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Urgent Medical Device Notice
Medtronic HVAD™ Power Cables, Monitor Data Cables, and Controller Ports

Product Name	Product Number
Controller AC Adapter	1425, 1430
Controller DC Adapter	1440
Battery	1650, 1650DE, 1650CA-CLIN
Alarm Adapter	1450
Monitor Data Cable	1575
Controller	1400, 1401, 1403, 1407, 1407CA_CLIN

February 2021

Dear Healthcare Professional,

Medtronic is informing you of an issue related to the HeartWare HVAD Controller. Specifically, there is the potential for the Controller power cables (AC Adapter, DC Adapter, and Battery cables), HVAD™ Alarm Adapter, and HVAD™ Monitor data cables to cause damage to the HVAD™ Controller ports when inserting the cables into the Controller ports, due to misalignment of the cables to the port. Over time, repeated misalignment causes wear on the power cables and data cables and may cause damage or bending on the Controller port metal pins. This damage can result in the inability to fully lock the cable connectors into the Controller, potentially causing interruptions or disconnections in power to the Controller, which may result in controller power loss and HVAD™ Pump stop or loss of communication to the HVAD™ Monitor. When this occurs, it may be necessary to exchange the Controller to restore connections between the power sources and Controller.

To reduce the risk of damage to the HVAD™ Controller power cables and data cables that can be caused by the misalignment, Medtronic is providing more detailed instructions in an updated Instruction For Use (IFU) and Patient Manual (PM) about the criteria and frequency for inspecting the cables and Controller ports. Appendix A.1 (attached) includes excerpts from the current IFU and PM and describes the additional instructions. Appendix B (attached) includes a visual representation of the impacted components.

From 21 March 2017 to 07 January 2021, Medtronic has received 855 (2.96%) complaints related to this issue on Controller 2.0. Of the 855 complaints received, Medtronic has identified one (1) death related to the inability to reconnect power cables to the Controller due to this issue, seven (7) deaths related to complications from a controller exchange where bent pins were observed on a controller port, three (3) deaths unrelated to this issue, but where bent pins were observed on a controller data port, and six (6) cases where a controller exchange was performed and patient harms ranging from minor cardiac arrhythmias and anxiety to hospitalization and cardiac arrest were observed. No patient harm was observed in the remaining 838 cases, including 817 cases where a controller exchange was performed with no long term patient effects.

Medtronic is in the process of redesigning the HVAD™ Controller power cables (AC Adapter, DC Adapter, and Battery cables), HVAD™ Alarm Adapter, and HVAD™ Monitor data cables using a new internal connector plug material intending to reduce the risk of damage caused by this issue. Medtronic will provide further information on the material change and IFU and PM changes after the necessary regulatory approvals are obtained.

YOUR ACTIONS:
Medtronic records indicate that your facility has received affected product. As a result, Medtronic requests that you take the following actions:

- Please review the content in Appendix A.1 that provides additional instructions on the frequency of inspecting the HVAD™ Controller, HVAD™ Controller power cables (AC Adapter, DC Adapter, and Battery cables), and HVAD™ Monitor data cables.
- Please review the content in Appendix A with your patients who are currently on support.
- This notice must be shared with all those who need to be aware within your organization or to any organization where potentially affected patients have been transferred.
- Please complete the enclosed Customer Confirmation Form and email to RS.CFQFCA@medtronic.com. >

Adverse reactions or quality problems experienced with the use of 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 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

In the future, as the redesigned HVAD™ Controller power cables, HVAD™ Alarm Adapter, and HVAD™ Monitor data cables are made available, Medtronic will contact you with more information. No further actions are needed at this time. If you have questions regarding this material, please contact your Medtronic Field Representative.

Sincerely,

Gail Schroeder
Senior Director, Quality
Medtronic Mechanical Circulatory Support

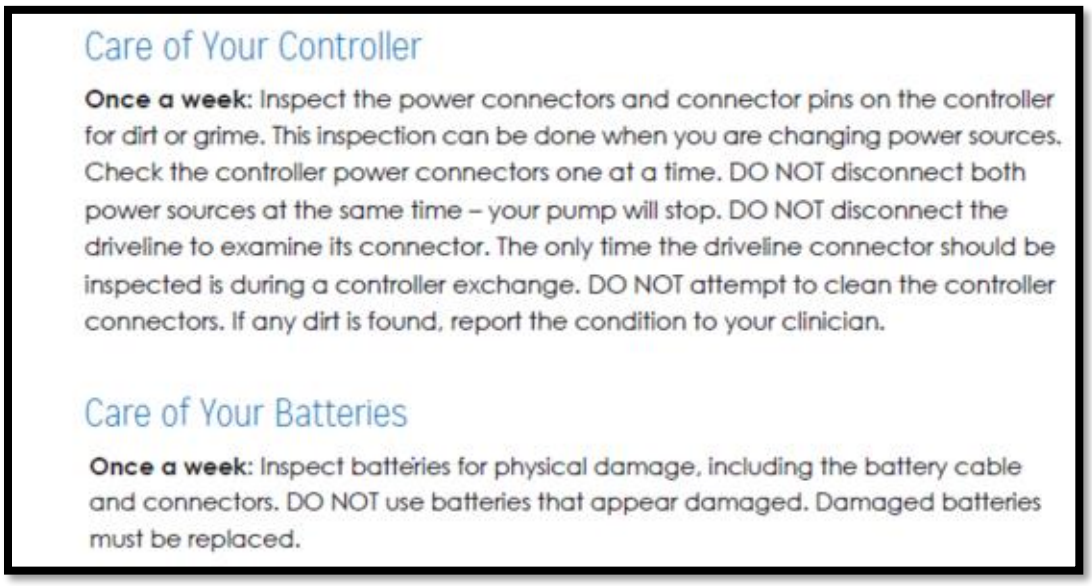
Appendix A.1 – Patient Management Recommandations

1. Medtronic is making the following recommendations in order to mitigate damage to connector pins:

- **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 your clinician and replaced.

2. 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.

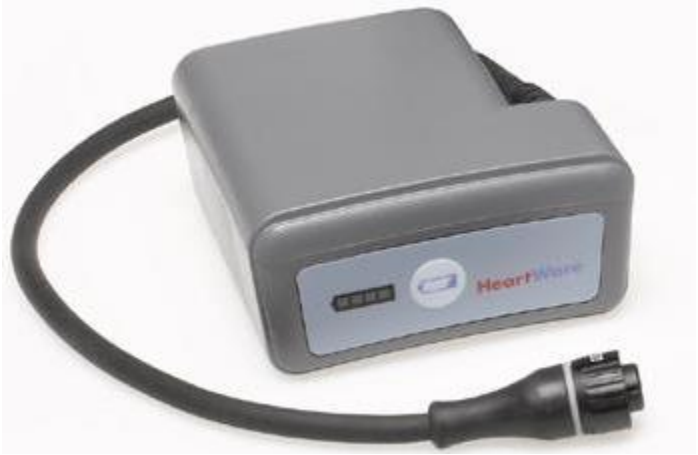
Appendix B

Below are examples of the impacted devices impacted by this communication:

1. HVAD™ Controller AC Adapter

2. HVAD™ Controller DC Adapter

3. HVAD™ Battery



4. HeartWare™ Data Cable

5. HeatWare™ Alarm Adapter

6. Controller Ports