


**IMPORTANT MEDICAL DEVICE CORRECTION**  
**Medtronic HeartWare™ HVAD™ System Battery Charger**

	Device Name	Model Numbers	Serial Numbers
	Battery Charger	<b>1600US</b>	Refer to Appendix A for list of specific Serial Numbers in scope of this advisory.

November 2018

Dear Physician or Healthcare Professional:

HeartWare, now a part of Medtronic, has been notified by an outside vendor that a quantity of HVAD battery charger units (see image above) may have been manufactured with an incorrect circuit component. This subset may exhibit one or more of the battery charging bays not fully charging the battery and/or battery charger indicators (LED) not lighting.

The behaviors may occur in any individual bay, independent of the other charging bays. In analyzed units, up to 2 charging bays exhibited one of the above behaviors. In all cases, at least 2 of the remaining bays were able to continue to charge batteries as needed. We are not able to predict if, or when, one of the identified battery charger units may malfunction. The potential exists, however, that all circuits responsible for charging batteries and LED function may fail due to the incorrect component.

In the population of potentially affected product, Medtronic has observed a malfunction rate of 16.7%. The number of potentially affected battery chargers remaining in distribution is estimated to be 2031 worldwide. These units were distributed between June 2017 and June 2018. Charging units outside of the serial numbers listed in Appendix A, all new manufactured battery chargers, and the individual batteries are not in scope of this advisory.

Through November 02, 2018, Medtronic has received zero (0) reports of patient injuries associated with this issue.

**Patient Management Recommendations**

We realize that each patient requires unique clinical considerations. In consultation with Medtronic’s Independent Practitioner Quality Panel (IPQP), the following recommendations are provided:

**For patients with a HeartWare Battery Charging Unit in the identified list of Serial Numbers (refer to Appendix A):**

- **Instruct patients to monitor the battery charging unit for any of the following behaviors:**
  - One or more battery charging bays not fully charging the battery and/or battery charger indicator LEDs not lighting
  - The battery connected to the charger and the charger status light flashing red after 8 hours of attempted charging

It is normal for the battery charging unit to be warm during the charging process. However, there have been reports of the unit becoming abnormally hot and sometimes producing a burning odor due to this issue. Even though the charger may become hot, no fire hazard or risk of damage to the outer surfaces of the battery charger has been identified.

- **Instruct patients to immediately report any of the above observations to their VAD Coordinator so a replacement can be ordered.**
  - If any single bay in the battery charging unit experiences any of the conditions listed above, an alternate bay or AC or DC adaptor can be used until a replacement charging unit can be obtained from Medtronic.
  - If a user is unsure if a battery has successfully charged, the battery status can be observed by pressing the battery Test button to show how much capacity was restored during the charging process.

See the enclosed Customer Notification Detail Report for a list of units distributed to your location.

Please complete the enclosed Clinician Confirmation Certificate and return via email to [RS.CFQFCA@medtronic.com](mailto:RS.CFQFCA@medtronic.com)

Report all events as described above to your local Medtronic HeartWare representative by:

- Requesting a replacement charging unit for the patient per normal process; For charging units included in the list of affected Serial Numbers, a replacement will be provided at no additional cost.
- Returning the suspected malfunctioning unit after the replacement charging unit has arrived.

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.

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](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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,



Chris Harrold  
Vice President, Quality and Regulatory  
Medtronic Cardiac Rhythm and Heart Failure