Medtronic

**URGENT FIELD SAFETY NOTICE**

# Capnostream™ 20 and Capnostream™ 20p Bedside Patient Monitors

## Product Codes:

| | | | |
|---|---|---|---|
| CS051COV | CS08652-03 | CS08658-01 | CS78652 |
| CS051COV-03 | CS08654 | CS08658-02 | CS78654 |
| CS08651 | CS08654RA | CS08658-03 | CS78658 |
| CS08651-01 | CS08654RN | CS08660 | CS78659 |
| CS08652 | CS08657 | CS08796 | CS78660 |
| CS08652-01 | CS08657-01 | CS08798 | |
| CS08652-02 | CS08658 | CS08799 | |

August 16th, 2018

Medtronic Reference: FA833

**Attention: Directors of Respiratory Care, and Clinical Engineering**

Dear Valued Customer:
The purpose of this letter is to advise you that Medtronic is issuing a software update for Capnostream™ 20 and Capnostream™ 20p Bedside Patient Monitors.

### Issue Description:

This notification is being provided following receipt of customer reports that the date/time, nurse call and alarm settings of Capnostream™ 20 and Capnostream™ 20p bedside patient monitors may reset to the factory default settings when the monitor is powered off. There have been no reports of patient injury related to this issue.

Our investigation revealed that the cause for the reset to the factory default settings is the accelerated discharge of the internal coin cell battery. User-defined institutional default settings are not lost if the monitor is not powered off, even when the internal coin cell battery is depleted.
This issue does not affect the operation of the monitor's removable Li-ion battery or any other aspect of the monitor's operation. Only the reset of user-defined institutional default settings as described above are affected.

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## Issue Resolution:

- Medtronic is developing a software update that will ensure user-defined institutional default settings are not lost if the monitor is powered off, except the date/time, regardless of the internal coin cell battery charge level. **This software update will be available in October 2018.** Medtronic will issue an update to the Operator's Manual to note that the date/time setting should be verified at power on.

## Actions you should take:

- Share this notification with all care environments where the Capnostream™ 20 and Capnostream™ 20p bedside patient monitors are used, particularly in the areas where nurse call may be enabled (general care floors). If your facility has distributed these bedside patient monitors to other persons or facilities, please promptly forward a copy of this letter to those recipients.
- Medtronic is recommending continued use of Capnostream™ devices. Users should confirm that the date/time is accurately displayed. If the date/time requires reset, all user defined settings, such as alarms and nurse call, will also require reset until the software is updated. Please follow the instruction in the Operator's Manual to set user-defined default settings. The Operator's Manual is available at http://www.medtronic.com/covidien/en-us/support/product-manuals.html, refer to the "Institutional Settings" section.
- Return the completed Acknowledgement and Receipt Form by fax or email even if you have no inventory.
- In October 2018, download the software update from the Medtronic website via the following link which includes directions on how to download and install the software: http://www.medtronic.com/covidien/en-us/support/patient-monitoring-equipment-software-upgrades.html.

If you are aware of any incidents related to this issue or if you have any questions, please contact your local Medtronic representative to provide information regarding those events so regulatory reporting obligations can be fulfilled.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records. We apologize for this inconvenience. If you have any questions regarding this communication, please contact your Medtronic representative at XXX XXXX XXXX.

Sincerely,

Subu Mangipudi
Vice President, Quality
Respiratory, Gastrointestinal and Informatics
Medtronic

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# Urgent Medical Device Correction

## Acknowledgement and Receipt Form Response is Required

## Capnostream™20 and Capnostream™20p Bedside Patient Monitors

**Please complete this form in its entirety and return it to Medtronic once you have completed the software upgrade in October 2018.**

Date: _____

Name of Person Completing this form: _____

Title:_____

Direct Phone#:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____State: _____Zip Code:_____

Telephone Number:_____

**I have read and understand the instructions provided and acknowledge receipt of the Urgent Medical Device Correction regarding the Capnostream™20 and Capnostream™20p bedside patient monitors. I confirm that the software update has been performed for all Capnostream devices at my facility. I also agree to further distribute and communicate this important information within my facility as required.**

_____ _____ _____

Name: (print) Signature: Date:

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**If you have any questions regarding this notification, please contact your local Medtronic representative at XXXX XXXX**

**Please fax the completed form to XXX XXX XXX or email to XXXXXX@Medtronic.com**