Mechanical Circulatory Support (MCS)

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

Regional Field Corrective Action Plan
(based on revision A of the global plan)

Plan developed by

Name	Title	Signature & Date
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FCA Package Approval (Denotes approval of FCA Plan and all communication documents)

Name	Title	Signature & Date
Chloe Tan	**QARA Director** Southeast Asia	Signed by: Signer Name: Chloe Tan Signing Reason: I approve this document Signing Time: 08 January 2025 | 15:31 SGT 90D0724C9B1C402A99B286449A1644B8

1. Executive Summary

The purpose of this document is to outline the intended Global Field Corrective Action (FCA) plan for initiating communications to consignees to inform them of the availability of updated educational materials which will help reinforce the proper steps required to program an HVAD controller prior to performing a controller exchange. This communication is required due to an increasing number of complaints related to controllers reported to be inadvertently left in manual start mode, which resulted in HVAD pumps not starting automatically once a driveline was connected to the controller. The approval of this plan will initiate the FCA.

- No Product Hold Order (PHO) for this issue.
- CAPA # 660445 was opened.
- Risk assessment details are available in MCS Issue Impact Assessment (IIA) for DVSA Enabled During Controller Exchange Events, document # D01205647.

2. Background

2.1. Device Description and Intended Use

Medtronic announced, on 03-Jun-2021, the stop of sale and distribution of the HVAD System indefinitely. Patients with an HVAD will continue to be supported through the life of their system using the Pioneer II peripherals.

The HeartWare™ HVAD™ System utilizes a centrifugal blood pump, the HVAD™ Pump (the "pump"), which is implanted in the pericardial space with left ventricular apex to ascending aortic cannulation for left ventricular support. The HeartWare™ HVAD™ System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned. A percutaneous driveline cable connects the pump to an external controller. The controller regulates pump function and monitors the system. The controller requires two power sources for safe operation: either two batteries, or one battery and an AC adapter or DC Adapter. While active, patients will typically use two batteries. While relaxing or sleeping, patients should use power from an electrical outlet (AC Adapter) because it provides power for an unlimited period of time.

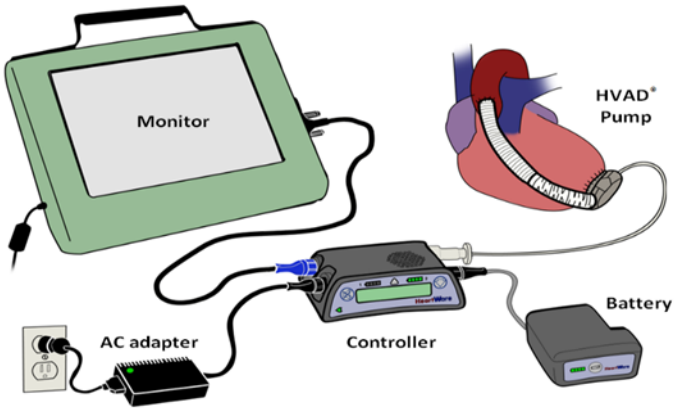

Figure 1. HeartWare™ HVAD™ System

The monitor as shown in Figure 1 is a touch screen tablet PC that uses proprietary software to display system performance and permit adjustment of selected controller parameters. When connected to a controller, the monitor receives continuous data from the controller and displays real-time and historical pump information. The monitor also displays alarm conditions.

2.2. Problem Description and Technical Summary

Issue:

This IIA was initiated to assess an increase in events in relation to the Controller 2.0 Disable-VAD-Stopped-Alarm (DVSA) feature enabled via a monitor during a controller exchange event. This results in the controller with the autorun mode disabled (manual VAD start mode), and the controller cannot start the pump during a controller exchange. Per the Instructions for Use (IFU), the DVSA method is a feature to allow the programming of a controller when it is not connected to a pump (or a motor fixture). The IFU instructions state to disconnect the power sources from the controller as the final step for the DVSA method. Disconnecting power from the controller will put it into autorun mode and turn off DVSA mode. The controller is unable to start the pump if the power sources are not disconnected from a DVSA-mode enabled controller as instructed in the IFU.

Risk Assessment:

The hazard associated with this issue is HHM-14AB: Hazard H-14, Missing/ misleading information causing insufficient/ inappropriate medical intervention, with a hazardous situation of “Alarm - False negative - delay in treatment or no treatment administered due to no alarm” (HHM-14AB). HHM-14AB was chosen because if the Disable-VAD-Stopped-Alarm (DVSA) method is used via a monitor to disable the “VAD Stopped” alarm when a new controller is being programmed prior to connecting to a pump and the alarm is not re-enabled before the controller exchange is performed, the pump will not automatically start and the VAD Stop Alarm will not sound to alert the clinician that the pump is not starting. Therefore, a delay in providing VAD treatment can occur. The interrelated hazard is HHM-01CF: Hazard H01, "HVAD pump stops working and does not restart, no blood flow through pump; pump issue), for which D00300954 (Issue Impact Assessment- HVAD Pump Failure or Delay to Start/Restart) captures the risk assessment. No 01CF hazards were observed with the in-scope events. An occurrence rate calculation was performed. The observed Risk Zone of 1 aligns with the predicted Risk Zone of 2 in both the Risk Analysis Report (RAR), the clinical Failure Mode Clinical Failure Mode and Effect Analysis (cFMEA), and the Design Failure Modes & Effects Criticality Analysis (DFMECA). The harms are predicted within RAR0001 and the DFMECA. The observed harms associated with risk of the DVSA enabled during controller exchange issue event range in severity from 1-Negligible to 4-Critical. Updates to the RAR and DFMECA were recommended in revision A of this IIA and completed to clarify sequence of events and failure modes. Update to the DFMECA was recommended in revision A of this IIA and completed to align the occurrence rate with the observed occurrence rate and the RAR. Updates to the CFMEA are recommended to clarify sequence of events and failure modes and add failure modes with severity 1 and 4.

Root Cause:

There is no observed product malfunction. This situation occurs when the DVSA is enabled during programming of the controller and power is not disconnected (as instructed in the IFU) prior to the controller exchange. The root cause of this issue is being investigated in CAPA PR 660445.

Complaints:

As of 21-Nov-2024, a total of fourteen (14) controller 2.0 complaints were identified related to this issue. The events have occurred since the HVAD System received FDA approval for destination therapy.

Table 2: Complaints Related to DVSA Enabled During Controller Exchange

As of Date: 21-Nov-2024	Total Number of Complaints Related to Issue: 14		
Complaint Region**	**Number of Complaints**	**Number of Complaint Products***	**Number of Complaints with Regulatory Reports**
US	11	11	11
International	3	3	3

* Note: One complaint can have multiple affected products.
**Note: This is the region where the complaint occurred

Overall Risk Summary and Acceptability

There were 14 events in scope of this assessment for DVSA feature enabled during a controller exchange. The binomial probability method risk assessment was performed for controller 2.0 only, reflecting the current population in the field. Ten (10) of the events resulted in Negligible patient harm (Severity-1). The hazard and hazardous situation related to this issue are 14AB in RAR0001 Rev AC: Missing/ misleading information causing insufficient/ inappropriate medical intervention, Alarm - False negative - delay in treatment or no treatment administered due to no alarm. There were no in scope events in which inter-related hazard 01CF, Unplanned/unexpected HVAD Pump Stop or delay/failure to restart pump due to pump/system issue, was observed. The observed risk with in-scope events was observed to be Low/ Risk Zone 1. The predicted risk for H-14AB and inter-related hazard H-01CF goes up to Medium/ Risk Zone 2; thus, the risk of this issue is within predicted values at all severities.

The risk of the issue is determined to be ACCEPTABLE based on the rationale below:

- There is no product non-conformance or malfunction.
- Risk reduction mitigations are in place in the form of IFU literature including details on performing controller exchanges with the use of the DVSA feature.
- This issue can only occur at clinical facilities with the use of a HVAD monitor.
- The observed risk zone for events in scope of this assessment was Low/Risk Zone 1. This rate is within risk management file predictions.

2.3. Actions to be taken

A voluntary FCA will be implemented to communicate the issue to all consignees who have received affected product according to Medtronic records. See 3.1 Consignee Communications for details.

Consignees will be asked to confirm receipt of FCA notification.

Additional Medtronic Actions:

- Update applicable Medtronic website.
- Field representatives may assist consignees with the timely return of the consignee signed Consignee Confirmation Form.
- Other associated Corrective/Preventive Actions established in associated CAPA.

2.4. Distributed product in scope of this FCA by Country and Quantity

The scope of this FCA includes products listed below:

Product Name	Model #/ CFN
MONITOR 1521KR EXPLORE TECH	1521KR
MONITOR 1521TW EXPLORE TECH	1521TW
MONITOR 1521IN XPLORE TECH	1521IN
MONITOR 1521GB EXPLORE TECH	1521GB
MONITOR 1521DE EXPLORE TECH	1521DE
MONITOR 1521BR EXPLORE TECH	1521BR
MONITOR 1521IT EXPLORE TECH	1521IT
MONITOR 1521AU EXPLORE TECH	1521AU
MONITOR 1521CH EXPLORE TECH	1521CH
MONITOR 1521IL EXPLORE TECH	1521IL
MONITOR 1521CA EXPLORE TECH	1521CA
MONITOR 1521US EXPLORE TECH	1521US
MONITOR 1521JP EXPLORE TECH	1521JP
MONITOR 1520US XPLORE TECH	1520US
PACKAGED MONITOR	1500
PACKAGE MONITOR	1500AU
PKG MONITOR	1500DE
PKG MONITOR GB	1500GB
PACKAGED MONITOR	1500US
PACKAGED MONITOR	1510US
PACKAGED MONITOR	1511AR
PACKAGED MONITOR	1511AU
PACKAGED MONITOR	1511BR
PACKAGED MONITOR	1511CA
PACKAGED MONITOR	1511CH
PACKAGED MONITOR	1511DE

Product Name	Model #/ CFN
PACKAGED MONITOR	1511GB
PACKAGED MONITOR	1511IL
Packaged Monitor, India	1511IN
PACKAGED MONITOR	1511IT
PACKAGED MONITOR, JAPAN	1511JP
Pkg Monitor, Malaysia	1511MY
PACKAGED MONITOR	1520CLIN-AU
PACKAGED MONITOR	1520CLIN-DE
PACKAGED MONITOR	1520CLIN-GB
MONITOR, XPLORE TECH -	1520JP
PACKAGED MONITOR, XPLORE	1522CA
1522CA-CLIN - HEARTWARE	1522CA-CLIN

Rationale for Scope of this FCA: Product scope is documented in D01289946 that included identified consignees as an “Active” via the active sites list provided by the OU.

The table below provides an overview of the distribution and inventory status for affected units in scope of this FCA as of 19-NOV-2024 as described in the Regional Consignee List.

Country	Customer Consigned	Sold to Customer	Total
Malaysia	0	2	2
Singapore	1	1	2
Grand Total	**1**	**3**	**4**

Consignees:

Country	Active	Primary SharedCare	SharedCare	Traditional SharedCare	Grand Total
Malaysia	1	0	0	0	1
Singapore	1	0	0	0	1
Grand Total	**2**	**0**	**0**	**0**	**2**

Note: Number of consignees by country will be finalized at time of FCA closure.

Product affected by this issue and identified as in Medtronic Control is not in scope of FCA consignee activities and is listed in the table below as of 19-NOV-2024:

Country	Inactive	Internal	Scrapped Previous to FCA	Vendor	Warehouse (WH)	Trunk Stock	Grand Total
Singapore	2	0	10	0	1	0	13
Grand Total	**2**	**0**	**10**	**0**	**1**	**0**	**13**

3. Communication Plan

FCA communication documents, included as attachments and approved with this plan, are:

- Consignee Notification and Customer Confirmation Form (Consignee sign)
- Medtronic Representative Confirmation Form (UTC)

3.1. Consignee Communications

3.1.1. Regional Consignees

- Medtronic will send the Consignee Notification and Consignee Confirmation Form (or equivalent record) via a regionally approved method (e.g., courier, registered mail, hand delivery, electronic system) to each listed consignee.
- Distributors are responsible for forwarding the Urgent Medical Device Correction or Removal Letter to those consignees to which they have distributed (forwarded) impacted product. Where the distributor is the owner of the product license, distributors are responsible to notify the Regulator of the FCA.
- Follow-up communications to consignees (with assistance from field representatives as necessary) will be made until all Consignee Confirmation Forms (or equivalent record) have been received, or three unsuccessful attempts to obtain the signed confirmation certificate are documented.

Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
Consignees with Affected HeartWare™ monitor	Consignee Notification and Customer Confirmation Form	Beginning 09-JAN-2025 *or starting on the date approved by country's regulatory authority, whichever comes later*.	Mail, Other Regionally Approved Method	Local Sales & Marketing

3.2. Regulatory Body Communications

Note: See section 5.1 *FCA Plan Execution* for regulatory reporting actions.

3.2.1. U.S. FDA Reporting

This field action is considered exempt from reporting to U.S. FDA for the following reasons:

This justification has been documented in accordance with the requirements of 21 CFR Part 806 using 115-F368, *Corrections and Removals* and can be found in D01312537.

3.2.2. Regional Regulatory Body Reporting

This FCA will be reported to Notified Bodies and Regulatory Authorities regionally as required and/or applicable per local regional requirements.

4. FCA Effectiveness Check Methods

International Confirmation and Effectiveness Check Methods:

Each region or country is required to execute consignee communication and effectiveness check methods in alignment with the global plan and in accordance with local regulatory requirements. Additional regional plans may be developed that further outline actions required for completing FCA activities.

5. Field Action Plan Activity and Timing

5.1. FCA Plan Execution (Including Closure)

This section outlines FCA plan execution activities with owners and plan dates.

Activity	Responsible	Plan Date dd-mmm-yyyy
Report to local regulatory authority (if applicable)	Country RA	*within the required timeline of local regulations*
Initiate consignee communications and confirmations; including special accounts.	Local Sales & Marketing	Beginning 09-JAN-2025 *or starting on the date approved by country's regulatory authority, whichever comes later*.
Second communication attempt	Local Sales & Marketing	Beginning 07-FEB-2025
Third communication attempt	Local Sales & Marketing	Beginning 07-MAR-2025
Completion of 3rd attempt notifications (see Effectiveness Checks/Closure Criteria)	Local Sales & Marketing	21-MAR-2025
Reconciliation of all communication attempts	Center-Led FCA QA	08-APR-2025

Country/Region Closure Forms due upon confirmation – all affected Countries/Regions	Center-Led FCA QA	04-AUG-2025
Confirm FCA Status reporting aligns with Country/Region closure form	Global FCA Execution Specialists/ Center-Led FCA QA	14-AUG-2025

* If an extension was initiated / an update was made by global team, refer to the latest revision of the global plan for this FCA.

6. Closure Criteria/ Effectiveness

6.1. FCA Activities Completion Criteria/ Effectiveness Checks:

- Confirmation that 100% identified consignees were notified of the issue and/or despite three documented attempts, consignee was not located or did not provide a response (documented on Country/Region Closure Form).
- 100% of Country/Region Closure Forms are completed and returned to the Global Execution Specialist.