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URGENT: MEDICAL DEVICE CORRECTION

HVAD™ System Useful Life IFU and PM Update

26 October 2023 | 14:40 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional:

Medtronic is writing to inform you of upcoming updates to the HVAD™ system instructions for use (IFU) and patient manual (PM). These updates will clarify (1) the conditions under which an HVAD [Controller Fault] alarm may sound and the recommended troubleshooting actions and (2) instructions relating to the useful life of the HVAD system components. The anticipated availability of the updated IFU and PM is dependent upon your country/region regulatory approval. Your Medtronic representative will notify you when the IFU and PM are available for your country/region. Medtronic is not requesting any return of product from your facility.

Issue Description:

As of 15 August 2023, Medtronic has received eight (8) complaints relating to inadequate information regarding useful life content within the IFU or PM. Of the eight (8) complaints, no patient complications were reported.

A high-level summary of the updated content and recommendations regarding the care and management of HVAD system components is provided below. Further details are provided in Appendix A and B.

- A [Controller Fault] alarm is designed to occur when the controller's internal battery reaches its end of life. This will be indicated in the logfiles and typically occurs after the controller has surpassed its expected 2-year useful life.

- If the primary controller has reached the end of its expected useful life (2 years from when it was provided to the patient), download the log files and send them to Medtronic HeartWare for analysis.
- If the back-up controller has reached the end of its expected useful life (2 years from when it was provided to the patient), take it out of service and replace it with a new controller.
- **The risk associated with the internal battery reaching its end of life is that the controller may not sound the [No Power] alarm when both power sources are disconnected. However, all other controller functions and alarms are not impacted by the internal battery reaching its end of life.**
- The clinician should assess on an individual basis if the risk associated with the internal battery end of life outweighs the risk associated with performing a controller exchange (see Appendix A). Additionally, clinicians should consider whether the patient is at higher risk for failure/delay to restart (reference patient management recommendations per August 2023 Urgent Medical Device Communication update regarding failure/delay to restart pump events). If an elective controller exchange is deemed necessary to address a [Controller Fault] alarm due to internal battery end of life, program a new controller to use for the exchange which becomes the patient's primary controller. Following a controller exchange, evaluate the back-up controller's remaining useful life and replace as warranted.
- Instruct patients to inspect their back-up controller once a week. All four (4) connections and their pins should be inspected for dirt or debris. Patients should contact their clinician if dirt or debris are identified.
- WARNINGS have been updated in the IFU and PM (see appendix A and B)

Actions:

Medtronic records indicate that your facility and patients are impacted by these IFU and PM changes. As a result, Medtronic requests that you take the following actions:

- Please review the IFU and PM updates as included in Appendix A and B, respectively, and share appendix B with patients as needed.
- This notice must be shared with all those who need to be aware within your organization or to any organization where potentially affected patients have been transferred.
- Please complete the enclosed Customer Confirmation Form and hand or scan then send back to your local Medtronic field representative once completed.

Additional Information:

Medtronic is communicating this information to the appropriate regulatory agency in your country.

Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic field representative.

This letter serves as a notification for your records regarding the upcoming updates to the HVAD system's IFU and PM; the content within this letter is intended to bridge the time until the new IFU and PM are available. If you have any questions regarding this communication, please contact your local Medtronic field representative.

Sincerely,

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 26 October 2023 | 14:38 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director
Mainland and Island Southeast Asia

Appendix A - IFU summarized anticipated updates for OUS (text may change)

HVAD controller:

The [Controller Fault] alarm indicates that a controller malfunction may have occurred, but the pump is still working. The [Controller Fault] alarm is designed to also be a signal that the controller has reached the end of its expected useful life.

Patients should bring all controllers, power sources (batteries, AC and DC adapters), and alarm adapters to clinic visits. During clinic visits, the healthcare provider or clinician should ensure that the controller is within the expected useful life:

- If the primary and back-up controllers are within expected useful life (2 years from when they were provided to the patient), then continue to routinely inspect the controller connections and their pins.
- If the back-up controller has reached the end of its expected useful life (2 years from when it was provided to the patient), take it out of service and replace it with a new controller.
- If the primary controller has reached the end of its expected useful life (2 years from when it was provided to the patient), download the log files and send them to HeartWare for analysis:
    - If the log file analysis indicates that there are [Controller Fault] alarms after the end of the expected useful life, refer to the [Controller Fault] alarm instructions.
    - If the log file analysis indicates that there have been no [Controller Fault] alarms after the end of the expected useful life, the clinician should decide whether the patient can continue to use the controller:
        - In the future, there may be a [Controller Fault] alarm if the internal battery reaches its end of life. This [Controller Fault] alarm will be an active alarm that does not resolve. **The risk associated with internal battery end of life is that the controller may not sound the [No Power] alarm when both power sources are disconnected.** The clinician should assess on an individual basis if the risk associated with the internal battery end of life outweighs the risk associated with performing a controller exchange. If a controller exchange is deemed necessary to address a [Controller Fault] alarm due to internal battery end of life, program a new controller instead of using the back-up controller.

Factors that should be considered before performing a controller exchange include, but are not limited to:

- Consider whether the patient can tolerate a pump stop during the controller exchange.
- Patient and caregiver understanding/compliance of alarm responses and power source management.
- Distance/time it will take for the patient to reach the hospital/clinic for support.
- Length of time the patient is expected to remain on therapy.

If a controller exchange is deemed necessary, confirm that the remaining useful life of the back-up controller exceeds the length of time the patient is expected to remain on therapy. The expected useful life of the primary and back-up controller is 2 years from when it was provided to the patient.

A [Controller Fault] alarm is designed to occur after the end of the controller's expected useful life if there is an internal battery end of life. This will be indicated in the log files analysis. This [Controller Fault] alarm will be an active alarm that does not resolve. The alarm will continue to sound an intermittent beep unless it is permanently silenced by the clinician using a monitor. The risk associated with internal battery end of life is that the controller may not sound the [No Power] alarm when both power sources are disconnected. Thus, the clinician should assess on an individual basis if the risk associated with the internal battery end of life outweighs the risk associated with performing a controller exchange. If a controller exchange is deemed necessary to address a [Controller Fault] alarm due to internal battery end of life, program a new controller instead of using the back-up controller.

WARNING: A [Controller Fault] alarm may occur after the end of the controller's expected useful life. If the alarm is due to the controller's internal battery end of life, the controller may not sound the [No Power] alarm when both power sources are disconnected.

WARNING: Always assess if the patient can tolerate a pump stop before exchanging the controller. The pump will stop for the duration of a controller exchange.

The [Controller Fault] alarm audio can be permanently muted but this cannot be done by the patient. It requires a monitor. The patient is only able to mute the alarm for 5 min or 1 hr. Muting the alarm does not resolve the [Controller Fault] alarm.

Recommendations for back-up controller:

Once a week: Instruct the patient to inspect all 4 connections and their pins for dirt or debris. The patient should not attempt to clean the controller connectors. The patient should be instructed to contact their clinician if they notice the connectors contain dirt or debris. Exterior surfaces of the controller should be cleaned using a clean cloth. A damp cloth may be used but a wet cloth should not.

Recommendations for the HVAD batteries:

Ensure that the batteries are within their expected useful life:

- Download the controller log files to determine the number of times the battery has been charged and discharged. The expected useful life is 500 charge and discharge cycles; if the use of the batteries is rotated, this should provide patient support for 1 year. Batteries that reach the end of their expected useful life should be taken out of service and replaced. If a battery lasts less than 2 hours after being fully charged, it should be taken out of service and replaced.

Recommendations for all HVAD system components:

Inspect all HVAD system components for signs of damage. Damaged equipment should be reported to Medtronic and replaced.

The HVAD peripherals and accessories were designed and tested to function for the following periods starting from when it was provided to the patient:

HVAD system peripherals or accessories	Expected useful life (starting from when it was provided to the patient)
HVAD controller (primary and back-up)	2 years
HeartWare batteries	500 charge and discharge cycles
Controller AC adapter	6 months
Controller DC adapter	1 year
Alarm adapter	1 year
Monitor data cable	1 year
HeartWare battery charger	1 year
Carry cases (HeartWare shoulder pack, waist pack, convertible patient pack)	1 year

Appendix B – Patient Manual (PM) summarized updates

A consolidated summary of the language being added to the US PM is provided below. Note that this information may be provided within various sections of the PM as appropriate. For specific updates per section, please reach out to your Medtronic field representative to request a copy.

HVAD controller:

The [Controller Fault] alarm indicates that a controller malfunction may have occurred, but the pump is still working. The [Controller Fault] alarm is designed to also be a signal that the controller has reached the end of its expected useful life.

WARNING: A [Controller Fault] alarm may occur after the end of the controller's expected useful life. Do not exchange the controller. Always call your clinician for appropriate action. The controller may not sound the [No Power] alarm when both power sources are disconnected.

WARNING: If a controller has reached the end of its expected useful life, do not exchange your controller. Always call your clinician for appropriate action.

Recommendations for back-up controller:

Once a week, inspect all 4 connections and their pins on the controller for dirt or debris. Do not attempt to clean the controller connectors. If any dirt or debris is found, report the condition to your clinician.

Recommendations for the HVAD batteries:

Ensure that the batteries are within their expected useful life:

- Each fully charged battery provides approximately 4 to 7 hours of use for normal activities such as reading or watching TV. The battery may last for less time as your activity level increases. Similar to the battery in a cell phone (or mobile phone), the HeartWare batteries lose charge over time. If a battery lasts less than 2 hours after being fully charged, take it out of service and contact your clinician for a replacement.

Recommendations for all HVAD system components:

Inspect all HVAD system components for signs of damage. Damaged equipment should be reported to your clinician and replaced.

The HVAD system components were designed and tested to function for the following periods starting from when it was provided to you:

HVAD system peripherals or accessories	Expected useful life (Starting from when it was provided to you)
HVAD pump	2 years
HVAD controller (primary and back-up)	2 years
HeartWare batteries	500 charge and discharge cycles
Controller AC adapter	6 months
Controller DC adapter	1 year
Alarm adapter	1 year
HeartWare battery charger	1 year
Carry cases (HeartWare shoulder pack, waist pack, convertible patient pack)	1 year

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Customer Confirmation Form

Urgent Medical Device Correction

Medtronic HeartWare™ HVAD™ IFU and PM Updates

For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately.

Customer Contact Details	Medtronic Contact Details
Distributor/Hospital/Clinic/Patient name:	Name:
	Contact:
Address:	Email:

By signing this form I confirm that I have read the Urgent Medical Device Correction Notification Letter, dated 26 October 2023 | 14:40 SGT **, from Medtronic regarding the HeartWare™ Ventricular Assist Device (HVAD) System IFU and PM Updates and taken appropriate action.**

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic field representative.

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy

Note: The addressee may continue to receive reminders of this notice until a response is received.

For questions, contact your local Medtronic field representative.