Medtronic

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URGENT FIELD SAFETY NOTICE
For Battery Packs used in Capnostream™20 and Capnostream™20p Patient Monitors

April 25, 2016

Dear Risk Manager:

Please forward this information immediately to Directors of Respiratory Care, Directors of Critical Care, and the Clinical Engineering Department.

The purpose of this letter is to advise you that Covidien Respiratory and Monitoring Solutions, now a part of Medtronic, is issuing a Field Safety Corrective Action (FSCA) for the battery pack used in Oridion labeled Capnostream™20 and Capnostream™20p patient monitors. The scope of this FSCA includes battery packs that were manufactured between April 2014 and February 2016. The FSCA includes battery packs included with the monitors and spare replacement parts purchased separate from the monitor.

This FSCA is due to a supplier defect in battery manufacturing that may increase the risk of thermal damage to the battery pack. Medtronic has received seven reports of thermal damage out of 9,817 battery packs. Of these seven reports, one involved a fire resulting in smoke inhalation and minor burns.

Our records indicate that you have purchased Capnostream™20 and/or Capnostream™20p patient monitors equipped with the affected battery packs, and affected replacement battery packs.

Actions you should take:

- Identify, remove and appropriately dispose of affected battery packs inside Capnostream™20 and Capnostream™20p patient monitors using the directions provided in Attachment A.
- Prepare each monitor for use without the battery pack as identified in Attachment A.
- Review and follow directions as stated in the "Safe Monitor Use without a Battery Pack" document, see Attachment B.
- Return the completed Acknowledgement and Receipt Form by fax or email

Please Note: Once the batteries are removed, the Patient Monitor must be connected to AC power and can no longer be used for intra- hospital transport of patients until replacement batteries are provided.

If your facility has distributed Capnostream™20 and/or Capnostream™20p patient monitors or battery packs to other persons or facilities, please promptly forward a copy of this letter to those recipients.

Actions being taken by Medtronic:

Medtronic is manufacturing new battery packs. Once new battery packs are available and the Acknowledgment and Receipt Form is received by Medtronic, replacement batteries will be shipped to you free of charge.

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If you have any questions about the products involved in this FSCA, contact your local Medtronic Representative at XXX-XXX-XXX

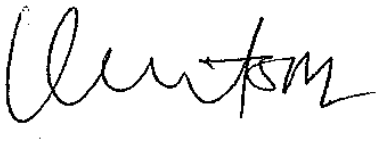
This notification is being issued with the knowledge of the (Insert Local Competent Authority Name).

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information detailed above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

Please communicate this important information within your facility as required.

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 Assurance
Patient Monitoring and Recovery
Medtronic

Attachments:
Attachment A: Procedure for Removal of Battery Pack
Attachment B: Safe Monitor Use without a Battery Pack