Medtronic News

Medtronic Announces Worldwide Voluntary Field Corrective Action For Newport(TM) HT70 and Newport(TM) HT70 Plus Ventilators

DUBLIN - April 5, 2017 - Medtronic (NYSE: MDT) is notifying customers worldwide of a voluntary field corrective action for all its Newport HT70 and Newport HT70 Plus ventilators manufactured since 2010. The voluntary field corrective action is being conducted following reports that the ventilator may reset spontaneously during normal operation, without an accompanying alarm. The reported incidence of this condition is approximately one (1) reset in every seven million hours of ventilation. Following the reset, the ventilator enters standby mode and will not resume ventilation without intervention. In the event of the rare occurrence of a reset, healthcare professionals and/or caregivers are required to transfer the patient to another ventilator.

A Newport HT70 ventilator is used to support a patient's breathing. This prescription device is operated by trained healthcare professionals in a clinical setting and in the home for infant, pediatric and adult patients.

Since Aug. 2012, and of the more than 14,000 ventilators in use, Medtronic has received 12 reports of the reset without an accompanying alarm. Of these 12 reports, 11 patients required ventilator transfer and one (1) incident did not involve a patient. No patient injury or impairment has been reported.

Medtronic has established the root cause of this alarm failure and will provide a software service update to resolve the issue as soon as the correction can be implemented. We expect the service update to be available in May.

Medtronic is advising that you may continue to use your Newport HT70 series ventilators in accordance with institutional policies and as described below.

Actions you should take:

- Ensure patients on the Newport HT70 and HT70 Plus ventilators are appropriately monitored by trained caregivers as described in the Operator's Manual. The descriptions include:
    - A patient connected to a ventilator requires the constant attention of trained caregivers to the patient's condition.
    - Always have an alternate power source and means of ventilation available when the ventilator is in use in case of a mechanical or system problem.
    - Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and/or a capnograph) when the Newport HT70 or HT70 Plus ventilators are in use on a patient.
    - If able, use the appropriate remote alarm/nurse call cable (CBL3223 or 10104494) to project ventilator alarm states outside the patient room. This alarm will annunciate even with an unexpected reset. Consult the Operator's Manual or call Technical Service for further information on this accessory.
    - If, at any time, the patient is not responding to ventilation appropriately, the patient should be taken off the ventilator immediately and connected to an alternate method of ventilation. Contact your health care provider or physician immediately.
- Immediately notify all care environments in which the Newport HT70 and HT70 Plus ventilators are used about this notification.
- If your facility has distributed Newport HT70 or HT70 Plus ventilators to other persons or facilities, please promptly forward this announcement to those recipients.
- Work with Medtronic Technical Support Department if you require assistance finding alternative ventilation devices.

Medtronic has contacted the FDA and other regulatory bodies to share information related to this issue. We will continue working directly with government authorities and our customers on this voluntary field corrective action.

If you are aware of any incidents related to these issues 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.

- Online: Complete and submit the report to www.fda.gov/medwatch/report.htm
- 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

- Email Medtronic Post Market Vigilance at: HQTSWEB@COVIDIEN.COM
- Call Medtronic Post Market Vigilance at: +1-800-255-6774 option 4, then option 2.

List of countries with Newport HT70 and Newport HT70 Plus ventilators

Algeria, Argentina, Australia, Bahrain, Bangladesh, Belgium, Bolivia, Brazil, Brunei, Bulgaria, Cambodia, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Dominican Republic, Ecuador, Egypt, Greece, Hong Kong, Hungary, India, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Korea, Lebanon, Lithuania, Malawi, Malaysia, Mauritius, Myanmar, Mexico, Namibia, Nepal, Nigeria, Norway, Oman, Pakistan, Palestine, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Saudi Arabia, Senegal, Serbia, Singapore, Slovenia, South Africa, Spain, Sri Lanka, Switzerland, Taiwan, Thailand, Tunisia, Turkey, United States, United Arab Emirates, United Kingdom, and Vietnam.

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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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.

-end-

Contacts:
John Jordan
Public Relations
+1-508-452-4891

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2017-04-05-Medtronic-Announces-Worldwide-Voluntary-Field-Corrective-Action-For-Newport-TM-HT70-and-Newport-TM-HT70-Plus-Ventilators