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URGENT: MEDICAL DEVICE COMMUNICATION

HeartWare™ Ventricular Assist Device (HVAD™) System:
Availability of controller with unapproved software

05 December 2023 | 18:08 PST

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, 09 March 2022, 14 October 2022, and 24 August 2023 communications titled "Urgent Medical Device Communication," regarding the HeartWare™ Ventricular Assist Device (HVAD™) Systems. Medtronic communicated that an identified subset (defined as subgroups 1, 2 and 3) of HVAD pumps may experience a delay to restart or failure to restart at a higher rate than the overall population of HVAD Systems. Those three distinct subgroups were from specific component manufacturing lots that have exhibited differing failure rates. The subgroups are referred to as "Subgroup 1", "Subgroup 2" and "Subgroup 3". At three years implant duration, pumps in Subgroup 1 have a 2.7% cumulative probability of experiencing a failure/delay to restart event, pumps in Subgroup 2 have a 31% cumulative probability and pumps in Subgroup 3 have a 3.3% cumulative probability. However, Medtronic recognizes that pumps delaying or failing to restart have also occurred outside of the subgroup populations at a rate of 0.5%.

This communication is to notify you that Medtronic has developed an alternate pump start algorithm within the controller software that may help restart pumps for patients. Medtronic is making the algorithm available to any healthcare professional with a patient on HVAD support, regardless of the subset. Distribution of controllers with the modified software algorithm has been allowed by the MDA.

A. Issue Description:

The new algorithm is within the controller software and may help restart pumps if patients experience a pump stop. While the software is currently unapproved and there is very limited testing completed, some patients may have no alternative options for support if the standard controller fails to restart the pump. We have limited knowledge of the performance of this algorithm or its potential impact on other controller functions. Therefore, controllers with the modified algorithm should only be used when a controller exchange has been deemed necessary for a patient after a standard controller has been unable to restart the pump. The enclosed Physician Acknowledgement Form provides further details on the risk and benefit of using a controller with the modified software algorithm.

The software modification changes the way the controller sends power to the pump when it is starting and provides increased force to start the impeller in the pump. Based on the design of the software and the testing performed to date, the other software within and functionality of the controller are unchanged. This controller software was initially developed for patients implanted within the subset of devices as a back-up option to attempt to restart an HVAD pump when a controller exchange is required, and the standard controller is unsuccessful at restarting the pump.

Information about unapproved HVAD controller software

This unapproved controller software has not been approved as being safe or effective for use, which means it has not been tested to the same level as software that has been approved by the MDA. As stated earlier, **this unapproved controller software should ONLY be used if the pump has stopped, and the standard controller is unsuccessful at restarting the pump.** The long-term durability and functionality of a controller with the unapproved software is not yet known.

Internal bench testing, using pumps from the subset population confirmed to have the fail to restart condition, has provided mixed results suggesting that the controller with the unapproved software may have a low success rate in restarting pumps that do not restart with a standard controller.

While the potential for this unapproved software to restart a pump may be low and the impact of the software on other controller functionality has not been fully characterized at this time, we recognize that some patients may have no alternative options for support if the standard controller fails to restart the pump.

Clinical experience with unapproved controller software

There have been six instances where the unapproved controller software was used in attempting to restart a pump. The pump restarted in four of the six instances. Of the four restarts, one (1) was in

subgroup 2, one (1) was in subgroup 3 and two (2) were in the general population. For the pumps that restarted with the unapproved controller software, no adverse events have been reported from use.

- The first instance was for a patient who required a controller exchange in March 2022. This patient's pump was in the subgroup 2 population, and the patient was not a candidate for a pump exchange. During the three years preceding this event, the pump had multiple successful restarts with a standard controller. In this instance, a standard back-up HVAD controller failed to restart the pump after five attempts. The clinician then used the HVAD controller with the unapproved software and was able to restart the pump on the first attempt. Hence, the unapproved software controller became the patient's primary controller.
- The second instance was for a patient who required a controller exchange in July 2022. This patient's pump was in the general population and the patient was not a candidate for a pump exchange. The patient's pump had been off for over 18 hours. After five failed restart attempts using a standard back-up HVAD controller, the clinician exchanged to the HVAD controller with the unapproved software. After multiple attempts with the unapproved software HVAD controller, the pump did not restart. The patient was placed under hospice care.
- The third instance was for a patient who required a controller exchange in March of 2023. The patient's pump was in the subgroup 3 population. The controller exhibited a controller fault alarm, and the patient exchanged the controller. The standard back-up controller failed to restart, and the patient switched back to the primary controller where the pump successfully restarted. The patient was hospitalized for observation and the controller exhibited a controller fault alarm again. A controller exchange was performed directly to the controller with the unapproved controller software and the pump started after 5 attempts. Hence, the unapproved controller became the patient's primary controller.
- The fourth instance was for a general population patient that required a controller exchange due to a high priority alarm in April of 2023. The pump did not restart with the standard back-up controller, however restarted after 2 attempts with the controller with the unapproved software. Hence, the unapproved controller became the patient's primary controller.
- The fifth instance was for a general population patient that required a controller exchange due to a controller fault alarm, also in April of 2023. After the standard back-up controller was not able to restart the pump, a controller with the unapproved software was used and able to restart the pump. Hence, the unapproved controller became the patient's primary controller.
- The sixth instance was for a general population patient who experienced an unexpected pump stop and VAD Stop alarm at home. The patient exchanged the controller to the back-up controller, which failed to restart. The patient was transferred to the hospital where the controller with the unapproved software was attempted, but unsuccessful and the pump remained off. The next day, the patient received a pump exchange to a commercially available device.

It is not known if any of these results will be typical or representative.

Availability of unapproved controller software

If you determine in your medical judgment that having this controller on-hand at your facility is the best option to support your patients, Medtronic will make the controller available to you at no cost. Upon your request, Medtronic will provide you with a controller specifically programmed with the unapproved software for use in your facility if a patient's standard back-up controller is unable to restart his or her pump. These controllers will have additional labeling to differentiate them from a standard controller and indicate that the unapproved software is included. The additional labeling will be on both the outer packaging as well as the controller itself (see Image 1 and 2 below) and should NOT be removed or labeled over.

Image 1 – Outer Packaging of controller with unapproved software

Image 2 – Controller with Unapproved Software Label

How to request a controller with unapproved software

To request a controller with the unapproved software, please follow the steps below:

- Send a request with your hospital name and signed physician acknowledgement form to the Medtronic MCS Office of Medical affairs at: rs.mcsmedicalaffairs@medtronic.com; with your local Medtronic field representative copied (CC) on the email.
- Your Medtronic Representative will reach out with the specific steps required to order a controller with the unapproved software. Because these controllers are not fully released, if you attempt to initiate the order before reaching out to the Medtronic MCS Office of Medical Affairs, the order cannot be fulfilled.
- Please note that controllers with the unapproved software are non-CE marked product.

B. Patient Management Recommendations:

All Controllers (standard controllers and controllers with the unapproved algorithm)

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.

Use of controller with unapproved algorithm

- Controllers with this unapproved software should **only** be used when a controller exchange has been deemed necessary for a patient after a standard controller has been unable to restart the pump.
- As previously recommended, continue to avoid unnecessary pump stops. It is not known how effective the unapproved controller software will be in restarting pumps.
- Considerations should be made on an individual case-by-case basis when deciding whether or not to electively perform a controller exchange. If you determine in your medical judgment that potentially using a controller with the unapproved software is the best option for your patient, consider waiting to perform an elective exchange until a controller with the unapproved software has been provided to you.
- The availability of a controller with the unapproved software should not influence your decision to perform an elective controller exchange.
- A controller exchange will stop the pump which can result in a pump failure to restart. The controller with the unapproved software may have a low success rate in restarting pumps that do not restart with a standard controller.

- Prior to use Medtronic asks that you work with your institution's review processes (such as IRB or Risk Management Board).
- It is recommended that you discuss the unapproved controller software with your patients in advance and obtain consent in the event that the unapproved controller software is needed.

C. Customer Actions:

- Complete the enclosed Customer Confirmation Form and hand or scan then send back to your local Medtronic field representative.
- Please notify Medtronic in writing when a controller with unapproved software is provided to a patient.
- Please share this notice with all those who need to be aware within your organization.

D. Additional Information:

Medtronic has made the MDA aware of this course of action.

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

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

Sincerely,

DocuSigned by:
Siak Wah Yew
Signer Name: Siak Wah Yew
Signing Reason: I have reviewed this document
Signing Time: 05 December 2023 | 17:57 PST
99B5834721984194B5948835E56FD5D9

Quality and Regulatory Affairs Lead
Malaysia

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Customer Confirmation Form

Urgent Medical Device Communication

Medtronic HeartWare™ Ventricular Assist Device (HVAD) system

Availability of controller with unapproved software

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:	

Medtronic is asking that you sign and date this form to acknowledge receipt of the enclosed letter.

By signing this form, I confirm that I have read the Urgent Medical Device Communication Notification Letter, dated 05 December 2023 | 18:08 PST 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

Note: The addressee may continue to receive reminders of this notice until a response is received.

For questions, contact your local Medtronic field representative.