


Urgent Field Safety Notice

Medtronic HeartWare™ HVAD™ System Battery Charger

	Device Name	Model Numbers	Serial Numbers
	Battery Charger	1610CH, 1610DE, 1610GB, 1610IN, 1610IT	Refer to Appendix A for list of specific Serial Numbers in scope of this advisory.

November 2018

Medtronic reference: FA852

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 managing physician 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.



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.

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.

Medtronic has notified the Competent Authority of your country of this action.

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 HeartWare Representative.

Sincerely,

Enclosure:

- Appendix A: List of Affected Serial Numbers
- Appendix B: Patient Letter Template which can be used to inform your patients

Appendix A: List of Affected Serial Numbers

BCH000401	BCH000449	BCH000500	BCH000562	BCH000617	BCH000674	BCH000736	BCH000872
BCH000402	BCH000450	BCH000501	BCH000563	BCH000618	BCH000676	BCH000737	BCH000875
BCH000403	BCH000451	BCH000502	BCH000564	BCH000619	BCH000677	BCH000738	BCH000876
BCH000404	BCH000452	BCH000504	BCH000565	BCH000620	BCH000678	BCH000739	BCH000877
BCH000405	BCH000453	BCH000505	BCH000568	BCH000622	bch000679	BCH000741	BCH000878
BCH000406	BCH000454	BCH000506	BCH000569	BCH000623	bch000681	bch000742	BCH000879
BCH000407	BCH000455	BCH000509	BCH000570	BCH000624	bch000682	BCH000743	BCH000881
BCH000408	BCH000456	BCH000510	BCH000571	BCH000625	bch000683	BCH000744	BCH000886
BCH000409	BCH000457	BCH000511	BCH000573	BCH000626	BCH000684	BCH000745	BCH000887
BCH000410	BCH000458	BCH000512	BCH000574	BCH000628	BCH000685	bch000746	bch000889
BCH000411	BCH000459	BCH000515	BCH000575	BCH000629	BCH000686	bch000747	BCH000890
BCH000412	BCH000460	BCH000516	BCH000576	BCH000630	BCH000687	BCH000748	BCH000891
BCH000413	BCH000461	BCH000517	BCH000577	BCH000631	BCH000688	bch000749	BCH000892
BCH000414	BCH000462	BCH000518	BCH000578	BCH000632	BCH000691	BCH000750	BCH000893
BCH000415	BCH000463	BCH000519	BCH000579	BCH000633	BCH000693	BCH000751	BCH000895
BCH000416	BCH000464	BCH000520	BCH000581	BCH000634	BCH000694	BCH000752	BCH000896
BCH000417	BCH000465	BCH000521	BCH000582	BCH000635	BCH000695	BCH000754	BCH000897
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<Patient Letter Template – For Clinic and Physician Use Only>

Important Medical Device Information
Medtronic HeartWare™ HVAD™ System Battery Charger

November 2018

Dear Patient,

HeartWare, now a part of Medtronic, recently notified our office about important information related to the battery charger unit for the HVAD System. We are sending this letter to provide information on the next steps to address this situation.

Medtronic has determined that your battery charger unit may experience an issue that results in battery charging bays not fully charging the battery. Medtronic has provided us with additional information that explains this issue in more detail.

Recommendation:

1. Continuously watch for any of the following behaviors on the battery charging unit. If you see any of these behaviors, report it to your managing physician immediately:
 - One or more battery charging bays not fully charging and/or LEDs not lighting
 - The battery connected to the charger and the charger status light flashing red after 8 hours of attempted charging
2. The battery charging unit may become abnormally hot which may produce a burning odor.

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.
3. Use a different charging bay or charging unit if any single bay in the battery charging unit has one of the described issues. Do this until a replacement charging unit is received.
4. To determine a battery's level of charge, press the Test Button on the battery. The lights on the battery will indicate how much the battery has charged.

It is important that you contact our office at <Insert clinic contact information> to speak with your physician about your battery charging unit, the impact to your HVAD, and this issue.

We sincerely apologize for any difficulties this may cause you and your family.

<Insert Physician Practice Information>