

Urgent Field Safety Notice HeartWare Ventricular Assist Device (HVAD™)

Instructions for Use and Patient Manual Updates - Cleaning of Controller Connector and Power Source Connector Pins

Notification

Product Name	Product Number
Controller AC Adapter	1425, 1430
Controller DC Adapter	1440
Battery	1650DE

January 2022

Medtronic reference: FA1226

Dear VAD Coordinators,

Medtronic is writing to inform you of upcoming updates to the Instructions for Use (IFU) and the Patient Manual (PM) for the HeartWare Ventricular Assist Device (HVAD™) System. While performing a review of the IFU and PM, we determined that additional clarity was required regarding cleaning the Power Source Connectors (Controller AC Adapter, DC Adapter, and Battery). Specifically, the pins (see figures 1 and 2) on the interior of the power source connectors are coated with a lubricant that should not be removed, as it is intended to help prevent pin wear that can lead to unexpected power switching. Power switching can occur when there are transient interruptions to the electrical connection with the HVAD System power sources.

1 Pins (6)

2 Power Source Connector

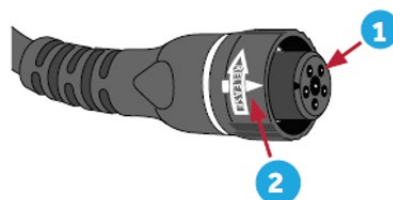


Figure 1 - Side view of Power Source Connectors



Figure 2 - Front view of Power Source Connectors

Below is a summary of the changes to the cleaning instructions for the Controller AC Adapter, DC Adapter, and Battery:

- DO NOT clean the Controller AC Adapter, DC adapter, or Battery connector pins.
- Attempting to clean the interior of the connectors may damage HeartWare™ HVAD™ System components. If the connector pins contain any dirt or debris, do not use the device, and report the condition to your Medtronic Representative.

- You may clean the external surfaces per the IFU and PM, but do not clean the interior of the connectors.

Through 10 January 2021 Medtronic has received five (5) complaints involving eight (8) batteries where users cleaned the battery connector in an attempt to resolve issues experienced with the batteries (e.g. power switching or not charging). In all instances the batteries were exchanged, and in one instance a controller exchange was performed and no additional patient harms were reported. Attempting to clean the interior of a power source connector can lead to damage of the HeartWare HVAD system components which may impact controller and pump performance. Potential performance issues from damaging the power source connectors range from negligible harm to an unanticipated VAD Stop.

Customer Instructions:

Medtronic records indicate that your site has patients that may still be on active support; we request that you to do the following:

- Please ensure your patients on active support receive the updated cleaning instructions
- Please share this notice with everyone in your organization who needs to be aware
- Continue to monitor patients per your practice's normal follow-up procedures.

Additional information:

The Competent Authority of your country has been notified of this action. 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 questions regarding this material, please contact your Medtronic Field Representative at <XXXX>.

Sincerely,

Local/OU manager