

URGENT FIELD SAFETY NOTICE **Puritan Bennett™ 980 (PB980) ventilator series**

September 2018

Medtronic reference: FA843

Attention: Directors of Respiratory Care, Critical Care Units, and Risk Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is releasing maintenance software update MR5.4 for all models of Puritan Bennett™ 980 (PB980) ventilator series.

Reason for voluntary correction

This software update for PB980 ventilators is being deployed to address routine customer feedback and complaints and concerns raised by Australia's regulatory authority, the Therapeutic Goods Administration (TGA). This maintenance software update also provides additional product enhancements. We are notifying customers globally of this software update that will enhance the functionality of PB980 ventilators and correct the concerns raised by TGA. The concerns raised by TGA surround External USB Drive performance and its impact on Graphic User Interface (GUI) functionality and labeling of the scalar waveform displayed on GUI during ventilation.

Risk to health

While there have been previous reports of patient transfer in the event of ventilator GUI malfunctions in general, in this case, there have been no such reports. To date, there have been no reports of serious injury or death associated with any of the changes associated with this software release. Based on Medtronic's internal data analysis and a thorough review of potential patient safety risk, we conclude that there is remote risk to patients. As such, we are advising that you can continue to use your PB980 in accordance with your institutional policies.

Actions being taken by Medtronic

- Medtronic has developed a software update, Maintenance Release (MR) 5.4. This software release is now available for installation.
- In addition, Medtronic has made modifications to the PB980 Operator's Manual. The section on GUI functionality and recovery from GUI failures has been updated with additional information for users and we have added detailed information surrounding the labeling of the tidal volume wave form on the scalar display. The updated manual can be accessed at: https://www.medtronic.com/content/dam/covidien/library/us/en/product/acute-care-ventilation/PB980_Operators_Manual_EN_10077893G00.pdf
- For all warranty and contract customers, Medtronic Service Engineers will load the MR5.4 software during your next scheduled or planned maintenance visit. For those customers outside of warranty or not on an active service agreement, Medtronic's Service Team will contact you to set up a time to perform the update at no cost when your response form is received.

Actions you should take

- Immediately notify all care environments in which the PB980 ventilators are 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 form and return it as directed to confirm your receipt and understanding of this information.

Additional information

If you are aware of any incidents related to this issue or if you have any questions, please contact your local Medtronic sales representative to provide information regarding those events so regulatory reporting obligations can be fulfilled.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

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

Sincerely,



Subu Mangipudi
Vice President, Quality Assurance
Respiratory, Gastrointestinal & Informatics
Medtronic

URGENT FIELD SAFETY NOTICE

Acknowledgement and Receipt Form—Response is Required

Puritan Bennett™ 980 Ventilator Series

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Account Number: _____

Account Address: _____

City: _____ Zip Code: _____

Telephone Number: _____

I have read and understand the instructions provided and acknowledge receipt of the Urgent Field Safety Notice related MR5.4 maintenance software release for PB980 ventilators by signing below. I also agree to further distribute and communicate this important information within my facility and to any facility that I have further distributed PB980 ventilators as required.

Name: (print) Signature: Date:

If you have any questions regarding this software release, please contact Medtronic Technical Support

Please fax the completed form to XXXX XXXX or email to XXXXXX@Medtronic.com