Medtronic (Schweiz) AG
Talstrasse 9
3053 Münchenbuchsee
www.medtronic.com

# Urgent Field Safety Notice

## HVAD™ System Useful Life IFU and PM Update

Customer Notification

October 2023

**Medtronic Reference: FA1372**

EU Manufacturer Single Registrations Number (SRN): US-MF-000019976

Dear Madam/Sir,

Medtronic is writing to inform you of upcoming updates to the HVAD™ system instructions for use (IFU) and patient manual (PM). These updates will clarify (1) the conditions under which an HVAD [Controller Fault] alarm may sound and the recommended troubleshooting actions and (2) instructions relating to the useful life of the HVAD system components. The anticipated availability of the updated IFU and PM is dependent upon your country regulatory approval. Your Medtronic representative will notify you when the IFU and PM are available for your country. Medtronic is not requesting any return of product from your facility.

**Issue Description:**

As of 15 August 2023, Medtronic has received eight (8) complaints relating to inadequate information regarding useful life content within the IFU or PM. Of the eight (8) complaints, no patient complications were reported.

A high-level summary of the updated content and recommendations regarding the care and management of HVAD system components is provided below.

- A [Controller Fault] alarm is designed to occur when the controller's internal battery reaches its end of life. This will be indicated in the logfiles and typically occurs after the controller has surpassed its expected 2-year useful life.
- If the primary controller has reached the end of its expected useful life (2 years from when it was provided to the patient), download the log files and send them to Medtronic HeartWare for analysis.
- If the back-up controller has reached the end of its expected useful life (2 years from when it was provided to the patient), take it out of service and replace it with a new controller.

- **The risk associated with the internal battery reaching its end of life is that the controller may not sound the [No Power] alarm when both power sources are disconnected. However, all other controller functions and alarms are not impacted by the internal battery reaching its end of life.**
- The clinician should assess on an individual basis if the risk associated with the internal battery end of life outweighs the risk associated with performing a controller exchange. Additionally, clinicians should consider whether the patient is at higher risk for failure/delay to restart (reference patient management recommendations per August 2023 Urgent Medical Device Communication update regarding failure/delay to restart pump events). If an elective controller exchange is deemed necessary to address a [Controller Fault] alarm due to internal battery end of life, program a new controller to use for the exchange which becomes the patient's primary controller. Following a controller exchange, evaluate the back-up controller's remaining useful life and replace as warranted.
- Instruct patients to inspect their back-up controller once a week. All four (4) connections and their pins should be inspected for dirt or debris. Patients should contact their clinician if dirt or debris are identified.
- WARNINGS have been updated in the IFU and PM.

**Actions:**

Medtronic records indicate that your facility and patients are impacted by these IFU and PM changes. As a result, Medtronic requests that you take the following actions:

- Please review the IFU and PM updates and share with patients as needed.
- This notice must be shared with all those who need to be aware within your organization or to any organization where potentially affected patients have been transferred.
- Please complete the enclosed Customer Acknowledgement Form and email to rs.dusregulatory@medtronic.com.

**Additional Information:**

Medtronic has notified the Competent Authority of your country of this action. This letter serves as a notification for your records regarding the upcoming updates to the HVAD system's IFU and PM; the content within this letter is intended to bridge the time until the new IFU and PM are available. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,
Medtronic (Schweiz) AG