Medtronic
Mechanical Circulatory Support
8200 Coral Sea St. NE
Mounds View, MN 55112
USA
www.medtronic.com

URGENT: MEDICAL DEVICE RECALL

UPDATE: HeartWare™ Ventricular Assist Device (HVAD™) System Battery Retrieval

January 17, 2023

Dear VAD Coordinators,

Medtronic is providing this letter as a follow-up to our May 2022 (FA1257) and June 2022 (FA1265) communications to request the retrieval of 12 batteries distributed globally for ongoing engineering analysis due to a potential weld nonconformance. Our records indicate one or more of these batteries were delivered to your facility. The serial numbers of the affected batteries are listed in Attachment A. We are requesting the return of these batteries and will replace them with new product. Actions have been taken to improve control of the welding process.

The May and June 2022 letters communicated the potential for battery weld nonconformances and provided patient management recommendations. A potential weld nonconformance could result in a battery malfunction such that power is no longer provided or the battery is prevented from holding a complete charge, or properly recharging. Battery electrical data from 2019 to present was reviewed, and this review identified batteries that have been distributed with an electrical signature that may be indicative of a weld nonconformance. Medtronic would like to retrieve these batteries to allow further engineering analysis, which is important in our efforts to continue to develop improved methods for weld issue detection. Although actions have been taken to improve control of the welding process, batteries manufactured prior to the improved weld detection methods may still be in use and it is not known if this new electrical data screen will identify all latent weld nonconformances. Therefore, it is important to continue to follow the instructions in the patient manual as highlighted in the patient management recommendations made in the May 2022 communication.

There are no new patient management recommendations since the May 2022 communication.

The May 2022 communication can be found here:
https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/heartware-medical-device-notice-battery-weld-may-2022.pdf

The June 2022 communication can be found here:
https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad-system-battery-performance-update.pdf

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. If a [Power Disconnect] alarm occurs while a battery is physically connected, that battery should be taken 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
[Power Disconnect] **[Reconnect Power 1]**	Power Source 1 disconnected or defective	**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.
[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

Customer Actions:

- Immediately identify and quarantine all affected batteries listed in Attachment A.
- Immediately notify patients with affected batteries that Medtronic is conducting this retrieval and have them remove these batteries from service.
- Please use the Patient Letter Template provided by Medtronic to communicate directly with patients
- Your Medtronic Field Representative can assist you in the return and replacement of the affected product.

- Complete the enclosed Customer Confirmation Form and follow the instructions to initiate an exchange. When complete please return the form to rs.cfqfca@medtronic.com.
- Please share this notice to all those who need to be aware within your organization or to any organization where the affected batteries has been transferred.

Additional Information:
Medtronic will notify all applicable regulatory agencies and competent authorities about this matter.

Adverse reactions or quality problems experienced with this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form from www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Sincerely,

Gail Schroeder

Vice President, Quality and Regulatory

Medtronic Mechanical Circulatory Support

Attachment A: Impacted Serial Numbers

Country	Model	Serial Number
United States	1650DE	BAT812912 BAT852357 BAT853371 BAT855648 BAT855887 BAT931960 BAT932211 BAT933823 BAT936133