

**URGENT: Field Safety Notice**  
For the Puritan Bennett™ 980 Series Ventilator System

December XX, 2014

**FSCA**  
**Reference:** *GUI display replacement - Revision to BLI PCBA field action*

Dear Valued Customer,

Covidien Respiratory and Monitoring Solutions [RMS] previously communicated in a letter dated (DATE OF PRIOR LETTER in COUNTRY) a voluntary field corrective action related to a possible capacitor failure in the backlight inverter (BLI) printed circuit board assembly (PCBA) in the graphic user interface (GUI) display in certain Puritan Bennett™ 980 ventilators. However, this prior action is not fully effective because Covidien RMS has been unable to obtain BLI PCBAs with the quality and reliability required to ensure that the device continues to perform as intended.

Therefore, Covidien RMS will update all affected ventilators to LED illumination display, which does not utilize a backlight inverter (BLI) and thereby completely eliminates the potential for this component failure.

**Explanation of the potential issue**

In complaints reported to date, the BLI capacitor failure has been accompanied by a burning odor, smoke or visible haze emanating from the display, has caused the display to dim (reduced illumination) or blank (loss of illumination), and has in some cases prompted the caregiver to transfer the patient to an alternate ventilator. Please note that in all cases, the Puritan Bennett 980 ventilator continued to provide ventilatory support to the patient when this occurred.

Covidien RMS has had no reports of fire, serious patient injury or death associated with this issue. Covidien engineering assessment and external consultant evaluation, have determined that future occurrences, if any, of this capacitor failure would present a low probability for a fire to propagate within or outside the GUI enclosure.

You may continue to use your Puritan Bennett 980 ventilator(s) pending the upgrade to the LED configuration. If you have any questions regarding continued use of the Puritan Bennett 980 ventilator prior to the replacement of the BLI PCBA to the LED circuitry, or would like to discuss alternative arrangements, including equipment loaners or other solutions, please contact your local Covidien Representative at LOCAL CONTACT INFORMATION.

**Actions to be taken by the customer/user**

Even if you responded to the Field Corrective Action announced in October (DATE OF PRIOR LETTER in COUNTRY), you must respond to this communication. Covidien will initiate the scheduling and

coordinate a visit by a Covidien Service Representative to update your ventilator to LED illumination circuitry.

Please complete the attached acknowledgement and receipt form, and fax it to the Covidien contact indicated on the form for our tracking of this action.

### **Important Safety Reminders**

Please be reminded of the following important safety instructions contained in Section 1.3 of the Puritan Bennett™ 980 ventilator operator's manual:

- **WARNING:** Explosion hazard — Do not use in the presence of flammable gases. An oxygen-rich environment accelerates combustibility.
- **WARNING:** In case of fire or a burning smell, immediately take the following actions if it is safe to do so: disconnect the patient from the ventilator and disconnect the ventilator from the oxygen supply, facility power, and all batteries. Provide alternate method of ventilatory support to the patient, if required.
- **WARNING:** In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death. An alternative source of ventilation, such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4 with mask) should always be available when using the ventilator.

### **Further communication**

This notification is being issued with the knowledge of the Competent Authority **(OR OTHER HEALTH AUTHORITY)**. Please further distribute and communicate this important information within your facility as required.

If your facility has distributed Puritan Bennett 980 ventilators to other persons or facilities, please promptly forward a copy of this letter to those recipients.

If you are aware of any incidents related to this issue, please contact your local Covidien Representative immediately at **LOCAL CONTACT INFORMATION**, to provide information regarding those events so regulatory reporting obligations can be fulfilled.

If you have any questions, please contact your local Covidien Representative as described above.

Thank you for your attention to this issue. We sincerely apologize for any inconvenience this situation may cause you or your facility.

Sincerely,

**Local RA Name**  
Covidien