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URGENT MEDICAL DEVICE CORRECTION

Medtronic HeartWare™ HVAD™ System

Device Name	Model Numbers (may include various suffixes)	Serial Numbers
Controller/ Controller Kits	**1400, 1401, 1403, 1407, 1420**	All
DC Adapter	**1435, 1440**	All
AC Adapter	**1425, 1430**	All
Battery Pack	**1650**	All

May 2018

Dear Physician or Healthcare Professional:

HeartWare, now a part of Medtronic, is providing this letter to inform you of the potential for a transient interruption of the electrical connection between an HVAD System power source (Battery, AC Adapter, or DC Adapter) and the HVAD Controller that may result in unintended power switching to the secondary power source and/or unexpected audible tones ("beeping"). This interruption, which occurs while the power source remains physically connected, is due to oxidation of connecting surfaces between a power source connector and the controller's power source socket, and typically lasts 1-2 seconds.

Unexpected beeping occurs when the interruption automatically resolves and may cause confusion to the patient or caregiver, as the controller may display sufficient battery capacity or AC/DC connectivity at the time of the audible tone. A Critical Battery Alarm may also be momentarily displayed due to this phenomenon.

The projected occurrence rate of unexpected power source switching with the HVAD System over a 2-year period on a per patient basis is approximately 25%. Approximately 97% of reported occurrences of this issue resulted in no patient symptoms. However, the potential harm associated with transient power source interruptions can vary, depending on whether two power sources are connected (as instructed in the Instructions for Use and Patient Manual) versus a single source, and the patient's underlying health. The per patient probability of serious adverse events due to this issue is approximately 0.003.

Medtronic has continued to develop and implement enhancements into the HVAD System to improve power source connectivity and reduce the potential for unintended power source switching. Specific mitigations for current patients, and future system enhancements to be applied during manufacturing, have been identified and will be implemented pending required FDA and other regulatory agency approvals. We will inform you as they become available.

Patient Management Recommendations
We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Practitioner Quality Panel (IPQP), Medtronic provides the following recommendations for effective power source management of HVAD Systems:

- **Reinforce the importance of always ensuring TWO power sources (AC or DC adapter plus a battery, OR two batteries) are connected at all times (except when changing a power source)**.

- **Reinforce best practice guidance for managing power sources when going to sleep and awakening:**
  - When going to bed, connect a fully charged battery and then connect the AC adapter.
  - When getting out of bed in the morning, make sure to connect two fully charged batteries.

- **Instruct patients to report any <u>persistent</u>, <u>unexpected</u> audible tones to the VAD team for additional instructions.**
  - Refer to Attachment A: *HVAD System with Controller 1.0 - Identifying Unexpected Power Source Switching Behaviors*

OR

Refer to Attachment B: *HVAD System with Controller 2.0 - Identifying Unexpected Power Source Switching Behaviors*

- Report all unexpected events to your local Medtronic representative, and submit a complaint, including logfiles per normal processes.
- If the unexpected behavior persists, and is responsible for potential patient confusion or anxiety, first consider replacing the suspect power source and return it to Medtronic for analysis under your normal complaint handling process.
- If unexpected behavior continues after replacement of the suspect power source, consider replacing the Controller - if the patient condition allows according to clinician judgement. Refer to the HVAD System Instructions for Use for detailed guidance on performing a controller replacement.

Please complete the enclosed Clinician Confirmation Certificate and return via email to **RS.CFQFCA@medtronic.com.**

Medtronic will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization as appropriate. We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

Adverse reactions or quality problems experienced with the use of 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 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**

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Heart Failure

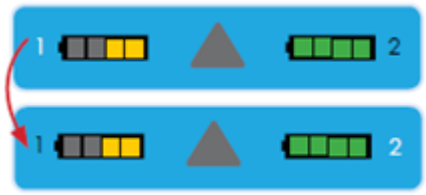
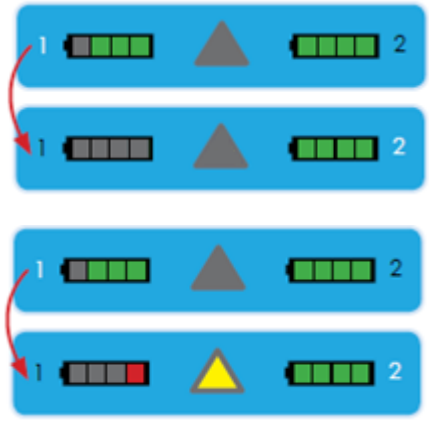
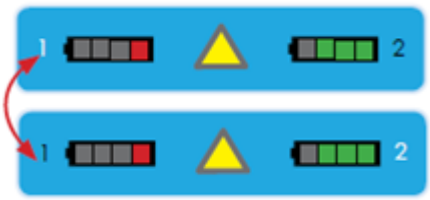
Attachment A: HVAD System with Controller 1.0 - Identifying Unexpected Power Source Switching Behaviors
Attachment B: HVAD System with Controller 2.0 – Identifying Unexpected Power Source Switching Behaviors

ATTACHMENT A

HVAD System with Controller 1.0 - Identifying Unexpected Power Source Switching Behaviors

The information below provides guidance on monitoring for power source switching behaviors and how to identify unexpected power source switching that requires further investigation. Refer to the HVAD Instructions for Use for a full list of precautions, warnings and potential complications as well as for normal power source switching behaviors.

Table 1: Unexpected behaviors include, but are not limited to:

Description of unexpected behavior	Controller Display	Actions
A controller that changes to the second battery when the first battery has greater than (>) 25% capacity (2 or more LEDs) remaining.		Replace the first battery and remove from service.
There is a sudden change in charge capacity on a battery (for example, a sudden change from 3 LEDs to 0 LEDs, or from 3 LEDs to 1 LED).		Replace the abnormally behaving battery and remove from service.
"Beeping" and the controller rapidly switches back and forth between batteries.		Replace the battery with more lit LEDs first, then replace the battery with fewer lit LEDs. Remove the battery with more lit LEDs as it may be a faulty battery.

A power source that persistently exhibits any of these unexpected behaviors should be taken out of service and replaced. Consider replacing power sources before replacing the controller.

Important! If any unexpected power source switching behavior is observed, do NOT try to force the controller to go back to power source "1" by manually disconnecting the port 2 battery/AC.

Reporting a problem:
For patients reporting this issue, remind them to bring all power sources (AC and DC adapters and batteries) into the clinic. Inspect batteries and obtain logfiles from the patient's controller and send the files to Medtronic for analysis.

ATTACHMENT B

HVAD System with Controller 2.0 - Identifying Unexpected Power Source Switching Behaviors

The information below provides guidance on monitoring for power source switching behaviors and how to identify unexpected power source switching that requires further investigation. Refer to the HVAD Instructions for Use for a full list of precautions, warnings and potential complications as well as for normal power source switching behaviors.

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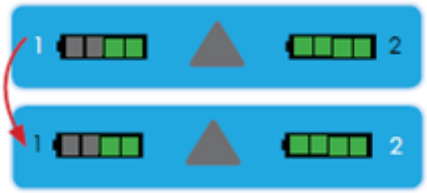
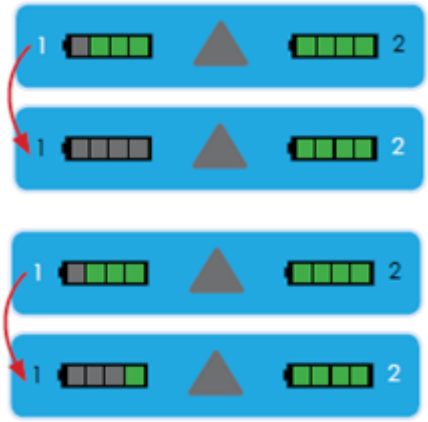
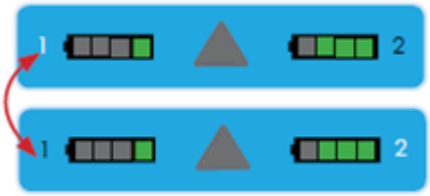
A controller that changes to the second battery when the first battery has greater than (>) 25% capacity (2 or more LEDs) remaining.		Replace the first battery and remove from service.
There is a sudden change in charge capacity on a battery (for example, a sudden change from 3 LEDs to 0 LEDs, or from 3 LEDs to 1 LED).		Replace the abnormally behaving battery and remove from service.
"Beeping" and the controller rapidly switches back and forth between batteries.		Replace the battery with more lit LEDs first, then replace the battery with fewer lit LEDs. Remove the battery with more lit LEDs as it may be a faulty battery.

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