Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate*</td>
<td>bpm</td>
<td>1</td>
<td>60</td>
<td>1</td>
<td>13</td>
<td>Max RTOT</td>
</tr>
</tbody>
</table>

*When Sigh is set to YES, the Rate value cannot be set to less than 4.

Range, resolution and accuracy values are shown below:

<table>
<thead>
<tr>
<th>Ventilator Settings</th>
<th>Range/Resolution/Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory rate (R-Rate) PB560</td>
<td>Range: 1 bpm to 60 bpm in P A/C and V A/C modes; 1 bpm to 40 bpm in P SIMV and V SIMV modes</td>
</tr>
<tr>
<td>Respiratory rate (R-Rate) PB520</td>
<td>Range: 1 bpm to 60 bpm in P A/C mode</td>
</tr>
</tbody>
</table>
1.3.2 Manual Sections Affected

The respiratory rate change and its description affect the following Puritan Bennett 560 Clinician’s Manual and Puritan Bennett 520 Clinician’s Manual sections and tables:

- 3.3: P A/C Mode Parameters and Setting Ranges
  - Table 3-5: Ventilation Parameters in P A/C Mode Menu
- 3.4: V A/C Mode Parameters and Setting Ranges (PB560 only)
  - Table 3-7: Ventilation Parameters in V A/C Ventilation Mode (PB560 only)
- B.6: Range, Resolution and Accuracy
  - Table B-10: Ventilator Range, Resolution and Accuracy

1.4 Inspiratory Time

Previous versions of the Puritan Bennett 560 & Puritan Bennett 520 ventilator software limited inspiratory time (Insp Time) adjustments to the I/T% or I:E ratio settings in P A/C mode on either ventilator, and in V A/C mode on the Puritan Bennett 560.

With this update, in P A/C or V A/C mode users may set Insp Time to 0.3-6.0 s. (The Insp Time range in P SIMV and V SIMV modes is unchanged.)

1.4.1 Detailed Description

Note:
To allow the clinician to continue to prescribe I:E ratio or I/T%, the ventilator displays I:E ratio or I/T% in the settings window when changing Insp Time or Rate settings. The ventilator constrains these settings to a maximum I:E of 1:1 in P A/C and V A/C modes, and to a maximum I:E of 1:2 in P SIMV and V SIMV modes.

The Insp Time parameter adjustable in P A/C and V A/C modes is shown below:

<table>
<thead>
<tr>
<th>Name</th>
<th>Units</th>
<th>Min. Value</th>
<th>Max. Value</th>
<th>Adjustment Resolution</th>
<th>Default Value</th>
<th>Linked Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insp Time</td>
<td>s</td>
<td>0.3</td>
<td>6.0</td>
<td>0.1</td>
<td>1.5</td>
<td>Rate V_t*, Apnea Time</td>
</tr>
</tbody>
</table>

* PB560 only
Range, resolution and accuracy values are shown below:

<table>
<thead>
<tr>
<th>Ventilator Settings</th>
<th>Range/Resolution/Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>I:E ratio (I:E)</td>
<td>No longer applicable. Reference Monitored Parameters section.</td>
</tr>
<tr>
<td>I/T ratio (I/T)</td>
<td>No longer applicable. Reference Monitored Parameters section.</td>
</tr>
</tbody>
</table>
| Inspiratory time (Insp Time) PB560 | Range: 0.3 s to 6.0 s in P A/C and V A/C modes; 0.3 s to 2.4 s in P SIMV and V SIMV modes  
Resolution: 0.1 s  
Accuracy: ± 50 ms or 10%, whichever is greater  
Default value: 1.5 s  
Depends on: R-Rate in P SIMV mode; R-Rate and Vf in V SIMV mode |
| Inspiratory time (Insp Time) PB520 | Range: 0.3 s to 6.0 s  
Resolution: 0.1 s  
Accuracy: ± 50 ms or 10%, whichever is greater  
Default value: 1.5 s  
Depends on: R-Rate |

Menus

The **Insp Time** parameter appears on the menu in P A/C mode, as shown in Figure 1-1 and Figure 1-2.

*Figure 1-1. Menu in P A/C Mode with Inspiratory Time Parameter (Exhalation Valve Configuration)*
Cycling Mode

The cycling mode is used to set which calculated value (I:E or I/T%) appears in the parameter zoom window when changing **Insp Time** or **Rate** settings. It is also used to set the monitored data value (I:E or I/T%) displayed in the monitored data window and graphics screen.

The two cycling modes represent the relationship between inspiration time and exhalation time as follows:

1. **I:E** is the ratio of inspiratory time ($T_i$) to exhalation time ($T_e$).
   
   $$I:E = 1/(T_e / T_i)$$

2. **I/T%** is inspiratory time ($T_i$) as a percentage of total breath cycle time ($T_i + T_e$).
   
   $$I/T% = (T_i / (T_i + T_e)) \times 100$$

In P A/C and V A/C modes, the cycling ratio changes based on patient inspiration; however, the rate remains constant and corresponds to the inspiratory time and cycling ratio settings.
Note:
When adjusting T, or Rate, the corresponding calculated I:E ratio or I/T% is displayed in the parameter zoom and in the monitoring and information window.

1.4.2 Manual Sections Affected

The inspiratory time change and its description affect the following Puritan Bennett 560 Clinician’s Manual and Puritan Bennett 520 Clinician’s Manual sections, figures and tables:

• 3.3: P A/C Mode Parameters and Setting Ranges
  – Figure 3-5: Menus in P A/C Mode with exhalation valve configuration
  – Figure 3-6: Menus in P A/C Mode with leakage configuration
  – Table 3-5: Ventilation Parameters in P A/C Mode Menu

• 3.4: V A/C Mode Parameters and Setting Ranges (PB560 only)
  – Figure 3-7: Menus in the V A/C Mode (PB560 only)
  – Table 3-7: Ventilation Parameters in V A/C Ventilation Mode (PB560 only)

• 7.2.2: Changing the Setup Menu Parameters

• B.6: Range, Resolution and Accuracy
  – Table B-10: Ventilator Range, Resolution and Accuracy

1.5 Circuit Check

This release of the Puritan Bennett 560 & Puritan Bennett 520 ventilator software offers a new Circuit Check feature, allowing users to find potential leaks in the patient circuit that could adversely affect the volume of gas delivered to the patient.

1.5.1 Detailed Description

Perform Circuit Check whenever replacing or altering a patient circuit. The patient cannot be connected while performing this test.
Performing a Circuit Check

To activate Circuit Check, press and hold the MENU key during powerup.

![Circuit Check (before starting)](image)

**Note:**
Before performing a circuit check, stop ventilation using the VENTILATION ON/OFF key, not the I/O switch. If the I/O switch was used to stop ventilation, the Circuit Check function cannot be used unless first stopping ventilation using the VENTILATION ON/OFF key.

To perform a circuit check:

1. Ensure the patient is fully disconnected from the ventilator.
2. Verify that the proximal pressure tube of the patient circuit is properly connected to the proximal pressure port. Reference section 6.4 (Patient Circuit) in the Clinician's Manual.
3. Verify that the exhalation valve tube is connected to the exhalation valve port.
4. Block the patient connection as follows:
   a. If using a single-limb circuit, block the patient connection port of the patient circuit. Reference Figure F-1 in either Clinician’s Manual, or Figure E-1 in the Puritan Bennett 560 User’s Manual, or Figure C-1 in the Puritan Bennett 520 User’s Manual.
   b. (PB560 only) If using a dual limb circuit, obstruct the patient wye’s open connector, using the fleshy portion of the palm of the hand to create an effective seal. Reference Figure 10-1 of the Puritan Bennett 560 User’s Manual.
5. Activate the circuit test by pressing the ENTER key.
6. During the circuit check (which typically takes about 10 seconds to complete), the ventilator will do the following:
   a. sound a short beep;
   b. close the exhalation valve;
c. display Test Status as RUNNING:

Figure 1-5. Circuit Check (running)

CIRCUIT CHECK
- Leak Test
  - Leak : 0.0 Lpm
  - Test Status : RUNNING

Figure 1-6. Circuit Check (complete, passed)

CIRCUIT CHECK
- Leak Test
  - Leak : 0.0 Lpm
  - Test Status : PASS

Ensure patient is disconnected.
Block circuit at patient connection.
Press ENTER key to start test.
7. Review the results. A FAIL result indicates leak(s) of greater than 1 L/min exist.

To rerun Circuit Check, press the ENTER key again. To cancel the circuit check while it is running, press the UP, DOWN, ENTER, VENTILATION ON/OFF or MENU key.

**Troubleshooting a Failed Check**

If the circuit check fails, do the following:

1. Ensure an approved circuit is in use. Reference Table H-2 in either Clinician’s Manual, or Table F-2 in the Puritan Bennett 560 User’s Manual, or Table E-2 in the Puritan Bennett 520 User’s Manual.
2. Check patient circuit connections to the ventilator, examining each for leakage and tightness.
3. Replace the patient circuit if necessary.
4. Rerun Circuit Check.
5. If the failure persists, have the ventilator evaluated by a qualified technician.

### 1.6 Alarm Tone

Software version LX010103 for the PB560 ventilator and LS010103 for the PB520 ventilator provides the user the option to select a secondary alarm tone.

#### 1.6.1 Detailed Description

Users can select either Original (louder) or Compliant (softer) for the secondary alarm tone. The default setting is Compliant. The audible sound of Compliant is softer than the Original tone, and meets the requirements of standard EN 60601-1-8. Original refers to the alarm tone that was shipped with the ventilator from initial product launch until the LX010101/LX010023 and LS010101/LS010011 software updates.
Changing the Alarm Tone

1. Use the UP or DOWN arrows to place the cursor on Alarm Tone.
2. Press ENTER.
3. Use the UP or DOWN arrows to select Compliant or Original.
4. Press ENTER to confirm the selection.

1.7 Restore Defaults

Software version LX010103 for the PB560 ventilator and LS010103 for the PB520 ventilator allows the user to reset all settings back to the original manufacturer defaults, except for the Language, Date and Time.

Restoring Settings to the Manufacturer Defaults

1. Press the UP or DOWN arrows to place the cursor on Restore Defaults, as shown in Figure 1-8.

![Figure 1-8. Restoring Default Settings (1)](image)

2. Press ENTER. OFF flashes.
3. Press the UP or DOWN arrows to change OFF to YES, as shown in Figure 1-9.

![Figure 1-9. Restoring Default Settings (2)](image)
4. Press ENTER to reset all settings back to the manufacturer defaults, except for Language, Date and Time. OFF will reappear, as shown in Figure 1-10.

**Figure 1-10.(293,383),(658,612) Restoring Default Settings (3)**

The addition of the options to select the secondary alarm tone and restore default settings resulted in an updated SETUP menu, as shown in Figure 1-11.

**Figure 1-11.** SETUP Menu
The Cycling Mode, Relative pressure and E Sens setting parameters moved from the SETUP menu to the SETUP 2 menu, as shown in Figure 1-12.

**Figure 1-12. SETUP 2 Menu**

![SETUP 2 Menu](image)

**Entering SETUP 2 Menu**

1. On the SETUP menu, use the UP or DOWN arrows to place the cursor on NEXT.
2. Press ENTER. The SETUP 2 menu is displayed.

The Back parameter on the SETUP 2 menu allows the user to return to the SETUP menu.

**1.8 Labelling Updates**

Various updates affecting manual content and the appearance of screens are included in this release of the Puritan Bennett 560 & Puritan Bennett 520 ventilator software.

**1.8.1 E Sens (PB560 only)**

The E Sens alarm now accounts for breaths only within the same 60-second time cycle. This is intended to prevent a nuisance alarm condition that cannot be cleared without either changing ventilation modes or switching from standby mode to ventilation.
Detailed Description

The updated E Sens alarm is shown below:

<table>
<thead>
<tr>
<th>Alarm Message</th>
<th>Cause / Ventilator Response</th>
<th>Priority</th>
<th>Audio Paused Avail.</th>
<th>Alarm Paused Avail.</th>
</tr>
</thead>
<tbody>
<tr>
<td>E SENS FAULT OR CIRC LEAK</td>
<td>At least four of the last six breaths within the last minute are terminated by time.</td>
<td>MP</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Manual Sections Affected

The E Sens alarm change and its description affect the following Puritan Bennett 560 User’s Manual section and table:
- 3.7: Overview of Alarms
  - Table 3-1: Overview of Alarms

The E Sens alarm change and its description affect the following Puritan Bennett 560 Clinician’s Manual section and table:
- 5.7: Overview of Alarms
  - Table 5-1: Overview of Alarms

1.8.2 BUZZER FAULT4

The BUZZER LOW BATTERY alarm is now displayed in instances where the BUZZER FAULT4 alarm would be displayed instead.

Detailed Description

The BUZZER LOW BATTERY alarm is shown below:

<table>
<thead>
<tr>
<th>Alarm Message or Symptom</th>
<th>Possible Reason(s) for the Alarm Event</th>
<th>Corrective Action(s)</th>
</tr>
</thead>
</table>
| BUZZER LOW BATTERY       | Internal technical problem that prevents the battery warning buzzer from sounding POWER SUPPLY LOSS alarm. | Connect the ventilator to an AC power source and power on using the I/O switch located on the rear of the ventilator.  
Allow the ventilator to charge for a minimum of 15 minutes and up to 2 hours.  
If alarm persists, restart ventilator to see if alarm clears. If not, contact Covidien or a local Covidien representative. |
Manual Sections Affected

The BUZZER FAULT4 alarm change and its description affect the following Puritan Bennett 560 User’s Manual and Puritan Bennett 520 User’s Manual section and table:

- 3.8: Troubleshooting
  - Table 3-2: Alarms and Corrective Actions

The BUZZER FAULT4 alarm change and its description affect the following Puritan Bennett 560 Clinician’s Manual and Puritan Bennett 520 Clinician’s Manual section and table:

- 5.8: Troubleshooting
  - Table 5-2: Alarms and Corrective Actions

1.8.3 Inspiratory Pressure

In previous releases of the Puritan Bennett 560 & Puritan Bennett 520 ventilator software, the abbreviation used for the Inspiratory Pressure parameter was PIP (in P A/C mode) and P Control (in P SIMV mode).

With this update, the abbreviation for Inspiratory Pressure in both of these modes is Pi. (This is a labelling change only; functionality is unchanged.)

Detailed Description (PIP to Pi—P A/C Mode)

The Inspiratory Pressure (Pi) parameter in P A/C mode is shown below:

<table>
<thead>
<tr>
<th>Name</th>
<th>Units</th>
<th>Min. Value</th>
<th>Max. Value</th>
<th>Adjustment Resolution</th>
<th>Default Value</th>
<th>Linked Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pi</td>
<td>cmH₂O, mbar or hPa</td>
<td>Standby: 2 Valve config.: 5 Leak config.: 6</td>
<td>Standby: 55 Valve config.: 55 Leak config.: 30</td>
<td>1</td>
<td>15</td>
<td>PEEP</td>
</tr>
</tbody>
</table>
The \textbf{Pi} parameter appears on the menu in P A/C mode as shown in Figure 1-13 and Figure 1-14.

\textbf{Figure 1-13.} Menu in P A/C Mode with Pi Abbreviation (Exhalation Valve Configuration)

\textbf{Figure 1-14.} Menu in P A/C Mode with Pi Abbreviation (Leakage Configuration)

\textit{Pi—Inspiratory Pressure}

When relative pressure is set to YES in the SETUP menu, \textbf{Pi} allows the user to determine inspiratory pressure added to \textbf{PEEP} during the inspiratory phase. In this configuration, the sum of \textbf{Pi} and \textbf{PEEP} must not exceed 55 mbar.

When relative pressure is set to OFF in the SETUP menu, \textbf{Pi} allows the user to determine inspiratory absolute pressure. In this configuration, \textbf{Pi} and \textbf{PEEP} are related, and their settings must maintain a minimum difference between 2 mbar in leak configuration and 5 mbar in valve configuration.
Detailed Description (P Control to Pi—P SIMV Mode) (PB560 only)

The Inspiratory Pressure (Pi) parameter in P SIMV mode is shown below:

<table>
<thead>
<tr>
<th>Name</th>
<th>Units</th>
<th>Min. Value</th>
<th>Max. Value</th>
<th>Adjustment Resolution</th>
<th>Default Value</th>
<th>Linked Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pi</td>
<td>cmH₂O, mbar or hPa</td>
<td>5</td>
<td>55</td>
<td>1</td>
<td>15</td>
<td>PEEP</td>
</tr>
</tbody>
</table>

The Pi parameter appears on the menu in P SIMV mode as shown in Figure 1-15.

**Figure 1-15. Menus in P SIMV Ventilation Mode**

**Pi—Inspiratory Pressure**

When relative pressure is set to YES in the SETUP menu, Pi allows the user to determine inspiratory pressure added to PEEP during the inspiratory phase or controlled breaths. In this configuration, the sum of Pi and PEEP must not exceed 55 mbar.

When relative pressure is set to OFF in the SETUP menu, Pi allows the user to determine inspiratory absolute pressure of controlled breaths. In this configuration, Pi and PEEP are related, and their settings must maintain a minimum difference between 2 mbar in leak configuration and 5 mbar in valve configuration.

**Manual Sections Affected**

The PIP to Pi change and its description affect the following Puritan Bennett 560 Clinician’s Manual and Puritan Bennett 520 Clinician’s Manual section, figures and table:

- 3.3: P A/C Mode Parameters and Setting Ranges
  - Figure 3-5: Menus in P A/C Mode with exhalation valve configuration
  - Figure 3-6: Menus in P A/C Mode with leakage configuration
  - Table 3-5: Ventilation Parameters in P A/C Mode Menu
The **P Control to Pi** change and its description affect the following *Puritan Bennett 560 Clinician’s Manual* section, figure and table:
- 3.5: P SIMV Mode Parameters and Setting Ranges
  - Figure 3-8: Menus in P SIMV Ventilation Mode
  - Table 3-9: Ventilation Parameters in P SIMV Ventilation Mode

### 1.8.4 Sigh (PB560 only)

The Sigh feature now can be enabled only with a respiratory rate (**Rate**) setting of 4 or more.

#### Detailed Description

The **Sigh** parameter adjustable in V A/C mode is shown below:

<table>
<thead>
<tr>
<th>Name</th>
<th>Units</th>
<th>Min. Value</th>
<th>Max. Value</th>
<th>Adjustment Resolution</th>
<th>Default Value</th>
<th>Linked Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sigh* Rate</td>
<td>-</td>
<td>50</td>
<td>250</td>
<td>50</td>
<td>50</td>
<td>-</td>
</tr>
</tbody>
</table>

* When Sigh is set to YES, Sigh Vt and Sigh Rate are displayed. A Sigh Rate of 50 means a sigh is delivered every 50 breaths. Sigh can be set to YES for Rate values of 4 or more.

#### Manual Sections Affected

The Sigh change and its description affect the following *Puritan Bennett 560 Clinician’s Manual* section and table:
- 3.4: V A/C Mode Parameters and Setting Ranges
  - Table 3-7: Ventilation Parameters in V A/C Ventilation Mode

### 1.8.5 Monitored Parameters

Some ranges for ventilator parameters have been modified. Although the ventilator-displayed values may exceed the Range values specified below, the range and tolerances are limited to those specified in Table 4-1 in the Clinician’s Manual. (Display names and tolerances are unchanged.)
Detailed Description

The updated ranges are shown below:

<table>
<thead>
<tr>
<th>Ventilator Parameter</th>
<th>Range**</th>
<th>Tolerances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspiratory Pressure (PIP)</td>
<td>0 to 99 mbar</td>
<td>± (2 mbar + 8%)</td>
</tr>
<tr>
<td>Positive End Expiratory Pressure (PEEP)</td>
<td>0 to 99 mbar</td>
<td>± (2 mbar + 8%)</td>
</tr>
<tr>
<td>Inspiratory Tidal Volume ($V_{TI}$)*</td>
<td>0 to 3000 ml</td>
<td>± (10 ml + 10% $V_{TI}$) x Rate</td>
</tr>
<tr>
<td>Exhalation Tidal Volume ($V_{TE}$)*</td>
<td>20 to 3000 ml</td>
<td>± (10 ml + 10% $V_{TE}$) x $V_{TE}$</td>
</tr>
<tr>
<td>Total Breath Rate ($R_{TOT}$)</td>
<td>0 to 99 bpm</td>
<td>± 1 bpm</td>
</tr>
<tr>
<td>I:E Ratio (IE)</td>
<td>9.9:1 to 1:199</td>
<td>± 50 ms or 10%, whichever is greater</td>
</tr>
<tr>
<td>I/T Ratio (I/T)</td>
<td>1 to 95%</td>
<td>± 50 ms or 10%, whichever is greater</td>
</tr>
<tr>
<td>Inspiratory Time (I Time)</td>
<td>0 to 6.0 s</td>
<td>± 100 ms</td>
</tr>
<tr>
<td>Exhalation Time (E Time)*</td>
<td>0 to 59.7 s</td>
<td>± 100 ms</td>
</tr>
<tr>
<td>Inspiratory Minute Volume (M Vol)</td>
<td>0 to 99.9 L</td>
<td>± (10 ml + 10%)</td>
</tr>
<tr>
<td>FiO₂*</td>
<td>0 to 99%</td>
<td>± (2.5% + 2.5% FiO₂)</td>
</tr>
<tr>
<td>Leak</td>
<td>0 to 150 lpm</td>
<td>± (3 lpm + 20%)</td>
</tr>
<tr>
<td>Apnea Index (AI)</td>
<td>0 to 99 ev/h</td>
<td>± 1 ev/h</td>
</tr>
<tr>
<td>Apnea Time</td>
<td>0 to 999 s</td>
<td>± 1 s</td>
</tr>
<tr>
<td>% Spontaneous (Spont)</td>
<td>0 to 100%</td>
<td>± 1%</td>
</tr>
</tbody>
</table>

* The Puritan Bennett 560 and Puritan Bennett 520 ventilators do not have the capability to reduce pressure below the PEEP pressure during the exhalation phase.

* PB560 only

** The ventilator parameters' displayed values could vary based on patient settings.

Manual Sections Affected

The monitored parameter changes affect the following Puritan Bennett 560 User’s Manual and Puritan Bennett 520 User’s Manual section and table:

- A.5: Monitored Parameters
  - Table A-9: Monitored Parameter Specifications and Tolerances

The monitored parameter changes affect the following Puritan Bennett 560 Clinician’s Manual and Puritan Bennett 520 Clinician’s Manual section and table:

- B.5: Monitored Parameters
  - Table B-9: Monitored Parameter Specifications and Tolerances
1.8.6 Alarms

The alarm system complies with IEC 60601-1-8:2006 and EN 60601-1-8:2007. Labelling has been revised for clarification.

Detailed Description

Particular conditions are denoted by icons, as described below:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Icon" /></td>
<td>Alarm Off (Apnea Off)</td>
<td>The Apnea Alarm has been set to OFF in the Preference menu.</td>
</tr>
<tr>
<td><img src="image2" alt="Icon" /></td>
<td>Alarm Pause (alarm key twice)</td>
<td>An alarm pause and/or reset condition has occurred. The alarm is paused until the alarm condition is corrected and the condition reoccurs.</td>
</tr>
<tr>
<td><img src="image3" alt="Icon" /></td>
<td>Audio Pause (alarm key once)</td>
<td>Audible alarm sounds are currently disabled. (This period lasts for 60 seconds.)</td>
</tr>
</tbody>
</table>
The updated alarm table is shown below:

<table>
<thead>
<tr>
<th>Alarm Message</th>
<th>Audio Paused Avail.</th>
<th>Alarm Paused Avail.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BATTERY FAULT1 RESTART/SRVC</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>CHECK BATTERY CHARGE IF PERSISTS RESTART/SRVC</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>CHECK EHXH VALVE* IF PERSISTS RESTART/SRVC</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>POWER SUPPLY LOSS (no message)</td>
<td>No - Alarm Cancel ONLY</td>
<td>No - Alarm Cancel ONLY</td>
</tr>
<tr>
<td>CONTROLLED CYCLES</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

In addition, the Cause/Ventilator Response for the following alarms has been updated:

<table>
<thead>
<tr>
<th>Alarm Message</th>
<th>Cause/Ventilator Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEVICE FAULTS RESTART/SRVC</td>
<td>Detection of a fault in the electrical power supply system. Alarm activation occurs: Once the ventilator is on for at least 3 seconds, and a power supply fault is detected for at least 5 seconds thereafter. Consequence: the internal battery capacity is not displayed beside the battery symbol.</td>
</tr>
<tr>
<td>CHECK REMOTE ALARM</td>
<td>Failure of ventilator remote alarm relay circuit.</td>
</tr>
</tbody>
</table>

Additional clarification of alarms follows.

- Setting any alarm limits to OFF or to extreme high or low values can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations that may require intervention.

- All configurable alarm settings are recorded in the ventilator’s non-volatile internal memory, and are retained when powering down or in the event of a total loss of power.

- All alarms are recorded in the ventilator’s non-volatile internal memory at the time of activation, and are retained when powering down or in the event of a total loss of power.

- High-priority alarms will sound at the maximum level of 80 dB(A).
1.8.7 Nurse Call

The alarm delay, once generated from the ventilator, to the nurse call output/input cable connectors is less than 100 ms.

Note:
The PB520/PB560 has been designed to accommodate connectivity with Nurse Call/monitoring systems. Because it is not possible to anticipate every configuration of hardware and software associated with Nurse Call/monitoring system, it is the user’s responsibility to confirm proper functionality of the system when used in conjunction with the PB520/PB560. Verification of alarms, alerts and patient data transmissions is required. If the system performance is not as expected, contact Technical Support for assistance troubleshooting the setup. Do not use the PB520/PB560 ventilator with a Nurse Call/monitoring system until the functionality of the ventilator/system combination has been confirmed.
Note:
Complete a self-test after the cable has been installed and at regular intervals to ensure the system is operating as intended. A self-test consists of inducing an alarm and confirming the Nurse Call/monitoring system unit emits an audio alarm, and also confirming the audio alarm ceases once the alarm in the ventilator has been reset.

Manual Sections Affected
The nurse call revision affects the following *Puritan Bennett 560 User’s Manual* section:
- 4.12: Connecting the Nurse Call Cable

The nurse call revision affects the following *Puritan Bennett 520 User’s Manual* section:
- 4.11: Connecting the Nurse Call Cable

The nurse call revision affects the following *Puritan Bennett 560 Clinician’s Manual* and *Puritan Bennett 520 Clinician’s Manual* section:
- 6.11: Connecting the Nurse Call Cable

1.8.8 Mouthpiece Ventilation

The list of breathing interfaces used to connect the patient to the ventilator has been updated to include mouthpieces.

Manual Sections Affected

The inclusion of the mouthpiece interface affects the following *Puritan Bennett 560 User’s Manual* and *Puritan Bennett 520 User’s Manual* sections:
- 2.3: Operational Use
- 4.4.2: Installing the Patient Circuit

The inclusion of the mouthpiece interface affects the following *Puritan Bennett 560 Clinician’s Manual* and *Puritan Bennett 520 Clinician’s Manual* sections:
- 2.3: Operational Use
- 6.4.2: Installing the Patient Circuit
1.8.9 Standards Compliance and IEC Classification

The Standards Compliance and IEC Classification data has been revised to document compliance with updated revisions to standards.

Detailed Description

Standards with updated revisions are listed below:

General Standards


Collateral Standards


Manual Sections Affected

The standard compliance revision affects the following Puritan Bennett 560 User's Manual section:
• A.10: Standards Compliance and IEC Classification

The standard compliance revision affects the following Puritan Bennett 520 User's Manual section:
• A.11: Standards Compliance and IEC Classification

The standard compliance revision affects the following Puritan Bennett 560 Clinician's Manual and Puritan Bennett 520 Clinician's Manual section:
• B.11: Standards Compliance and IEC Classification