Covidien Deutschland GmbH ・Gewerbepark 1 ・D-93333 Neustadt/Donau

Neustadt, 14.08.2015

URGENT Field SAFETY Notice

For the Puritan Bennett™ 980 Series Ventilator System

For Universal and Neonatal Models

Reference: PB980 Neonatal Ventilation 07/15

Attention: ICU Department & Medical Director

Dear Customer,

The purpose of this letter is to advise you that Covidien, now part of Medtronic, is issuing a field safety corrective action (FSCA) for neonatal applications (NeoMode software) on Puritan Bennett™ 980 (PB980) neonatal and universal ventilator models.
PB980 pediatric and adult ventilator models or ventilation modalities are not affected by this field action
As a reminder, PB980 universal model ventilator is designed for neonatal, pediatric and adult patients. This action is being taken in response to reports in which tidal volumes reaching patients were lower than set tidal volumes in neonatal Volume Control Plus (VC+) Mode with active humidification. This situation may potentially lead to respiratory compromise if not recognized. There have been no serious injuries or deaths related to these reports.

Covidien's investigation has identified a software anomaly that contributes to this volume delivery issue in neonatal VC+ mode. This issue has not been observed during neonatal pressure control ventilation, or with pediatric or adult modes of ventilation.

Actions being taken by Covidien (Medtronic):

Covidien will develop and implement a software update for neonatal and universal models of ventilators with NeoMode capability. Until that time, we will disable the clinician's ability to use the NeoMode feature in the PB980 ventilator. Our service engineers will be in contact with you soon to help coordinate this process.

Actions you should take:

Immediately assess all neonatal patients on a PB980 ventilator using VC+ in NeoMode to ensure each patient is achieving sufficient ventilation per institutional protocol and attending physician discretion. This may include, but is not limited to, chest rise, blood gases, and pulse oximetry.

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- When neonatal patients are clinically stable and can be provided ventilation with an alternative device, Medtronic recommends transferring patients to other ventilators. The decision to transfer a patient however must outweigh the risk of injury due to the transfer process. If clinically necessary, patients may remain on PB980 ventilators until it is safe to transfer them to different ventilator.
- Immediately notify all care environments in which the PB980 ventilator with the NeoMode feature is used, including NICU, PICU, Pediatric Cardiovascular ICU, and Pediatric ED about this action and that the NeoMode feature should not be used pursuant to this notification.
- If you currently use the PB980 ventilator with the NeoMode feature in only pressure control modes, please transfer the patient to another ventilator at your earliest possible opportunity, taking into consideration the patient's clinical status and institutional protocol.
- Universal model ventilators in use on adult or pediatric patients may remain in use until it is safe to remove the ventilator from use so the configuration can be changed to disable the NeoMode feature. The reconfigured ventilator can be returned to service for use with adult and pediatric patients.
- 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.
- Work with Covidien service engineers to allow them to update the ventilator to remove the NeoMode software from the system. We realize eliminating the NeoMode feature substantially impacts our neonatal customers. Our Technical Support Department will be available to assist you if you require assistance finding alternative ventilation devices.

This notification is being issued with the knowledge of BfArM. Please communicate this important information within your facility as required and maintain awareness of this notice and resulting action for an appropriate time period to ensure effectiveness of the corrective action.

If you are aware of any incidents related to this issue, please contact your local Covidien Representative to provide information regarding those events so regulatory reporting obligations can be fulfilled. If you have any questions, please contact your local Covidien Representative as described above.

Thank you for your attention to this issue. We sincerely apologize for any inconvenience this situation may cause you or your facility.

Sincerely,

Covidien Deutschland GmbH
A Medtronic plc company

[redacted]

Alexander Walter
Regulatory Affairs Manager DACH & Norden