

Field Corrective Action Notice Puritan Bennett™ 840 Ventilators and Newport™ e360 Ventilators

June XX, 2018

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a voluntary field corrective action notice for its Puritan Bennett™ 840 ventilators and Newport™ e360 ventilators in China. During routine inspection by Chinese import authorities, it was found that during the visual flashing of the medium priority alarms, the indicators remained illuminated for longer than the time specified in the regulations for the Puritan Bennett™ 840 ventilator and flashed at a frequency that exceeds the standard for the Newport™ e360 ventilator. In normal operation, users of the Puritan Bennett™ 840 or Newport™ e360 ventilators would not notice the flash anomalies. Software corrections have been developed to address these flash anomalies in Puritan Bennett™ 840 and Newport™ e360 ventilators. These anomalies present no safety risk to patients. A review of worldwide complaints did not identify any reports related to these flash non-conformances.

Additionally, the Chinese import authorities determined that software corrections were required for the high and medium auditory alarms for the Newport™ e360 ventilators to comply with current regulations. All issues have been thoroughly risk assessed; there are no safety risks associated with these software issues. There have been no reports from users related to any of these issues worldwide.

Actions being taken by Medtronic:

Medtronic has developed the software corrections to address the flash and auditory alarm issues for both the Puritan Bennett™ 840 and Newport™ e360 ventilators. We will provide software service updates for all ventilators in China that were manufactured since June 1, 2014.

Actions you should take:

- Continued use of Puritan Bennett™ 840 ventilators and Newport™ e360 ventilators is appropriate; there are no safety risks posed to patients by these visual and auditory alarms standard non-conformances.
- If your facility has distributed Puritan Bennett™ 840 Ventilators or Newport™ e360 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.



Medtronic

60 Middletown Avenue
North Haven, CT 06473
www.Medtronic.com

- Contact Medtronic Technical Support (or your distributor) to schedule installation of the software correction.

If you are aware of any incidents related to these issues or if you have any questions, please contact our Technical Support Department at XXX-XXX-XXXX. This notification is being issued with the knowledge of the China Inspection and Quarantine (CIQ).

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

Sincerely,

Subu Mangipudi
Vice President, Quality
Respiratory, Gastrointestinal and Informatics
Medtronic



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Field Corrective Action Customer Acknowledgment Form
Puritan Bennett™ 840 and Newport™ e360 Ventilators in China

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____ Title: _____

Direct Phone #: _____ Email: _____

Account Name: _____ Medtronic Account Number: _____

Account Address: _____

City: _____ State: _____ Zip Code: _____

Did you distribute the Puritan Bennett™ 840 or Newport™ e360 ventilators to another location or user? If so, please provide the details below and confirm you provided them this Field Corrective Action Notice.

Name of User/ Location: _____

Address: _____

City: _____ State: _____ Zip Code: _____

I have read and understand the instructions provided and acknowledge receipt of the Field Corrective Action Notice regarding the Puritan Bennett™ 840 and Newport™ e360 ventilators in China by signing below. I also agree to further distribute and communicate this important information within my facility as required.

Name: (print) _____ Signature: _____ Telephone: _____ Date: _____

No Inventory (Please check): _____

Serial Number	Location (Name of Department)	Address

If you have any questions regarding this field corrective action notice, please contact Technical Support at XXX-XXX-XXXX.

Please fax the completed form to XXX-XXX-XXXX or email to XXXX@Medtronic.com