Medtronic
60 Middletown Avenue
North Haven, CT 06473
www.medtronic.com

Urgent Field Safety Notice

December X, 2017

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

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a field correction for the

Rechargeable Li-ion Batteries with Incorrect Firmware Used in Puritan Bennett™ 980 Ventilators- Item Code 10086042. (Affected Serial Numbers begin with 1201xxxxxx through 1712xxxxxx)

We are issuing this notification following reports that the batteries may not fully charge after installation. The scope of this notice includes batteries that were manufactured between December 2013 and May 2017, with serial numbers beginning with 1201xxxxxx through 1712xxxxxx. (See Attachment A).

A functional battery installed in the PB980 ventilator automatically recharges when the battery depletes and the ventilator is connected to AC power. In the case of a battery with incorrect firmware, it may fail to fully charge. **This situation does not impact the ventilator's operation when it is connected to AC power.** However, if the ventilator is operated on battery power alone, this situation could limit the amount of time the ventilator is operational.

- When the battery is installed in the ventilator, the battery charge level indicated on the ventilator (primary GUI, secondary status display, and LED battery charge bars) is accurate on AC or DC power.
- During battery powered ventilation, an alarm will sound when 10 minutes and 5 minutes of battery power remain. The 10-minute and 5-minute audio and visual alarms are unaffected by this issue.
- In the unlikely event of complete loss of power, an alarm alerts the operator that there is insufficient battery power and no AC power to support ventilator operation. This high urgency continuous tone alarm will sound for at least 120 seconds while the ventilator's power switch is in the ON position. There have been no reports of this occurring.
- As indicated in the Owner Manual, an optional, extended battery is available to lengthen the amount of time the ventilator can operate on battery power.

No patient injury or impairment has been reported for this issue. However, over the last three years, we received four reports where an insufficiently charged battery with the incorrect firmware possibly resulted in a patient being transferred to another ventilator. Based on Medtronic's internal data analysis and review of potential risk to patient safety, we are advising that you can continue to use your PB980 in accordance with institutional policies and as described below.

Actions being taken by Medtronic:

- Medtronic has collaborated with our battery supplier and identified that the root cause of the issue is incorrect firmware on the battery. We have developed a tool to inspect and identify the firmware on the batteries. While batteries produced prior to May 2017 are potentially affected, our data shows a low

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probability of no more than 5% of these batteries are affected by this issue.

- Medtronic service engineers will inspect batteries at your facility. Batteries found to have the incorrect firmware will be replaced. If your PB980 unit is under warranty or a service agreement, Medtronic Service will conduct this inspection during your next scheduled maintenance visit. For units outside of warranty or without a service agreement, Medtronic will contact you and schedule a service inspection visit. Our target is to schedule a maintenance visit in the next 6 months.

Actions you should take:

- Critical care teams transporting intubated patients (intra-hospital) on the PB980 ventilator should have the standard backup emergency equipment present for all such transports. This includes monitoring, pulse oximetry, manual bag ventilation equipment, and bottled oxygen supply.
- For intra-hospital transport, ICU teams should ensure inspection of the battery charge level before transport begins. As stated above, this can be done while on AC or DC power on the primary GUI, secondary status display or the LED bars on the battery itself when the battery is installed on the ventilator.
- 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.

Important Safety Reminders:

Always adhere to the instructions described in the Puritan Bennett™ 980 Ventilator Operator's Manual.

- Ensure patients on PB980 ventilators are appropriately monitored by medical personnel and suitable monitoring devices as described in the Operator's Manual and ensure that access to a means of back-up ventilation is available.
- Always have an alternate means of ventilation available when the ventilator is in use in case of a mechanical or system problem.
- Always be mindful of the ventilator's alarms and their meaning. Alarm information can be found in the PB980 Operator's Manual section 6.5.

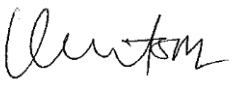
Additional Information:

- The battery serial number can be found on a white label on the side of the battery.
- Based on our review of manufacturing records, all batteries with serial number 1720MM or greater are confirmed to be conforming and not affected by this firmware issue.

If you are aware of any incidents related to this issue or if you have any questions, please contact your local Medtronic Sales Representative or Medtronic Technical Support Department immediately to provide information regarding those events so regulatory reporting obligations can be fulfilled.
This notification is being issued with the knowledge of <insert name of country Competent Authority>

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

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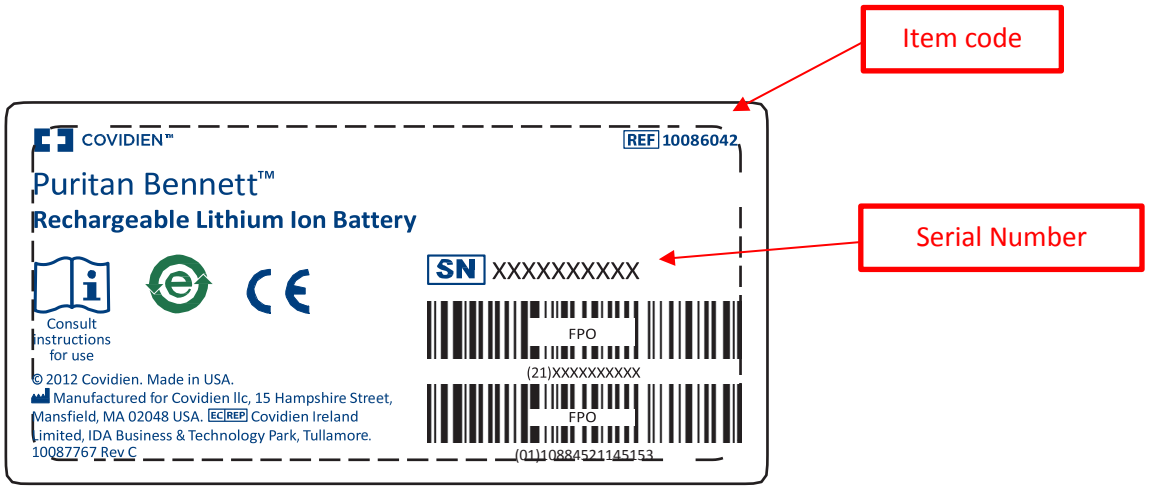
Vice President, Quality Assurance
Respiratory, Gastrointestinal & Infomatics
Medtronic

Attachment A



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URGENT: MEDICAL DEVICE Field Safety Corrective Action

Rechargeable Li-ion Batteries Used in Puritan Bennett™ 980 Ventilators

VERIFICATION FORM

Please complete this form in its entirety and fax/e-mail it using the contact details below.

[Please insert date the form was sent]

Customer Contact Details	Medtronic Contact Details
Hospital: **Medtronic Account Number:**	**To:** [*insert name Medtronic commercial office*]
Address: **Department:** Street: City: Postal Code: Contact Person: Opening Hours:	**Address:** [*insert Medtronic address*]
Telephone n°:	**Telephone n°:** [*insert Medtronic telephone number*]
Fax n°:	**Fax n°:** [*insert Medtronic fax number*]
E-mail:	**E-mail:** [*insert contact e-mail address*]

Does your facility currently have Rechargeable Li-ion Batteries Used in Puritan Bennett™ 980 Ventilator Systems?
Or, did your facility distribute Rechargeable Li-ion Batteries Used in Puritan Bennett™ 980 Ventilator Systems?
Please provide the details in the table below and confirm that you provided them with a copy of this Field Safety Notice.

I have read and understand the instructions provided and acknowledge receipt of the Field Safety Notice regarding the batteries used with the Puritan Bennett™ 980 ventilator by signing below. I also agree to further distribute and communicate this important information within my facility and to any other facility to which I have distributed the PB980 ventilator.

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

No Inventory at my location (Please check):_____

Information related to batteries <u>at your</u> location(s)		
Battery Serial Number	**Location (Name of Department)**	**Address**

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Please fill out the table and information below if you distributed the PB980 batteries outside of your facility.

Name of User/ Location:_____

Address:_____

City: _____ State: _____ Zip Code: _____

Information related to batteries <u>you distributed</u>		
Battery Serial Number	**Location (You Distributed To)**	**Address**

Please attach additional pages as needed.

Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.