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Urgent Field Safety Notice

Puritan Bennett™ 500 Series Ventilators

Important Information Related to Length of Cumulative Use

Notification

June 2024

Medtronic Reference: FA1380

EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000028763

This document is intended for physicians, health care professionals, distributors, and users of these medical devices. This letter contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

The purpose of this letter is to inform customers of important information related to the long-term use of Puritan Bennett™ 500 series ventilators (PB500). You are receiving this letter because Medtronic records indicate that PB500 series ventilators were shipped to your facility.

Affected Devices:

Product Name	Model #/ CFN	UDI-DI/ GTIN
PURITAN BENNETT™ 560 VENTILATOR	4096600	10884521087798
PURITAN BENNETT™ PB560 VENTILATOR EU-DIV	4096600-01	10884521195998
PURITAN BENNETT™ 560 VENTILATOR JAPAN	4096600-02	10884521196001
PURITAN BENNETT™ 560 VENTILATOR APAC	4096600-03	10884521196018
Puritan Bennett™ 560 Ventilator LATAM	4096600-04	10884521196025
Puritan Bennett™ 560 Ventilator EMEA	4096600-05	10884521196032
Puritan Bennett™ 560 Ventilator CAN ANZ	4096600-06	10884521196377
Puritan Bennett™ 540 Ventilator USA	4097100	4097100
Puritan Bennett™ 520 Ventilator	4098300	10884521183636
Puritan Bennett™ 520 Ventilator EU-DIV	4098300-01	10884521195943
Puritan Bennett™ 520 Ventilator Japan	4098300-02	4098300-02
Puritan Bennett™ 520 Ventilator APAC	4098300-03	10884521195967
Puritan Bennett™ 520 Ventilator EMEA	4098300-05	10884521195981
Puritan Bennett™ 520 Ventilator CAN/ANZ	4098300-06	10884521196384

Product Name	Model #/ CFN	UDI-DI/ GTIN
DL4096600 DL PB560 VENTILATOR	DL4096600	10884521786509
DL4096600-06 RFB PB560 VENT CAN ANZ	DL4096600-06	10884521786516
REFURBISHED PB540 VENTILATOR	DL4097100	DL4097100
Puritan Bennett™ 540 Ventilator Refurbished	DS4097100	DS4097100

Standard toxicological test methods were employed to characterize the risk of exposure to volatile organic compound (VOC), 2-propanol, 1,3-dichloro released from some components in the gas pathway of Puritan Bennett™ 500 series ventilators. Medtronic determined that the PB500 series devices are safe for both intermittent and continuous use, for invasive and non-invasive ventilation for both pediatric and adult patients, over the entire duration of their labeled service life (10 years) and are in compliance with international published standards. For patients that require ventilation therapy beyond the full duration of the device's service life, a second unit may be required to allow the patient to continue receiving ventilation therapy beyond the initial 10 years. Additional test analyses suggest that cumulative use of over 14 years may potentially pose a harm to health. These conclusions are derived from chemical testing and risk assessment from literature, including animal laboratory testing. There are no conclusive human clinical data describing quantifiable risk. No customer complaints have been received reporting any of these potential harms.

There are no anticipated harms associated with exposure to the identified chemical[1] so long as the cumulative use of these devices does not exceed 14 years. Toxicological assessment based on small animal laboratory testing suggests that, with greater than 14 cumulative years of use of PB500 series ventilators, exposure to the identified chemical has a maximum

potential risk of 1 in 10,000 for cancer, birth defects/deformity, infertility, or abnormal fetal development.

Patient Management

Continued, sequential, use of PB500 series ventilators is appropriate for patients who currently are using the devices for invasive and non-invasive ventilation therapy for up to and including 14 years of cumulative use. Any single PB500 series ventilator should only be used for the 10-year labelled service life, but if ventilatory support is required for a longer period using more than one PB500 series ventilator over time, the use of these devices for more than 14 years of cumulative duration is not advised. It is recommended that caregivers of patients approaching 14 years of cumulative use of PB500 series ventilators discuss changing their ventilatory support to an alternate ventilator with the patient's prescribing physician.

Actions Taken by Medtronic:

- Medtronic has updated the labeling. Please refer to the User Manual and Clinician's Manual addendum attached to this notice.

Actions to be taken:

- Please provide this notice to those who need to be aware within your organization or to any organization or person where the product has been transferred or distributed.
- Any single PB500 series ventilator should only be used for the 10-year labelled service life. If a patient requires ventilatory support for a longer period of time, cumulative sequential use of more than one PB500 series ventilator should be limited to 14 years. After 14 years of cumulative use, patients should be transitioned to an alternate device.
- When approaching 14 years of cumulative use of a PB500 series ventilator, it is recommended that patients or their caregivers discuss transitioning to an alternate ventilator with the prescribing physician.

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions related to this issue, please contact your local Medtronic representative at 01 511 1400.

Sincerely,

Bethany Moxon

Associate Regulatory Affairs Specialist, UK and Ireland

Addendum to the User Manual

Puritan Bennett™

PB500 Series Ventilator

1 Overview

This addendum describes an additional warning to the PB500 series User's Manual and Clinician's Manual.

This addendum applies to the following:

- Puritan Bennett 560 Ventilator
- Puritan Bennett 540 Ventilator
- Puritan Bennett 520 Ventilator

2 Warning

Warning: Patient management

Continued, sequential use of PB500 series ventilators is appropriate for patients who currently are using the devices for invasive and non-invasive ventilation therapy for up to and including 14 years of cumulative use.

Any single PB500 series ventilator should only be used for the 10-year labelled service life, but if ventilatory support is required for a longer period using more than one PB500 series ventilator over time, the use of these devices for more than 14 years of cumulative duration is not advised.

It is recommended that caregivers of patients approaching 14 years of cumulative use of PB500 series ventilators discuss changing their ventilatory support to an alternative ventilator with the patient's prescribing physician.