Medtronic

Urgent Field Safety Notice

HeartWare™ Ventricular Assist Device (HVAD™) System

Availability of controller with unapproved software

November 2022

Medtronic Reference: FA944

<For use in countries that follow EU MDR: EU Manufacturer Single Registrations Number (SRN): US-MF-000019976>

Dear <Health Care Professional>,

Medtronic is providing this letter as a follow-up to our <December 2020, May 2021, December 2021, and October 2022> communications titled " Urgent Field Safety Notice," regarding the HeartWare™ Ventricular Assist Device (HVAD™) Systems. Medtronic communicated that an identified subset (defined as subgroups 1 and 2) 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 two distinct subgroups were from specific component manufacturing lots that have exhibited differing failure rates. The 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 failure/delay to restart event, and pumps in Subgroup 1 have a 2.1% cumulative probability. However, Medtronic recognizes that pumps delaying or failing to restart have also occurred outside of the subgroup populations at a rate of 0.15%.

There are no new HVAD devices identified within subgroup 1 or subgroup 2 as part of this communication. 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 approved by the competent authority under derogation.>

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, the algorithm is recommended only as a rescue for those patients where the pump does not restart. 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 Notified Body. 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

To date there have been two instances where this unapproved controller software was used in attempting to restart a pump. The first instance was for a patient who required a controller exchange in March 2022. This patient's pump was in the subset population (subgroup 2), and the patient was not a candidate for a pump exchange. After five failed attempts to restart the pump using a standard HVAD controller in the exchange, the clinician used the HVAD controller with the unapproved software and was able to restart the pump on the first attempt. The second instance was for a patient who required a controller exchange in July 2022. This patient's pump was not in the subset population and the patient was not a candidate for a pump exchange. The patient's pump had been off for over 18 hours prior to the restart attempt with the modified controller software. After five failed restart attempts using a standard HVAD controller, the clinician exchanged to the HVAD controller with the unapproved software. After multiple attempts with the second HVAD controller, the pump did not restart. The patient was placed under hospice care. It is not known if either of these results will be typical.

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).

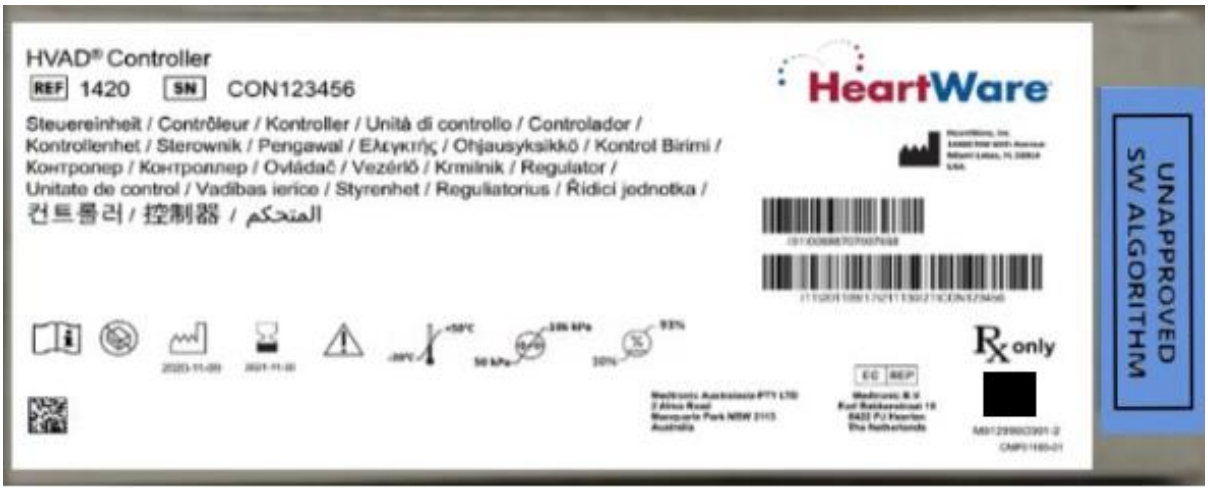

Image 1 – Outer Packaging of controller with unapproved software

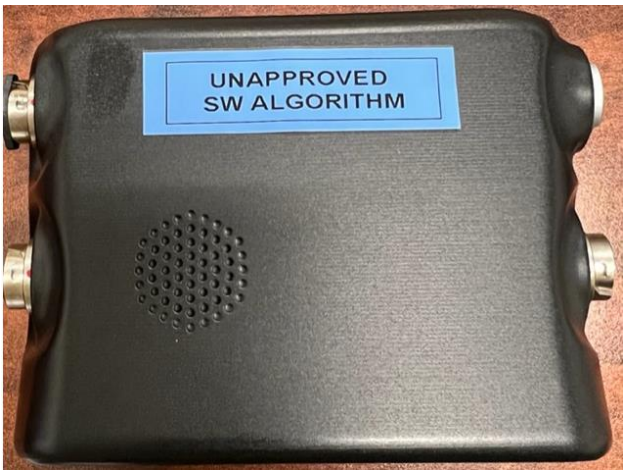

Image 2 – Controller with Unapproved Software Label

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
- 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:

- <Please complete the enclosed Customer Acknowledgment Form and email to <XXXXX>.
- Please notify Medtronic in writing when a controller with unapproved software is provided to a patient. Medtronic is obliged to inform the IGJ of each case where a controller with the 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 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 at <XXXXX>.

Sincerely,

Local / OU Manager