



## URGENT FIELD SAFETY NOTICE

HeartWare Clinician  
Site Name  
Street Address  
City, State, Zip Code

**Product:** HeartWare® Battery  
**Identifier:** FSCA APR2014.1  
**Type of Action:** HeartWare® Battery Recall  
**Product Code:** 1650, 1650-DE  
**Range of Serial #s:** BAT000001 to BAT039999; BAT090000 to BAT099999

Dear HeartWare Clinician,

### Details on affected devices

HeartWare is expanding its voluntary Field Safety Corrective Action, FSCA APR2014, to include the recall of certain batteries of the HeartWare® Ventricular Assist System, product codes 1650 and 1650-DE.

### Description of the Problem

In May 2014, HeartWare distributed Field Safety Notice FSCA APR2014 following an increase in reported power management complaints related to earlier than expected battery depletion. Information on early battery depletion, identification of potentially faulty batteries, and recommended practices for power management were provided in the Field Safety Notice. A copy of the Field Safety Notice is attached to this letter for your reference.

HeartWare is expanding the field safety corrective action to include the recall of batteries produced within the serial number ranges: BAT000001 to BAT039999 and BAT090000 to BAT099999. Batteries produced in these ranges are more likely to exhibit premature or unrecognized deterioration of battery capacity, which poses a risk to the patient since it may result in a pump stop.

### Actions to be taken by the Clinician

Batteries in the serial number ranges BAT000001 to BAT039999 and BAT090000 to BAT099999 should be identified and removed from service. Please take the following actions:

1. **Promptly sign the “Acknowledgment Form” and return it to HeartWare via fax: +1 305 364 2665 or email: [FSCA@heartware.com](mailto:FSCA@heartware.com).**
2. **Identify and quarantine batteries within serial number ranges BAT000001 to BAT039999 and BAT090000 to BAT099999.**
  - Review your hospital's current inventory. Remove and quarantine any affected batteries.
  - At each patient's next regularly scheduled visit, inspect their batteries and replace affected batteries with batteries having serial numbers BAT040000 to BAT089999 or BAT100000 and above.
  - If a patient does not have a regular visit scheduled within the next 90 days, contact that patient by telephone to check the serial numbers of the patient's batteries.
    - For patients with affected batteries, schedule a visit as soon as practicable.
    - Instruct these patients to prioritize use of batteries with serial numbers BAT040000 to BAT089999 or BAT100000 and above to the extent possible until their scheduled visit.

The serial number is located on the white label on the back of the battery (refer to Figure 1 below).



Figure 1. Example of HeartWare® Battery

### 3. Return all affected batteries to HeartWare.

- Apply a blue “HeartWare FSCA APR2014.1” sticker to each affected battery (refer to Figure 1 above).
- Obtain a unique Return Goods Authorization (RGA) number for batteries to be returned by contacting:
  - HeartWare Customer Service via telephone: +49 511 67693690 (Germany) or email: [cseurope@heartware.com](mailto:cseurope@heartware.com).
  - Your local HeartWare representative.

Replacement batteries for patients currently on support will be shipped upon issuance of the RGA. As necessary, your HeartWare representative will work with you to establish an appropriate stock of replacement batteries.

### 4. Within 4 months of receipt of this letter, complete, sign and return the “Completion Form” to HeartWare via fax: +1 305 364 2665 or email: [FSCA@heartware.com](mailto:FSCA@heartware.com). Please indicate:

- All batteries in inventory have been checked and batteries within serial number ranges BAT000001 to BAT039999 and BAT090000 to BAT099999 have been removed and returned to HeartWare.
- All batteries from patients on support have been checked and batteries within serial number ranges BAT000001 to BAT039999 and BAT090000 to BAT099999 have been removed and returned to HeartWare.
- If your site has no affected batteries in inventory and no patients on support with affected batteries.

### 5. For serial numbers BAT040000 to BAT089999 or BAT100000 and above, continue to monitor battery performance and report any abnormal battery behavior as described in Field Safety Notice FSCA APR2014.

### 6. This expanded action does not replace the required actions for FSCA APR2014, initiated in May 2014. Please continue to complete all requirements of FSCA APR2014 and return the required forms to HeartWare by the due dates.

**NOTE:** HeartWare® Batteries are consumable items and are expected to have a useful operating life of 500 charge and discharge cycles; this should provide patient support for one year. Batteries that reach the end of their useful life should be taken out of service.



## Transmission of this Field Safety Notice

Forward this notice to all those who need to be aware within your organization as well as any organization where the potentially affected batteries have been transferred.

Should you have any concerns or if you require further clarification, please contact your local HeartWare® representative or email us at [FSCA@heartware.com](mailto:FSCA@heartware.com).

The undersigned confirms that this notice will be provided to the appropriate Regulatory Agencies consistent with applicable regulations.

Thank you for your cooperation.

Sincerely,

[Redacted Signature]

Sr. VP, Regulatory

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### Company Address

HeartWare, Inc.  
14400 NW 60th Avenue  
Miami Lakes, Florida 33014 USA

### 24-Hour Clinical Support

Telephone: +49 511 676936911 (Germany)  
Telephone: +44 7534 245492 (UK)  
Fax: +1 305 364 2665  
Email: [FSCA@heartware.com](mailto:FSCA@heartware.com)

**Europe:** HeartWare may also be reached via the European Authorized Representative, MedPass International Ltd., on +44 (0) 1452 619 222 (telephone and fax) and [MedPass.AR@medpass.org](mailto:MedPass.AR@medpass.org) (email).

### Attachments:

Attachment 1: Acknowledgment Form (Required)  
Attachment 2: Completion Form (Required)  
Attachment 3: Reference copy of Field Safety Notice FSCA APR2014  
HeartWare "FSCA APR2014.1" Blue Stickers



## Acknowledgement Form

### Response Required

**Identifier:** FSCA APR2014.1  
**Type of Action:** HeartWare® Battery Recall  
**Product Name:** HeartWare® Battery  
**Catalog #:** 1650, 1650-DE  
**Serial #:** BAT000001 to BAT039999; BAT090000 to BAT099999

Clinical Institution/ Hospital Name	
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The undersigned hereby acknowledges receipt and understanding of actions required to comply with HeartWare's Urgent Field Safety Notice, FSCA APR2014.1.

**A response is required for both questions below.**

1. Do you have batteries with serial numbers BAT000001 to BAT039999 or BAT090000 to BAT099999 in your hospital inventory?

☐ No

☐ Yes

2. Did you transfer any batteries with serial numbers BAT000001 to BAT039999 or BAT090000 to BAT099999 to other institutions?

☐ No

☐ Yes. Please provide the details of any affected batteries that have been transferred.

Clinical Institution/ Hospital Name	
Number of affected batteries transferred	

\_\_\_\_\_  
Position/ Title

\_\_\_\_\_  
Full Name

\_\_\_\_\_  
Signature/ Date

Please promptly scan and return the signed form via fax or email below.

Quality Compliance Manager

Fax: +1 305 364 2665

Email: FSCA@heartware.com