Medtronic
Mechanical Circulatory Support
8200 Coral Sea St. NE
Mounds View, MN 55112
USA
www.medtronic.com

URGENT: MEDICAL DEVICE COMMUNICATION

HeartWare™ Ventricular Assist Device (HVAD™) System:
Approval of HVAD™ Controllers with Updated Software

August 20, 2025

Dear Health Care Professional,

As a follow-up to prior communications†, Medtronic is providing this letter to **(1)** notify you that Medtronic has obtained regulatory approval for an HVAD controller with a new pump start algorithm software that may help restart HVAD pumps that have stopped, and **(2)** provide updates to patient management recommendations to discontinue the option of power cycling during pump restart attempts. **The recommendations about when to exchange a controller have not changed with the introduction of this algorithm.**

Updated rates relating to delay or failure to restart events can be found in Appendix C. Medtronic is sending this communication to clinicians with patients currently on HVAD support in geographies that have received regulatory approval for the controller with the updated software.

Overview:

1. **Regulatory approval of HVAD controllers with updated software:**
   In that a stopped HVAD pump may not always successfully restart with a **standard controller (i.e., algorithm A controller)**, Medtronic developed an HVAD controller with **modified software (i.e., algorithm B controller)** that could be used to attempt to restart a stopped pump. This controller with modified software was only available in geographies where regulatory authorization to distribute was granted or where such authorization was not required. Based on clinical use of the algorithm B controller, an HVAD controller with **updated software (i.e., algorithm C controller),** comprised of algorithms A and B has been developed. The algorithm C controller received regulatory approval in May 2025 from the FDA.

   The algorithm C controller will initially attempt to restart a stopped pump by gradually increasing voltage to the pump's impeller using algorithm A. If the pump does not restart after two attempts using algorithm A, the software will then attempt to restart the pump using algorithm B, which immediately applies the maximum amount of voltage to start the impeller. This approach will continue to be used for the remaining 28 restart attempts before stopping.

In addition, the updated algorithm C software mitigates the controller from inadvertently resetting, which can occur with controllers that contain either algorithm A or B. This issue was discussed in the April 2024 Urgent Medical Device Communication under "Patient power source management recommendations."

There are blue line highlights on the algorithm C controller exterior to differentiate it from previous versions - algorithm A and B controllers (see Appendix A). Apart from the updates discussed, all other functions and software of the HVAD controller are unchanged.

As part of this field action, Medtronic will replace hospital shelf stock controllers and patient-issued backup controllers with the updated algorithm C controller. Thereafter, the algorithm C controller will be the only distributed version of the controller. Your Medtronic field representative will set up training with your team once the product is available for your hospital.

2. **Patient management recommendations:**
   Patient management recommendations are provided in Appendix B. Medtronic continues to recommend that considerations should be made on an individual case-by-case basis by the clinicians when deciding whether or not to electively perform a controller exchange. A controller exchange will stop the pump which can result in a pump delay or failure to restart. The algorithm C controller may not be successful in restarting all pumps.

   Recommendations regarding the use of power cycling (i.e., disconnecting and reconnecting all power sources) have been updated for the algorithm C controller. Power cycling is no longer recommended after five failed start attempts with the algorithm C controller. Performing a power cycle resets the start-up algorithm with the first two attempts using gradually increasing voltage (algorithm A) instead of continuing with the maximum voltage (algorithm B).

   Prior recommendations regarding the use of the algorithm B controller have been removed from Appendix B. Until algorithm C controller replacements are available for your hospital, clinicians should continue to reference patient management recommendations in the Urgent Medical Device Communication from April 2024.

   Once the algorithm C controller is available at your hospital, all future controller exchanges should be performed using this controller.

Customer Actions:

- Complete the enclosed Customer Confirmation Form. When complete please return the form to rs.cfqfca@medtronic.com .
- Please share this letter including appendices with all those who need to be aware within your organization.
- Please share the topics and relevant patient management recommendations content of this letter with your patients in a timely manner.
- Medtronic has provided a Patient Communication Template to facilitate your discussions with patients.

- Once the algorithm C controller is available for your hospital, you will be asked to replace and return all unopened, unexpired algorithm A controllers and all algorithm B controllers in your inventory to Medtronic by working with your Medtronic field representative.
- Once the algorithm C controller is available for your hospital, you will be asked to replace all patient-issued backup controllers. Patient-issued backup controllers with algorithm A should be disposed of locally. All patient-issued backup controllers with algorithm B should be returned to Medtronic.

Additional Information:

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,

William McNaughton
Senior Director, Quality
Medtronic Mechanical Circulatory Support

†Prior global communications: December 2020, May 2021, December 2021, October 2022, August 2023, December 2023, and April 2024.

Detailed Information:

- **Appendix A** – Visual differences between HVAD controller versions
- **Appendix B** – Patient management recommendations
- **Appendix C** – Current and cumulative delay or failure to restart events by subgroup.
- **Appendix D** – Model and serial numbers of active devices included in the existing subgroups. Device serial numbers for pumps that are confirmed to no longer be in use are not included in this list.

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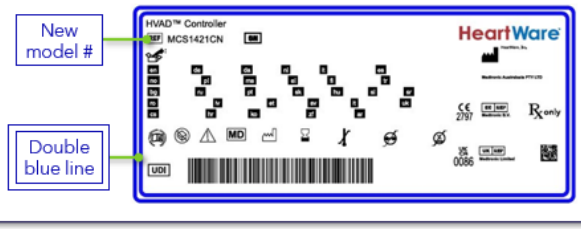
APPENDICES

Appendix A: Visual Differences Between HVAD Controller Versions

Controller version	Controller face	Controller bottom label
Current controllers *(algorithm A & B)* (REF: 1420)		
Controller with updated software *(algorithm C)* (REF: MCS1421CN)		

Controller version	Controller box label
Current controllers *(algorithm A & B)* (REF: 1420)	
Controller with updated software *(algorithm C)* (REF: MCS1421CN)	

Appendix B: Patient Management Recommendations

The recommendations about when to exchange a controller have not changed with the introduction of the algorithm C controller. Medtronic recommends that treatment decisions for all patients should be determined on an individual case-by-case basis, and that healthcare providers prepare an individualized patient management plan for each subgroup patient, especially patients in subgroup 2. Controller exchanges should be performed in a clinical setting unless directed by a high priority alarm or your VAD clinical team.

It is recommended that healthcare providers speak with their patients to emphasize avoidance of unnecessary pump stops and reinforce education regarding device management and alarm troubleshooting on a regular basis. It is important to note that this issue does not cause a running pump to stop; rather, a failure to restart may follow a pump stop event.

A controller AC adapter should be attached to any controller being used to restart a stopped pump. Using an AC adapter will provide consistent power for restart attempts. If a controller AC adapter is unavailable, connect two fully or partially charged batteries to the controller as soon as possible during any pump restart attempt.

Additionally, during sustained periods of high-power consumption with repeated start attempts while on battery power only, the batteries may be temporarily unable to provide power. This is a safety design of the batteries. Using an AC adapter will avoid this issue and provide consistent power.

<u>Reinforce the HVAD system patient manual (PM) and instructions for use (IFU)</u>

Since failure to restart events are based on a pump stop event, reinforce directions within the PM and IFU to patients and staff to prevent unnecessary pump stops:

- Do NOT disconnect the driveline from the controller.
- ALWAYS ensure two power sources are connected to 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.

If current versions of the HVAD system patient manual (PM) and instructions for use (IFU) are required, please contact your Medtronic field representative.

<u>When Considering a Controller Exchange</u>

- 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.

  - The length of time the patient is expected to remain on therapy. Examples include but are not limited to bridge to transplant status and/or therapeutic recovery potential.
  - Distance and time it will take for the patient to reach the hospital/clinic for support.
  - Patient and caregiver understanding and compliance with alarm response protocols and power source management to prevent unnecessary pump stops.
- 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.
- 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 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 by the VAD team using a HeartWare monitor; however, clinicians should consider the associated risks before doing so.
- A controller exchange will stop the pump which can result in a pump failure to restart. The updated controller (algorithm C) may not be successful in restarting all pumps.

<u>When a Controller Exchange is Deemed Necessary</u>

- Inform patients to contact their VAD coordinator prior to any controller exchange, and to coordinate performing an exchange of controllers in a clinical setting unless directed by a high priority alarm.
- **Controller exchanges for subgroup patients should be performed under clinician supervision in a controlled environment with the immediate ability to support the patient hemodynamically.**
- **Once the algorithm C controller is available at your hospital, all future controller exchanges should be performed using this controller.**
- When performing a controller exchange:
  - Ensure a controller AC adapter is attached as one of the power sources, when possible.
  - If a controller AC adapter is unavailable, connect two charged batteries to the controller as soon as possible during any pump restart attempt.
  - If the pump does not restart after five (5) attempts a high priority [VAD Stopped] alarm will be triggered. The controller automatically attempts to restart the pump a maximum of 30 times.
    - Power cycling (i.e., disconnecting and reconnecting all power sources) is no longer recommended after five failed start attempts with the algorithm C controller.

Performing a power cycle resets the start-up algorithm, beginning with the first two pump attempts using gradually increasing voltage (algorithm A) instead of continuing with the maximum voltage (algorithm B).

- If the pump still does not start, proceed with hemodynamic support, and possible pump exchange.

When Considering a Pump Exchange

- Routine prophylactic explant of the HVAD pump is not recommended as risks associated with explantation may outweigh the potential benefits[1]. 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.
- Whether the patient is a candidate for an elective pump exchange depends on, but is not limited to:
  - whether the patient has a Do Not Resuscitate (DNR) order,
  - co-morbidities, and/or
  - length of time the patient is expected to remain on therapy, whether the patient is bridge to transplant, or the patient is destination therapy.

[1] Salerno CT, Jorde UP, Molina E, Cantor R, Pagani FD, Kirklin J. Elective HeartWare HVAD to HeartMate 3 Pump Exchange: Risk Mitigation or Increasing Risk? Ann Thorac Surg. 2022 Dec 23:S0003-4975(22)01610-1. doi: 10.1016/j.athoracsur.2022.12.023. Epub ahead of print. PMID: 36572060.

Appendix C: Current and Cumulative Delay or Failure to Restart Rates

Tables 1 and 2 summarize pump populations and as of March 2025 current cumulative event totals for the issue of HVAD pump delay or failure to restart:

Group	Cumulative # of Pumps Distributed	Cumulative Event Totals	Cumulative Related Death Events
Subgroup 1	316	13	4
Subgroup 2	174	47	15
Subgroup 3	1,026	55	16
General Population	21,511	168	37
Totals	**23,027**	**283**	**72**

Table 1: Cumulative event data by pump population

Category	# of Events
Death	35
Reoperation with VAD exchange	21
VAD Thrombus	2
Pump Exchange during initial HVAD implant	4
Outflow Graft Occlusion	1
Cardiac Arrest	1
Hospitalization	16
Worsening Heart Failure	1
Neurological	2
Hypoperfusion	1
Asymptomatic VAD stop event	31
Total # of Events	**115**

Table 2: Total number of events categorized for Subgroups 1, 2 and 3

Table 3 below presents as of March 2025, the cumulative probabilities of experiencing a pump stop resulting in either a delay or failure to restart, or a delay or failure to restart leading to a device exchange, decommission, or death by three years post-implant. These probabilities are similar to what have been previously communicated.

Group	Patients on support globally	Cumulative probability of experiencing a pump stop resulting in delay or failure to restart by 3 years post-implant	Cumulative probability of device exchange, decommission, or death due to a delay or failure to restart pump event by 3 years post-implant
Subgroup 1	17	2.7%	1.4%
Subgroup 2	8	31.0%	27.0%
Subgroup 3	~154	5.3%	3.7%
General Population	~1,141	0.5%	0.2%

Table 3. Cumulative probabilities for each subgroup and general population by 3 years post-implant

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Appendix D: Serial numbers of delivered devices by country

Note: The below lists for each subgroup population only include devices that Medtronic has either confirmed to be active or has not confirmed to be inactive as of 30-April-2025. The lists below do not include confirmed inactive pumps, and accordingly, are not all inclusive of all affected pumps ever sold/implanted.

Devices in Subgroup 1

Country	Model Number	Serial Number
United States	1103	HW31041, HW31099, HW31181, HW31191, HW31344, HW31613, HW31785, HW32417, HW40169

Devices in Subgroup 2

Country	Model Number	Serial Number
United States	1103	HW35425

Devices in Subgroup 3

Country	Model Number	Serial Number
United States	1103	HW40875, HW40902, HW40916, HW41044, HW41076, HW41077, HW41098, HW41104, HW41137, HW41154, HW41158, HW41388, HW41394, HW41400, HW41410, HW41419, HW41421, HW41424, HW41427, HW41432, HW41435, HW41441, HW41453, HW41456, HW41459, HW41468, HW41497, HW41519, HW41529, HW41548, HW41577, HW41578, HW41603, HW41616, HW41627, HW41630, HW41657, HW41664, HW41679, HW41703, HW41719, HW41731, HW41735, HW41795, HW41816, HW41820, HW41821, HW41823, HW41841, HW41844, HW41867