

## Recall detail

Type of Product <sup>i</sup>	Medical Device
TGA Recall Reference <sup>ii</sup>	RC-2015-RN-01261-1
Product Name/Description <sup>iii</sup>	HeartWare HVAD Controller AC Adapter and HeartWare HVAD Battery  Controller AC Adapter Product Code: 1430XX Serial Numbers: CAC000001 to CAC005796  HVAD Battery Product Code: 1650XX and A00035 Serial Numbers: BAT000001 to BAT199999  ARTG Number: 181875
Recall Action Level <sup>iv</sup>	Hospital
Recall Action Classification <sup>v</sup>	Class I
Recall Action Commencement Date <sup>vi</sup>	24/12/2015
Responsible Entity <sup>vii</sup>	Heartware Pty Ltd
Reason / Issue <sup>viii</sup>	HeartWare AC Adapters with serial numbers CAC000001 to CAC005796 are vulnerable to power grid surges above 220 volts. If an AC Adapter fails, the patient's Controller will alarm and automatically switch to the other power source. If patients follow HeartWare's Patient Manual, there are no elevated risks to health. However, if a patient is not connected to two power sources, or if the second power source is insufficient to power the system during the time that it takes to replace a failed AC Adapter, the system could lose power, which may lead to serious injury or death.  In addition, there have been complaints related to earlier than expected battery depletion for batteries with serial numbers BAT000001 to BAT199999. Premature or unrecognised battery depletion may pose a risk to the patient, if the patient is not connected to two power sources, or if the second power source is insufficient to power the system during the time that it takes to replace a depleted battery.
Recall Action <sup>ix</sup>	Hazard Alert
Recall Action Instructions <sup>x</sup>	The sponsor is advising healthcare professionals to identify and quarantine the affected units in hospital inventory and arrange for current patients to bring their AC Adapters and Batteries to a clinic as soon as possible (at least within the next three months), with urgency dependent upon individual patient circumstances. During their scheduled appointment, a qualified representative will assist with the quarantine and replacement of the affected product.