

# Medtronic

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## **Urgent Medical Device Safety Notice** **Puritan Bennett™ 980 Series Ventilator**

31 March 2022

### **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 issuing a safety notice related to all serial numbers of Puritan Bennett™ 980 (PB980) series ventilators.

### **Reason for this safety notice**

This voluntary medical device safety notice is being issued following receipt of seventeen reports from customers stating that during alarm conditions, the audible alarm may not sound and/or the omni-directional LED visual alarm may not illuminate as described in the operator's manual. The associated visual alarm banner(s) continues to display as expected on the graphic user interface (GUI). A visual display of the alarm banner(s) on the GUI without expected audible alarm or omni-directional LED visual alarm indicates that these alarms have failed. Failure of the audible alarm to sound and/or the omni-directional LED visual alarm to illuminate does not impact ventilator operation.

In the event the audible alarm fails to sound and/or the omni-directional LED alarm fails to illuminate, the clinical team should transfer the patient to another form of ventilation. Following transfer of a patient to another form of ventilation, the PB980 ventilator can be power cycled to reset inoperable audible and visual alarms; while this restores proper alarm operation for a period of time, note that power cycling may not prevent recurrence of inoperable alarms.

No patient harm has occurred in association with the seventeen customer reports. In thirteen of seventeen customer reports, it was stated that the patient was transferred to an alternate source of ventilation with no patient harm. The frequency of occurrence for this issue is improbable and corresponds to an annual rate of 0.05%. Based on our internal review, including the rate of occurrence for the reports, Medtronic is advising that continued use of PB980 ventilators is appropriate when the actions listed below are taken into consideration, unless this continued use is inconsistent with your facility's internal policies and procedures.

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## **Risk to health**

In the event of a failure of a PB980 ventilator audible alarm and/or a failure of the omni-directional LED visual alarm, a clinician's awareness of the alarm condition may be delayed if the GUI banner visual alarm is not noticed in a timely manner. This delayed awareness can lead to delayed response or a delay of treatment, potentially resulting in hypoxia, dyspnea, cardiac arrest, or death. In the event the audible alarm fails to sound, and/or the omni-directional LED visual alarm fails to illuminate, the clinical team should transfer the patient to another form of ventilation.

## **Actions you should take**

- Ensure patients on PB980 ventilators are appropriately monitored by medical personnel as described in the General Warnings section of the operator's manual and ensure that access to an alternate form of ventilation is available.
- Please institute workflow modifications to ensure visibility of the GUI visual alarm banner to ensure awareness of an active alarm condition in the absence of a functioning audible alarm and/or omni-directional LED visual alarm.
- In the event the audible alarm fails to sound, and/or the omni-directional LED alarm fails to illuminate, the clinical team should transfer the patient to another form of ventilation.
- Following transfer of a patient to another form of ventilation, the PB980 ventilator can be power cycled to reset inoperable audible and omni-directional visual alarms; while this restores proper alarm operation for a period of time, note that power cycling may not prevent recurrence of inoperable alarms.
- Immediately notify all personnel in all care environments in which the PB980 series ventilators are used about this medical device safety notice.
- Please post this notification in a prominent location and maintain awareness of the issues until the issue has been resolved with a pending device update.
- 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.
- If you are aware of any incidents related to this issue, please contact your local Medtronic field representative.

## **Actions being taken by Medtronic**

- Medtronic will release a software update in the coming months to address this issue. Medtronic Technical Service will contact you to arrange for installation of the new software on all PB980 ventilators at your facility.

This notification is being issued with the knowledge of the U.S. Food and Drug Administration and other global regulatory agencies. Adverse events or quality problems experienced with the use of this product should be reported to your local Medtronic field representative.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic field representative.

Sincerely,



**Diana Teo**

Medtronic QRA Lead  
Singapore and Malaysia



**Chloe Tan**

Medtronic QRA Lead  
Indochina and Frontier Market Plus



**Parichart Bunjobchokchai**

Medtronic QRA Lead  
Thailand

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## Urgent Medical Device Safety Notice

### Puritan Bennett™ 980 Series Ventilator

#### Acknowledgment and Receipt Form—Response is Required

#### PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Distributor/HCP:	Name:
Address:	Contact:
Phone no:	Email:
E-mail:	

#### Please list down the serial numbers of the units IN YOUR FACILITY:

No Inventory (Please check):

Serial Number

Serial Number

Serial Number

Serial Number

*\*If these tables are not enough, please use the additional page provided. Additional page and/or attachments must be signed and dated.*

#### Did you distribute the PB980 product to ANOTHER LOCATION OR USER? If so, please provide the details below and confirm you provided them this Urgent Medical Device Correction Notification

Serial Number	Location Name	Contact Details (Name & Number or Email)	Have you provided them this Urgent Medical Device Correction Notification?
			<input type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no

*\*If this table is not enough, please use the additional page provided. Additional page and/or attachments must be signed and dated.*

**I have read and understand the instructions provided and acknowledge receipt of the Medical Device Safety Notice dated 31 March 2022, 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: \_\_\_\_\_ Stamp: \_\_\_\_\_ Date: \_\_\_\_\_



