



Mechanical Circulatory Support

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Mounds View, MN 55112
USA
www.medtronic.com



14400 NW 60th Avenue
Miami Lakes, FL 33014
USA
www.HeartWare.com

URGENT: MEDICAL DEVICE Correction

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

June 2022

Dear VAD Coordinators,

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 solely 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 nonconformance 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.

Medtronic will notify via mail all patients implanted with an HVAD device (per our records) of the battery issues and remind them of proper response to [Low Battery], [Power Disconnect], and [No Power] alarms. A copy of the patient letter has been included for your reference.

Issue 1: Weld Nonconformance

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.** The May 2022 communication can be found here: <https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance.html>. 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 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 Actions:

- Complete the enclosed Customer Confirmation Form please return the form to rs.cfqfca@medtronic.com.
- 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 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,

A handwritten signature in cursive script, appearing to read "Gail Schroeder".

Gail Schroeder

Vice President, Quality and Regulatory

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June 2022

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Issue Description:

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Medtronic will notify via mail all patients implanted with an HVAD device (per our records) of the battery issues and remind them of proper response to [Low Battery], [Power Disconnect], and [No Power] alarms. A copy of the patient letter has been included for your reference.

Issue 1: Weld Nonconformance

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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 not receive any of the affected batteries from the retrieved lot**, however we are communicating this failure to all HVAD sites to raise awareness and stress the importance of responding to alarms and removing faulty batteries from service. The May 2022 communication can be found here:

<https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance.html>.

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.

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- Battery may not accept a charge from the battery charger.
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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:

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| | | | |
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| | battery connected to power source 2 | | |
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| [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 Actions:

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

Sincerely,

A handwritten signature in cursive script that reads "Gail Schroeder".

Gail Schroeder

Vice President, Quality and Regulatory

Medtronic Mechanical Circulatory Support

URGENT: Important Information for Patients

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

June 2022,

Dear HVAD Patient,

Medtronic is writing to inform you about important information related to the batteries used with your Medtronic HVAD™ System, the device that is helping your heart pump blood to your body. This information has recently been provided to your VAD Clinical team (surgeon, physician, and VAD coordinator).

Please review all the information below and reach out to your VAD Clinical team with any additional questions on this notice.

Batteries are provided with your HVAD System and are used to power your HVAD Controller. If there is an issue with your battery, the controller is designed to provide an alarm indicating when power is not reaching the controller. Electrical issues can cause the battery to stop providing power to your controller or may prevent the battery from properly recharging or holding a charge. If this happens, your HVAD System may malfunction or stop functioning, and this could rapidly lead to serious health consequences. To lower the risk of experiencing an issue with your HVAD system due to a battery problem, it is important to follow the actions recommended below.

What should you do?

Medtronic recommends you take the following actions to lower the risk of experiencing an issue with your HVAD system caused by a battery problem:

- **Attend all scheduled medical and device check appointments.**
- **Keep two sources of power connected to the controller and have at least two fully charged spare batteries available at all times.**
- **Stop using batteries and immediately notify your VAD Clinical team if:**
 - they cause alarms,

- you notice that they have issues charging
 - they are not recognized when connected to your controller
- **Follow the instructions in your Patient Manual for proper battery management.** When you connect a battery to the controller, make sure the battery capacity display lights up and the battery indicator lights on the controller light up. **Do not use the battery if the indicator lights do not light up.** When using the battery charger, if the status light flashes red or yellow (figure 1), please follow the troubleshooting steps outlined in section 3.6 your patient manual.

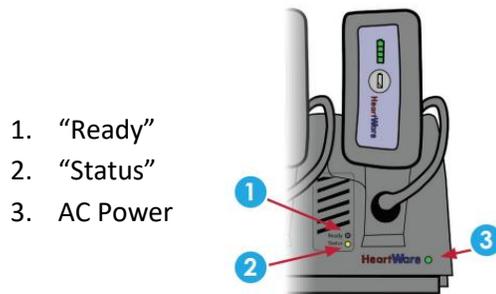


Figure 1. Battery Charger Indicators

- **Be aware if your battery capacity or battery indicator lights do not decrease over time while in use.** This could be a sign of a battery electrical fault. When reading the battery capacity (see Figure 2) or battery indicator (see Figure 3), one light indicates approximately 25% of a battery charge. A full battery charge lasts between 4 to 7 hours. **If you observe that your indicator lights do not decrease over time, stop using the battery, and reach out to your VAD Clinical team.**



Figure 2. Battery Capacity Display on Battery

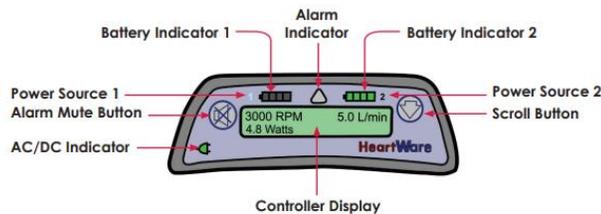


Figure 3. Battery Indicators on Controller

- **Report alarms to your VAD Clinical team.** If a [Power Disconnect] alarm occurs while a battery is physically connected to the controller. If this happens, you should **stop using that battery and contact your VAD Clinical team.** Below are the battery alarms from your 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 | | |

MAY 2022 Battery Recall

In addition, there is a specific lot of batteries that Medtronic recalled in May 2022. If you had any of the batteries from this lot, your VAD clinical team should have reached out to you about replacing those batteries.

Even if your batteries are not from this specific lot, it is still important that you take the recommended actions discussed in this letter to lower the risk of experiencing an issue with your HVAD system caused by a battery problem.

How can you find out if your battery is from the recalled lot?

- Batteries have unique serial numbers (abbreviated as SN). The battery's serial number can be found on the battery label (as indicated by the red box in the below image)



- A list of affected batteries' serial numbers is included in this communication as an attachment. Please review this list carefully to see if your battery is among those listed.
- If any of your batteries appear in the attached list, please contact your VAD team as soon as possible - they will file a warranty claim to replace any affected batteries.

Please confirm with your VAD Clinical that you have received this letter and discuss any questions about the information provided in this letter. If you need a new copy of the HVAD System Patient Manual, contact your VAD Clinical team. If you have questions after speaking with your VAD Clinical team, contact Medtronic at 1-800-635-3930. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs.

Sincerely,

Gail Schroeder

Vice President, Quality and Regulatory

Medtronic Mechanical Circulatory Support

| Country Battery Sold to | 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, |

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