Medtronic HeartWare

Urgent Field Safety Notice

HeartWare™ Ventricular Assist Device (HVAD™) System Battery Performance Update

Patient Management Recommendations

June 2022

Medtronic Reference: FA1265
EU Manufacturer Single Registration Number (SRN): MF-000019976

Dear VAD Coordinator, Health Care Professional,

The purpose of this letter is to advise you of product performance issues related to the HeartWare™ Ventricular Assist Device (HVAD™) System Batteries. Medtronic is taking action to improve battery performance and address quality issues. This letter provides information on two battery performance issues as well as Patient Management Recommendations. In both situations, it is important that patients respond to all battery related alarms as described in this letter. If both batteries connected to an HVAD controller malfunction, a pump stop event could occur due to controller loss of power. A malfunction of a single battery that is connected to the HVAD controller will cause the controller to rely on the second power source to power the pump. No batteries are being requested to be returned or exchanged as part of this communication.

Issue Description:

Medtronic is taking actions to address two separate battery issues: 1) a weld defect has been identified within some batteries that can cause the battery to fail to deliver power, 2) an interaction between the battery software configuration and the battery circuit board can cause electrical faults within some batteries.

Issue 1: Weld Defect

Medtronic has identified eight (8) batteries from six (6) unique supplier lots with a nonconformance in the weld connecting the battery cells. If present, this welding nonconformance may cause the battery to malfunction and no longer provide power, or prevent the battery from holding a complete charge, or properly recharge. Three (3) of these batteries were from the same battery manufacturing lot, and in May 2022, Medtronic initiated a retrieval for this specific lot of batteries. **Your account did receive one or more of the affected batteries from this lot and have already received a communication on the process for recalling these batteries in May 2022 (Medtronic reference FA1257)**. Actions have been taken to improve control of the welding process.

If a battery experiences this malfunction during use it will trigger a [Power Disconnect] alarm. This alarm will be visible on the controller screen and in the Alarm Log tab of the HVAD Monitor. Additionally, it may be accompanied by a [Critical Battery] alarm once battery capacity reaches 10%. The Battery Indicator Light on the controller will turn off once the battery is fully depleted. Batteries that have exhibited the [Power Disconnect] alarm may be able to be recharged and temporarily recover; however, this does not permanently resolve the issue and additional [Power Disconnect] alarms and loss of power may occur if use is continued. As a reminder, a [Power Disconnect] alarm alerts the user that no power source is connected to the indicated power port or that the connected power source is defective. A [Critical Battery] alarm alerts that the indicated battery has limited time remaining.

As of 26 APR 2022, Medtronic has received seven (7) complaints, involving eight (8) batteries from six different lots, where batteries have stopped providing power or failed to hold charge. Of the seven complaints, one (1) resulted in patient death where two batteries from the lot recalled in May 2022 simultaneously malfunctioned and stopped providing power to the patient's HVAD system. The other complaints resulted in no or negligible patient harm where a single battery malfunctioned, and a second, functioning power source was connected to the HVAD system. In the complaint resulting in a patient's death, there were multiple cases of active [Power Disconnect] alarms visible on the controller screen and logged in the Alarm tab of the HVAD Monitor. Since the battery was able to temporarily recover, the battery exhibiting [Power Disconnect] alarms continued to be used over several months potentially due to confusion as to whether the battery should be removed from service.

Issue 2: Battery Electrical Faults

A battery electrical fault is a broad term used to cover conditions which may be unresolvable to the battery. Batteries that experience an electrical fault can exhibit the following:

- Battery may not provide power to the 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, and battery indicator lights do not decrease 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.

As of 19 May 2022, there have been 1,159 complaints for battery electrical faults. Of these events, 1,152 resulted in no patient harm. Battery electrical faults resulted in five (5) events where either both batteries malfunctioned or became disconnected from the controller. Reported patient outcomes varied based on a variety of factors and included one death, one pump exchange, one cardiac arrest, one episode of dizziness, and one instances of hospitalization. There were also two (2) separate events where one battery malfunctioned due to battery electrical faults where reported patient outcomes indicate two (2) separate hospitalizations.

Medtronic has identified the root cause for this issue as the interaction between the software configuration that governs the HVAD battery and an internal component (electronic chip) that causes an increase in battery electrical faults. Medtronic has replaced the internal component for all new batteries and is in the process of seeking regulatory approval to make a change to the battery software configuration.

Patient Management Recommendations:

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 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 Actions:

- Please share this letter with all those who need to be aware within your organization or to any organization where patients have been transferred.

Additional Information:

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

We appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,

Medtronic