

Urgent Field Safety Notice **Software Update for Puritan Bennett™ 980 Series Ventilator** Software Update

October 2020

Medtronic Reference: FA936

Dear Customer / Risk Manager,

The purpose of this letter is to advise you that Medtronic is releasing software update, R7.1, for all models of Puritan Bennett™ 980 (PB980) series ventilators.

This software is being released in response to in-house lab observations and customer reports of overheating and/or thermal damage to the battery pack. Since July 2019, a total of eight (8) such events occurred for an installed base of over 45,000 battery packs. There have been no incidents of patient or user injury in relation to these failures. The new software version is now available.

Reason for software update

R7.1 software update is being provided to improve the overall battery management system for the PB980 series ventilators. This software will:

- Optimize the battery pack charge voltage level to improve overall battery pack reliability.
- Alert and direct users to replace battery packs if a faulty battery cell contained within the battery pack is detected.
- Provide users with a real-time alert (advisory prompt) on the Graphic User Interface (GUI) when a battery pack is past its useful-life (approximately three years) or within 90 days of its end-of-useful-life.

Risk to health

Rechargeable battery packs used past their end-of-useful-life may not fully charge or hold charge, or otherwise perform as intended. Such batteries may also have the potential to overheat and create the risk of exposure to smoke or hazardous materials, which may result in burns and/or bronchospasm, albeit at a very low or remote likelihood.

Medtronic advises that you can continue to use your PB980 series ventilator in accordance with your institutional policies. Our internal data analysis and review of potential patient safety risks concluded the potential for harm to patients, users, property, or the environment is unlikely.

Actions being taken by Medtronic

- Medtronic developed a software update, R 7.1. This software release is available for installation.
- For all warranty and service contract customers, Medtronic Service will load the R 7.1 software during your next scheduled or planned maintenance visit.
- For those customers outside of warranty or not on an active service agreement, when your response form is received Medtronic's Service Team will contact you to set up a time to perform the update.
- In addition, Medtronic made modifications to the PB980 Series Ventilator Operator's Manual. The manual has been updated with additional information for users regarding the new software update. The revised manual can be accessed at: <https://www.medtronic.com/covidien/en-us/support/product-manuals.html>

Actions you should take

- Immediately notify all care environments in which the PB980 series ventilators are used about this letter.
- If your facility has distributed PB980 series 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.
- Please adhere to the instructions described in the PB980 Series Ventilator Operator's Manual and battery addendum for Li-Ion Battery Pack Handling, Storage, and Replacement.
- Promptly dispose of the battery packs that are faulty or have reached their end-of-useful-life according to local regulations.

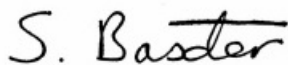
As a general reminder, per section 3.6.1 of the Operator's Manual, use only Covidien batteries. Using other manufacturers' brands or remanufactured batteries could result in the batteries operating the ventilator for less than the specified amount of time or could cause a fire hazard.

Medtronic has notified the Competent Authority of your country of this action.

If you have any questions, please contact your Medtronic representative at 01 511 1400.

Thank you for your attention to this notification.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager
UK and Ireland

Urgent Field Safety Notice
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Acknowledgment and Receipt Form — Response is Required

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: _____ County: _____ Post Code: _____

Telephone Number: _____

By signing this form, I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding the R7.1 software release for PB980 series ventilators dated October 2020.

I also agree to further distribute and communicate this important information within my facility and to any facility that I have further distributed PB980 series ventilators as required.

Name: (print)

Signature:

Date:

Please email this form back to Medtronic within 10 days to rs.regulatoryuk-ire@medtronic.com.