

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Medtronic Respiratory and Monitoring Solutions Recalls Battery Pack Used on Patient Monitors Due to Potential Fire Risk

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- Battery Pack used on Capnostream™ 20 and Capnostream™ 20p Patient Monitors
- Model numbers: 016400 and 010520
- Manufacturing dates: April 1, 2014 to February 3, 2016
- Distribution dates: April 1, 2014 to February 3, 2016
- Devices recalled in the U.S.: 9,817 battery packs nationwide, including Washington D.C.

Device Use

The battery pack powers the monitor of the Capnostream™ 20 and Capnostream™ 20p when electrical power is not available. The Capnostream™ 20 and Capnostream™ 20p are used to monitor vital signs and levels of oxygen and carbon dioxide in neonatal, pediatric, and adult patients. The patient monitors and battery packs are used in hospitals or during patient transport.

Reason for Recall

Medtronic Respiratory & Monitoring Solutions is recalling the battery packs due to a manufacturing defect that causes an increase in temperature within battery that may cause a fire in the system monitor.

The use of affected products may cause serious adverse health consequences, including death.

Who May be Affected

- Patients whose vital signs are being monitored using the Capnostream™ 20 and Capnostream™ 20p supplied with the defective battery pack
- LHealth care providers using the Capnostream™ 20 and Capnostream™ 20p supplied with the defective battery pack

What to Do

On April 15, 2016, Medtronic Respiratory & Monitoring Solutions sent an "Urgent: Medical

Device Recall" letter to affected customers. The letter instructed customers to:

- Identify, remove, and appropriately dispose of affected battery packs
- Prepare the monitoring units to work without the battery pack by following the instructions provided attached with the letter
- Avoid using the monitoring units for patient transport
- Complete and return the acknowledgement and receipt form by email at HQTSWEB@covidien.com (<mailto:HQTSWEB@covidien.com>)

New batteries will be provided free of charge once the acknowledgment and receipt form are received.

Contact Information

Customers can contact Medtronic Respiratory & Monitoring Solutions at 1-800-635-5267. At the prompt, press 1, then 1.

Date Recall Initiated:

April 13, 2016

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls
(</MedicalDevices/Safety/ListofRecalls/default.htm>)

2016 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm480134.htm>)

2015 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm429489.htm>)

2014 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm384921.htm>)