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Urgent Field Safety Notice

Puritan Bennett™ 980 Series Ventilator

Notification Upcoming Software Update

March 2022

Medtronic reference: FA1238

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

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 series ventilators.

Reason for this Safety Notice

This voluntary medical device safety notice is being issued following reports from seventeen 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 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 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, 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.

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 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 and suitable monitoring devices as described in the Operator's Manual and ensure that access to back-up ventilators 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.

Actions being taken by Medtronic

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

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 Medtronic representative at 01 511 1400.

Sincerely,

Samantha Baxter
Regulatory Affairs, UK and Ireland