Medtronic

Dear Healthcare Professional Letter

4.26.2018

HAZARD ALERT

HeartWare® Ventricular Assist Device (HVAD) System

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Medical Device Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Dear Healthcare Professional,

HeartWare Inc.(HeartWare), in consultation with the Health Sciences Authority (HSA), is issuing this letter to inform you of the introduction of an updated HVAD Controller (Controller 2.0) and the removal procedures for previous generation HVAD Controllers with serial numbers lower than CON300000, and all HeartWare DC Adapters, product code 1435 (all serial numbers), which are incompatible with the new HVAD Controller. This is to address the safety issues associated with the current HVAD controller. The removal of these HVAD Controllers and DC Adapters will occur concurrently with the introduction of the new HVAD Controller.

The HeartWare™ Ventricular Assist System (ventricular assist device (VAD)) is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare HVAD System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

Further information and recommendation

As described in the previous letters issued in July 2015 and June 2016, there was the potential for the following safety issues associated with the current HeartWare® HVAD System Controller, including:

1. Worn alignment guides, which could allow connectors to rotate or move, potentially resulting in damaged connector pins.
2. Internal "double disconnect (no power) alarm" battery failure, which could prevent the controller from sounding an alarm in the event of a complete interruption of power.
3. Loose power and data connectors, which could allow the ingress of fluid, resulting in controller malfunction.

The new HVAD Controller includes enhancements to address these potential safety issues, including:

1. Strengthened power and serial port alignment guides to reduce the incidence of wear that could lead to damaged connector pins.
2. Functionality that monitors internal battery performance and sounds an alert when the internal battery is nearing its end of life.

3. Redesigned connectors and housing to prevent the risk of connectors loosening and moisture ingress.

In addition, the new HVAD Controller introduces upgraded internal circuitry designed to improve overall device reliability.

While HeartWare recommends that all patient HVAD Controllers be exchanged, clinicians should weigh the benefits of the updated HVAD Controller against the risks of a controller exchange procedure. Based on data reported to HeartWare, 0.2% of patients who underwent a controller exchange experienced a serious adverse event that required additional intervention. Serious adverse events reported were inclusive of neurological events, events requiring resuscitative efforts, and death due to pump failing to restart after the controller exchange.

As a reminder, as with all HVAD Controllers, continue to reinforce the following with your patients and staff at all opportunities:

- Patients should continue to have a backup HVAD Controller ready at all times in the event of a primary HVAD Controller failure.
- *Staff only:* The driveline extension cable is to be used during the pre-implant test only. It is not intended to be used after the pump is implanted in the patient.
- It is important to maintain dual power sources as described in the product labeling. While the enhanced HVAD Controller mitigates the potential safety issues mentioned above, we continue to monitor events related to intermittent power disconnects that results in power switching or momentary power loss if only one power source is connected to the controller. Incidences of unexpected power switching should be reported to HeartWare for investigation and analysis.

Advisory to Healthcare Professionals

With the introduction of the HVAD Controller modifications described, HeartWare requires that your site be trained by your local HeartWare representative on the new HVAD Controller prior to allowing distribution and use to occur at your hospital and with your patients. Your HeartWare Representative will work with you to identify a time that is best for your facility. HeartWare requests that you complete the following actions in the order below:

1) **Review** the enclosed notice and forms and **forward** the notice to those individuals within your organization who need to be aware of its contents.

2) **Complete, sign,** and **return** the "Acknowledgement Form" to HeartWare within thirty (30) days of receipt of this letter.

3) **Complete Training.** Training will cover the new product labeling including the Instructions for Use and Patient Manual. This training will be scheduled and conducted by your HeartWare Representative and is required before new HVAD Controllers will be distributed

to your hospital. There may be a period of weeks to months between receipt of this letter and the date individuals at your site are trained.
Patients must be educated on using the new HVAD Controller by hospital staff who have received training from a HeartWare representative. Do not exchange current HVAD Controllers and DC Adapters until after your site is trained.

4) **Quarantine and replace** affected HVAD Controllers, DC Adapters, Instructions for Use, Emergency Responder Guides and Patient Manuals in hospital inventory after training is complete.

   For every patient, quarantine and replace the following under clinical supervision in an environment where appropriate support equipment is readily available:
   - Primary and Backup HVAD Controller;
   - Affected DC Adapters; and
   - Patient Manual and Emergency Responder Guide.

   Clinicians are reminded not to perform an HVAD Controller exchange during an active electrical fault alarm as the HVAD Pump will be running a single stator. If an electrical fault is present, download patient log files and contact your HeartWare representative to resolve the electrical fault before executing the controller exchange.

5) **Return** all quarantined HVAD Controllers and DC Adapters to HeartWare. Your HeartWare representative will assist you with this process.

6) **Completion Form.** Once affected product in inventory has been identified and returned, complete and return the attached "Completion Form" to con2.0@medtronic.com or your HeartWare representative no later than twelve (12) months from the date of this letter according to the instructions on the form.

Reporting of Adverse Event:
Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with the use of the HeartWare Ventricular Assist Device to your HeartWare representative, or Perle Reye, representative of Emergo Consulting at +65 6832 5625. Alternatively, healthcare professionals may report adverse events to the Medical Device Branch, Health Products Regulation Group, HSA at Tel: 6866 1048, Fax: 6478 9028, or report online at www.hsa.gov.sg/ae online. Events that are reported to Emergo Consulting Pte. Ltd. will be investigated and subsequently reported to HSA.

Please contact your local HeartWare Representative with questions. We regret any inconvenience that this action may cause and appreciate your understanding as we take action to ensure patient safety and customer satisfaction. Thank you in advance for your cooperation.

Sincerely,

[redacted]

Tim Samsel
Vice President, Quality, CRHF
Medtronic

Registrant Contact Details:
Emergo Consulting Pte. Ltd.:
1 Fullerton Rd., #02-01 One Fullerton
Singapore 049213

Office: +65 6832 5625
Email: SEAvigilance@emergogroup.com

Attachments
Attachment 1: Healthcare Professional Acknowledgement Form
Attachment 2: Completion Form

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Healthcare Professional Acknowledgement Form
HAZARD ALERT

(To be completed by site representative)

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Clinical Institution / Hospital Name:

The undersigned hereby acknowledges receipt and understanding of the Dear Healthcare Professional Letter HeartWare's Hazard Alert, FSCA JAN2017.

Position / Title	**Printed Healthcare Professional Name**	**Signature**	**Date**	**Official Stamp**

No later than 30 days from the date of this notification, please:

- Return this signed, stamped form to your HeartWare representative; or
- Email an electronic copy of this signed form to con2.0@medtronic.com.

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Product Return Completion Form
HAZARD ALERT

(To be completed by site representative)

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Clinical Institution / Hospital Name:

The undersigned hereby acknowledges:

- That all affected controllers and DC adapters in inventory and from current patients (if any) have been identified, quarantined, and replaced (or not replaced due to clinician judgment), and
- That quarantined controllers have been returned to HeartWare.

Position / Title	Printed Name	Signature	Date	Official Stamp

Please provide this form upon return of all impacted hospital and patient controllers.
Please:

- Return this signed, stamped form to your HeartWare representative; or
- Email an electronic copy of this signed form to con2.0@medtronic.com.