

URGENT FIELD SAFETY NOTICE

Li-ion battery packs used in BIS™ Vista and BIS™ View Monitoring Systems.

August, 2018

Medtronic reference: FA832

Attention: OR Materials Management, Risk Management, Biomedical Engineering Department

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a voluntary field correction to revise the replacement instructions for the Li-ion battery packs used in BIS™ Vista and BIS™ View Monitoring Systems.

These revised instructions will require battery pack replacement after 4 years. We are issuing this revision due to the potential for aged battery packs to experience an internal short that may result in a thermal event. Medtronic has received two reports of thermal damage representing a .005% (1 in 20,000) rate of occurrence. 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. A thermal event can lead to smoke emission and/or in rare occurrences, fire, potentially resulting in bronchospasm or burns.

Based on Medtronic's internal data analysis and review of potential risk to patient and user safety, we are advising that you can continue to use your BIS™ Vista and View monitoring systems in accordance with institutional policies and as described below. Medtronic will replace customers' battery packs which exceed 4 years of age or fail the capacity test outlined in Attachment A Section 3 at no cost to you upon receipt of the completed Field Corrective Action Customer Acknowledgement Form.

Actions you should take:

- Immediately notify all care environments in which the BIS™ Vista and View monitoring systems are used about this notification. If your facility has distributed BIS Vista™ and View™ monitoring systems to other persons or facilities, please promptly forward a copy of this letter to those recipients.
- Identify the age of the battery pack within your BIS™ View and Vista Monitors using the directions provided in Attachment A Section 1. Complete the Field Corrective Action Customer Acknowledgement Form and return it as directed to confirm your receipt and understanding of this information.
- If the monitor is to be operated without a battery pack installed, it must be connected to an AC power source with backup. Apply the "No Battery Installed" label provided with this notification as detailed in Attachment A Section 4.

Additional actions being taken by Medtronic:

- Medtronic is updating the User Manual for the BIS™ monitoring systems to include the updated battery pack replacement instructions in February 2019.
- New battery packs manufactured will be labeled with an expiration date.

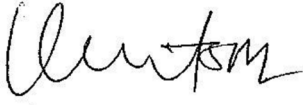
We request that you contact Medtronic if you experienced quality problems or adverse events.

Medtronic

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

We sincerely apologize for any inconvenience this situation may cause you or your facility. Thank you for your attention to this notification. If you have any questions regarding this communication, please contact your Medtronic representative at 01 511 1400.

Sincerely,



Subu Mangipudi
Vice President, Quality Assurance
Respiratory, Gastrointestinal & Informatics
Medtronic



Samantha Baxter
Regulatory Affairs Manager
UK and Ireland

Attachment A

Please consult your Operators Manual for general guidance on service on this device.

Section 1: Identifying the Age of a Battery Pack

- The battery pack is located at the rear of the monitor
- To inspect the battery, you will need a Philips #2 screwdriver. Follow the 4 steps below to access and identify the age of the battery pack:
 - Unplug A/C line cord from the monitor.
 - Lay monitor screen-side-down on a smooth work surface so that the Battery/Power Supply cover is accessible. If necessary, protect display screen from being scratched by the work surface.
 - Remove 4 screws from the Battery/Power Supply cover using a Philips #2 screwdriver and remove the cover.
 - The battery manufacture date (in the form WWYY) can be found on a white label on the back of the battery pack. See photo below for details on how to locate the manufacture date.

Manufacture date (WWYY)



Section 2: Determine if your Battery Pack Requires Replacement

- Batteries with date code 3114 or older (Week 31 of 2014) exceed 4 years of age and should be removed from the monitor and disposed of according to your facility's standard process.
- Batteries that are more than two years old and less than four years old (Date codes ranging from 3114 to 3016) should be tested as described below.
- Batteries with date code 3116 or newer (Week 31 of 2016 to present) are confirmed to be conforming and not affected by this issue.

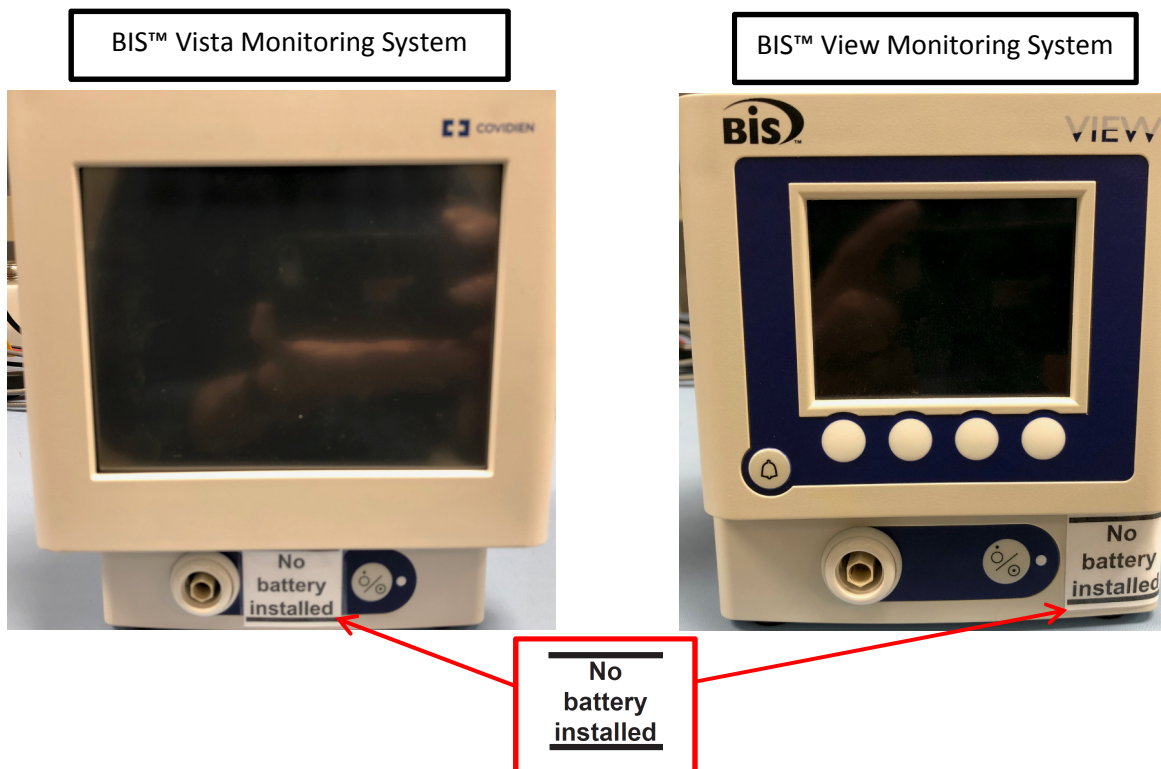
Attachment A (continued)

Section 3: Conducting the Battery Pack Capacity Test

- Charge the unit via AC power as described in the Operator's Manual for a minimum of six hours.
- Disconnect the BIS™ monitor from the wall socket and power on the monitor. After approximately 2 hours and 40 minutes have passed, check to see if the monitor remains powered. (If connecting a BISx or BISx4 to the monitor during this test, check after approximately 1 hour and 45 minutes)
- If the monitor has shut down, then the battery needs to be replaced.
- Battery packs failing this test should be removed and disposed of in accordance with institutional disposal procedures for disposal of Lithium Ion batteries. If a replacement battery is needed and is not immediately available, apply the "No Battery Installed" sticker on the BIS™ Monitoring Systems as described below.

Section 4: Applying No Battery Installed Stickers

- Included with this notification are stickers to be placed on BIS™ monitors when the battery pack is removed
- The stickers should be placed on the monitors as shown below.



Attachment A (continued)

Section 5: Safe Monitor Use Without a Battery Pack

The BIS™ Vista and View monitoring systems may be used without a battery pack only if connected to AC power source with emergency power backup system. The following instructions will ensure safe use of the monitor without a battery pack.

- The monitor must have the “No Battery Installed” label applied to the front bezel.
- The monitor will not function if it is not connected to AC power; therefore, it cannot be used for transport of patients, or other instances where it is necessary to operate it without connection to AC power.
- During use, the monitor must be plugged into an outlet that is connected to an AC source with emergency power backup system, so that it will continue to monitor patients if there is a power outage. If such a system is not available, do not use the monitor before receiving and installing your replacement battery.
- If there is an AC power failure while the monitor is not connected to an emergency power backup system, it will shut off, resulting in the following:
 - The monitor will not alarm or transmit data to an external system.
 - The monitor will not automatically restart after power is returned. The ON button must be pressed by an operator.
 - The last 4 minutes of measured patient data may not be recorded in monitor trend memory.

Section 6: Disposal of Battery Packs

The battery packs for the BIS™ Vista and View monitoring systems contain Lithium-Ion cells. Disposal of these battery packs should be done in accordance with your facility's procedures.

Field Corrective Action Customer Acknowledgement Form
Record of Disposed Battery Packs
BIS™ Monitoring Systems

Please complete this form in its entirety.

Date: _____
Name of Person Completing this form: _____ Title: _____
Direct Phone #: _____ Email: _____
Account Name: _____ Medtronic Account Number: _____
Account Address: _____
City: _____ State: _____ Postcode: _____

I have read and understand the instructions provided and acknowledge receipt of the August, 2018, Urgent Field Safety Notice regarding the batteries used with the BIS™ Vista and View monitoring systems by signing below. I also agree to further distribute and communicate this important information within my facility and to any other facilities to which I have distributed BIS™ Vista and View monitoring systems.

Name: (print) Signature: Telephone: Date:

No Inventory at my location (Please check): _____

Battery Packs indicated above have been disposed of according to the user facility procedure for disposal of Li Ion batteries

Information related to battery packs <u>at your location(s)</u>		
Number of battery packs	Location (Name of Department)	Address

Please fill out the table and information below if you distributed the BIS™ monitoring systems outside of your facility.

Name of User/ Location: _____
Address: _____
City: _____ Postcode: _____

Information related to battery packs <u>you distributed</u>		
Number of battery packs	Location (You distributed To)	Address

Please attach additional pages as needed.

If you have any questions regarding this field corrective action notice, please contact your Medtronic Representative
Please fax the completed form to +44 1923 205190 or email to rs.regulatoryuk-ire@Medtronic.com