Medtronic News

Medtronic Announces Worldwide Voluntary Field Corrective Action; Company Issues Software Update for Puritan Bennett(TM) 980 (PB980) Ventilator Series

DUBLIN - December 4, 2018 - Medtronic (NYSE:MDT) is notifying customers worldwide of a voluntary field corrective action for its Puritan Bennett(TM) 980 (PB980) ventilator series. Medtronic initiated this field action on September 19, 2018.

A Puritan Bennett 980 ventilator is a mechanical ventilator used to support a patient's breathing. This prescription device is operated by trained healthcare professionals in an acute and or critical care clinical setting for neonatal, pediatric and adult patients.

The voluntary field corrective action is a software update to address customer feedback. The software updates the external USB Drive performance and its impact on Graphical User Interface (GUI) functionality and the labeling displayed on the GUI during ventilator use. The software update also provides additional product enhancements. Medtronic is currently updating all PB980 ventilators to this new software version at customer facilities.

The company has updated the PB980 ventilator Operator's Manual with additional information for users. The revised manual is available at: https://www.medtronic.com/content/dam/covidien/library/us/en/product/acute-care-ventilation/PB980_Operators_Manual_EN_10077893G00.pdf

Medtronic is advising customers that they can continue to use their PB980 ventilators, before the MR5.4 software update is installed, in accordance with institutional policies. Medtronic has not received any confirmed reports of serious adverse health consequences related to the issues this software update addresses. FDA has classified this action as a Class I recall.

If you are aware of any incidents related to this issue or if you have any questions, please contact our Technical Support Department immediately at +1-800-255-6774 to provide information regarding those events so regulatory reporting obligations can be fulfilled. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax.

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- Online: Complete and submit the report to www.fda.gov/medwatch/report.htm
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- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call +1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to +1-800-FDA-0178

or

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- Email Medtronic Post Market Vigilance at: HQTSWEB@COVIDIEN.COM
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- Call Medtronic Post Market Vigilance at: +1-800-255-6774 option 4, then option 1.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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