

URGENT MEDICAL DEVICE COMMUNICATION

HeartWare™ Ventricular Assist Device (HVAD™) System

Patient Management Recommendations

Model	Geography
1103	US
1104	OUS
1104JP	Japan

May 2021

Dear Physician or Healthcare Professional:

Medtronic is providing this letter as a follow-up to our December 2020 communication titled "Urgent Medical Device Communication" (attached). The December 2020 communication described an issue with implanted Medtronic HeartWare™ Ventricular Assist Device (HVAD™) Systems, where an identified subset of pumps may experience a delay to restart or failure to restart. This follow-up communication is being sent to clinicians that have patients with pumps in the sub-population that are currently implanted.

As of April 22, 2021, Medtronic has identified additional events related to the delay/failure to restart issue within the identified subset: four (4) new deaths (totaling 6) and six (6) new cases of critical harm (such as cardiac arrest or reoperation for pump exchange) (for a total of 15), two (2) new case of major harm (such as hospitalization or prolonged implant procedure due to interoperative pump exchange)(for a total of 9), and two (2) new cases of patients who had a life-threatening event (pump delay to restart) but recovered without long term effects (for a total of 10).

In Medtronic's December 2020 communication, we provided a number of patient management recommendations, provided on page 2 below. The purpose of this communication is to reinforce the same patient management recommendations and provide an update with the following information to assist in clinical decision making when considering a controller exchange:

- **In addition to the December recommendation, 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. Patient considerations to take into account include but are not limited to:**
 - **Is the patient a candidate for a pump exchange if the pump does not restart? Examples include, but are not limited to: Patient with a Do Not Resuscitate (DNR) order, 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.**
- **In addition to the December recommendation, BE ADVISED: The pump will not stop due to a Medium Priority alarm alone. A Medium Priority alarm can be temporarily muted pursuant to the IFU to allow time to bring the patient in to a clinic to determine 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.**

Please note, as stated in the previous communication, that 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. If a delay to restart or failure to restart is experienced, please notify your Medtronic representative and FDA through FDA's MedWatch Adverse Event Reporting program.

The following patient management recommendations were included in the original letter. Updates below are in (BOLD).

Patient Management Recommendations

In consultation with our Independent Practitioner Quality Panel, Medtronic continues to recommend the following actions for the subset of devices that exhibit the higher rate of failure (the identified subset of pumps from three (3) specific lots):

Reinforcing IFU

- Reinforce to patients and staff the following points from the current Instructions for Use (IFU) to avoid 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 by 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.

Informing Patients

- 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.

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 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 words [Change Controller] or [Connect Driveline] in the Controller Display. Once power and driveline connections are reestablished, if the pump does not restart:
 - Consider power cycling 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 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 prior to receiving guidance from their clinician.
 - **In addition to the December recommendation, 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. Patient considerations to take into account include but are not limited to:**
 - **Is the patient a candidate for a pump exchange if the pump does not restart? Examples include, but are not limited to: Patient with a Do Not Resuscitate (DNR) order, 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.**

- **In addition to the December recommendation, BE ADVISED: The pump will not stop due to a Medium Priority alarm alone. A Medium Priority alarm can be temporarily muted pursuant to the IFU to allow time to bring the patient in to a clinic to determine 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.**

Medtronic will notify all applicable regulatory agencies about this matter.

Your Actions

- This notice must be shared with all those who need to be aware within your organization or to any organization where patients have been transferred
- Please complete the enclosed Confirmation Form and return via 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

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have any questions, please contact your local Medtronic Representative.

Sincerely,



Gail Schroeder
Senior Director, Quality
Medtronic Mechanical Circulatory Support