HeartWare®

11 August 2014

URGENT FIELD SAFETY NOTICE

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.**
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.
     - 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. 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

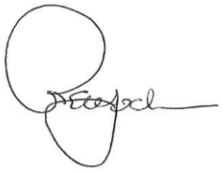
Forward this notice to all those who need to be aware within your organization as well as any organization where the potentially affected batteries have been transferred.

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

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

Thank you for your cooperation.

Sincerely,



Robert Yocher
Sr. VP, Regulatory

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

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 (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

HeartWare®

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	

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

ATTACHMENT 2

HeartWare®

Completion 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	

The undersigned hereby confirms the below information in connection with HeartWare's Urgent Field Safety Notice, FSCA APR2014.1.

Complete either SECTION 1 or SECTION 2 below.

SECTION 1 (All boxes in this section must be checked)

☐ All batteries in inventory have been checked and batteries within serial number range BAT000001 to BAT039999 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.

----------**OR**----------

SECTION 2

☐ My site has no affected batteries in inventory and no patients on support with affected batteries.

Position/ Title _____ Full Name _____ Signature/ Date _____

Within 4 months of receipt of this notice, please return the signed form via fax or email below.

Quality Compliance Manager
Fax: +1 305 364 2665 Email: FSCA@heartware.com

ATTACHMENT 3

HeartWare®

May 9, 2014

URGENT FIELD SAFETY NOTICE

Product:	HeartWare® Battery
Identifier:	FSCA APR2014
Type of Action:	Safety Notification
Product Code:	1650, 1650-DE
Range of Serial #s:	All HeartWare® Battery Serial Numbers

Dear HeartWare Clinician,

Details on affected devices:

HeartWare is voluntarily distributing a field safety notice regarding all HeartWare® Ventricular Assist System batteries, product codes 1650 and 1650-DE.

Description of the problem:

We have seen an increase in reported HeartWare® System power management complaints related to both premature battery failure and routine battery handling. Premature or unrecognized deterioration of battery capacity or lapses in recommended power management pose a risk to the patient and, although rare, may result in serious injury or death.

This field correction is intended to provide patients and healthcare providers with information to recognize batteries with less than two hours of run time, reemphasize instruction on actions to take when battery alarms occur and reinforce proper power management.

Advise on action to be taken by the clinician(1):

Early recognition of premature battery depletion, patient training and close attention to recommended power management practices are crucial to reduce patient risk. HeartWare is providing information to assist patients and clinicians to monitor battery performance and recognize abnormal behaviour. Please take the following steps to verify that all patients with the HeartWare® Batteries are managing their power sources in a safe manner and that batteries are handled in accordance with the Instructions for Use.

1. **Review the enclosed letter and familiarize yourself with its content. Promptly sign the "Acknowledgment Form" and return to HeartWare via fax: +1 305 364 2665 or email: FSCA@heartware.com.**
2. ***Reinforce the recommended practices (below) for early detection of abnormal battery behaviour and effective power management with your patients. Specifically, provide the enclosed letters to each of your current HeartWare® System patients at the next routine visit.***
3. **Within 7 months of receipt of this letter, complete and return the "Completion of Required Actions Form" to HeartWare via fax: +1 305 364 2665 or email: FSCA@heartware.com.**

(1)Text presented in ***Italics*** represents new information for the patient related to power management of the device not currently in the Patient Manual

HeartWare®

Recommended Practices for Effective Power Management [(1)]

- ***Monitor system for <u>abnormal</u> battery behaviour.***
  - The HeartWare® System's expected behaviour is as follows: A controller alerts and changes to the second power source only when the battery has less than (<) 25% capacity (1 indicator light) remaining.
    The HeartWare® System's <u>abnormal</u> behaviours are as follows:
    - ***A controller changes to the second battery when the first battery has greater than (>) 25% capacity (2 or more indicator lights) still remaining.***

      Replace the first battery and remove from service.

    - ***There is sudden change in charge capacity on a battery (for example, a sudden change from 4 lights to 1 light).***

      Replace the abnormally behaving battery and remove from service.

    - ***You hear "beeping" and the controller rapidly switches back and forth between batteries.***

      Replace the battery with <u>more</u> indicator lights first, then replace the battery with fewer lights. Remove the battery with more lights from service as it may be a faulty battery.

    Any of these behaviours <u>could</u> indicate a faulty battery and potentially lead to a critically low battery or possible loss of power. These batteries <u>must</u> be taken out of service and returned.

  - ***Identify any battery which is taken out of service due to abnormal behaviour by affixing one of the enclosed orange labels (marked "HeartWare FSCA APR2014") before returning the unit to HeartWare.***

- Refresh yourself and reinforce existing training with your patients.
  - NEVER disconnect both power sources (batteries and AC or DC adapter) at the same time since this will stop the pump. At least one power source must be connected at all times.
  - Except for the brief moments while exchanging one of the power sources, the controller should always be connected to two power sources.
    - This can be either two batteries, or one battery and an AC adapter or DC adapter (e.g., car adapter).
    - To preserve battery life, use the AC adapter when you are resting or sleeping. When disconnecting from AC power, always reconnect the HeartWare® System to two batteries.
  - Always investigate, and if possible, correct the cause of any alarm according to the HeartWare® Instructions for Use or Patient Manual. Silencing an alarm does not resolve the alarm condition.
  - Always recharge fully depleted batteries within 24 hours to avoid permanent battery damage.
  - Always have a fully charged battery available to replace the used or depleted battery.
  - Always have a backup controller handy and, whenever possible, a caregiver nearby when changing power sources or controllers. Be watchful for unusual changes in power or flow alarms following equipment changes.
  - ALWAYS confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector or the power cables may come loose and result in an alarm or the pump stopping.
  - Inspect batteries at least once a week, including the battery cable and connectors, for physical damage.

(1)Text presented in ***Italics*** represents new information for the patient related to power management of the device not currently in the Patient Manual

HeartWare®

- DO NOT use batteries that appear damaged. Damaged batteries must be taken out of service and exchanged.

o Rotating use of batteries will allow all batteries to age at a similar rate so no battery has significantly fewer charge cycles than the others. A patient who alternates the use of all his/her batteries should get about 1 year of service from their batteries.

o Remind patients to bring all batteries to clinic visits.

Battery Replacement

HeartWare® Batteries contain lithium ion cells which power the HVAD® System for approximately 4 to 6 hours when fully charged. Similar to consumer electronic batteries, HeartWare® Batteries lose their charge capacity over time. If a battery provides **less than 2 hours of support** duration, it should be taken out of service and exchanged.

NOTE: HeartWare® Batteries are expected to have a useful operating life of greater than **500 charge and discharge cycles**; this should provide patient support for at least one year. If you would like to obtain a battery cycle count, please send log files to HeartWare (hvadlogs@heartware.com) and request a review of the battery cycle count (available on controllers REF 1407XX/1408).

Action by HeartWare

Labeling language will be clarified in the IFU and Patient Manual to align with the information contained in this correction following review by the Regulatory Authorities. Complaints will continue to be closely monitored to ensure that the HeartWare® System functions as intended and to assess the effectiveness of this field correction. HeartWare will continue to investigate prematurely depleting batteries and will take additional actions as appropriate.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Should you have any concerns or if you require further clarification, please contact your HeartWare® Representative. Thank you for your cooperation.

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

Sincerely,

Ramon Augusto Paz
VP, Quality Assurance

Company Address

HeartWare, Inc.

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Miami Lakes, Florida 33014 USA

24-Hour Clinical Support
+49 511 676936911 (Germany)
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Email: FSCA@heartware.com

(1)Text presented in ***Italics*** represents new information for the patient related to power management of the device not currently in the Patient Manual

HeartWare

Europe: HeartWare may be reached via the European Authorized Representative, MedPass International Ltd., on +44 (0) 1452 619 222 (phone and fax).

Attachments:

Acknowledgment Form
Patient Letter
Orange labels, “HeartWare FSCA APR2014”
Completion of Required Actions Form

(1)Text presented in ***Italics*** represents new information for the patient related to power management of the device not currently in the Patient Manual

ATTACHMENT 3

Acknowledgment Form

Response is Required

Identifier: FSCA APR2014
Type of Action: Safety Notification
Product Name: HeartWare® Battery
Catalog #: 1650, 1650-DE
Serial #: All HeartWare® Battery Serial Numbers

Clinical Institution/ Hospital Name	

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

Position/ Title	Name	Signed/ Date

Please promptly scan and return the signed form via fax or email to:

Quality Compliance Manager
F: +1 (305) 364-2665 Email: FSCA@heartware.com

Completion of Required Actions

Response is Required

Identifier: FSCA APR2014
Type of Action: Safety Notification
Product Name: HeartWare® Battery
Catalog #: 1650, 1650-DE
Serial #: All HeartWare® Battery Serial Numbers

Clinical Institution/ Hospital Name	

The undersigned hereby confirms completion of actions required to comply with HeartWare's Urgent Field Safety Notice, FSCA APR2014.

Position/ Title	Name	Signed/ Date

Within 7 months of receipt of this notice, please return the signed form via fax or email to:

Quality Compliance Manager
F: +1 (305) 364-2665 Email: FSCA@heartware.com

IMPORTANT INFORMATION FOR HEARTWARE PATIENTS

Product Name: HeartWare® Battery

Reason for this letter

The manufacturer of the HeartWare® System recently notified us that they have observed an increase in battery complaints related to earlier than expected battery depletion. We want to communicate and reinforce to you proper power management instructions, including how to recognize abnormally behaving batteries and when your batteries need to be replaced.

HeartWare wants to assist you to identify an abnormally behaving battery and we want to reinforce the training your hospital provided to help you manage your power supplies. This letter covers the importance of **monitoring the power sources connected to your HeartWare® Controller and actions to take when a battery alarm occurs or a battery needs to be replaced**.

Risk to health

Power is vital to keep your pump running. If your pump stops due to loss of power, reconnect to another power source right away. If not, you may experience dizziness, fainting, and other symptoms. In rare cases, death can occur.

What should you do?

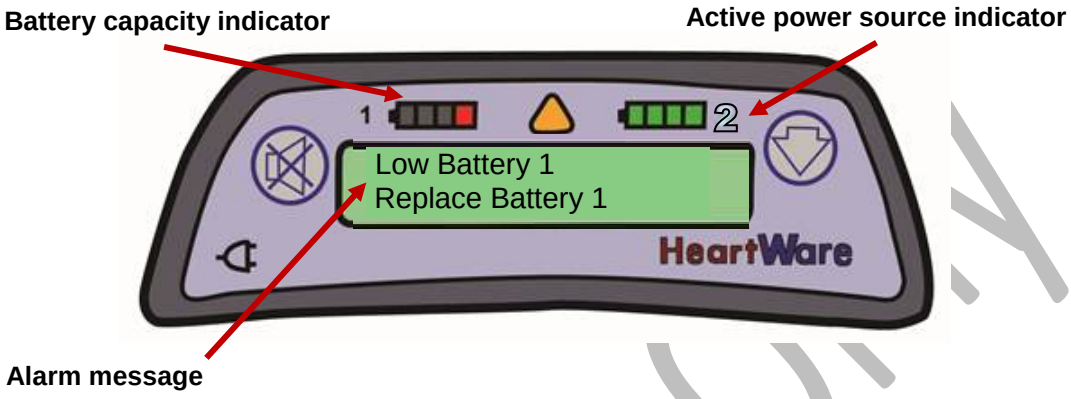
- Familiarize yourself with this letter and review your Patient Manual about proper power management. Discuss with your VAD Coordinator any questions you may have about the HeartWare System or this letter.
- **Always keep two (2) power sources connected to your** controller; never leave your controller connected to only one (1) power source except while briefly switching to another power source.
- Review the recommended practices for power management provided later in this letter. If a battery shows any of the abnormal battery behaviour described, stop using that battery and contact your doctor or VAD Coordinator immediately to replace it.

More information about your power sources can be found in your Patient Manual in the section called “Power Sources for the HeartWare® Controller”.

(1) Text presented in ***Italics*** represents new information related to power management of the device not currently in the Patient Manual.

Battery performance indicators

Lights on the controller, and on each battery, will tell you about battery charge capacity. Alarms will tell you when it is time to change a battery.



Example of HeartWare® Controller Display

When a battery is charged and ready for use, all 4 green lights will be on. As the battery loses charge, fewer lights will appear.

Battery Capacity	Battery Capacity Display on BATTERY	Battery Indicator on CONTROLLER
75-100%	4 GREEN lights	4 GREEN lights
50-74%	3 GREEN lights	3 GREEN lights
25-49%	2 GREEN lights	2 YELLOW lights
Less than 24%	1 GREEN light	1 RED light

RECOMMENDED PRACTICES FOR POWER MANAGEMENT (1)

- **Keep 2 power sources connected to your controller at all times:**
  - Two charged batteries or
  - One charged battery and an AC Adapter or
  - One charged battery and a DC (car charger) Adapter

- **Check your batteries throughout the day. Pay attention to any abnormal behaviour.**
  - The HeartWare® System's *expected* behaviour is as follows: A controller alerts and changes to the second power source only when the battery has less than (<) 25% capacity (1 indicator light) remaining.
  - ***The HeartWare® System's abnormal behaviours are as follows:***

(1) Text presented in ***Italics*** represents new information related to power management of the device not currently in the Patient Manual.

- ***A controller changes to the second battery when the first battery has greater than (>) 25% capacity (2 or more indicator lights) still remaining.***

  ACTION TO BE TAKEN BY PATIENT: Replace the first battery and remove from service.

- ***There is sudden change in charge capacity on a battery (for example, a sudden change from 4 lights to 1 light).***

  ACTION TO BE TAKEN BY PATIENT: Replace the abnormally behaving battery and remove from service.

- ***You hear "beeping" and the controller rapidly switches back and forth between batteries.***

  ACTION TO BE TAKEN BY PATIENT: Replace the battery with more indicator lights first, then replace the battery with fewer lights. Remove the battery with more lights from service as it may be a faulty battery.

Any of these behaviours indicate a battery that needs to be replaced. and could potentially lead to a critically low battery or possible loss of power. These batteries must be taken out of service and returned.

- ***Similar to the battery in a mobile phone, the HeartWare® Batteries lose charge over time. If a fully charged battery lasts less than 2 hours, take it out of service and replace it with a new one.***

How do you return a battery?

Please separate any battery taken out of service due to unusual activity and return it to your doctor or VAD Coordinator for replacement.

Routine battery management [(1)]

- ***Rotate the use of your batteries. If you alternate the use of your batteries, you should get about 1 year of battery service.***
- ***Inspect batteries, battery cable and connectors for physical damage at least once a week.*** DO NOT use batteries that appear damaged***. Damaged batteries must be taken out of service and replaced with new ones.***
- When changing batteries, have the fresh battery within arm's reach before disconnecting the depleted battery. When possible, have a caregiver nearby in case an alarm occurs.
- When you travel, make sure you have fully-charged, spare batteries.
- ***When you come in for clinic visits, remember to bring all your batteries with you.***

(1) Text presented in ***Italics*** represents new information related to power management of the device not currently in the Patient Manual.

Important Patient Manual Information:

WARNING! NEVER disconnect both power sources (batteries, AC Adapter, DC Adapter*)* at the same time. This will stop the pump and activate the No Power alarm. At least one power source must be connected at all times.

WARNING! ALWAYS keep a spare controller and fully-charged batteries available at all times, in case of an emergency.

WARNING! ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.

CAUTION: ALWAYS confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.

CAUTION: ALWAYS recharge completely depleted batteries within 24 hours to avoid permanent battery damage.

Contact your doctor or VAD coordinator if you have questions about your HeartWare® System or believe that your batteries need to be replaced.

Thank you for your cooperation.

(1) Text presented in ***Italics*** represents new information related to power management of the device not currently in the Patient Manual.