HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

BIS™ Vista and BIS™ View Monitoring Systems

Priority 2 –Warning

HPRA Safety Notice: SN2018(26)

Issue Date: 14 August 2018

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Covidien llc	V36610

ISSUE
This field safety corrective action is being conducted due to the potential for aged battery packs in the BIS Vista and View monitoring systems to experience an internal short that may result in a thermal event. Medtronic has revised the replacement instructions for the Li-ion battery packs used in BIS™ Vista and BIS™ View Monitoring Systems.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Read the accompanying field safety notice (FSN) carefully, 2 Ensure that all relevant staff in your organisation are aware of this FSN.

3	Follow the instructions in the FSN regarding battery testing, replacement, and/or disposal.
4	Acknowledge receipt of the FSN if you have not already done so.
5	Report any concerns regarding this device or incidents involving this device to the manufacturer and the HPRA.

TARGET GROUPS

Risk Managers	Surgeons
Surgical Nurses	Anesthesiologists
Clinical Engineers	Theatre Staff
Supplies Managers	Equipment stores

BACKGROUND

The BIS™ Complete Monitoring System is a user-configurable patient monitoring system designed to monitor the hypnotic state of the brain based on acquisition and processing of EEG signals. The BIS Complete system processes raw EEG signals to produce a single number, called the Bispectral Index™, or BIS, which correlates with the patient's level of hypnosis.

Medtronic has received reports of overheating in the battery packs of the BIS Vista monitoring products. In these events, smoke was emitted from the battery compartment on the back of the monitor. No patient or user injury or impairment has been reported for this issue, however, a thermal event can lead to smoke emission and/or in rare occurrences fire.

Medtronic has written to customers to advise them that they intend to replace all battery packs which exceed 4 years of age or which fail the capacity test outlined in Attachment A Section 3 of the accompanying FSN. This replacement will be organised following receipt of the completed acknowledgment form. Medtronic are also updating the User Manual for the BIS™ monitoring systems to include the updated battery pack replacement instructions, these instructions are expected to be available in February 2019. All new battery packs manufactured will also be labelled with an expiration date.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Medtronic Limited,
Building 9, Croxley Park,
Hatters Lane
Watford, Herts, WD18 8WW
United Kingdom

Telephone: +44 1923 212 213
E-mail: vigilance.eu@medtronic.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie