Medtronic News

Medtronic Announces Worldwide Voluntary Recall for Battery Pack in Covidien Oridion Labeled Capnostream(TM)20 and Capnostream(TM)20p Patient Monitors

DUBLIN - April 20, 2016 - Medtronic is notifying customers worldwide of a voluntary recall for the battery pack used in its Covidien Oridion labeled Capnostream(TM)20 and Capnostream(TM)20p Patient Monitors. This voluntary recall is being conducted due to a battery manufacturing defect that may increase the risk of thermal damage in the battery pack. The scope of this recall includes battery pack model numbers 016400 and 010520. These packs were manufactured by a contract manufacturer between April 2014 and February 2016.

Capnostream monitors are external (non-implantable) medical devices used to assess patients' respiratory status and identify changes in breathing. The prescription device is operated by trained healthcare professionals in a clinical setting and in the home.

Medtronic has received seven reports of thermal damage out of 9,817 battery packs impacted by this field action. Of these seven reports, one involved a fire resulting in smoke inhalation and minor burns.

On April 15, 2016, Medtronic sent a letter to customers who have Capnostream battery packs affected by this voluntary recall. The Company also supplied a rework kit with full instructions for removal and proper disposal or recycling of the battery pack according to local policy. The eight cell, 14.3 volt, Lithium Ion battery pack is custom manufactured by third party contract manufacturers.

The company recommends that customers use the Capnostream monitors on AC power (with the battery pack removed) until a replacement battery pack is available.

The company has identified a manufacturing change conducted by the third party contract manufacturer as the probable root cause and is manufacturing new batteries that meet original specifications with a new contract manufacturer. The company will supply new batteries to affected customers when available. No other Medtronic products are affected by this supplier of battery packs.

Medtronic has contacted the FDA and other regulatory bodies to share information related to this issue. The company will continue working directly with government authorities and customers on this voluntary recall.

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 Minimally Invasive Therapies Group Post Market Vigilance at: HQTSWEB@COVIDIEN.COM
- Call Medtronic Post Market Vigilance at: +1-800-635-5267 option 1, option 1, and again 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 85,000 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.

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