

Urgent Field Safety Notice

Li-ion battery packs used in BIS™ Vista and BIS™ View Monitoring Systems Operator Manual Update

August 2019

Medtronic reference: FA832 Phase II

Dear Healthcare Professional,

The purpose of this letter is to inform you about an update to our August 2018, voluntary field corrective action. This field corrective action was related to the replacement instructions for the Li-ion battery packs used in BIS™ Vista and BIS™ View Monitoring Systems.

These instructions are updated in the operator manual, available on the Medtronic website:

https://www.medtronic.com/content/dam/covidien/library/global/multi/product/brain-monitoring/BISBatteryTest_Addendum_Multi_PT00097180B00.pdf

Additionally, we have added an expiration date label on battery packs used with BIS™ systems. This label indicates the expiration date of the battery to assist with the annual preventive maintenance described in the updated manual.

Battery Expiration Date:
YYYY-MM-DD

If you have distributed BIS™ Vista and View monitoring systems to other persons or facilities, please promptly forward this information to those recipients.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at 01 511 1400.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager UK and Ireland