Medtronic

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MEDICAL DEVICE CORRECTION

Puritan Bennett™ 980 (PB980) ventilator series.

25 September 2018

Attention: Risk Management Director and O.R. Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

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.

- 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

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. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

nce this may cause. We are committed to patient safety and appreciate your atter.

[redacted]

Diana Teo
Quality Management System Manager
Medtronic

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Field Action Acknowledgement Form
Puritan Bennett™ 980 Ventilator Series

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

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

Please tick (either one) only:

☐ **No**, affected inventory at my location.

☐ **Yes**, affected inventory are at my location. (Please fill up below table if chosen)

Item code	Product Description	Serial #	QTY (Each)	Address if distributed to another facility

I have read and understand the instructions provided and acknowledge receipt of the Medical Device Correction 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 by signing below:

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