

Medtronic

Mechanical Circulatory Support

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URGENT: MEDICAL DEVICE RECALL

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

May 2022

Dear VAD Coordinators,

The purpose of this letter is to advise you that Medtronic is issuing a recall of a single lot of HeartWare™ Ventricular Assist Device (HVAD™) System batteries (429 batteries total). The serial numbers of the affected batteries are listed in Attachment A. Medtronic is retrieving the affected lot of batteries listed in Attachment A for further investigation. The retrieved batteries will be replaced with new product, and actions have been taken to improve control of the welding process.

Issue Description:

This single lot of batteries has been found to have multiple occurrences of a welding defect affecting internal components within the HVAD Battery. If present, the welding defect may:


- cause the battery to malfunction and no longer provide power.
- prevent the battery from holding a complete charge or properly recharging.

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 power reaches 10%. The Battery Indicator Light on the controller will turn off once the battery power 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. A malfunction of both batteries connected to an HVAD controller could cause a pump stop event due to controller loss of power. A malfunction of a single battery that is connected to the HVAD controller could cause the controller to rely on the second power source to power the pump. As a reminder, a [Power Disconnect] alarm alerts 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 22 APR 2022, Medtronic has received two (2) complaints, involving three (3) batteries from the affected lot, where batteries have stopped providing power or failed to hold charge. Of the two complaints, one (1) resulted in patient death where two batteries from the affected lot simultaneously malfunctioned and stopped providing power to the patient’s HVAD system. The other complaint resulted in no patient harm where a single battery from the affected lot malfunctioned, but a second 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.

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 Template provided by Medtronic to communicate directly with patients
- Your Medtronic Field Representative can assist you in the return 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	BAT934844, BAT934846, BAT934848, BAT934849, BAT934850, BAT934851, BAT934852, BAT934855, BAT934857, BAT934859, BAT934861, BAT934862, BAT934863, BAT934865, BAT934866, BAT934867, BAT934868, BAT934869, BAT934870, BAT934871, BAT934873, BAT934874, BAT934875, BAT934876, BAT934877, BAT934878, BAT934880, BAT934881, BAT934882, BAT934883, BAT934884, BAT934886, BAT934887, BAT934889, BAT934891, BAT934893, BAT934894, BAT934895, BAT934899, BAT934901, BAT934903, BAT934904, BAT934905, BAT934906, BAT934908, BAT934909, BAT934910, BAT934912, BAT934914, BAT934915, BAT934916, BAT934917, BAT934918, BAT934919, BAT934920, BAT934924, BAT934927, BAT934932, BAT934935, BAT934940, BAT934979, BAT934981, BAT934982, BAT934987, BAT934988, BAT934989, BAT935032, BAT935038, BAT935039, BAT935040, BAT935042, BAT935043, BAT935051, BAT935068, BAT935074, BAT935085, BAT935089, BAT935093, BAT935094, BAT935095, BAT935098, BAT935099, BAT935100, BAT935101, BAT935102, BAT935103, BAT935104, BAT935105, BAT935106, BAT935107, BAT935108, BAT935109, BAT935112, BAT935116, BAT935117, BAT935120, BAT935122, BAT935124, BAT935127, BAT935132, BAT935133, BAT935134, BAT935136, BAT935137, BAT935138, BAT935140, BAT935141, BAT935142, BAT935143, BAT935144, BAT935145, BAT935146, BAT935147, BAT935148, BAT935149, BAT935150, BAT935151, BAT935152, BAT935154, BAT935155, BAT935156, BAT935157, BAT935158, BAT935159, BAT935160, BAT935161, BAT935162, BAT935163, BAT935164, BAT935165, BAT935166, BAT935167, BAT935168, BAT935169, BAT935170, BAT935171, BAT935172, BAT935173, BAT935174, BAT935175, BAT935176, BAT935177, BAT935178, BAT935179, BAT935180, BAT935181, BAT935182, BAT935183, BAT935184, BAT935185, BAT935186, BAT935187, BAT935188, BAT935189, BAT935190, BAT935191, BAT935192, BAT935193, BAT935194, BAT935195, BAT935196, BAT935197, BAT935198, BAT935199, BAT935200, BAT935201, BAT935202, BAT935203, BAT935204, BAT935205, BAT935206, BAT935207, BAT935210, BAT935212, BAT935213, BAT935216, BAT935217, BAT935218, BAT935219, BAT935222,

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Important Information for Patients Regarding

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

May 2022

Dear Patient,

We would like to let you know about concerns with Medtronic's HeartWare™ Ventricular Assist Device (HVAD™) System batteries, which might affect how well your system works.

Medtronic recently told our facility about a recall of a single lot of HVAD™ System batteries (429 batteries in total). The information we received from Medtronic is available on the website and can be found at: <https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance.html> posted under May 2022: Battery Weld Issue.

Some batteries in this lot have been found to have specific problems affecting the internal components. If there is an internal problem with your battery, it may:

- cause the battery to malfunction and no longer provide power.
- prevent the battery from holding a complete charge or properly recharging.

A malfunction of both batteries connected to an HVAD controller could cause a pump stop event due to loss of power. A malfunction of a single battery that is connected to the HVAD controller could cause the controller to rely on the second power source to power the pump.

Medtronic has reported to us two cases in which a patient's HVAD batteries stopped providing power or failed to hold charge. In one patient's case, there was no harm because although one battery failed, the HVAD was also connected to a second power source. Unfortunately, in another patient's case, both batteries failed, and this led to the patient's death.

Medtronic is recalling and retrieving all batteries in this specific lot. These will be replaced with a new battery.

What should you do?

- Keep and attend all your scheduled medical and device check appointments
- Always keep two sources of power connected to your controller and have fully charged spare batteries available at all times.

- ALWAYS investigate and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.
- If a [Power Disconnect] alarm occurs while a battery is physically connected, that battery should be taken out of service, and you should let us know immediately. Review 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		

How can I determine if a battery is impacted?

- Batteries have unique serial numbers (abbreviated as SN). A list of affected batteries' serial numbers is included in this communication as an attachment
- The Battery's serial number can be found on the battery label in the below image in the red box



Your VAD team will be filing a warranty claim to replace any affected batteries.

[< Insert specific instructions for returning defective batteries to your clinic here >](#)

Please contact our office at [<Insert clinic contact information>](#) to speak with your VAD team about this issue or if you have any questions.

We sincerely apologize for any difficulties this may cause you and your family.

[<Insert Physician Practice Information>](#)

< VAD clinics refer to Customer Detail Report or reach out to your Medtronic Representative for assistance in identifying Battery Serial Numbers shipped to your clinic. >

Country	Model	Serial Number
United States	1650DE	BAT934844, BAT934846, BAT934848, BAT934849, BAT934850, BAT934851, BAT934852, BAT934855, BAT934857, BAT934859, BAT934861, BAT934862, BAT934863, BAT934865, BAT934866, BAT934867, BAT934868, BAT934869, BAT934870, BAT934871, BAT934873, BAT934874, BAT934875, BAT934876, BAT934877, BAT934878, BAT934880, BAT934881, BAT934882, BAT934883, BAT934884, BAT934886, BAT934887, BAT934889, BAT934891, BAT934893, BAT934894, BAT934895, BAT934899, BAT934901, BAT934903, BAT934904, BAT934905, BAT934906, BAT934908, BAT934909, BAT934910, BAT934912, BAT934914, BAT934915, BAT934916, BAT934917, BAT934918, BAT934919, BAT934920, BAT934924, BAT934927, BAT934932, BAT934935, BAT934940, BAT934979, BAT934981, BAT934982, BAT934987, BAT934988, BAT934989, BAT935032, BAT935038, BAT935039, BAT935040, BAT935042, BAT935043, BAT935051, BAT935068, BAT935074, BAT935085, BAT935089, BAT935093, BAT935094, BAT935095, BAT935098, BAT935099, BAT935100, BAT935101, BAT935102, BAT935103, BAT935104, BAT935105, BAT935106, BAT935107, BAT935108, BAT935109, BAT935112, BAT935116, BAT935117, BAT935120, BAT935122, BAT935124, BAT935127, BAT935132, BAT935133, BAT935134, BAT935136, BAT935137, BAT935138, BAT935140, BAT935141, BAT935142, BAT935143, BAT935144, BAT935145, BAT935146, BAT935147, BAT935148, BAT935149, BAT935150, BAT935151, BAT935152, BAT935154, BAT935155, BAT935156, BAT935157, BAT935158, BAT935159, BAT935160, BAT935161, BAT935162, BAT935163, BAT935164, BAT935165, BAT935166, BAT935167, BAT935168, BAT935169, BAT935170, BAT935171, BAT935172, BAT935173, BAT935174, BAT935175, BAT935176, BAT935177, BAT935178, BAT935179, BAT935180, BAT935181, BAT935182, BAT935183, BAT935184, BAT935185, BAT935186, BAT935187, BAT935188, BAT935189, BAT935190, BAT935191, BAT935192, BAT935193, BAT935194, BAT935195, BAT935196, BAT935197, BAT935198, BAT935199, BAT935200, BAT935201, BAT935202, BAT935203, BAT935204, BAT935205, BAT935206, BAT935207, BAT935210, BAT935212, BAT935213, BAT935216, BAT935217, BAT935218, BAT935219, BAT935222, BAT935227, BAT935228, BAT935229, BAT935230, BAT935231,

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