Medtronic

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URGENT: Medical Device Recall

For Battery Packs used in Capnostream™20 and Capnostream™20p Patient Monitors

20th April 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 voluntary recall for the battery pack used in Oridion labeled Capnostream™20 and Capnostream™20p patient monitors. The scope of this recall includes battery packs that were manufactured between April 2014 and February 2016. The recall includes battery packs included with the monitors and spare replacement parts purchased separate from the monitor.

This voluntary recall 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:

- 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.
- Complete the attached verification form below and return it as directed to confirm your receipt and understanding of this information.
- Work with Medtronic service engineers to allow them to identify, remove affected battery packs and prepare for use for Capnostream 20 and Capnostream20p patient monitors.

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.

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 provided to you free of charge.

If you have any questions regarding this recall, contact Technical Services Department at Technical_support@covidien.com

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations.

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

Sincerely,

Gilbert Penaflor
QA Manager, South East Asia
Medtronic

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Recall Product Return Form

For Battery Packs used in Capnostream™20 and Capnostream™20p Patient Monitors

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**By E-mail:** Technical_Support@Covidien.com
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

Please tick one (only):

☐ All Capnostream™ 20 and Capnostream™ 20p battery packs have been collected and have be disposed of or battery packs have been segregated from use and will be disposed of according local policy on disposal of hazardous materials.

☐ There are no affected battery packs at this facility or in Capnostream™ 20 and/or Capnostream™ 20p patient monitors.

Please enter the information of affected battery packs removed from the Capnostream 20 and Capnostream 20p patient monitors and any replacement battery packs removed from your inventory in the below table:

Item code	Product Description	Serial number	Manufacture Date	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Voluntary Recall regarding the Capnostream 20 and Capnostream 20p patient monitors by signing below. I also agree to further distribute and communicate this important information within my facility as required.

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