Australian Government
Department of Health
Therapeutic Goods Administration

Recall Action Notification

Medtronic HeartWare HVAD System Battery Charger

Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2018-RN-01496-1
Product Name/Description[iii]	Medtronic HeartWare HVAD System Battery Charger Model Number: 1610AU Serial Numbers: BCH000405, BCH000406, BCH000422, BCH000426, BCH000428, BCH000440, BCH000451, BCH000486, BCH000493, BCH000495, BCH000527, BCH000553, BCH000579, BCH000703, BCH000722, BCH006008 ARTG 277518 (Medtronic Australasia Pty Ltd - HeartWare Ventricular Assist System - Battery charger)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	23/11/2018
Responsible Entity[vii]	Medtronic Australasia Pty Ltd
Reason / Issue[viii]	Medtronic has been notified by an outside vendor that a quantity of HVAD battery charger units 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 behaviours may occur in any individual bay, independent of the other charging bays. In analysed units, up to 2 charging bays exhibited one of the above behaviours. In all cases, at least 2 of the remaining bays were able to continue to charge batteries as needed. Medtronic are not able to predict if, or when, one of the identified battery charger units may malfunction. Medtronic has observed a malfunction rate of 16.7%. These units were distributed between June 2017 and June 2018. Through November 02, 2018, Medtronic has received zero (0) reports of patient injuries associated with this issue.
Recall Action[ix]	Product Defect Correction

Recall Action Instructions[x]	Medtronic advises customers to: ·Instruct patients to monitor the battery charging unit for any of the following behaviours: - 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. ·Instruct patients to immediately report any of the above observations to their VAD Coordinator so a replacement can be ordered. ·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.
Contact Information[xi]	0481 033 131 - Claire Cottrell (Medtronic Recall Assistant)

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the

market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

There are three distinct recall actions - recall, recall for product correction and hazard alert.

- Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
- Recall for product correction - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- Hazard alert - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

[x] Recall Action Instructions: What the customer should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.