

Urgent Field Safety Notice**Medtronic HeartWare™ HVAD™ System Battery Charger AC Adapter
Controller Power Port Incompatibility**

Device Description	Model Numbers (may include various suffixes)	Serial Numbers
HeartWare™ Battery Charger packaged with AC Adapter	1610	ALL
HeartWare™ Battery Charger AC Adapter	1640	ALL

January 2020

Medtronic reference: FA902

Dear Physician or Healthcare Professional,

Medtronic HeartWare is informing you of the potential for an HVAD™ System user to mistakenly insert the Battery Charger AC Adapter into an HVAD Controller power port. When this occurs, communication circuits between the battery and the Controller may be damaged. If circuit damage occurs, it will be necessary to exchange the Controller to restore communication between the batteries and Controller. Power to the Controller and to the HeartWare HVAD™ Pump will continue to be maintained if a Battery Charger AC Adapter is mistakenly inserted into a Controller power port and a secondary power source also is connected to the Controller.

The Battery Charger AC Adapter is not intended to be attached to a Controller power port. See Figure 1 for a visual depiction of the differences between the Controller AC Adapter and the Battery Charger AC Adapter.

Battery Charger kits (Model 1610) and Battery Charger AC Adapters (Model 1640; refer to Figure 2) have the potential for this connection issue to occur. No other models are affected by this issue. Through January 13, 2020, there have been 36 complaints reported to Medtronic potentially related to this issue. From this population, there has been one reported death resulting from complications associated with a related Controller exchange. Other potential harms are described below. The predicted rate of occurrence for this issue is 0,6%.

CORRECT

Connector for Controller

INCORRECT

Connector

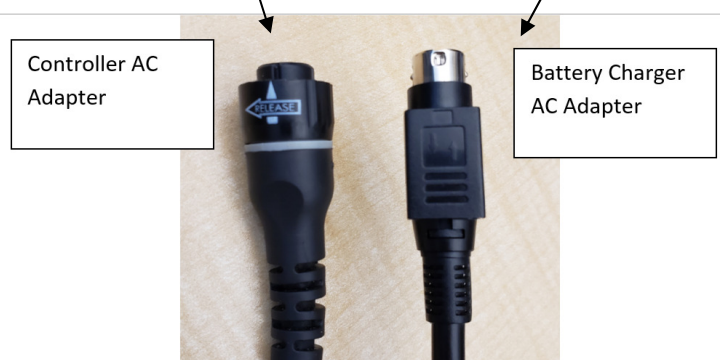


Figure 1

Battery Charger kit with
Battery Charger AC Adapter power cable



Figure 2

Mistakenly inserting the Battery Charger AC Adapter into a Controller power port may cause damage to communication circuits within the Controller, resulting in the Controller no longer displaying LED indicators related to battery status. Additionally, alarms will also occur when any battery is connected to the Controller. The Controller will continue to receive power from any power source that remains successfully connected, including a secondary battery.

If circuits within the Controller are damaged as the result of this issue, it will be necessary to exchange the Controller to restore Controller-to-battery communications and resolve alarms. A Controller exchange could lead to patient harm due to pump stoppage. Temporary pump stoppage could lead to exacerbation of heart failure symptoms and/or symptoms related to hypoperfusion ranging from mild weakness to dizziness, anxiety, nausea, lightheaded/loss of consciousness, or death. The severity of harm is dependent on the patient's cardiac status.

Medtronic will be submitting to regulatory authorities an addition to the clinician HVAD IFU and Patient Manual. Proposed key language includes:

WARNING! ONLY use the HeartWare-supplied Controller AC Adapter, Controller DC Adapter, or Batteries to plug into the Controller power connectors. Attempting to use another cable (e.g. Battery Charger AC adapter or Data Cable) may damage the Controller and require a Controller exchange.

Please note: When released in your geography, the updated IFU and Patient Manual content may differ from the proposed content based on the IFU and Patient Manual approved by local regulatory agencies, where required.

Patient Management Recommendations

We realize that each patient requires unique clinical considerations. Medtronic recommends the following for HVAD patients using Battery Charging units with a Battery Charger AC Adapter (Models 1610 and 1640, respectively):

- Instruct patients to carefully follow the guidance provided in the patient manual related to connecting a power source (refer to image right). Pay attention when connecting and disconnecting power supply cables to ensure users verify the correct cable is being connected to their Controller.
- Instruct patients to report any persistent, unexpected audible tones to their Clinician for additional instructions.
 - Report all unexpected events to your local Medtronic representative, and submit a complaint, including logfiles, per normal processes.
 - If audible tones do not resolve upon reconnection of power source, a Controller exchange may be required to restore status communication and clear the alarm conditions. Controller exchanges should be performed only if patient condition allows, according to clinician judgment.

Medtronic will notify all applicable regulatory agencies about this matter. This notice must be passed to all those who need to be aware within your organization or to any organization where potentially affected devices have been transferred. 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. If you have any questions, please contact your Medtronic Representative at <XXXX>.

Sincerely,

3.2.2 Power Source Connections

To Connect a Power Source:

1. To connect all power supplies (battery, AC adapter or DC adapter) grasp the power cable near its connector. Leave the connector free to rotate.



2. Line up the solid white arrow on the cable connector with the dot on the controller (Figure 24).



3. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will result in an audible click.

NOTE: When pushing the connector into the controller the white arrow will shift slightly into the correct locking position.



4. Confirm that the power cable is properly locked to the controller by gently pulling on the cable near the connector.

Repeat steps above for second power source.



WARNING! NEVER disconnect both power sources (batteries, AC adapter, DC adapter) at the same time since this will stop the pump and activate the [No Power] alarm. At least one power source must be connected at all times.



CAUTION: ALWAYS confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.

CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HVAD® System may not function as intended.