COVIDIEN

URGENT: Field Corrective Action Notice
For the Puritan Bennett™ 980 Series Ventilator System
For Universal and Neonatal Models

20 July 2015

Reference: Puritan Bennett 980 Neonatal Ventilation

Dear valued customer,

The purpose of this letter is to advise you that Covidien, now part of Medtronic, is issuing a voluntary field corrective action notice for neonatal applications (NeoMode software) on Puritan Bennett™ 980 (PB980) neonatal and universal ventilator models.

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.

PB980 pediatric and adult ventilator models are not affected by this field action.

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.

- 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.

COVIDIEN PRIVATE LIMITED
CO. REGISTRATION NO: 199800515M

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- 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 verification form below 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 the US FDA and other relevant regulatory bodies have been notified or will be notified according to applicable regulations. Please maintain awareness on this notice and resulting action for an appropriate time period to ensure effectiveness of the corrective action. Please communicate this important information within your facility as required.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Covidien representative.

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

Sincerely,

[redacted]

Gilbert Penaflor – QA SEA

COVIDIEN

Field Corrective Action Verification Form

For the Puritan Bennett™ 980 Series Ventilator System

For Universal and Neonatal Models

Customer Contact Details	Covidien Contact Details
Hospital / HCP:	**By E-mail:**
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

1) Indicate in the columns below all serial numbers you have in your facility. If you have forwarded affected Puritan Bennett 980 ventilator to other persons or facilities, provide the serial numbers and the recipient's name and address, if known. Forward the FSCA notification to these facilities.

Puritan Bennett 980 ventilator serial numbers	Still in Service for Patient Use Yes/No	Sent to another facility Yes/No	Facility name and address (if different than above)

2) Should we unable to disable the NeoMode feature on above listed units, please check on below for the reason: (Please tick one ONLY)

☐ The equipment is condemned

☐ Hospital staff did not provide authorization for our staff to perform the disability function

☐ Other reason(s) please specify: _____

I have read and understand the instructions provided and acknowledge receipt of the Field Safety Corrective Notice 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: _____ Date: _____

Please post or email this form to Covidien (Medtronic) according to the contact details stated on top of this form.

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