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URGENT: MEDICAL DEVICE COMMUNICATION

HeartWare™ Ventricular Assist Device (HVAD™) System

Patient Management recommendation for power source

14 October 2022

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Health Care Professional,

Medtronic is providing this letter as a follow-up to our 22 December 2020, 02 July 2021, and 09 March 2022 communications titled "Urgent Medical Device Communication: HeartWare™ Ventricular Assist Device (HVAD™) System" where Medtronic communicated that an identified subset (defined as subgroups 1 and 2) of HeartWare™ Ventricular Assist Device (HVAD™) Systems may experience a delay to restart or failure to restart at a higher rate than the overall population of HVAD Systems. Those two distinct subgroups were from specific component manufacturing lots that have exhibited differing failure rates. Those two subgroups are referred to as "Subgroup 1" and "Subgroup 2". At two years implant duration, pumps in Subgroup 2 have a 21.8% cumulative probability of experiencing a pump stop that leads to a failure/delay to restart event and pumps in Subgroup 1 have a 2.1% cumulative probability. **There are no new HVAD devices identified as part of this communication**. Medtronic is sending this communication to all clinicians with patients currently on support.

Through ongoing investigation, it is recommended that all users worldwide, regardless of pump subpopulation, when possible, attach a controller AC adapter to the controller prior to a pump restart attempt.

Described below are the patient management recommendations previously provided regarding the delay or failure to restart issue preceded by the new recommendation added in (**BOLD**).

Patient Management Recommendations

All Patients on support

- **It is recommended that all HVAD healthcare professionals and all HVAD patients, when possible, attach a Controller AC adapter to the controller being used to restart a stopped pump (e.g., during a controller exchange connect the AC adapter to the oncoming controller). Using an AC adapter will provide consistent power and allow for the most efficient troubleshooting and restart attempts. During a sustained period of high-power consumption (i.e., when the HVAD pump is attempting to restart repeatedly), the battery may be temporarily unable to provide power.**

In consultation with our Independent Practitioner Quality Panel, composed of cardiologists, surgeons and VAD coordinators, Medtronic recommends that treatment decisions for patients with a pump identified in the subset of devices (Subgroup 1 and Subgroup 2) should be determined on an individual case-by-case basis, and that healthcare providers speak with their patients with affected devices to emphasize avoidance of unnecessary pump stops. It is important to note that this issue does not cause a running VAD to stop; rather, a failure to restart follows a pump stop event.

Reinforcing IFU

- Since failure to restart is predicated on a pump stop event, reinforce directions to patients and staff within the IFU to prevent unnecessary pump stops:
  - Do NOT disconnect the driveline from the controller.
  - NEVER disconnect both power sources (batteries and AC or DC adapter) from the controller at the same time; one external power source should remain connected to the controller at all times.
  - Do NOT exchange the controller unless explicitly directed by a High Priority alarm condition or a VAD team member.
  - Reinforce the proper response to a [Controller Fault] alarm and [Electrical Fault] alarm. These are Medium Priority alarms unrelated to an immediate pump stop. These alarms will result in the word [Call] in the Controller Display, notifying the patient to call their clinician.
  - Reinforce making good connections of power sources and the data cable in the controller ports.

Controller Exchange

- Inform patients implanted with one of these identified pumps to contact their VAD coordinator prior to any controller exchange, and to coordinate performing an exchange of controllers in a clinical setting.
- Factors that should be considered for a controller exchange include but are not limited to:
  - Whether the patient is a candidate for a pump exchange if the pump does not restart.
  - Patients with a Do Not Resuscitate (DNR) order and co-morbidities.

- Length of time the patient is expected to remain on therapy. Examples include but are not limited to bridge to transplant care, therapeutic recovery potential.
- Distance/time it will take for the patient to reach the hospital/clinic for support.
- Patient and caregiver understanding/compliance to alarm response protocols and power source management to prevent unnecessary pump stops.

When a Controller Exchange is Deemed Necessary

- If a controller exchange is deemed necessary for patients implanted with one of these identified pumps, consider the following:
  - Controller exchanges should be performed under clinician supervision in a controlled environment with the immediate ability to put the patient on hemodynamic support. Failure to restart can be fatal.
  - Upon a pump stop, a High Priority [VAD Stopped] alarm will result in the text [Change Controller] or [Connect Driveline] on the Controller Display. Once power and driveline connections are reestablished, if the pump does not restart:
    - Consider power cycling (disconnect both power sources and reconnect) of the current controller or consider a controller exchange. This will allow the restart algorithm to reset and start over. The controller automatically attempts to restart the pump a maximum of 30 times; the [VAD Stopped] alarm begins after five (5) attempts.
    - If the pump still does not restart, proceed with hemodynamic support, and possible pump exchange.

When Considering a Controller Exchange

- If a patient's controller is beyond two (2) years of service, consider proactively scheduling a controller exchange prior to the internal controller battery reaching end of life and triggering a [Controller Fault] alarm.
- Although a [Controller Fault] alarm is a Medium Priority alarm that is not related to a pump stop, proactively scheduling a controller exchange could help avoid a patient reacting to the alarm by exchanging a controller outside of a clinical setting. Per the IFU, patients should call their clinician upon receiving a Medium Priority alarm and not take any action before receiving guidance from their clinician.
  - BE ADVISED: The pump will not stop due to a Medium Priority alarm alone. A Medium Priority alarm can be temporarily muted according to the IFU to allow time to bring the patient into a clinic to determine the next steps while the pump is still functioning. A Medium Priority alarm can also be permanently silenced pursuant to the IFU; however, clinicians should consider this risk before doing so.
  - BE ADVISED: Considerations should be made on an individual case-by-case basis when deciding whether or not to electively perform a controller exchange. Depending on a number

of clinical factors that Medtronic does not have visibility to, clinicians should use their clinical judgment in proceeding with individual patient treatment decisions, as noted above.

When Considering a Pump Exchange

Routine prophylactic explant of the HVAD device is not recommended, as risks associated with explantation may outweigh the potential benefits. The decision regarding explant and exchange of the HVAD pump should be made by physicians on a case-by-case basis, considering the patient's clinical condition and surgical risks. If a physician determines that pump exchange is appropriate, we recommend exchanging to an alternative commercial LVAD.

Whether the patient is a candidate for an elective pump exchange depends on, but is not limited to:

- Whether patients have a Do Not Resuscitate (DNR) order
- Co-morbidities
- Length of time the patient is expected to remain on therapy, whether patient is bridge to transplant, or the pump is destination therapy.

Customer Actions:

- Complete the enclosed Customer Confirmation Form. When complete please scan then email or hand back to your local Medtronic field representative.
- Please share this notice with all those who need to be aware within your organization.

Additional Information:
Adverse reactions or quality problems experienced with this product should be reported your local Medtronic field representative.

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

Sincerely,

DocuSigned by:
Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 07 October 2022 | 13:29 SGT
90D0724C9B1C402A99B286449A1644B8

QARA Director
Southeast Asia and Frontier Markets Plus
Malaysia-Singapore | Indochina | Frontier Markets Plus | Thailand

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Customer Confirmation Form

Urgent Medical Device Communication

Medtronic HeartWare™ Ventricular Assist Device (HVAD) system

For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

By signing this form, I confirm that I have read the Urgent Medical Device Communication Notification Letter, dated 14 October 2022, from Medtronic regarding the HeartWare™ Ventricular Assist Device (HVAD) system listed above and will take appropriate action.

Name (print): _____ Signature: _____ Stamp: _____ Date: ☐☐ DD ☐☐☐ MMM ☐☐☐☐ YYYY

For questions, contact your local Medtronic field representative

Medtronic Internal Q & A

Urgent Medical Device Communication

Medtronic HeartWare™ Ventricular Assist Device (HVAD) system

October 2022

This document is intended to provide additional information for Medtronic personnel regarding the **Urgent Medical Device Communication** regarding availability of controllers with unapproved software and patient management recommendations for power source for the HVAD system.

1. **What is the issue?**

   Medtronic is informing all healthcare professionals (no longer only subgroups) caring for HVAD patients about a new patient management recommendation related to using a controller AC adapter if available when restarting a stopped pump.

2. **Who is receiving the customer letter?**

   Beginning 14 Oct 2022, any HCP in each region that follow patients will receive the customer letter.

3. **Why is Medtronic recommending the use of the AC adaptor?**

   During a sustained period of high-power consumption (i.e., when the HVAD pump is attempting to restart repeatedly), the battery may be temporarily unable to provide power due to reaching overcurrent discharge (OCD) safety limits. When a battery reaches its' OCD safety limits, it will power down for a period of seconds to recover and the controller will switch to the other power source. If a second battery is connected which also reaches its' OCD safety limit, loss of power to the controller may occur. Under bench testing conditions, using the controller AC adapter in place of an external battery eliminates the issue of the battery OCD protection, and that the adapters would provide continuous power during repeated pump restart attempts. Therefore, it is recommended to use an AC adapter to provide consistent power and allow for the most efficient troubleshooting and restart attempts.

4. **What is Overcurrent Discharge (OCD)?**

   Overcurrent is an excess amount of current, or amperage, in an electrical circuit. An overcurrent occurs when the current exceeds the rated amperage capacity of that circuit. An overcurrent can be caused by overloading the circuit or by a short circuit, a ground fault, or an arc fault. Overcurrent discharge limits are established to limit continued exposure to this condition.

5. **How does OCD present?**

   Overcurrent discharge is when a large amount of electrical current is drawn from the HVAD battery pack when powering the HVAD system. If that large amount of current continues to be drawn, the battery is designed to limit continued exposure to this condition by powering down for a period of seconds to recover. When this happens, a

patient will ***not*** initially receive an alarm, but the controller will switch power sources. The Power Source number light and the green bars displayed on the Battery Indicator portion of the controller, for the battery powering down, will turn off during this recovery period. The Power Source number light will illuminate on the controller for the other connected power source. After several seconds the controller will display and sound the "Power Disconnect, Reconnect Power 1 (or 2 if applicable)" alarm for the battery currently powered down. When the battery completes recovery and powers back up, the green bars on the Battery Indicator portion of the controller will turn back on. The "Power Disconnect, Reconnect Power 1 (or 2 if applicable)" alarm will no longer be displayed on the controller once the battery powers back up. Since all batteries are designed with OCD protection and if the high electrical current condition isn't resolved (i.e., the HVAD pump is still repeatedly attempting to restart) both batteries may power down to recover and a loss of power event may occur.

6. How many events have been identified where an OCD event occurred?

Through review of complaint log files for failure/delay to restart, 29 events were identified during which OCD occurred. In all cases, the OCD event was found to not impact the ultimate outcome of the event (i.e., in the course of troubleshooting and attempting to restart the pump, alternate power sources were used and additional restart attempts were made after the OCD event).

7. Was an AC adapter used in restarting any pumps where an OCD event occurred?

In the 29 events, mentioned in question eight, further analysis revealed that in eight instances a controller AC adapter was used to restart the pump. In one of those instances the pump restarted when using the controller AC adapter. The use of a controller AC adapter does not mean the pump will restart; however, it is being recommended as its use will provide consistent power and allow for the most efficient troubleshooting while attempting to restart a stopped pump.

8. What are the Patient Management Recommendations?

From the OUS letter:

Medtronic is recommending the following to customers in the customer letter:

All Patients on support

- It is recommended that all HVAD healthcare professionals and all HVAD patients, when possible, attach a Controller AC adapter to the controller being used to restart a stopped pump (e.g., during a controller exchange connect the AC adapter to the newly connected controller). Using an AC adapter will provide consistent power and allow for the most efficient troubleshooting and restart attempts. During a sustained period of high-power consumption (i.e., when the HVAD pump is attempting to restart repeatedly), the battery may be temporarily unable to provide power.

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- Whether patients have a Do Not Resuscitate (DNR) order
- Co-morbidities
- Length of time the patient is expected to remain on therapy, whether patient is bridge to transplant or the pump is destination therapy.

9. What is Medtronic asking customers to do?

From the Customer Letter…

Customer Actions:

- Complete the enclosed Customer Confirmation Form. When complete please scan then email or hand back to your local Medtronic field representative.

- Please share this notice to all those who need to be aware within your organization.

10. What and when do my customers need to sign?

In addition to the customer letter, Medtronic is sending 3 documents that require signatures:

- **Confirmation Form:**
  - **Intent:** To document that HCPs have received the customer letter
  - **Required Signatory:** HCPs are asked to sign and return

Field Representative Responsibilities

11. What are my responsibilities as a Rep?

- Assist in gathering Customer confirmations to acknowledge receipt of official communication
- Assist with completion of Physician Acknowledgement Form and Patient Consent Form.
- Assist customers in ordering new controllers
- **Confirmation Forms are due no later than 19-Jan-2023**

12. What materials will customers receive as part of the customer communication?

Customers with patients on support will receive:

- OUS Customer letter
- Confirmation Form (to be signed in ink)
- Optional Patient Letter Template

13. How is Medtronic confirming notifications were received?

Medtronic is requesting a signed confirmation form from HCPs.

14. What documentation will I receive as a Medtronic Field Representative?

Field Representatives will receive:

- Customer Letter
- Customer Confirmation Form (to acknowledge receipt of the notification letter)
- Optional Patient Letter Template
- Internal Q&A

Medtronic Actions

15. Will Medtronic post this advisory on Medtronic.com?

Yes. The "Urgent Medical Device Communication" letter will be posted for Physicians / Healthcare providers section on Medtronic.com on 13 Oct 2022 CT.

16. Is this being reported to Regulatory Agencies?

Yes. This FCA is being reported to the U.S. FDA and other applicable regulatory agencies as required.

17. Will the FDA post this as a recall?

FDA has already classified this issue as a Class 1 recall, the most severe risk to patients.

Medtronic Representative Confirmation

Form

Medtronic

Unable to Obtain Confirmation Form - Customer Site Completion
CVG-21-Q3-21 HVAD Pump Failure to Restart (Rev K, Phase VII)

Account Name: _____
Account Number: _____
Address: _____
City, State, Zip: _____

This form is for use by Medtronic Representatives to confirm Field Corrective Action (FCA) consignee notification, product returns (as applicable), or to document three attempts to communicate (one form per customer/physician).

Despite multiple attempts, Medtronic was unable to obtain a signed consignee confirmation for the account noted above. See guidelines at the end of the form.

Please document confirmation attempts in the table below.

Attempt	Date	Communication method	Contact Name and Title
1	Click or tap to enter a date.	☐Telephone ☐ Site Visit ☐ Email ☐ Other _____	Name: Title:
2		☐Telephone ☐ Site Visit ☐ Email ☐ Other _____	Name: Title:

OR
I confirm that multiple attempts were not necessary because:
☐ Account is no longer in business
☐ Account refused to sign (provide reason) _____
☐ Other (provide details) _____

As a Medtronic Representative, I certify that the information on this form is, to the best of my knowledge, complete and accurate. Medtronic Representative Name (Print): _____

Medtronic Representative Title (Print): _____

Medtronic Representative Signature (Ink):_____ Date: _____

Please send this completed form (or questions) via email to Medtronic at rs.seaandfmplusfca@medtronic.com

Important Guidelines:

- 2 documented attempts (in addition to the initial mailing) must be included in the table above,
- There should be at least 7 calendar days from first attempt to the last attempt to conform to FDA expectation of good faith attempts
- Please provide as much detail as is available

<Optional Patient Letter Template – For Clinic and Physician Use Only>

Urgent safety information
For the HeartWare™ Ventricular Assist Device (HVAD™)

October 2022

Dear Patient,

Medtronic HeartWare™ recently notified our office about important information related to a new patient management recommendation:

When possible, attach a Controller AC adapter (see Figure 1) to the controller being used to restart a stopped pump. Using an AC adapter will provide consistent power and allow for the most efficient troubleshooting and restart attempts.

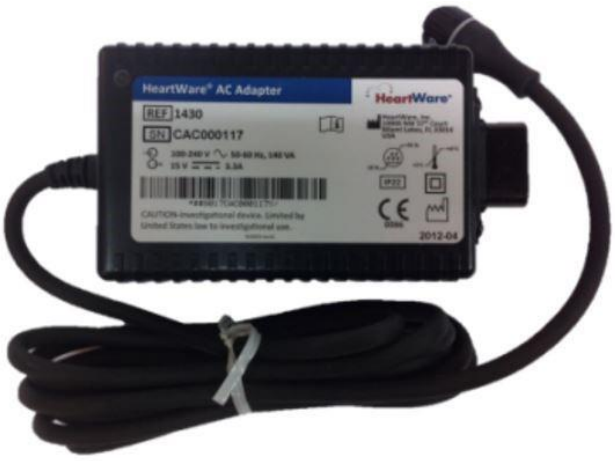

Figure 1. HVAD AC Adapter

Please note, that even if a pump has successfully restarted after a pump stop event, a delay to restart or failure to restart could be experienced in the future.

You may contact our office at _____to speak with your VAD team about
(clinic phone number)
this issue or if you have any questions.

Physician's Name: _____

Signature: _____

Date: _____