

Urgent Medical Device Notice

HeartWare Ventricular Assist Device (HVAD™)

Instructions for Use and Patient Manual Updates – Power Source Connector Cleaning

February 2022

Dear VAD Coordinators,

Medtronic is writing to provide updated cleaning instructions for the Controller AC Adapter, DC Adapter, and Battery. While performing a review of the IFU and PM it was identified that additional clarity was required around cleaning the Power Source Connectors (Controller AC Adapter, DC Adapter, and Battery). The pins (see figures 1 and 2) of the power source connectors are coated with a lubricant, that should not be removed as it is intended to help prevent 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

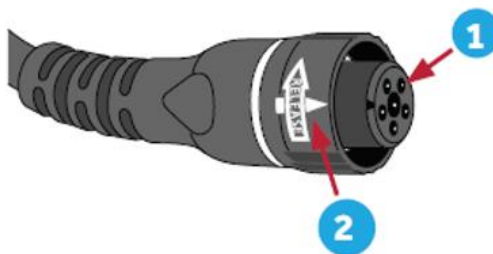


Figure 1 – Side view of Power Source Connectors



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 pins of the Controller AC Adapter, DC adapter, or Battery connectors.
- Attempting to clean the pins 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 of the power source connector per the IFU and PM, but do not clean the pins of the connectors.

Through 11 January 2022 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 pins of the power source connectors can damage 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.

Medtronic will provide further information on the IFU and PM updates after the necessary regulatory approvals are obtained.

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 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 standard follow-up procedures.
- Please complete the enclosed Customer Confirmation Form and email to RS.CFQFCA@medtronic.com.

Adverse reactions or quality problems experienced with 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 from 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

Medtronic will notify all applicable regulatory agencies of this matter. 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.

Sincerely,

A handwritten signature in cursive script, reading "Gail Schroeder". The ink is dark and the signature is fluid, with a large initial "G" and a long, sweeping "S".

Gail Schroeder

Vice President, Quality and Regulatory

Medtronic Mechanical Circulatory Support