

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 that Medtronic has revised the replacement instructions for the Li-ion battery packs used in BIS™ Vista and BIS™ View Monitoring Systems.

In August 2018, Medtronic notified customers about the upcoming revised replacement instructions via an Urgent Field Safety Notice. Our records indicate you have received BIS™ devices after July 2018. The updated manual includes battery pack replacement instructions for all BIS™ devices.

The updated manual is available on the Medtronic website at:

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™ system. 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 the information from this letter 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