

Urgent Field Safety Notice

HeartWare™ Ventricular Assist Device (HVAD™) System: HVAD™ Controller Programming and Use of the Disable “VAD Stop” Alarm Button

Customer Notification

January 2025

Medtronic Reference: FA1455

Dear Healthcare Professional:

Medtronic is writing to inform you of an increase in the number of complaints related to controllers reported to be inadvertently left in manual start mode during controller exchanges. We are providing updated educational materials, which will help reinforce the steps required to program an HVAD controller using the HeartWare™ monitor. It is critical that the recommended steps be followed prior to performing a controller exchange so that the HVAD™ pump restarting is not delayed inadvertently.

Feature Description:

The Disable “VAD Stop” Alarm button on the monitor is a feature designed to silence the high priority [VAD Stopped] alarm during the programming of an HVAD controller. This alarm occurs when a controller has been powered on, but a driveline has not yet been connected to it. In addition to silencing the [VAD Stopped] alarm, this feature also disables the HVAD pump from starting automatically when a driveline is connected to the controller.

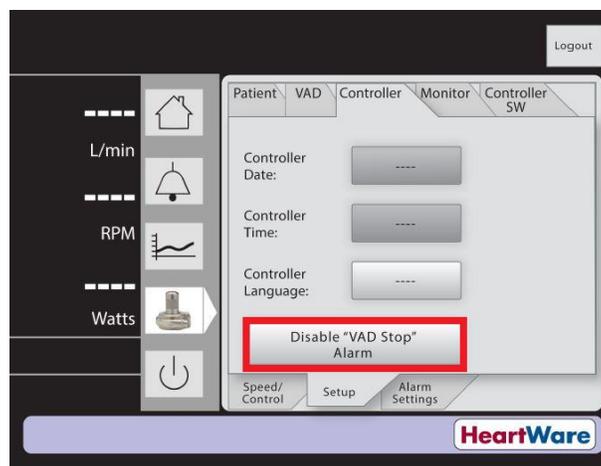


Figure 1: HeartWare monitor image highlighting in red the Disable “VAD Stop” Alarm button.

Issue Description:

HVAD controllers inadvertently left in manual start mode during a controller exchange result in HVAD pumps not starting automatically once a driveline is connected to the controller. If steps for

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programming an HVAD controller are not followed correctly and a patient's driveline is connected to a controller that was not powered down after programming, the pump will not restart and could lead to patient harm. As of 21-NOV-2024, there have been 14 complaints related to this issue. In all 14 cases, the pump successfully restarted after the clinician connected the patient's driveline to a controller that was not in manual start mode. As a result, after pump off time, there were 4 reports of serious harm, including need for hospitalization, neurological dysfunction, and cardiac arrest. No deaths have been attributed to this issue.

It is recommended to power down the programmed controller and disconnect the monitor data cable before performing a controller exchange.

Medtronic requests that your team review the current HVAD system instructions for use (IFU), in addition to Appendix A which has detailed steps for programming an HVAD controller prior to performing a controller exchange. Your Medtronic field representative will also provide a digital version of the *HVAD system reference guide for clinicians* which provides an overview of the HVAD system and highlights the proper steps for programming and exchanging an HVAD controller. It is recommended that this guide be placed on every HeartWare monitor in use at your facility to ensure these materials are available to staff when performing these tasks. Please contact your Medtronic field representative if you need a copy of the IFU or would like printed copies of the reference guide ordered for your program.

Customer Actions:

Medtronic records indicate that you currently follow active HVAD patients. As a result, Medtronic requests that you take the following actions:

- Review the IFU, Appendix A, and the reference guide provided by your Medtronic field representative and share with staff.
- This notice must be shared with all those that need to be aware within your organization or to any organization where potentially affected patients have been transferred.
- Please complete the enclosed Customer Acknowledgement Form and email to rs.ranordic@medtronic.com
- Maintain a copy of this notice for your records.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,

Local / OU Manager

Appendix A

Programming or checking settings on an HVAD controller

1. Turn on the monitor by pressing the power button.
2. Connect the monitor data cable to the data port of the controller.
3. Press the System screen icon and enter password 68773.
4. Press the [Setup] tab, followed by the [Controller] tab.
5. Press the [Disable VAD Stop Alarm] button.
6. Connect a power source to either of the power connection ports of the controller. After connecting power, the yellow message box on the monitor will disappear and [VAD OFF] will appear on the monitor display.
7. Move from left to right through the tabs on the monitor and program parameters to match the patient's current controller settings:
 - [Speed/Control] tab – program speed to match current set speed
 - [Setup] [Patient] tab – program Patient ID, implant date, and current hematocrit level
 - [Setup] [VAD] tab – program pump ID, turn Lavare Cycle and Suction Response 'On' if they are currently enabled for the patient
 - [Setup] [Controller] tab – make sure date, time, and language are set
 - [Alarm Settings] tab – program the alarm limits to match that of the patient's primary controller
8. To prevent the controller from alarming as it is powered down, use one of the following options:
 - Option 1: If a red alarm adapter is available, remove the data cable from the controller and insert the alarm adapter into the data port of the controller. Then, remove power.
 - Option 2: If a red alarm adapter is not available, press and hold the Alarm Mute and Scroll buttons at the same time until a beep is heard or for at least five seconds. Then, remove power.

Note: After programming the settings, it is recommended to power down the controller and disconnect the monitor data cable before performing a nonemergent controller exchange.

Note: If the controller is not powered down after programming, the controller will remain in manual "start mode." In this case, the blue START button on the monitor under the [Speed/Control] tab must be pressed to manually start the pump after a controller exchange.