# Medtronic

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<span style="color:red">**URGENT:  MEDICAL DEVICE COMMUNICATION**</span>

**Availability of controller with unapproved software for the**
**HeartWare™ Ventricular Assist Device (HVAD™) System**

June 2022

Dear Health Care Professional,

Medtronic is providing this letter as a follow-up to our December 2020, May 2021, and December 2021 communications titled "Urgent Medical Device Communication," where Medtronic communicated that an identified subset 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, as well as our verbal communication that began on 18 May 2022 indicating that a new pump start algorithm has been developed which may help start these pumps.  **There are no new HVAD devices identified as part of this communication**.

**Issue Description**

Our records indicate you have a patient in this subset of pumps at higher risk for not restarting.  **This communication is to notify you that an alternate pump start algorithm within the controller software has been developed that may help restart pumps for patients within this subset.  The software is currently unapproved and there is very limited testing completed at this time to understand its performance and impact there may be on other controller functionality.**  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.  This controller software has been developed for patients implanted within the subset of devices as a back-up option to attempt to re-start an HVAD pump when a controller exchange is required, and the standard controller is unsuccessful at restarting the pump.  As communicated in the December 2021 letter, Medtronic has identified two distinct subgroups from specific component manufacturing lots that have exhibited differing failure rates.  These two subgroups are referred to as "Subgroup 1" and "Subgroup 2".

Patients in both Subgroup 1 and Subgroup 2 remain at higher risk for the pump not restarting, which is why the controller with unapproved software is being made available for this population.

**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 FDA. **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. Therefore, we are making this software available now, and further testing will continue to attempt to define the magnitude of effect of the software's change.

**Clinical experience with unapproved controller software**

To date there has been one instance where this unapproved controller software was used in attempting to restart a pump. This use 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. It is not known if this result 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 patient it can be made available to you at no cost. Upon your request, Medtronic will provide you with two HVAD controllers (one primary and one backup) specifically programmed with the unapproved software for use in your facility for patients within the subset population if the patient's standard back-up controller is unable to re-start 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).
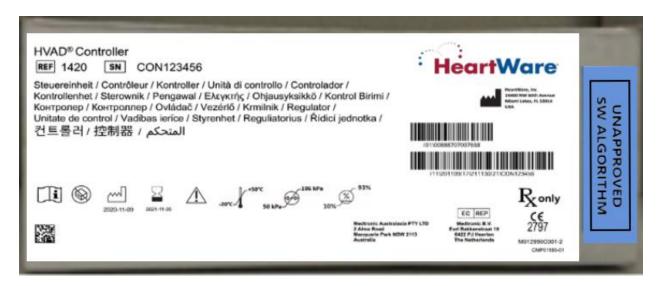
**Image 1 – Outer Packaging of controller with unapproved software**



**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 to the Medtronic MCS Office of Medical affairs at: rs.mcsmedicalaffairs@medtronic.com.  The request should include your hospital name and pump serial number of the patient within the subset population.
- 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.

- Medtronic will send you a physician confirmation form acknowledging the risks, benefits, and details on recommended use of the unapproved controller software and deliver a controller to your site as soon as possible.

**Patient Management Recommendations**

- Controllers with this unapproved software should **only** be used when a controller exchange has been deemed necessary for a patient within the previously defined subset of pumps at higher risk of failing to restart 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.
- Medtronic will also provide you with a patient informed consent form (ICF) template to be completed and signed by the patient prior to use of the unapproved controller software.  Prior to use Medtronic asks that you work with your institution's review processes (such as IRB or Risk Management Board).

**Customer Actions:**
- Complete the enclosed Customer Confirmation Form.  When complete please return the form to rs.cfqfca@medtronic.com.
- Please share this notice with all those who need to be aware within your organization.

**Additional Information**:
Medtronic has made the FDA aware of this course of action including the specific scenarios under which use of the unapproved controller might be clinically justified.

Adverse reactions or quality problems experienced with 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 from 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 appreciate your prompt attention to this matter.  If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,

Gail Schroeder

Vice President, Quality and Regulatory

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