Medtronic

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URGENT Field Corrective Action Notice
For the Puritan Bennett™ 980 Series Ventilator System

Reference: PB 980 GUI Unresponsive and Loss of Primary Ventilation

18th January, 2016

Attention: Directors of Respiratory Care, Critical Care Units, and Risk Management Directors
Please forward this communication to all surgeons, surgical personnel and any other potential users of the product.

Dear Valued Customer:

The purpose of this letter is to advise you that Covidien Respiratory and Monitoring Solutions, now a part of Medtronic, is issuing a voluntary field corrective action notice for two issues on all models of Puritan Bennett™ 980 (PB980) ventilator. You may continue to use your PB980 ventilators as advised herein. We will develop and implement corrections for these issues.

1. Graphical user interface (GUI) unresponsive to touch.

    - In this situation, the ventilator continues to operate at existing settings, all real-time waveforms and pressure/volume measurements, as well as alarm functions and the bezel keys (hard keys below the touch screen), remain active. However, in this situation, users are unable to change ventilator settings or the configuration of the GUI display. Should this occur, the clinical team should transfer the patient to another ventilator.

    - Medtronic is currently investigating the root cause responsible for this issue.

    - The frequency of occurrence based on reported complaints is 1.3%, corresponding to an annual rate of 0.7%.

2. Loss of primary ventilation under certain circumstances.

    - Medtronic has received reports of the PB980 ventilator losing primary ventilation capabilities, in which case the Backup Ventilation (BUV) design feature is activated.

    - When BUV is initiated, high urgency audio and visual alarms are annunciated immediately and cannot be silenced. The clinical team should transfer the patient to another ventilator.

- In some cases, the ventilator subsequently progressed to a ventilator inoperative condition, in which case, by design, the ventilator opens all valves to atmospheric pressure and room air, and ventilation ceases. High urgency audio and visual alarms are annunciated. The clinical team should transfer the patient to another ventilator.

- Our investigation revealed that background diagnostic software responsible for monitoring ventilator system function inappropriately determines a hardware problem exists. The ventilator then moves to BUV and occasionally into ventilator inoperative. As stated above, when this occurs the clinical team should transfer the patient to another ventilator.

- The frequency of occurrence based on reported complaints is 1.6% corresponding to an annual rate of 0.9%. Approximately 50% of these events occurred at ventilator power-on/start-up.

There have been no reports of patient injury or death associated with either of these situations, nor have there been any issues resulting from subsequent patient transfer.

Should either of the above conditions occur, please contact your local Medtronic Representative immediately, and please remove the unit from use until the unit has been serviced by Medtronic or a Medtronic authorized service representative.

Actions being taken by Medtronic:

Medtronic is investigating the root cause of these conditions and will provide a service update to resolve the issues as soon as corrections can be implemented.

Actions you should take:

- Ensure patients on PB980 ventilators are appropriately monitored by medical personnel and suitable monitoring devices as described in the Operator's Manual.

- Immediately notify all care environments in which the PB980 ventilator is used about this notification.

- If your facility has distributed PB980 ventilators to other persons or facilities, please promptly forward a copy of this letter to those recipients.

- Complete the attached Acknowledgement form and return it as directed to confirm your receipt and understanding of this information.

- If you are aware of any incidents related to these issues or if you have any questions, please contact our local Medtronic Representative, to provide information regarding those events so regulatory reporting obligations can be fulfilled.

- Work with your local Medtronic Representative if you require assistance finding alternative ventilation devices.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required.

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

Sincerely,

[redacted]

QA Manager, South East Asia

Medtronic

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Field Safety Notice - PB 980 GUI Unresponsive and Loss of Primary Ventilation

Acknowledgement Form

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**By E-mail:**
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

Indicate in the columns below all serial numbers you have in your facility. If you have forwarded affected Puritan Bennett™ 980 Series Ventilator System to other persons or facilities, provide the serial numbers and the recipient's name and address, if known. Forward the Field Safety Notice notification to these facilities.

Puritan Bennett™ 980 Series Ventilator System Serial Numbers	**Still in Service for Patient Use Yes/No**	**Sent to another facility Yes/No**	**Facility name and address (if different than above)**

I have read and understand the instructions provided and acknowledge receipt of the Field Safety Notice regarding the Puritan Bennett 980 ventilator by signing below. I also agree to further distribute and communicate this important information within my facility as required.

Name: _____ (print) Signature: _____ Date:_____