

Urgent Medical Device Recall

Replacement of Medtronic HVAD™ System Power Sources, Monitor Data Cables for Controller Port Bent Pins

Component Name	Active Component Number	Serial Number
Controller AC Adapter	1425US, 1430US	CAC499999 and below
Controller DC Adapter	1440	CDC599999 and below
Battery	1650DE	BAT949999 and below
Monitor Data Cable	1575	N/A
Monitor Kit	1520US, 1521US	N/A
Controller Kit	1403US	N/A

August 23, 2022

Dear Healthcare Professional,

This letter is a follow-up to Medtronic’s February 2021 customer notification letter titled “Urgent Medical Device Notice” regarding the potential for damage or bending on the Controller port metal pins due to wear on the HVAD™ Power Cables (AC adapter, DC adapter, and batteries), and HeartWare™ Monitor data cables which is available at <https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance.html>.

The purpose of this letter is to inform you that a design change to power and data cables is being implemented. The newly designed components are available. Additionally, Medtronic is informing you of the availability of the updated Instructions for Use (IFU) and Patient Manual (PM) regarding useful life and inspection of HVAD System components (see Appendix A.1. and A.2.). Appendix B (attached) includes a visual representation of the impacted components.

Medtronic has redesigned the connector of the HVAD Controller power sources and monitor data cables using a new internal connector plug material (see image 1 below for illustration) intended to reduce the risk of damage caused by wear of the cable connectors. Over time, repeated misalignment when the power and data cables are inserted into the Controller causes wear on the power cables’ connectors and data cable connectors and may cause damage or bending on the controller ports’ metal pins. This damage can result in the inability to connect or fully lock the cable connectors to the controller, which can lead to interruptions or disconnections in power and possibly controller power loss and HVAD Pump stop, or loss of communication to the monitor. When this occurs, it may be necessary to exchange the controller to restore connections between the power sources or data cable and the controller.

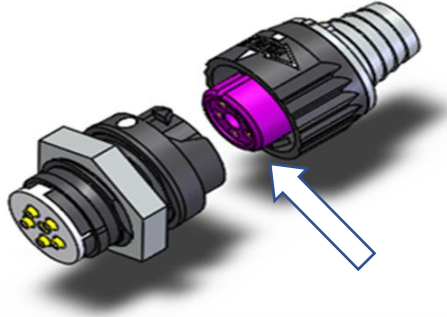


Image 1. Illustration of new core plug material (shown in purple for illustrative purposes only)

We will begin exchanging affected components (listed above) for the newly designed components when available in your region. Medtronic will notify you when components are available. Until you receive the new components, you should continue to use the current components, along with the previously communicated instructions for inspection, included in the Patient Management Recommendations, to reduce the risk of damage or bending of the HVAD Controller ports' metal pins.

As of April 30, 2022, the rate of bent pins complaint occurrence is 6.60% considering 1,022 events over 15,495 primary HVAD Controller 2.0 devices sold. Of the 1,022 complaints, Medtronic has identified 15 deaths: one (1) death related to the inability to reconnect power to the controller due to this issue, four (4) deaths due to reported driveline and/or double power source disconnections where bent pins were found upon product return and may have contributed to the event, seven (7) deaths due to complications from a controller exchange where bent pins were observed on a controller port upon product return, and three (3) deaths unrelated to this issue but where a bent pin was observed on the data port. Also identified were 12 complaints where a controller exchange was performed, and patient harms ranged from minor cardiac arrhythmias and anxiety to hospitalization and cardiac arrest. There were 995 complaints with no patient harm.

Additionally, Medtronic is informing you of the availability of the electronic Instructions for Use (eIFU). The latest update to the eIFU includes updated useful life information and the additional instructions related to inspection steps, to reduce the risk of damage or bending of the HVAD Controller port metal pins (see appendix A.1 and A.2). See Appendix C for applicable countries. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. Paper manuals are available to customers free of charge. They should arrive in 3-7 days. To view, download, print or order go to www.medtronic.com/manuals, or contact your Medtronic Field Representative.

Patient Management Recommendations

This design change impacts the power sources and data monitor cable - it does not impact the controller itself. **It is not necessary or recommended to change the controller due to this action.**

As communicated in the February 2021 letter, Medtronic has now added the following recommendations to mitigate damage to connector pins to the Instructions for Use (IFU) and Patient Manual (PM). Inspection for wear and replacement if plugs are worn is important with both the current and new design to prevent damage to the controller port if the plug becomes damaged or worn:

- **During clinic visits:** the healthcare provider or physician should inspect the following HeartWare HVAD System components: Controller AC and DC Adapters, Batteries and Alarm Adapter for wear and damage. Damage and wear include but are not limited to:
 - Connector plugs: scratches on plug face, surface irregularity, dents, chips or cracks.
 - Cables: dents, chips, or cracks.

Damaged or worn AC Adapters, DC Adapters, Batteries and Alarm Adapters should be taken out of service and replaced with new components. Damaged equipment should be reported to HeartWare and replaced.

Medtronic also wants to reinforce the following section from the existing IFU and PM:

- Instruct patients to carefully follow the guidance provided in the patient manual related to Controller Care and Battery Care. Pay attention when connecting and disconnecting power supply cables to ensure connections are not forced together without proper alignment.

Care of Your Controller

Once a week: Inspect the power connectors and connector pins on the controller for dirt or grime. This inspection can be done when you are changing power sources. Check the controller power connectors one at a time. DO NOT disconnect both power sources at the same time – your pump will stop. DO NOT disconnect the driveline to examine its connector. The only time the driveline connector should be inspected is during a controller exchange. DO NOT attempt to clean the controller connectors. If any dirt is found, report the condition to your clinician.

Care of Your Batteries

Once a week: Inspect batteries for physical damage, including the battery cable and connectors. DO NOT use batteries that appear damaged. Damaged batteries must be replaced.

- Reinforce existing Instructions for Use and Patient Manual Cautions and Warnings associated with the connections.

CAUTION: When connecting cables, DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

CAUTION: ALWAYS confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector or the power cables may come loose and result in an alarm or the pump stopping.

CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare HVAD System may not function as intended.

WARNING! DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported to HeartWare and inspected.

CAUTION: DO NOT attempt to repair or service any components of the HeartWare® System. If HeartWare® System equipment malfunctions, contact HeartWare.

Customer Instructions

- Please complete the enclosed Customer Confirmation Form and return via email to rs.mcsdataupdates@medtronic.com to the attention of CFQ FCA Team.
- Please share this notice (including the Appendix A and B and C) 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 components are available for your site. Additional instructions will be provided for component exchange at that time.
- At the time of component availability in your region, you will be asked to return all unused identified components in your inventory to Medtronic by working with your Medtronic representative. Used patient components should be exchanged upon component availability and will be disposed of locally.

Additional Information

Regulatory notification:

Medtronic is communicating this information to FDA.

Local contact details:

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail), or
- Call FDA (800) FDA-1088

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 local Medtronic Field Representative. Medtronic Patient Services is available to assist patients at 800-635-3930 (Monday-Friday, 8 a.m.-5 p.m. Central Time). For any additional questions you can reach out to the Medtronic Office of Medical Affairs at rs.mcsmedicalaffairs@medtronic.com.

Sincerely,

A handwritten signature in cursive script that reads "Gail Schroeder". The ink is a light grey color.

Gail Schroeder
Vice President, Quality
Medtronic Mechanical Circulatory Systems

Appendix A.1 IFU (Instruction for Use)

#	Change From	Change To
1	<p>WARNING! Damaged equipment should be reported to HeartWare and inspected.</p>	<p>WARNING! Damaged equipment should be reported to HeartWare and inspected replaced.</p>
2	N/A	<p>During clinic visits: the healthcare provider or physician should inspect the Batteries for wear and damage. Damage and wear include but are not limited to:</p> <ul style="list-style-type: none"> • Connector plugs: scratches on plug face, surface irregularity, dents, chips, or cracks. • Cables: dents, chips, or cracks. <p>Damaged or worn Batteries should be taken out of service and replaced.</p> <p>WARNING! Damaged equipment should be reported to HeartWare and replaced.</p>
3	N/A	<p>Expected Useful Life of the HVAD™ Controller AC and DC Adapters</p> <ul style="list-style-type: none"> • The HVAD™ Controller AC Adapter was designed and tested to function for six months. • The HVAD™ Controller DC Adapter was designed and tested to function for one year. <p>During clinic visits: the healthcare provider or physician should inspect the AC and DC Adapters for wear and damage, Damage and wear include but are not limited to:</p> <ul style="list-style-type: none"> • Connector plugs: scratches on plug face, surface irregularity, dents, chips or cracks. • Cables: dents, chips or cracks. <p>Damaged or worn AC and DC Adapters should be taken out of service and replaced.</p> <p>WARNING! Damaged equipment should be reported to HeartWare and replaced.</p>

4	N/A	<p>Expected Useful Life of the HVAD™ Monitor Data Cable</p> <p>The Monitor Data Cable was designed and tested to function for one year.</p> <p>Inspect all Monitor Data Cables periodically for wear and damage. Damage and wear include but are not limited to:</p> <ul style="list-style-type: none"> • Connector plugs: scratches on plug face, surface irregularity, dents, chips or cracks. • Cables: dents, chips or cracks. <p>Damaged or worn Monitor Data Cables should be taken out of service and replaced.</p> <p>WARNING! Damaged equipment should be reported to HeartWare and replaced.</p>
5	N/A	<p>Expected Useful Life of the HVAD™ Alarm Adapter</p> <p>The Alarm Adapter was designed and tested for one year.</p> <p>During clinic visits: the healthcare provider or physician should inspect the Alarm Adapters for wear and damage. Damage and wear include but are not limited to:</p> <ul style="list-style-type: none"> • Connector plugs: scratches on plug face, surface irregularity, dents, chips, or cracks. <p>Damaged or worn Alarm Adapters should be taken out of service and replaced.</p> <p>WARNING! Damaged equipment should be reported to HeartWare and replaced.</p>

Appendix A.2 Patient Manual

	Change From	Change To
1	<p>WARNING! Damaged equipment should be reported to your clinician and inspected.</p>	<p>WARNING! Damaged equipment should be reported to your clinician and inspected replaced.</p>
2	<p>How Long HeartWare™ HVAD™ System Equipment Should Last</p> <p>The HeartWare™ HVAD™ System components were designed and tested to function for the following periods:</p> <ul style="list-style-type: none"> • HVAD® Pump for two years. • The controller for two years. • Each fully charged battery provides approximately 4 to 7 hours of use for normal activities such as reading or watching TV. The battery may last for less time as your activity level increases. However, if any battery provides less than 2 hours of support, it should be replaced. • Similar to the battery in a cell phone (or mobile phone), the HeartWare® Batteries lose charge over time. If a fully charged battery lasts less than 2 hours, take it out of service and replace it with a new one. • During your clinic visit, your health care provider might inspect your battery and download information from your controller to determine the number of times your battery has been charged and discharged. The batteries are expected to have a useful operating life 	<p>How Long HeartWare™ HVAD™ System Equipment Should Last</p> <p>The HeartWare™ HVAD™ System components were designed and tested to function for the following periods:</p> <ul style="list-style-type: none"> • HVAD® Pump for two years. • The controller for two years. • The Controller AC Adapter for six months. • The Controller DC Adapter for one year. • The Alarm Adapter for one year. • Each fully charged battery provides approximately 4 to 7 hours of use for normal activities such as reading or watching TV. The battery may last for less time as your activity level increases. However, if any battery provides less than 2 hours of support, it should be replaced. • Similar to the battery in a cell phone (or mobile phone), the HeartWare® Batteries lose charge over time. If a fully charged battery lasts less than 2 hours, take it out of service and replace it with a new one.

<p>of 500 charge and discharge cycles. Batteries that reach the end of their useful life should be taken out of service and replaced.</p> <ul style="list-style-type: none"> • If you rotate the use of your batteries, you should get 1 year of battery service. 	<ul style="list-style-type: none"> • During your clinic visit, your health care provider might inspect your battery and download information from your controller to determine the number of times your battery has been charged and discharged. The batteries are expected to have a useful operating life of 500 charge and discharge cycles. Batteries that reach the end of their useful life should be taken out of service and replaced. • If you rotate the use of your batteries, you should get 1 year of battery service. <p>During clinic visits: the healthcare provider or physician should inspect the following HeartWare™ HVAD™ System components: Controller AC and DC Adapters, Batteries (figures 6,7 and 8) and Alarm Adapter (figure 5) for wear and damage. Damage and wear include but are not limited to:</p> <ul style="list-style-type: none"> • Connector plugs: scratches on plug face, surface irregularity, dents, chips or cracks. • Cables: dents, chips, or cracks. <p>Damaged or worn AC Adapters, DC Adapters, Batteries and Alarm Adapters should be taken out of service and replaced with new components.</p> <p>WARNING! Damaged equipment should be reported to your clinician and replaced.</p>
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Appendix B

Below are images of the devices impacted by this communication:

1. HVAD Controller AC Adapter



2. HVAD Controller DC Adapter



3. HVAD Battery



4. HeartWare Monitor Data Cable



Appendix C

Countries applicable to the eIFU

Country
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia

Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Netherlands
Norway
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
Switzerland
United Kingdom
United States