Medtronic

Urgent Field Safety Notice

HeartWare™ Ventricular Assist Device (HVAD™) System

Patient Management recommendation for power source

October 2022

Medtronic Reference: FA944

EU Manufacturer Single Registrations Number (SRN): US-MF-000019976

Dear Health Care Professional,

Medtronic is providing this letter as a follow-up to our communications titled "Urgent Field Safety Notice," 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:

- Please share this notice with all those who need to be aware within your organization.
- Please complete the enclosed Customer Acknowledgement Form and email to your Medtronic Representative

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

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

Sincerely,

Local / OU Manager