Medtronic GmbH
40670 Meerbusch · Earl-Bakken-Platz 1
40639 Meerbusch · Postfach 1444
Telefon 02159/8149-0
Telefax 02159/8149-100
E-Mail: deutschland@medtronic.com
Internet: www.medtronic.de

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Urgent Field Safety Notice
HeartWare™ Ventricular Assist Device (HVAD™) System Battery Performance Update
Recall

Component Name	Active Component Number	Serial Number
Battery	1650DE	BAT974999 and below

May 2023

Medtronic Referenz: FA1265
EU Manufacturer Single Registrations Number (SRN): US-MF-000019976

Dear Ladies and Gentlemen,

This letter is a follow-up to Medtronic's existing June 2022 customer notification letter titled "Urgent Field Safety Notice" regarding the interaction between the battery configuration mode and the battery internal circuit board which can cause electrical faults within some batteries.

The purpose of this letter is to inform you that the change to the battery configuration mode to mitigate the battery electrical fault issue has been implemented, and Medtronic will begin exchanging all batteries for the new batteries with the mode change. As described in the June 2022 letter, battery electrical faults (issue #2) were caused by an interaction between the software configuration that governs the HVAD battery and an internal component. Medtronic field representatives will notify you when the new batteries are available for your site. Please note that this new configuration mode change affects the external batteries only and does not affect the controller's internal battery.

Batteries that experience an electrical fault can exhibit the following:
- Battery may not provide power to the HVAD controller.
- Battery Capacity Display may become frozen and may not accurately display the battery depletion. This could result in the following: [Low Battery] or [Critical Battery] alarms failing to occur or battery indicator lights not decreasing over time while in use.
- Battery may not accept a charge from the battery charger.
- Battery capacity display or battery indicator lights may not turn on.

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Please note that this is a separate issue from the “Bent Pins” product exchange. Please take the appropriate action below based on your site’s product exchange status:

- If your site has received batteries through the “Bent Pins” exchange (FA958, initiated 23 August 2022), you will again need to exchange all hospital and patient-owned batteries for the new batteries with this configuration mode change.
- If your site has not already exchanged the batteries through the “Bent Pins” exchange, you will need to do one exchange of all hospital and patient-owned batteries to receive new batteries that include both the changes for the “Bent Pins” communication and this configuration mode change.
- If you are unsure if your site has performed prior exchanges related to the “Bent Pins” exchange, please contact your local Medtronic field representative for assistance.

Until you receive the new batteries, you should continue to use the current batteries, along with the previously communicated Patient Management Recommendations (see below).

Clinical Complaint data:
Since 2009 there have been 1,300 complaints for battery electrical faults including 1,385 batteries out of 134,137 batteries sold (1.03%). Of these events, 1,291 resulted in no patient harm and/or asymptomatic temporary pump stops. Battery electrical faults resulted in nine (9) events where either both batteries malfunctioned or stopped providing power to the controller resulting in patient symptoms/harm. Reported patient outcomes for these events included one death, one pump exchange, one cardiac arrest, one episode of dizziness, one psychiatric episode, one cardiac arrhythmia and three instances of hospitalization.

Patient Management Recommendations

This mode change impacts the batteries - it does not impact the controller itself. **It is not necessary or recommended to change the controller due to this action.**

Please remind your patients to always keep two sources of power connected to their controller and have fully charged spare batteries available at all times.

Remind patients to acknowledge and report alarms. While a battery electrical fault might not trigger a [Low Battery] or [Critical Battery] alarm, the [Power Disconnect] alarm will still sound if no power is being provided by the battery. If a [Power Disconnect] alarm occurs while a battery is physically connected, take that battery out of service. Reference the following instructions from the patient manual:

Alarm (Line 1 on controller) **Action** (Line 2 on controller)	Meaning	Alarm Indicator	Alarm Sound
[Critical Battery] **[Replace Battery 1]**	Limited time remaining on battery connected to power source 1	**Flashing Red**	Loud Unable to mute alarm
[Critical Battery] **[Replace Battery 2]**	Limited time remaining on battery connected to power source 2		
[Low Battery 1] **[Replace Battery 1]**	Battery 1 is low	**Yellow**	Alarm gets louder after 5 minutes and even louder after 10 minutes if alarm is not muted. Able to mute alarm for 5 minutes by pressing Alarm Mute Button.
[Low Battery 2] **[Replace Battery 2]**	Battery 2 is low		
[Power Disconnect] **[Reconnect Power 1]**	Power Source 1 disconnected or defective		
[Power Disconnect] **[Reconnect Power 2]**	Power Source 2 disconnected or defective		

- WARNING! ALWAYS investigate and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.
- WARNING! ALWAYS keep a spare controller and fully charged spare batteries at a temperature between 0°C and 50°C (+32°F to 122°F) available at all times in case of an emergency

Follow the Instructions for Use (IFU) for proper power source management. Ensure that the battery capacity display lights up, battery indicator on the controller lights up, and the battery charger status light does not flash red or yellow after connecting a battery.

Inform patients to be vigilant if the battery indicator lights do not decrease over time while the battery is in use. This could be a sign of a battery electrical fault. One segment of light on the battery indicator or the battery capacity display represents approximately 25% of a battery charge, and a full battery charge lasts between 4 to 7 hours. If you observe that your indicator lights do not decrease over time, take the battery out of service.

Customer Instructions

- Complete the enclosed Customer Confirmation Form please return the form to rs.dusregulatory@medtronic.com
- Please share this notice with all those who need to be aware within your organization or to any organization where the existing product has been transferred.
- Your Medtronic Representative will reach out once new batteries are available for your site. Additional instructions will be provided for battery exchange at that time.
- At the time of battery availability in your region, you will be asked to return all unused, unexpired identified batteries in your inventory to Medtronic by working with your Medtronic representative. Used or expired patient batteries should be exchanged upon battery availability and will be disposed of locally.

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Additional Information
Medtronic has notified the Competent Authority of your country of this action.

We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative. For any additional questions you can reach out to the Medtronic Office of Medical Affairs at rs.mcsmedicalaffairs@medtronic.com.

Sincerely,
Medtronic GmbH