Overal 10.2.e., tenzij anders aangegeven

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Doc. 1

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? MHRA
Type of report ○ Initial report ○ Follow-up report ◉ Final report
Date of this report
Reference number assigned by the manufacturer FSCA JAN2013
FSCA reference number assigned by NCA MHRA Ref
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable) U.S.: Food and Drug Administration; Europe: MHRA

2 Information on submitter of the report
Status of submitter ○ Manufacturer ◉ Authorised Representative within EEA and Switzerland ○ Others: (identify the role)

3 Manufacturer information	new

Name HeartWare Inc	
Contact Name	
Address 14000 NW 57th Court	
Postcode FL 33014	**City** Miami Lakes, FL
Phone +1 :	**Fax** +1 305 364 2665
E-mail @heartwareinc.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd	
Contact Name	
Address Windsor House, Barnet Way, Barnwood	
Postcode GL4 3RT	**City** Gloucester
Phone +4	**Fax** +44
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 National contact point information

new

National contact point name MedPass International Ltd	
Name of the contact person	
Address Windsor House, Barnet Way, Barnwood	
Postcode GL4 3RT	**City** Gloucester
Phone +4	**Fax** +44
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977
Nomenclature text	
Circulatory Assist System	
Commercial name/ brand name / make	
HeartWare Ventricular Assist System	
Model number	**Catalogue number**
1100, 1102, 1104, 1205	
Serial number(s)	**Lot/batch number(s)**
All HeartWare HVAD® Pumps	
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number
0086 BSI PRODUCT SERVICES CE marked: 2009-01-29
Accessories / associated devices (if applicable)
Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

An investigation of customer complaints has confirmed a small number of events (11 of approximately 2900 implants) where the rear portion of the HVAD® Pump's driveline connector housing becomes partially separated or fully separated from the front portion of the driveline connector. In the unlikely event of a separation, a repair may be necessary. If left unattended, electrical connection to the controller could be affected and a VAD stop alarm could result. A temporary loss of mechanical circulatory support occurred in 6 of 11 cases of reported connector separations. None of the 6 patients experienced a serious adverse event, such as arrhythmia, acute heart failure or sudden death.

Description and justification of the action (corrective / preventive)

As a corrective action HeartWare has developed a modification to the driveline manufacturing process to prevent future occurrences of this problem. This revised process was approved by the Notified Body (BSI Product Services) and has been implemented in the manufacturing process.

Additionally, HeartWare has developed a Technical Bulletin to alert clinicians to the potential for driveline connector separation and to provide recommended steps to inspect and maintain the integrity of the driveline and driveline connector for product in use.

Should any patients be found to have a loose connector, whether they had a previous repair or not, they should be evaluated in a hospital setting where the repair procedure or a driveline splice can be performed. These procedures are performed by trained HeartWare personnel under the observation of medical staff who can intervene with appropriate methods in the unlikely circumstance that arrhythmia, acute heart failure or loss of consciousness should occur during the brief repair.

Advice on actions to be taken by the distributor and the user

Regular inspection of the driveline is recommended. During routine clinic visits, please inspect the driveline for twisting and for separation of the driveline connector housing. To do this, pull back the white rubber driveline cover and check the connector housing to make sure no separation (partial or complete) is present. If any threads are exposed between the rear and front portion of the connector please follow the steps outlined in the Technical Bulletin, TB00001.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Pursuant to HeartWare's FSCA Strategy, HeartWare has achieved 100% effectiveness monitoring success for the distribution of Technical Bulletin TB00001.

# of Direct Clinical Sites/Distributors Notified	85
# of Non-Direct Clinical Sites Notified	22
# of Sites Reconciled	107
% Effectiveness	100% Effectiveness

In conjunction with the technical bulletin, HeartWare developed a field service repair procedure (MP00306) to repair the loose connector in the rare occasion that a connector separation is observed as a result of the inspection recommended by the technical bulletin.

Additionally, as a long-term preventive action, HeartWare has developed a modification to the driveline manufacturing process to prevent future occurrences of this problem. This revised process was submitted to the Notified Body (BSI Product Services) and has been implemented in the manufacturing process and all new product being shipped to EU sites utilized the revised manufacturing process.

Based on the above information, HeartWare considers all actions related to this Field Safety Corrective Action to be complete.

Time schedule for the implementation of the different actions

1. A modification to the driveline manufacturing process was developed to prevent future occurrences and the manufacturing process changes were implemented on 21-Dec-2012.
2. A field service repair procedure (MP00306) was developed to repair the loose connector and was released for use on 21-Jan-2013.
3. Distribution of the Field Safety Corrective Action containing Technical Bulletin TB00001, FSCA JAN2013, was initiated on 08-Feb-2013.
4. At the request of the French Competent Authority (ANSM), six (6) un-implanted pumps were replaced at five (5) French sites and quarantined at the HeartWare Miami Lakes facility by 18-Apr-2013.
5. Receipt of acknowledgment forms from all EU clinical sites and distributors confirming receipt of the FSN and understanding of the requested actions was completed on 25-Apr-2013.

Attached please find

- ☐ Field Safety Notice (FSN) in English
- ☐ FSN in national language
- ☐ Others (please specify)

FSN Status

- ○ Draft FSN
- ◉ Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☐ CZ	☒ DE	☒ DK
☐ EE	☐ ES	☒ FI	☒ FR	☒ GB	☒ GR	☐ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☐ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☐ RO	☒ SE	☐ SI	☐ SK	☒ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

[redacted]

Van: [redacted] [[redacted]@medpass.org]
Verzonden: donderdag 17 januari 2013 16:09
Aan: _dienstpostbus IGZ meldpunt
CC: MedPassAR
Onderwerp: HeartWare - NL - Follow-up Incident report - [redacted]
Bijlagen: [redacted]_Supplemental-1-MDV_Signed.pdf; [redacted]_Supplemental-1-MDV_Signed_data.xml

Our Reference: Follow-up Incident report [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Madam, dear Sir,

On behalf of HeartWare Inc, the sponsor of the medical device mentioned above, and acting as the European Authorized Representative, we would like to provide you with this follow-up report in pdf and XML format regarding an incident which was already notified to you .

Please, do not hesitate to contact us for further information you may require.

Yours truly,

[redacted]
Regulatory Affairs Assistant

MEDPASS
MedPass International
95 bis, Boulevard Pereire
75017 Paris – France
www.medpass.org

Tel.: +33 (0) 1 [redacted]
Fax.:+33 (0) 1 40 53 81 11
[redacted]@medpass.org

From: [redacted]
Sent: jeudi 22 novembre 2012 09:53
To: 'meldpunt@igz.nl'
Cc: MedPassAR
Subject: HeartWare - NL - initial Incident report - [redacted]

Our Reference: Initial Incident report [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Madam, dear Sir,

On behalf of HeartWare Inc, the sponsor of the medical device mentioned above, and acting as the European Authorized Representative, we would like to provide you with this initial report in pdf and XML format regarding an incident which occurred in the Netherlands .

Please, do not hesitate to contact us for further information you may require.
Yours truly,

Yours sincerely,

[redacted]
Regulatory Affairs Assistant

MedPass International
95 bis, Boulevard Pereire
75017 Paris – France
www.medpass.org

Tel.: +33 (0) 1 [redacted]
Fax.:+33 (0) 1 40 53 81 11
[redacted]*@medpass.org*

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.24en
2012-05-25

1 Administrative information

Recipient (Name of NCA)

[redacted], [redacted]

Stamp box

Address of National Competent Authority

P.O. Box 2680
NL - 3500BS
Utrecht

Date of this report

2013-0[redacted]

Reference number assigned by the manufacturer

[redacted]

Reference number assigned by NCA

Type of report

- ○ Initial report
- ◉ Follow-up report
- ○ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

2 Information on submitter of the report

Status of submitter

- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare, Inc.	
Contact Name	
Address 14420 NW 60th Ave	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail @heartwareinc.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Barnett Way, Barnwood	
Postcode GL43RT	**City** Gloucester
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name HeartWare, Inc.	
Contact Name	
Address 14420 NW 60th Ave	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail @heartwareinc.com	**Country** US - USA

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text
Circulatory Assist System

Commercial name/ brand name / make
HVAD Assist System

Model number	**Catalogue number**
1401DE	

Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
[redacted]	

Software version number (if applicable)

Device Mfr Date	**Expiry date**

Implant date (For implants only)	**Explant date (For implants only)**

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]

User facility report reference number, if applicable
NA

Manufacturer's awareness date
2012-[redacted]

Number of patients involved (if known)	**Number of medical devices involved (if known)**
1	1

Medical device current location/disposition (if known)
The controller has been returned to HeartWare and is awaiting further evaluation.

Operator of the medical device at the time of incident (select one)

- (•) Healthcare Professional
- ( ) Patient
- ( ) Other

Usage of the medical device (select from list below)

- (•) initial use
- ( ) reuse of a single use medical device
- ( ) reuse of a reusable medical device
- ( ) re-serviced/refurbished
- ( ) other
- ( ) problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

Age of the patient at the time of incident, if applicable	**units** ( ) Years ( ) months ( ) days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility
UMC Utrecht

Contact person within the facility

Address
Heidelberglaan 100

Postcode	**City**
3508 GA	Utrecht
Phone	**Fax**
+31	
E-mail	**Country**
@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)
Manufacturer's preliminary analysis
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
Initial corrective actions/preventive actions implemented by the manufacturer
To be reported on follow-up report.
Expected date of next report
2013-03-18

11 Results of manufacturers final investigation (Final report)
The manufacturer's device analysis results
Remedial action/corrective action/preventive action / Field Safety Corrective Action
Time schedule for the implementation of the identified actions
Final comments from the manufacturer
Further investigations
Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?
○ Yes ○ No
Number of similar incidents
0
If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☐AT	☐BE	☐BG	☐CH	☐CY	☐CZ	☐DE	☐DK
☐EE	☐ES	☐FI	☐FR	☐GB	☐GR	☐HU	☐IE
☐IS	☐IT	☐LI	☐LT	☐LU	☐LV	☐MT	☐NL
☐NO	☐PL	☐PT	☐RO	☐SE	☐SI	☐SK	☐TR

Candidate Countries

☐HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Updated sections on 17JAN2013:
Section 7: Medical device current location/disposition updated to include latest information available.

Additional information will be submitted within sixty (60) days from receipt, as the device is still being evaluated.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

[redacted]

Van: [redacted] [[redacted]@medpass.org]
Verzonden: dinsdag 13 augustus 2013 10:32
Aan: [redacted]; [redacted]; '[redacted]@mhra.gsi.gov.uk'; [redacted]
Onderwerp: RE: HeartWare - CMP-[redacted] CON [redacted] BAT[redacted]

Dear [redacted],

I think the answer here is simple. We did not copy Heartware in to our response to you, as we felt that it was not appropriate to share the content of that correspondence with a manufacturer. Thus Heartware was not aware that we had already addressed this issue. In fact we are in the process of confirming to Heartware that this issue has been dealt with.

From our earlier exchange of emails, I gathered that you were happy to close this particular issue. However, if there are any other points I can clarify, I would be happy to do so.

Best wishes

[redacted]

From: [redacted] [mailto:[redacted]@igz.nl]
Sent: 13 August 2013 10:22
To: [redacted]; [redacted]; '[redacted]@mhra.gsi.gov.uk'; [redacted]
Subject: RE: HeartWare - CMP-[redacted] CON [redacted] BAT[redacted]

Dear [redacted],

I think the discussion we had on the role of the AR (for which you last replied at 17-7-2013) is about to come to an end. We have received the reply from HeartWare to our questions and we are evaluating those now, in collaboration with the MHRA. I would like to take this final opportunity however, to point out which answer HeartWare has given when I addressed the issue of the not-answered emails:

"14. DHCI: Regarding the communication of MedPass and HeartWare with the DHCI:

The DHCI has asked several questions regarding HeartWare incidents. The two emails are attached to the present email. Several deadlines for responses have passed and no reaction from MedPass has returned at all. In communication with the DHCI, the MHRA states that according to MedPass "simple technical explanations" are accountable for this, like sending the answers to wrong email addresses. However, as you can see in the attached messages, the email-addresses at which we want to receive our replies are clearly stated. So this cannot be accepted as a possible explanation. Please explain why these questions have not been answered properly.

This response will be provided by MedPass."

Your answer to this issue (provided in the same email mentioned above) shows that MedPass is pointing at HeartWare for the responsibility to correctly reply to emails, while HeartWare now obviously points back at MedPass. Perhaps this is something which still needs to be sorted out with your client.

Met hartelijke groet,
With kind regards,

[redacted]

Senior Inspecteur
Senior Inspector

Programma Medische Technologie
Inspectie voor de Gezondheidszorg
Dutch Health Care Inspectorate
Wilhelmina van Pruisenweg 52 | 2595 AN | Den Haag
Postbus 90460 | 2509 LL | Den Haag

T +31 (0)70
F +31 (0)70 304 1570
M +31 (0)6 (preferred)
@igz.nl
http://www.igz.nl

Van: [mailto: @medpass.org]
Verzonden: maandag 12 augustus 2013 17:43
Aan: ; '@mhra.gsi.gov.uk';
CC: ; '@mhra.gsi.gov.uk'; '@mhra.gsi.gov.uk';
Onderwerp: RE: HeartWare - CMP- CON BAT

Dear ,

Please find attached response to your questions from HeartWare.

Please don't hesitate in contacting us again should you require any further information.

Best regards,

Regulatory Affairs Consultant
& AESU Coordinator
MedPass International
95 bis, Boulevard Pereire
75017 Paris – France
www.medpass.org
Tel.: +33 (0)
Fax.:+33 (0) 1 40 53 81 11
@medpass.org

From: [mailto: @igz.nl]
Sent: 05 July 2013 12:19
To: ; '@mhra.gsi.gov.uk';
Cc: ; @mhra.gsi.gov.uk'; '@mhra.gsi.gov.uk';
Subject: RE: HeartWare - CMP- CON BAT

Dear ,

Thank you for getting in touch with the Dutch Health Care Inspectorate (DHCI). Unfortunately, the information below does not answer any of the primary concerns the DHCI has with HeartWare, which should be addressed by the manufacturer through their Authorized Representative in Europe, which is MedPass. Therefore, these concerns by the DHCI will keep being directed at MedPass.

The DHCI still has concerns with respect to a number of incidents, if you would please be so kind to address these concerns appropriately:

- [redacted]: the DHCI has been in touch with the clinical site, who reported that the issue of susceptibility to ESDs was already known to HeartWare in [redacted] 2012 and a local corrective action has even taken place (devices with better shielding have been sent by HeartWare to replace those in use by patients at the time). Matters at this site have been handled by HeartWare representatives [redacted] and [redacted]. The site describes interaction between the site, the reps and the United States, after which the "diagnosis" of the device was clear according to the reps: ESDs. This was followed by replacement of the devices with devices with better ESD shielding. [redacted], so this was not likely to be an older type or anything. 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
  There are several follow-up concerns regarding this case:
  - The DHCI is concerned after receipt of the information from the clinical site. In the FSCA sent out by HeartWare, the manufacturer primarily points out problems may be caused by incorrect use and caution is adviced for patients. However, our information also suggests there are technical improvements available to decrease risks. What can and will HeartWare do to improve technical functionality of their devices?
  - The information provided to us by the clinical site suggests local corrective actions have already taken place, by replacement of the older devices with newer devices including improved ESD shielding. Have there been any similar corrective actions in The Netherlands? In Europe? In the World?
  - What is the status of ESD shielding of HeartWare devices? When was the latest improvement in ESD shielding and which actions have followed this improvement?
  - Do new products delivered by Heartware always include this 'better shielding'? How many older products may still be in use which may have less optimal shielding?
  - The advice mentioned in the FSCA "to stay away from tvs and computers" is practically impossible to follow for patients with these devices, especially in the present, because these devices cannot be avoided. The DHCI suggests that HeartWare comes up with alternative actions for this advice.
- [redacted] - Our information suggests that it had already been concluded that ESDs were responsible for this particular incident in [redacted], yet the final report reached us in [redacted] 2013.
  - Can HeartWare clarify why this final conclusion takes so much time?
  - The investigational site claims that all patients at that time have received new devices, including better shielding against ESDs, why is that corrective action not communicated to the DHCI?
  - The clinical site reported that two incidents had taken place which can be traced back to ESDs, leading to the local corrective action in both patients. Why is there only one reported to the DHCI?
  - How many incidents are known to HeartWare, which can be related to ESDs in The Netherlands? In Europe? In the world?

- Regarding event [redacted]:
  - The final comments from the manufacturer include comments like: "The battery's VDC pin insertion depths did not meet the latest specification", yet no corrective actions is warranted according to the manufacturer, why is this?
  - Is HeartWare claiming that this incident has occurred due to inappropriate assembly of the batteries by the patient? In this case: what would be appropriate steps to be taken by HeartWare to ensure proper instructions to patients for correct assembly?
  - If there are new devices on the market according to the latest specifications: how many older devices are still operational on the Dutch market at this point?

- Regarding the communication of MedPass and HeartWare with the DHCI:
  - The DHCI has asked several questions regarding HeartWare incidents. The two emails are attached to the present email. Several deadlines for responses have passed and no reaction from MedPass has returned at all. In communication with the DHCI, the MHRA states that according to MedPass "simple technical explanations" are accountable for this, like sending the answers to wrong emailaddresses. However, as you can see in the attached messages, the email-addresses at which we want to receive our replies are clearly stated. So this cannot be accepted as a possible explanation. Please explain why these questions have not been answered properly.
- The DHCI does not see the benefit of the follow-up incident reports, given that the additional information given in these reports is generally minimal. We strongly suggest to revise this reporting system and be more specific when final incident reports can be expected.

The DHCI is looking forward to receive a response to the issues described above as soon as possible, but due to the delays in the past, no later than [redacted] 2013. Please use the "reply to all"-functionality to keep all parties involved informed of your reply.

Met hartelijke groet,
With kind regards,

[redacted]
Senior Inspecteur
Senior Inspector

Programma Medische Technologie
Inspectie voor de Gezondheidszorg
Dutch Health Care Inspectorate
Wilhelmina van Pruisenweg 52 | 2595 AN | Den Haag
Postbus 90460 | 2509 LL | Den Haag

T +31 (0)70 [redacted]
F +31 (0)70 304 1570
M +31 (0)6 [redacted] (preferred)
[redacted]@igz.nl
http://www.igz.nl

Van: [redacted] [mailto[redacted]@medpass.org]
Verzonden: vrijdag 21 juni 2013 14:38
Aan: [redacted]
CC: [redacted]
Onderwerp: HeartWare - CMP-[redacted] CON [redacted] BAT [redacted]

Reference: CMP-[redacted] CON [redacted] BAT [redacted]

Dear [redacted],

I am contacting you in relation to the abovementioned incident and in particular to respond directly to you regarding your feedback that we received via the UK Medicines and Healthcare Products Regulatory Agency (MHRA). To address the issues raised, HeartWare, Inc. has prepared the following summary of activities related to the processing of this event and its reporting to the Dutch Health Care Inspectorate:

HeartWare became aware of the reported event on [redacted] 2012. MDR/MDV determination was completed on [redacted] 2012 (10 days from awareness). Additional information regarding the event details and patient outcome was requested from the clinical site by HeartWare on [redacted], 2012 and additional information was received from the site on [redacted], 2012. At this time the site indicated that no further event information would be forthcoming. An event description was written from the compiled information:

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

[redacted]. Attempts by HeartWare to obtain additional event information from the site were unsuccessful.

An initial request from HeartWare for the return of the controller (CON[redacted]) was submitted to the clinical site on [redacted] 2012. Two additional product return follow ups were performed and the product was received by HeartWare on [redacted] 2012. Following analysis and testing of the controller, the Product Quality Engineers requested that the battery in use at the time of the event (BAT[redacted]) be returned to HeartWare for additional testing and analysis. The site was contacted on [redacted], 2013 with an initial request to return the battery. HeartWare performed an additional seven product return follow ups, and the battery was finally received by HeartWare on [redacted], 2013. Since receipt, the controller and battery have been undergoing testing analysis, both individually and together as a system, in attempts to determine the cause of the reported event. The final investigation report was submitted in the HeartWare document control system on [redacted] 2013 and was fully approved on [redacted] 2013.

Over the course of the investigation, a total of 4 MDV reports (1 initial and 3 Supplemental) have been submitted in accordance with MEDDEV Guidelines to the Dutch Competent Authority via HeartWare's European Authorized Representative, MedPass International:

- Initial MDV: [redacted] 2012 (within 27 days of awareness)
- Follow-up Report #1: [redacted], 2013
- Follow-up Report #2: [redacted], 2013
- Follow-up Report #3: [redacted] 2013

The final MDV has now been drafted and is pending management approvals. We anticipate submission of the final MDV report for this event by the end of next week, [redacted] 2013.

While we can appreciate that this timescale might appear excessive, it is not untypical for a routine incident investigation with an LVAD.

Please be aware that MedPass International, Ltd. in it's capacity as Authorised Representative for HeartWare, Inc. passes on all communications received by Competent Authorities to the manufacturer and forwards all responses prepared by HeartWare directly to the applicable Authority, in accordance with our Standard Operating Procedures. Following a review of this case, MedPass International can confirm that all actions have been completed in accordance with the timelines set out in our procedures, which means that all correspondence was forwarded on the day it was received or the next working day.

Yours sincerely,

[redacted]
Regulatory Affairs Consultant
& AESU Coordinator
MedPass International
95 bis, Boulevard Pereire
75017 Paris – France
www.medpass.org
Tel.: +33 (0) [redacted]
Fax.:+33 (0) 1 40 53 81 11
[redacted]@medpass.org

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is toegezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. The State accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages. .

10.2.e, tenzij anders aangegeven.

Doc. 41

[redacted]

Van: [redacted] [redacted]@medpass.org]
Verzonden: woensdag [redacted] 2013 15:11
Aan: _dienstpostbus IGZ meldpunt
CC: MedpassAR
Onderwerp: HeartWare - NL - Combined Initial- final Incident report - CMP-[redacted]

Bijlagen: Initial-Final MDV for CMP-[redacted]_BAT[redacted]_BAT[redacted]_BAT[redacted]_BAT[redacted]_....xml; Initial-Final MDV for CMP-[redacted]_BAT[redacted]_BAT[redacted]_BAT[redacted]_BAT[redacted]_....pdf

Our Reference: Combined Initial /final Incident report CMP [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding combined incident report in pdf and xml format.
Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

Yours sincerely,

[redacted]
Regulatory Affairs Assistant

MedPass International
95 bis, Boulevard Pereire
75017 Paris – France
www.medpass.org

Tel.: +33 (0) [redacted]
Fax.:+33 (0) 1 40 53 81 11
[redacted]*@medpass.org*

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)

[redacted]

Stamp box

Address of National Competent Authority

Dutch Healthcare Inspectorate
Postal address: P.O. Box 2680, NL - 3500 BS Utrecht, Visitors address: St. Jacobsstraat 16, NL
E-mail: meldpunt@igz.nl

Date of this report

2013[redacted]

Reference number assigned by the manufacturer

CMP[redacted]

Reference number assigned by NCA

Type of report

- ○ Initial report
- ○ Follow-up report
- ◉ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter

- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name	
HeartWare, Inc.	
Contact Name	
[redacted]	
Address	
14400 NW 60th Ave	
Postcode	**City**
33014	Miami Lakes
Phone	**Fax**
1-[redacted]	1-[redacted]
E-mail	**Country**
[redacted]@heartwareinc.com	US - USA

4 Authorised Representative Information

new

Name	
MedPass International Ltd.	
Contact Name	
[redacted]	
Address	
Windsor House, Barnett Way, Barnwood	
Postcode	**City**
GL43RT	Gloucester
Phone	**Fax**
44(0)[redacted]	44(0)[redacted]
E-mail	**Country**
medpass.ar@medpass.org	GB - Great Britain

5 Submitter's information

new

Name	
HeartWare, Inc.	
Contact Name	
[redacted]	
Address	
14400 NW 60th Ave	
Postcode	**City**
33014	Miami Lakes
Phone	**Fax**
1-[redacted]	1-[redacted]
E-mail	**Country**
[redacted]@heartwareinc.com	US - USA

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977
Nomenclature text	
Artificial heart, temporary	
Commercial name/ brand name / make	
HeartWare® Ventricular Assist System	
Model number	**Catalogue number**
1650	
Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
BAT [redacted] BAT BAT BAT BAT BAT	
Software version number (if applicable)	
Device Mfr Date	**Expiry date**
2011-06-05	
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable)	
Battery-BAT [redacted]	
Notified Body (NB) ID-number	
0086 BSI Product Services	

7 Incident Information

Date the incident occurred

[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative

[redacted]

User facility report reference number, if applicable	
Manufacturer's awareness date 2013	
Number of patients involved (if known) 1	**Number of medical devices involved (if known)** 7
Medical device current location/disposition (if known) The devices are currently at HeartWare.	

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

[redacted]. 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

[redacted]. 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility
UMC Utrecht

Contact person within the facility
[redacted]

Address
Heidelberglaan 100

Postcode	**City**
CX	Utrecht
Phone	**Fax**
003 1[redacted]	
E-mail	**Country**
[redacted]@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

Functional testing on six of the seven returned batteries revealed a faulty cell pair.

Initial corrective actions/preventive actions implemented by the manufacturer

none

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

The products were returned to HeartWare. Various analyses were conducted and reviewed in order to evaluate the performance of the devices in relation to the reported event. Thorough external visual inspection of the batteries revealed no signs of physical damage or contamination. Review of Conformance Material Record confirmed that the batteries met all requirements for release. Functional analysis of the batteries revealed that six (BAT , BAT , BAT , BAT , BAT and BAT) of the seven returned batteries contained a faulty cell pair.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

An internal investigation (CAPA) has been open to address the issue.

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

Functional analysis of the batteries revealed that six (BAT , BAT , BAT , BAT , BAT and BAT) of the seven returned batteries contained a faulty cell pair. An internal investigation (CAPA) has been open to address the issue.

Further investigations

none

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(•) Yes ( ) No

Number of similar incidents

22 (data from June 2010 to June 2013)

If yes, state in which countries and the report reference numbers of the incidents.

Data from June 2010 to June 2013

CMP- Germany
CMP- Germany
CMP- Germany
CMP Germany
CMP Germany
CMP- Germany
CMP- Germany

CMP-	Germany
CMP-	Germany
CMP-	Germany
CMP-	Germany
CMP	Germany
CMP-	Greece
CMP-	Sweden
CMP-	United States
CMP-	United States
CMP-	United States
CMP-	United States
CMP-	United States
CMP-	United States
CMP-	United States
CMP-	United States

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☐ RO	☒ SE	☐ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, New Zealand, Malaysia, Hong Kong, Israel, Chile, South Africa, Saudi Arabia, (Continued in Section 12 Comments)

12 Comments

(Continued from Section 11 Distributed Countries) Belarus, Ukraine, Lebanon, Japan, India, Kazakhstan, Brazil, Singapore and Canada.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

[redacted]

Van: [redacted] [redacted]@medpass.org]
Verzonden: donderdag [redacted] 2013 16:47
Aan: _dienstpostbus IGZ meldpunt
CC: MedpassAR
Onderwerp: HeartWare - NL - Initial Incident report - CMP [redacted] - [redacted] - [redacted]
Bijlagen: Initial MDV for_CMP-[redacted]_Signed_data.xml; Initial MDV for_CMP-[redacted]_Signed.pdf; CMP-[redacted]_Cover_Letter_Late Reporting_Netherlands_CS.PDF

Our Reference: Initial Incident report CMP [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding initial incident report in pdf and xml format and a Late Report Memo . Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

[redacted]
Regulatory Affairs Assistant

MEDPASS

MedPass International
95 bis, Boulevard Pereire
75017 Paris – France
www.medpass.org

Tel.: +33 (0)[redacted]
Fax.:+33 (0) 1 40 53 81 11
[redacted]*@medpass.org*

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.24en
2012-05-25

1 Administrative information

Recipient (Name of NCA)
Dutch Healthcare Inspectorate - [redacted], [redacted]

Stamp box

Address of National Competent Authority
P.O. Box 2680
NL - 3500 BS
Utrecht

Date of this report
2013[redacted]

Reference number assigned by the manufacturer
CMP-[redacted]

Reference number assigned by NCA

Type of report
- (•) Initial report
- ( ) Follow-up report
- ( ) Combined initial and final report
- ( ) Final report

Does the incident represent a serious public health threat?
- ( ) yes
- (•) no

Classification of incident
- ( ) Death
- ( ) Unanticipated Serious Deterioration in State of Health
- (•) All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- (•) Manufacturer
- ( ) Authorised Representative within EEA and Switzerland and Turkey
- ( ) Others: (identify the role)

3 Manufacturer information

new

Name HeartWare, Inc.	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail @heartwareinc.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Barnett Way, Barnwood	
Postcode GL43RT	**City** Gloucester
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name HeartWare, Inc.	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail @heartwareinc.com	**Country** US - USA

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	Catalogue number
1104	

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
[redacted]	

Software version number (if applicable)

Device Mfr Date	Expiry date
2011-12-01	2012-12-31

Implant date (For implants only)	Explant date (For implants only)
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2013[redacted]

Number of patients involved (if known)	Number of medical devices involved (if known)
1	1

Medical device current location/disposition (if known)
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility
Leiden University Medical Center

Contact person within the facility

Address
Albinusdreef 2

Postcode	**City**
2333 ZA	Leiden
Phone	**Fax**
E-mail	**Country**
@lumc.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)
Manufacturer's preliminary analysis A preliminary review of controller log files revealed high LVAD ( ) power consumption.
Initial corrective actions/preventive actions implemented by the manufacturer To be reported on follow-up report
Expected date of next report 2014-02-07

11 Results of manufacturers final investigation (Final report)
The manufacturer's device analysis results
Remedial action/corrective action/preventive action / Field Safety Corrective Action
Time schedule for the implementation of the identified actions
Final comments from the manufacturer
Further investigations
Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause? ○ Yes ○ No
Number of similar incidents 0
If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☐ AT	☐ BE	☐ BG	☐ CH	☐ CY	☐ CZ	☐ DE	☐ DK
☐ EE	☐ ES	☐ FI	☐ FR	☐ GB	☐ GR	☐ HU	☐ IE
☐ IS	☐ IT	☐ LI	☐ LT	☐ LU	☐ LV	☐ MT	☐ NL
☐ NO	☐ PL	☐ PT	☐ RO	☐ SE	☐ SI	☐ SK	☐ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

December 11, 2013

Dutch Healthcare Inspectorate
P.O. Box 2680
NL - 3500 BS Utrecht

Re: Complaint # CMP-[redacted]
Product Serial Number: [redacted]

To whom it may concern,

Please find attached the Initial MDV report for the above referenced incident. We evaluated this reported event against MEDDEV 2 12-1 rev. 8 Vigilance and determined that this event meets the criteria for MDV reporting as a serious injury.

10.2.e

Please note that this event occurred on [redacted] and the HeartWare Field Clinical Specialist was notified of the event on [redacted]; however, the rep failed to enter the information into the Heartware Complaint Handling System in a timely manner.

Therefore, this event is being submitted as a late MDV report. This was determined to be an isolated deviation from internal HeartWare procedure. The HeartWare Field Clinical Specialist has been retrained to the HeartWare Complaint Handling Procedure and the documentation will be part of this complaint investigation.

Thank you and best regards,

[redacted]

HeartWare, Inc.
14400 NW 60th Ave. Miami Lakes, FL 33014
Tel: (305) [redacted] Fax: (305) 818-3950
www.heartware.com

cc: [redacted]

Scoreformulier meldingen medische technologie

WPM-nr	
Omschrijving incident	Incident met HeartWare® Ventricular Assist System VAD Coordinator reported patient hears single beeps coming from controller while power
A. Ernst van het incident	
geen letsel	
Matig letsel	x
Ernstig/levensbedreigend/overlijden	
B. Detecteerbaarheid van de gebeurtenis door gebruiker	
Zeer waarschijnlijk	
Waarschijnlijk	
Niet waarschijnlijk	x
Erg onwaarschijnlijk	
C. Frequentie en kans van de gebeurtenis	
Eenmalig; geïsoleerde gebeurtenis	
Meerdere incidenten; specifieke gebruiker / instelling gerelateerd	
meerdere incidenten: specifiek lot / serienummer gerelateerd	x
Meerdere incidenten: verschillende lotnummers / serienummer gerelateerd / instellingen	
D. Impact op de Nederlandse markt	
Geen impact	
Matige impact	
Hoge impact	x
Totale score	**90**
Risicogroep	**level II**
Eventuele opmerkingen:	

FSCA	INCIDENT

Let op: Als er geen gegevens beschikbaar zijn wordt bij A, B, C en D de op één na hoogste score ingevuld

A. Ernst van het incident

scoren als er geen gezondheidsrisico is. Als dat het geval is, had de fabrikant eigenlijk geen melding hoeven maken. Veel fabrikanten doen dat uit voorzorg echter wel. Bij dergelijke casussen kunnen de andere categorieën op het laagste aantal punten gescoord worden, zodat de melding in de categorie 'Trend'. MP handelt deze verder af	geen of nagenoeg geen schade, ongemak
Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden.	medische interventie volgend uit het letsel, uitstel van diagnose, incorrecte diagnose, vertraging van behandeling, incorrecte behandeling
Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden.	permanent of onherstelbaar letsel, onnodige operatie ten gevolge van het letsel, verlengde ziekenhuisopname
Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden.	levensbedreigend letsel, overdracht van een levensbedreigende infectie, dood van de patiënt

B. Detecteerbaarheid van de gebeurtenis door gebruiker

het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet worden gebruikt;	het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet worden gebruikt;
het defect aan het hulpmiddel is zichtbaar;	het defect aan het hulpmiddel is zichtbaar;
het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op een andere wijze nog duidelijk kunnen worden	het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op een andere wijze nog duidelijk kunnen worden
het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen.	het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen.

C. Frequentie en kans van de gebeurtenis

specifiek lotnummer EN ingeschatte kans op bedoelde risico door fabrikant laag ingeschat	geen eerdere vergelijkbare incidenten
specifiek lotnummer EN ingeschatte kans op bedoelde risico in grote mate aanwezig	soortgelijke incidenten bij dezelfde gebruiker/instellingen
meerdere lotnummers en/of serienummers aangedaan, enkele producten per lot- of serienummer. EN / OF ingeschatte kans op bedoelde risico door fabrikant laag ingeschat	soortgelijke incidenten met hetzelfde lot/serienummer
meerdere lotnummers en/of serienummers aangedaan, grote hoeveelheden per lot- of serienummer EN / OF ingeschatte kans op bedoelde risico in grote mate aanwezig	meerdere incidenten : verschillende lotnummers / serienummers gerelateerd / instellingen

D. Impact op de Nederlandse markt

het hulpmiddel is niet op de Nederlandse markt (deze situatie zal zich voornamelijk voordoen bij NCARs, waarbij Nederland niet genoemd staat. Per 1 januari 2012 worden deze NCARs als melding of signaal geregistreerd in WPM. Meldpunt sluit deze af).	het betrokken hulpmiddel is op de Nederlandse markt maar geen incidenten in Nederland gemeld, de fabrikant of de Europees Gemachtigde is in Nederland gevestigd
het betrokken hulpmiddel is op de Nederlandse markt	het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een incident dat in Nederland heeft plaatsgevonden
het betrokken hulpmiddel is op de Nederlandse markt EN er heeft een incident in Nederland plaatsgevonden; OF het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een gevoelig onderwerp (nog door P10 te formuleren).	het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een incident dat in Nederland heeft plaatsgevonden EN het betreft een gevoelig onderwerp (nog door P10 te formuleren).

Interpretatietabel uit Procedure meldingen over Medische technologie, versie 1 apnl 2014 pp 15-17

Overal 10.2.e, tenzij anders aangegeven.

Risicoscoreformulier [redacted]

WPM-nr	[redacted]	FSCA
Overweging incident/FSCA	power switching in the batteries and noticed that the controller displayed high watts alarms.	*Overweging: Toelichting incident / FSCA indien bekend: basisoorzaak, tijdelijk implementatie, aantal incidenten in WPM, klantenlijst(level II, III). Let op: Als e hoogste score ingevuld*
A. Ernst van het incident		A. Ernst van het incident
geen letsel		scoren als er geen gezondheidsrisico is. Als dat het geval is, had de fabrikant eigenlijk geen melding hoeven maken. Veel fabrikanten doen dat uit voorzorg echter wel. Bij dergelijke casussen kunnen de andere categorieën op het laagste aantal punten gescoord worden, zodat de melding in de categorie Trend - MP handelt deze verder af
Beperkt letsel	x	Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden
Matig letsel		Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden
Ernstig/levensbedreigend/overlijden		Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden
B. Detecteerbaarheid van de gebeurtenis door gebruiker		B. Detecteerbaarheid van de gebeurtenis door gebruiker
Zeer waarschijnlijk		het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet worden gebruikt
Waarschijnlijk	x	het defect aan het hulpmiddel is zichtbaar
Niet waarschijnlijk		het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op een andere wijze nog duidelijk kunnen worden
Erg onwaarschijnlijk		het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen
C. Frequentie en kans van de gebeurtenis		C. Frequentie en kans van de gebeurtenis
Eenmalig, geïsoleerde gebeurtenis		specifiek lotnummer EN ingeschatte kans op bedoelde risico door fabrikant laag ingeschat
Meerdere incidenten, specifieke gebruiker / instelling gerelateerd		specifiek lotnummer EN ingeschatte kans op bedoelde risico in grote mate aanwezig
meerdere incidenten, specifiek lot / serienummer gerelateerd		meerdere lotnummers en/of serienummers aangedaan, enkele producten per lot- of serienummer, EN / OF ingeschatte kans op bedoelde risico door fabrikant laag ingeschat
Meerdere incidenten, verschillende lotnummers / serienummer gerelateerd / instellingen	x	meerdere lotnummers en/of serienummers aangedaan, grote hoeveelheden per lot- of serienummer EN / OF ingeschatte kans op bedoelde risico in grote mate aanwezig
D. Impact op de Nederlandse markt		D. Impact op de Nederlandse markt
Geen impact		het hulpmiddel is niet op de Nederlandse markt (deze situatie zal zich voornamelijk voordoen bij NCARs, waarbij Nederland niet genoemd staat. Per 1 januari 2012 worden deze NCARs als melding of signaal geregistreerd in WPM. Meldpunt sluit deze af)
Matige impact	x	het betrokken hulpmiddel is op de Nederlandse markt
Hoge impact		het betrokken hulpmiddel is op de Nederlandse markt EN er heeft een incident in Nederland plaatsgevonden OF het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een gevoelig onderwerp (nog door P10 te formuleren)
Totale score	50	*Interpretatietabel uit Procedure meldingen over Medische technolog*
Risicogroep	**level I**	LET OP! Indien Fabrikant/AR gevestigd in NL, ongeacht of product wel of niet aanwezig op Nederlandse markt. Risicoscore level III, bij uitzondering level II, niet plus gevoel of PSR, verzend eventueel NCAR volgens NCAR-procedure
Eventuele opmerkingen		

INCIDENT

'o verbatermaatregel, structurele verbatermaatregel en voortgang
r geen gegevens beschikbaar zijn wordt bij A, B, C en D de op één na

geen of nagenoeg geen schade, ongemak
medische interventie volgend uit het letsel, uitstel van diagnose, incorrecte diagnose, vertraging van behandeling, incorrecte behandeling
permanent of onherstelbaar letsel, onnodige operatie ten gevolge van het letsel, verlengde ziekenhuisopname
levensbedreigend letsel, overdracht van een levensbedreigende infectie, dood van de patiënt

het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet worden gebruikt.
het defect aan het hulpmiddel is zichtbaar.
het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op een andere wijze nog duidelijk kunnen worden
het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen

geen eerdere vergelijkbare incidenten
soortgelijke incidenten bij dezelfde gebruiker/instellingen
soortgelijke incidenten met hetzelfde lot/serienummer
meerdere incidenten, verschillende lotnummers / serienummers gerelateerd / instellingen

het betrokken hulpmiddel is op de Nederlandse markt maar geen incidenten in Nederland gemeld, de fabrikant of de Europees Gemachtigde is in Nederland gevestigd
[redacted]
het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een incident dat in Nederland heeft plaatsgevonden EN het betreft een gevoelig onderwerp (nog door P10 te formuleren)

Scoreformulier [redacted]

WPM-nr	[redacted]	FSCA
Overweging incident/FSCA	FIR, incident Fabrikant, HeartWare. AR: MedPass International Limited Product: HeartWare® Ventricular Assist System. Artificial heart	*Overweging: Toelichting incident / FSCA indien bekend: basisoorzaak, tijdelijk implementatie, aantal incidenten in WPM, klantenlijst(level II, III). Let op: Als e hoogste score ingevuld*
A. Ernst van het incident		A. Ernst van het incident
geen letsel	x	scoren als er geen gezondheidsrisico is. Als dat het geval is, had de fabrikant eigenlijk geen melding hoeven maken. Veel fabrikanten doen dat uit voorzorg echter wel. Bij dergelijke casussen kunnen de andere categorieën op het laagste aantal punten gescoord worden, zodat de indeling in de categorie Trend MP handelt deze verder af
Beperkt letsel		Zie beschrijving incident. Scoren als de fabrikant het risico er plausibel inschat als de FSCA niet zou plaatsvinden
Matig letsel		Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden
Ernstig/levensbedreigend/overlijden		Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden
B. Detecteerbaarheid van de gebeurtenis door gebruiker		B. Detecteerbaarheid van de gebeurtenis door gebruiker
Zeer waarschijnlijk		het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet gebruikt
Waarschijnlijk	x	het defect aan het hulpmiddel is zichtbaar
Niet waarschijnlijk		het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op andere wijze nog duidelijk kunnen worden
Erg onwaarschijnlijk		het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen
C. Frequentie en kans van de gebeurtenis		C. Frequentie en kans van de gebeurtenis
Eenmalig, geïsoleerde gebeurtenis		specifiek lotnummer EN ingeschatte kans op bedoelde risico door fabrikant laag ingeschat
Meerdere incidenten, specifieke gebruiker / instelling gerelateerd		specifiek lotnummer EN ingeschatte kans op bedoelde risico in grote mate aanwezig
meerdere incidenten: specifiek lot / serienummer gerelateerd		meerdere lotnummers en/of serienummers aangedaan, echter per lot- of serienummer EN / OF ingeschatte kans op bedoelde risico door fabrikant laag ingeschat
Meerdere incidenten: verschillende lotnummers / serienummer gerelateerd / instellingen	x	meerdere lotnummers en/of serienummers aangedaan, grote mate per lot- of serienummer EN / OF ingeschatte kans op bedoelde risico in grote mate aanwezig
D. Impact op de Nederlandse markt		D. Impact op de Nederlandse markt
Geen impact		het hulpmiddel is niet op de Nederlandse markt (deze situatie zal zich voornamelijk voordoen bij NCARs, waarbij Nederland niet genoemd staat. Per 1 januari 2012 worden deze NCARs als melding of signaal geregistreerd in WPM. Meldpunt sluit deze af)
Matige impact	x	het betrokken hulpmiddel is op de Nederlandse markt
Hoge impact		het betrokken hulpmiddel is op de Nederlandse markt EN er heeft incident in Nederland plaatsgevonden OF het betrokken hulpmiddel Nederlandse markt EN het betreft een gevoelig onderwerp (nog te formuleren)
Totale score	46	*Interpretatietabel uit Procedure meldingen over Medische te*
Risicogroep	**level I**	LET OP: Indien Fabrikant/AR gevestigd in NL, ongeacht of product wel of niet aanwezig op Nederlandse markt. Risicoscore level III, bij uitzondering level II niet plus gevoel of PSR, verzend eventueel NCAR volgens NCAR procedure
Eventuele opmerkingen:	B: waarschijnlijk ingevuld ivm alarm	

INCIDENT

'e verbeteimaatregel, structurele verbeteimaatregel en voortgang r geen gegevens beschikbaar zijn wordt bij A, B, C en D de op één na

geen of nagenoeg geen schade, ongemak
medische interventie volgend uit het letsel, uitstel van diagnose, incorrecte diagnose, vertraging van behandeling, incorrecte behandeling
permanent of onherstelbaar letsel, onnodige operatie ten gevolge van het letsel, verlengde ziekenhuisopname
levensbedreigend letsel, overdracht van een levensbedreigende infectie, dood van de patient

het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet worden gebruikt
het defect aan het hulpmiddel is zichtbaar
het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op een andere wijze nog duidelijk kunnen worden
het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen

geen eerdere vergelijkbare incidenten
soortgelijke incidenten bij dezelfde gebruikersinstellingen
soortgelijke incidenten met hetzelfde lot/serienummer
meerdere incidenten, verschillende lotnummers / serienummers gerelateerd / instellingen

het betrokken hulpmiddel is op de Nederlandse markt maar geen incidenten in Nederland gemeld, de fabrikant of de Europees Gemachtigde is in Nederland gevestigd
het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een incident dat in Nederland heeft plaatsgevonden
het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een incident dat in Nederland heeft plaatsgevonden EN het betreft een gevoelig onderwerp (nog door P10 te formuleren)

Doc. 107

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Overal 10.2.e, tenzij anders aangegeven

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal address: P.O. Box 2680, NL 3500 BS Utrecht	

Date of this report

2014

Reference number assigned by the manufacturer

CMP-

Reference number assigned by NCA

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter

- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name	
HeartWare, Inc.	
Contact Name	
Address	
14400 NW 60th Avenue	
Postcode	**City**
33014	Miami Lakes
Phone	**Fax**
	1-
E-mail	**Country**
@heartwareinc.com	US - USA

4 Authorised Representative Information

new

Name	
MedPass International Ltd.	
Contact Name	
Address	
Windsor House, Barnett Way, Barnwood	
Postcode	**City**
GL43RT	Gloucester
Phone	**Fax**
	44(0
E-mail	**Country**
medpass.ar@medpass.org	GB - Great Britain

5 Submitter's information

new

Name	
HeartWare, Inc.	
Contact Name	
Address	
14400 NW 60th Avenue	
Postcode	**City**
33014	Miami Lakes
Phone	**Fax**
1	1-
E-mail	**Country**
@heartwareinc.com	US - USA

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN) GMDN	**Nomenclature code** 16977
Nomenclature text Artificial heart, temporary	
Commercial name/ brand name / make HeartWare® Ventricular Assist System	
Model number 1401DE	**Catalogue number**
Serial number(s) (if applicable) [redacted] - Controller	**Lot/batch number(s) (if applicable)**
Software version number (if applicable) 19	
Device Mfr Date 2010-[redacted]	**Expiry date**
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable)	
Notified Body (NB) ID-number 0086 BSI Product Services	

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2013-[redacted]

Number of patients involved (if known) 1	**Number of medical devices involved (if known)** 1

Medical device current location/disposition (if known)
The Controller is currently at HeartWare.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

None

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility

Leiden University Medical Center

Contact person within the facility

Address

Albinusdreef 2

Postcode	**City**
2333	Leiden, Noord-Holland
Phone	**Fax**
E-mail	**Country**
@lumc.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

none

Initial corrective actions/preventive actions implemented by the manufacturer

none.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

The controller was returned for analysis. Review of the manufacturing records indicates that this device met all specifications for release. The controller passed all visual as well as functional testing. The log files do confirm a PMC reset and an audible-only alarm most likely caused by an ESD event. This was addressed in a CAPA00201. This controller was built before the implementation of the CAPA00201.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

A CAPA has been implemented to resolve this issue.
This is related to FSCA APR2013 (ESD).

Time schedule for the implementation of the identified actions

none

Final comments from the manufacturer

This controller was built before the implementation of CAPA00201. The root cause is a PMC reset confirmed by the log files. Issue related to FSCA.

Further investigations

none

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(•) Yes ( ) No

Number of similar incidents

60 From October 1, 2011 thru September 30, 2014

If yes, state in which countries and the report reference numbers of the incidents.

From October 1, 2011 thru September 30, 2014, there have been 60 events related to a reset of the Pump Motor Controller (PMC).
United States [redacted]
Germany [redacted]
Canada [redacted]
United Kingdom [redacted]
Australia [redacted]
Sweden [redacted]

10.1.c + 10.2.g


South Africa
Kazakhstan
Netherlands

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☐ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☐ RO	☒ SE	☐ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, Israel, Chile, (Continued in Section 12 Comments)

12 Comments

Updated sections on 24JAN2014:
Section 7: Medical device current location/disposition updated to include latest information available.
Additional information will be submitted within thirty (30) days from receipt, as the device is still being evaluated.

Updated sections on 21FEB2014:
Additional information will be submitted within sixty (60) days from receipt, as the device is still being evaluated.

Updated sections on 08 OCT2014:
Section 1: Type of report
Section 7: Medical device current location/disposition updated to include latest information available.
Section 11: Results of manufacturers final investigation (Final report)
(Continued from Section 11 Distributed Countries) Singapore, South Africa, Saudi Arabia, Kazakhstan, Vietnam, Lebanon, Japan, Egypt, India, Brazil and Canada.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e

Doc. 125

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? MHRA Devices Federal Office for Safety in Healthcare - (BASG) Norwegian Directorate for Health AFMPS - Agence Fédérale des Medicaments et des Produits de Santé Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Valvira - National Supervisory Authority for Welfare and Health Swissmedic, Swiss Agency for Therapeutical Products Agence nationale de sécurité du médicament et des produits de santé (ANSM) The State Health Care Accreditation Agency Medical Products Agency´ 'Läkemedelsverket'Medical Devices National Organization for Medicines Federal Institute for Drugs and Medical Devices Danish Health and Medicines Authority Dutch Healthcare Inspectorate Ministry of Health, Department of Medical Device Services, Market Surveillance Section
Type of report (●) Initial report ( ) Follow-up report ( ) Final report
Date of this report 2014
Reference number assigned by the manufacturer FSCA APR2013.1
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable) US-FDA; MHRA

2 Information on submitter of the report
Status of submitter ( ) Manufacturer (●) Authorised Representative within EEA and Switzerland ( ) Others: (identify the role)

3 Manufacturer information	new

Name HeartWare, Inc.	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode FL 33014	**City** Miami Lakes
Phone +1	**Fax** +1 305-364-2665
E-mail FSCA@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International, Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 National contact point information

new

National contact point name MedPass International, Ltd.	
Name of the contact person	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpassar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text

Circulatory Assist System, Artificial Heart, Tempo

Commercial name/ brand name / make

HeartWare Ventricular Assist System

Model number	**Catalogue number**
1400 and 1401XX	
Serial number(s)	**Lot/batch number(s)**
through	
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0086 BSDI PRODUCT, SERVICES CE marked: 2009-01-29

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

In 2013, HeartWare distributed an Urgent Field Safety Notice (FSCA APR2013) following two incidents of patient deaths where the electrostatic discharge (ESD) was suspected to cause or contribute to data corruption in the pump motor Controller resulting in a loss of commutation. In these circumstances, the Controller software was no longer driving the pump's motor Controller circuit which led to a pump stop. HeartWare has not demonstrated conclusively that ESD caused the events in the field; only that symptoms are consistent with an ESD challenge replicated in the laboratory.

The 2013 Urgent Field Safety Notice indicated that ESD is a known risk for electronic equipment and identified techniques to reduce exposure to ESD. The HeartWare® Ventricular Assist System Instructions for Use (IFU) and Patient Manual also address ESD awareness and Controller alarm management. As stated in the 2013 Urgent Field Safety Notice, patients can reduce the risk of ESD by avoiding dry environments, certain fabrics and materials such as silk clothing and carpeting, electronic devices prone to static electricity and certain activities such as vacuuming and removing clothes from a dryer. Patients are instructed to carry backup Controllers at all times and are trained on how to perform a Controller exchange in emergency situations.

Following further analysis of complaint data and ongoing risks, HeartWare is expanding its voluntary Field Safety Corrective Action, FSCA APR2013, by initiating a Medical Device Recall of older HeartWare Controllers (product codes 1400 and 1401XX*) with Serial Numbers [redacted] through [redacted].

Using cumulative ESD complaint data between January 1, 2010 and July 31, 2014, a re-assessment was completed on November 26, 2014 to re-evaluate the risk benefit analysis related to Controller design changes potentially affecting the probability of Electrostatic Discharge (ESD) and the risk of Controller exchange (and consequent pump stop). The affected Controllers exhibit a higher susceptibility to ESD than enhanced Controllers. The recent analysis of the complaint data has conclusively shown that the enhanced Controller demonstrates improved performance when compared to the original Controller (see Attachment 1, Health Hazard Evaluation).

*XX represents country-specific designation.

Description and justification of the action (corrective / preventive)

HeartWare has made design enhancements to the Controller to improve the Controller's immunity to ESD. This recall only applies to the Controllers (product codes 1400 and 1401XX) with Serial Numbers [redacted] through [redacted]. Although HeartWare introduced the enhanced design prior to the 2013 Field Safety Corrective Action, HeartWare only recently accumulated sufficient complaint data to quantify and support the conclusion that enhanced Controllers reduce ESD risk to a level that potentially justifies an intentional pump stop inherent in the exchange of an older Controller.

HeartWare recommends that all affected Controllers be exchanged. It is the treating physician's responsibility to assess a patient's status and determine if the risk of a pump stop due to a Controller exchange is greater than the risk of a pump stop due to an ESD event. Controller exchanges may not be suitable for all patients. It is recommended that Controller exchanges be performed in a controlled setting under medical supervision.

Risks to Health

- Affected Controllers have a probability of an ESD event of 4% after twelve months of use according to analyzed complaint data. For comparison, the newer Controllers have a probability of an ESD event of 0.1% after twelve months of use. No serious adverse health consequences have been reported in connection with the newer Controllers.

- The risk of injury associated with ESD includes the interruption of circulatory support due to a pump stop. According to analyzed complaint data with respect to affected Controllers, approximately 25% of ESD events may cause or contribute to a pump stop requiring a Controller exchange.

- As described in the HeartWare IFU and Patient Manual, an ESD event may necessitate a Controller exchange. A brief pump stop during a Controller exchange poses a risk of injury in some patients, ranging from minimal temporary symptoms of hypoperfusion to cardiopulmonary arrest or death. In patients with a high risk of catastrophic cardiovascular collapse (e.g. patients with a fused aortic valve, patients with an aortic valve that has been sewn shut due to aortic valve regurgitation, patients with very poor endogenous ventricular function, etc.), ESD poses an elevated risk due to the patients' low tolerance of even a temporary pump stop. For reference, when looking at complaint data, only 2.9% of patients who underwent a brief pump stop (not necessarily related to ESD) experienced a serious adverse event or required additional intervention such as inotropic therapy.

Advice on actions to be taken by the distributor and the user

Actions to be Taken by the Clinician:

1. Quarantine Affected Controllers. Immediately review and quarantine all affected Controllers (product codes 1400 and 1401XX, Serial Numbers CON[redacted] through CON[redacted]) in your possession, including "hospital training" Controllers. The serial number is located on the white label on the back of the Controller.

2. Acknowledgement Form. Complete and return the attached "Acknowledgement Form" no later than 30 days from the date of this letter to your HeartWare representative or to email address FSCA@heartware.com (even if you have no affected patients or Controllers).

3. Identify Affected Patients. Review your current patients' equipment records and identify those patients who may possess affected Controllers (both primary and backup).

4. Primary Controllers. For each current patient using an affected Controller as their primary Controller, review the applicable

risks with the patient as soon as reasonably possible and, if medically advisable, exchange the affected Controller under medical supervision with a new Controller (serial number CON [redacted] or higher).

5. Backup Controllers. For each patient using an affected Controller as their backup Controller, contact the patient and arrange to have the backup Controller replaced with a new Controller (serial number CON [redacted] or higher).

6. Return Controllers to HeartWare**. Return all quarantined, affected Controllers to HeartWare. Your HeartWare representative will contact you to assist with this process and to help replace affected Controllers as may be necessary.

7. Completion Form. Complete and return the attached "Completion Form" no later than 6 months from the date of this letter to your HeartWare representative (or to email address FSCA@heartware.com) with the assistance of your HeartWare representative, as needed.

Forward the notice to individuals within their organization who need to be aware of the notice, or to any other organization to which affected controllers were transferred.

**If a site objects to the removal of affected Controllers used for training purposes only, the HeartWare Representative will mark those Controllers with a "Not For Human Use" sticker and document that the Controllers will not be returned to HeartWare.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

HeartWare will distribute FSN letters in English to the UK on December 29, 2014 (see Attachment 2, FSCA APR2013.1 Field Safety Notice). Language translations for remaining EU countries may take two to three weeks given the season to fully obtain from international translators for distribution to remaining EU countries. HeartWare targets to complete reconciliation of all actions of this FSCA within 9 months of initiation of distribution.

Attached please find

- ☒ Field Safety Notice (FSN) in English
- ☐ FSN in national language
- ☒ Others (please specify)

FSN Status

- ○ Draft FSN
- ◉ Final FSN

Attachment 1- FSCA APR2013.1 Health Hazard Evaluation, Attachment 2 - FSCA APR2013.1 Field Safety Notice

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☐ CZ	☒ DE	☒ DK
☐ EE	☐ ES	☒ FI	☒ FR	☒ GB	☒ GR	☐ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☐ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☐ RO	☒ SE	☐ SI	☐ SK	☒ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e, tenzij anders aangegeven.

Doc. 133

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal address: P.O. Box 2680, NL - 3500 BS Utrecht	

Date of this report
2015

Reference number assigned by the manufacturer
CMP

Reference number assigned by NCA
None Received

Type of report
- ○ Initial report
- ◉ Follow-up report
- ○ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1	**Fax** 1-3
E-mail @heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Barnett Way, Barnwood	
Postcode GL43RT	**City** Gloucester
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's Information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail @heartware.com	**Country** US - USA

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	Catalogue number
	1104

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
[redacted] - Pump	

Software version number (if applicable)

Device Mfr Date	Expiry date
2012-02-15	2013-01-31

Implant date (For implants only)	Explant date (For implants only)
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)
BAT [redacted] -Battery
BAT [redacted] -Battery

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]
24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2014-[redacted]

Number of patients involved (if known)	Number of medical devices involved (if known)
1	3

Medical device current location/disposition (if known)
[redacted] The batteries are currently at HeartWare.
24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

Age of the patient at the time of incident, if applicable	**units**
	◉ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility

UMC Utrecht

Contact person within the facility

Address

Heidelberglaan 100

Postcode	**City**
	Utrecht
Phone	**Fax**
E-mail	**Country**
@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

A review of the batteries incoming inspection records indicated there were no NCMR's generated that could be attributed to the reported event. Upon completion of the review, it was concluded that the units met all the internal requirements prior to its QA release process. Moreover, there is no evidence that the manufacturing process was a contributory factor to the events reported under this complaint. A review of the complaint data was completed for this patient, there is no record of previous servicing for this patient.
- Serial Number: BAT[redacted] Manufacturing Date: 2014-02: The returned battery passed visual inspection and functional testing in a lab environment. During testing, none of the battery cell pairs exhibited voltages below the 2.8 volts level and the full charge capacity remained above 2800 mAh. Log files analysis revealed the occurrence of a series of premature battery switches, which might have triggered the multiple Critical Battery alarm events noted. While the exact cause of the reported event cannot be conclusively determined, Log File Data points toward a potential communication anomaly between the controller and the connected battery. However, this battery performed per specification under testing conditions. Testing completed[redacted]2015.
- Serial Number: BAT[redacted] Manufacturing Date: 2014-06: The returned battery passed visual inspection and functional testing in a lab environment. During testing, none of the battery cell pairs exhibited voltages below the 2.8 volts level and the full charge capacity remained above 2800 mAh. Log files analysis revealed the occurrence of a series of premature battery switches, which might have triggered the multiple Critical Battery alarm events noted. While the exact cause of the reported event cannot be conclusively determined, Log File Data points toward a potential communication anomaly between the controller and the connected battery. However, this battery performed per specification under testing conditions. Testing completed 01/07/2015.

Initial corrective actions/preventive actions implemented by the manufacturer

to be reported on follow-up report.

Expected date of next report

2015-03-10

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

Remedial action/corrective action/preventive action / Field Safety Corrective Action

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause? ◯ Yes ◯ No
Number of similar incidents 0
If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☐AT	☐BE	☐BG	☐CH	☐CY	☐CZ	☐DE	☐DK
☐EE	☐ES	☐FI	☐FR	☐GB	☐GR	☐HU	☐IE
☐IS	☐IT	☐LI	☐LT	☐LU	☐LV	☐MT	☐NL
☐NO	☐PL	☐PT	☐RO	☐SE	☐SI	☐SK	☐TR

Candidate Countries

☐HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Updated sections on 9-Jan-15:
Section 1: Type of Report
Section 3: Contact name/Phone/Fax/Email
Section 5: Contact name/Phone/Fax/Email
Section 6: Catalog Number/Serial Number/Device Mfr date/Expiry date
Section 7: Medical device current location/disposition updated to include latest information available.
Section 8: Gender/Age of Patient/Weight in Kilograms
Section 10: Manufacturer's preliminary analysis

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)
10.2.e

Stamp box

Address of National Competent Authority
Dutch Healthcare Inspectorate
Postal address: P.O. Box 2680, NL - 3500 BS Utrecht, Visitors address: St. Jacobsstraat 16, NL

Date of this report
2015-

Reference number assigned by the manufacturer
CMP-

Reference number assigned by NCA

Type of report
- ○ Initial report
- ◉ Follow-up report
- ○ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone	**Fax**
E-mail @heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Barnett Way, Barnwood	
Postcode GL43RT	**City** Gloucester
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's Information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone	**Fax**
E-mail @heartware.com	**Country** US - USA

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	Catalogue number
	1104

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
[redacted] - Pump	

Software version number (if applicable)

Device Mfr Date	Expiry date
2014-04-22	2015-03-31

Implant date (For implants only)	Explant date (For implants only)
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)
CAC005199_CAC Adapter

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]
24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2014-[redacted]

Number of patients involved (if known)	Number of medical devices involved (if known)
1	2

Medical device current location/disposition (if known) 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
The site has indicated [redacted] and that the CAC Adapter has been received and is awaiting further analysis.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility
Leiden University Medical Center

Contact person within the facility

Address
Albinusdreef 2

Postcode	**City** Leiden
Phone	**Fax**
E-mail @lumc.nl	**Country** NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

CAC Adapter Analysis Results:
The Event code "No Power" was confirmed. The unit was connected and unable to power up during testing. An internal visual was performed on unit where the "RT1" fuse was found "open" rendering the unit inoperable. While the exact cause of the reported event cannot be conclusively determined, it is likely that a surge in power may have caused the event.

DHR Review Results:
A review of the contoller AC adapter's manufacturing records and incoming inspection records indicated there were no NCMRs generated that could be attributed to the reported event. Upon completion of the review, it was concluded that the AC adapter met all the internal requirements prior to its QA release process. Moreover, there is no evidence that the manufacturing process was a contributory factor to the events reported under this complaint.

Initial corrective actions/preventive actions implemented by the manufacturer

None

Expected date of next report

2015-04-14

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

Remedial action/corrective action/preventive action / Field Safety Corrective Action

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

○ Yes ○ No

Number of similar incidents

0

If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☐AT	☐BE	☐BG	☐CH	☐CY	☐CZ	☐DE	☐DK
☐EE	☐ES	☐FI	☐FR	☐GB	☐GR	☐HU	☐IE
☐IS	☐IT	☐LI	☐LT	☐LU	☐LV	☐MT	☐NL
☐NO	☐PL	☐PT	☐RO	☐SE	☐SI	☐SK	☐TR

Candidate Countries

☐HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Updated sections on 14-Jan-15:
Section 1: Reference number assigned by NCA, Date of Report
Section 1: Type of Report
Section 3: Manufacturer information
Section 5: Submitter Information
Section 10: Manufacturer's preliminary comments (Initial/Follow-up report)

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | sent on Wednesday, January 14, 2015 14:10:46

Overal 10.2.e, tenzij anders aangegeven.

Doc. 158

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal address: P.O. Box 2680, NL - 3500 BS Utrecht, Visitors address: St. Jacobsstraat 16, NL - 3511 BS Utrecht	

Date of this report

2015-

Reference number assigned by the manufacturer

CMP-

Reference number assigned by NCA

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter

- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare, Inc.	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail productquality@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Barnett Way, Barnwood	
Postcode GL43RT	**City** Gloucester
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name HeartWare, Inc.	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1	**Fax** 1-
E-mail productquality@heartware.com	**Country** US - USA

Doc. 158
new

6 Medical device information

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977
Nomenclature text	
Artificial heart, temporary	
Commercial name/ brand name / make	
HeartWare® Ventricular Assist System	
Model number	**Catalogue number**
1407DE	
Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
CON[redacted] - Controller BAT[redacted] - Battery	
Software version number (if applicable)	
1	
Device Mfr Date	**Expiry date**
2012-01-10	2013-05-31
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable)	
BAT[redacted] - Battery	
Notified Body (NB) ID-number	
0086 BSI Product Services	

7 Incident Information

Date the incident occurred [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
Incident description narrative [redacted] [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
User facility report reference number, if applicable
Manufacturer's awareness date [redacted]

Number of patients involved (if known)	**Number of medical devices involved (if known)**
1	3
Medical device current location/disposition (if known)	
The Controller and Batteries are currently at HeartWare.	

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

[redacted]

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility
UMC Utrecht

Contact person within the facility
[redacted]

Address
Heidelberglaan 100

Postcode	**City**
3584	Utrech
Phone	**Fax**
[redacted]	
E-mail	**Country**
[redacted]@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

Preliminary evaluation and testing revealed that one of the returned batteries contained a faulty cell.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

The HeartWare VAD is used for treatment not diagnosis. A controller (CON) and two batteries (BAT and BAT) were returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the devices in relation to the reported event. Thorough external visual inspection of the devices revealed no signs of physical damage or contamination. The reported event was confirmed via review of the controller log files, which revealed a critical battery alarm. Analysis of the devices revealed that the controller and a battery met specifications. The controller and battery (BAT) passed visual examination and functional testing; the analyzed devices performed per specification under testing conditions. Battery (BAT) passed visual examination but failed functional testing. During testing, the battery exhibited early depletion of cell pair #2. The confirmed malfunction is related to the reported event. There are no known clinical factors that could have contributed to this event. The most likely root cause of the critical battery alarms is a combination of a battery with a faulty cell and a communication error between the controller and batteries.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

The manufacturer has opened an internal investigation to evaluate these types of issues.

On April 30, 2014, HeartWare issued a Field Safety Notice (FSCA APR2014) and patient letter to physicians; the sites delivered the letter to patients currently on device. The Field Safety Notice and patient letter were intended to enable patients to recognize abnormally behaving batteries and to specify actions to take when a battery needs to be replaced. The communications outlined general power management requirements and focused on recognizing the alarms and message displays related to the specific failure modes. Instructions were given in the field safety notice to provide advice to patients and sites on how to respond in the event of premature battery switching, rapid capacity change, or rapid switching back and forth.

Additionally, FSCA APR2015A was issued as a voluntary "Urgent Medical Device Correction"; communication was issued to the sites and patients within the United States on May 11, 2015. An "Urgent Field Safety Notice" was sent to sites and patients not within the United States on May 14, 2015.

Time schedule for the implementation of the identified actions

None

Final comments from the manufacturer

The most likely root cause of the critical battery alarms is a combination of a battery with a faulty cell and a communication error between the controller and batteries.

Further investigations

None

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(•) Yes ( ) No

Number of similar incidents
25 from 2012-04-01 -to- 2015-04-01
If yes, state in which countries and the report reference numbers of the incidents.
Belgium [redacted] France [redacted] Germany [redacted] Italy [redacted] Netherlands [redacted] Poland [redacted]

10.1.c + 10.2.g

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒AT	☒BE	☒BG	☒CH	☒CY	☒CZ	☒DE	☒DK
☒EE	☒ES	☒FI	☒FR	☒GB	☒GR	☒HU	☒IE
☐IS	☒IT	☐LI	☒LT	☒LU	☒LV	☐MT	☒NL
☒NO	☒PL	☐PT	☒RO	☒SE	☒SI	☒SK	☒TR

Candidate Countries

☒HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, Israel, Chile, Chile, Singapore, South Africa, Saudi A

12 Comments

Updated sections on 7/15/2015:
Section 1: Type of report
Section 1: Reference number assigned by NCA
Section 2: Authorised Representative within EEA and Switzerland and Turkey
Section 3: Contact Name/Phone/E-mail
Section 5: Contact Name/Phone/E-mail
Section 7: Medical device current location/disposition
Section 11: The manufacturer's device analysis results
Section11: Final comments from the manufacturer
Section 11: Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause/ Number of similar incidents

The Ventricular Assist system is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The system is designed for in-hospital and out-of-hospital settings, including transportation.
Per the Instructions for Use (IFU): Patients are instructed to always keep a spare set of fully charged batteries and a back-up controller available at all times, beyond the two (2) power sources that are currently connected to the primary controller.

Updated sections on 16-JUN-2014
Section 6: Serial number(s); Accessories / associated devices
BAT[redacted] Battery Device Mfr. Date: 2012-01-10 Expiry Date: 2013-05-31

Section 7: Number of medical devices involved.

Section 10: Manufacturer's preliminary analysis and Expected date of next report.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature [redacted]

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

[redacted]

Van: [redacted] [redacted]@medpass.org]
Verzonden: donderdag 16 juli 2015 15:12
Onderwerp: HeartWare - NL - Final report CMP-[redacted]
Bijlagen: CMP-[redacted]_Final MDV_Signed_data.xml; CMP-[redacted]_Final MDV_Signed.pdf

Your reference : [redacted]

Our Reference: Final Incident report CMP [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding final incident report in pdf and xml format.
Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

[redacted]
Regulatory Affairs Assistant

MEDPASS

Tel: +33 (0)[redacted]
Fax: +33 (0)1 40 53 81 11
E: [redacted]@medpass.org
W: www.medpass.org

MedPass International
95 bis Boulevard Pereire
75017 Paris - France
+33 (0)1 42 12 83 30

From: [redacted]
Sent: vendredi 10 octobre 2014 16:37
To: 'meldpunt@igz.nl'
Cc: MedpassAR
Subject: HeartWare - NL - Follow-up information CMP-[redacted]

CA reference number: [redacted]
Our Reference: CMP [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear NCA contact,

Additional information will be submitted within sixty (60) days from receipt, as investigation is still ongoing.

The next Report Supplemental or Final will be submitted by: 09-DEC-2014.

Should you need further information, please let us know.

Best wishes,

[redacted]
Regulatory Affairs Assistant

MEDPASS

Tel: +33 (0)[redacted]
Fax: +33 (0)1 40 53 81 11
E: [redacted]@medpass.org
W: www.medpass.org

MedPass International
95 bis Boulevard Pereire
75017 Paris - France
+33 (0)1 42 12 83 30

From: [redacted]
Sent: mercredi 13 août 2014 13:50
To: 'meldpunt@igz.nl'
Cc: MedpassAR
Subject: HeartWare - NL - Additionnal information - Incident report - CMP-[redacted]

Your reference number: [redacted]
Our Reference: Incident report CMP[redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear NCA contact,

Additional information will be submitted within sixty (60) days from receipt, as investigation is still ongoing.

The next Report Supplemental or Final will be submitted by: 10-OCT-2014

Should you need further information, please let us know.

Best wishes,

[redacted]
Regulatory Affairs Assistant

MEDPASS

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+33 (0)1 42 12 83 30

From: [redacted]
Sent: mardi 17 juin 2014 15:41
To: 'meldpunt@igz.nl'
Cc: MedpassAR
Subject: HeartWare - NL - Follow-up- Incident report - CMP-[redacted]

Your reference number: [redacted]
Our Reference: Follow-up Incident report CMP [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding follow-up incident report in pdf and xml format.
Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

[redacted]
Regulatory Affairs Assistant

MEDPASS

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Fax: +33 (0)1 40 53 81 11
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W: www.medpass.org

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95 bis Boulevard Pereire
75017 Paris - France
+33 (0)1 42 12 83 30

From: [redacted]
Sent: vendredi 4 avril 2014 16:44
To: 'meldpunt@igz.nl'
Cc: MedpassAR
Subject: HeartWare - NL - Initial- Incident report - CMP-[redacted]

Our Reference: Initial Incident report CMP [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding initial incident report in pdf and xml format.
Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

[redacted]
Regulatory Affairs Assistant

MedPass International
95 bis, Boulevard Pereire
75017 Paris – France
www.medpass.org

Tel.: +33 (0)
Fax.:+33 (0) 1 40 53 81 11
@medpass.org

10.2.e

versie 25 aug 2015

Scoreformulier meldingen medische technologie

WPM-nr

batterij vervangen

Overweging incident/FSCA

FSCA

Overweging: Toelichting incident / FSCA indien bekend: basisoorzaak, tijdelijk implementatie, aantal incidenten in WPM, klantenlijst(level II, III). Let op: Als e hoogste score ingevuld

A. Ernst van het incident		**A. Ernst van het incident**
geen letsel	x	scoren als er geen gezondheidsrisico is. Als dat het geval is, had de fabrikant eigenlijk geen melding hoeven maken. Veel fabrikanten doen dat uit voorzorg echter wel. Bij dergelijke casussen kunnen de andere categorieën op het laagste aantal punten gescoord worden, zodat de melding in de categorie 'Trend'. MP handelt deze verder af.
Beperkt letsel		Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden.
Matig letsel		Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden.
Ernstig/levensbedreigend/overlijden		Zie beschrijving incident. Scoren als de fabrikant het risico hierop hoog inschat als de FSCA niet zou plaatsvinden.
B. Detecteerbaarheid van de gebeurtenis door gebruiker		**B. Detecteerbaarheid van de gebeurtenis door gebruiker**
Zeer waarschijnlijk		het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet worden gebruikt;
Waarschijnlijk	x	het defect aan het hulpmiddel is zichtbaar;
Niet waarschijnlijk		het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op een andere wijze nog duidelijk kunnen worden
Erg onwaarschijnlijk		het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen.
C. Frequentie en kans van de gebeurtenis		**C. Frequentie en kans van de gebeurtenis**
Eenmalig; geïsoleerde gebeurtenis		specifiek lotnummer EN ingeschatte kans op bedoelde risico door fabrikant laag ingeschat
Meerdere incidenten; specifieke gebruiker / instelling gerelateerd		specifiek lotnummer EN ingeschatte kans op bedoelde risico in grote mate aanwezig
meerdere incidenten: specifiek lot / serienummer gerelateerd		meerdere lotnummers en/of serienummers aangedaan, enkele producten per lot- of serienummer. EN / OF ingeschatte kans op bedoelde risico door fabrikant laag ingeschat
Meerdere incidenten: verschillende lotnummers / serienummer gerelateerd / instellingen	x	meerdere lotnummers en/of serienummers aangedaan, grote hoeveelheden per lot- of serienummer EN / OF ingeschatte kans op bedoelde risico in grote mate aanwezig
D. Impact op de Nederlandse markt		**D. Impact op de Nederlandse markt**
Geen impact		het hulpmiddel is niet op de Nederlandse markt (deze situatie zal zich voornamelijk voordoen bij NCARs, waarbij Nederland niet genoemd staat Per 1 januari 2012 worden deze NCARs als melding of signaal geregistreerd in WPM. Meldpunt sluit deze af).
Matige impact	x	het betrokken hulpmiddel is op de Nederlandse markt
Hoge impact		het betrokken hulpmiddel is op de Nederlandse markt EN er heeft een incident in Nederland plaatsgevonden; OF het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een gevoelig onderwerp (nog door P10 te formuleren).
Totale score	46	*Interpretatietabel uit Procedure meldingen over Medische technolog*
Risicogroep	**level I**	
Eventuele opmerkingen:		

INCIDENT

:e verbetermaatregel, structurele verbetermaatregel en voortgang
r geen gegevens beschikbaar zijn wordt bij A, B, C en D de op één na

geen of nagenoeg geen schade, ongemak
medische interventie volgend uit het letsel, uitstel van diagnose, incorrecte diagnose, vertraging van behandeling, incorrecte behandeling
permanent of onherstelbaar letsel, onnodige operatie ten gevolge van het letsel, verlengde ziekenhuisopname
levensbedreigend letsel, overdracht van een levensbedreigende infectie, dood van de patiënt

het defect aan het hulpmiddel is duidelijk, het hulpmiddel kan niet worden gebruikt
het defect aan het hulpmiddel is zichtbaar
het defect aan het hulpmiddel is niet zichtbaar, maar zou mogelijk op een andere wijze nog duidelijk kunnen worden
het is op geen enkele wijze mogelijk om het defect aan het hulpmiddel voor het gebruik waar te nemen.

geen eerdere vergelijkbare incidenten
soortgelijke incidenten bij dezelfde gebruiker/instellingen
soortgelijke incidenten met hetzelfde lot-serienummer
meerdere incidenten - verschillende lotnummers / serienummers gerelateerd / instellingen

het betrokken hulpmiddel is op de Nederlandse markt maar geen incidenten in Nederland gemeld, de fabrikant of de Europees Gemachtigde is in Nederland gevestigd
het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een incident dat in Nederland heeft plaatsgevonden
het betrokken hulpmiddel is op de Nederlandse markt EN het betreft een incident dat in Nederland heeft plaatsgevonden EN het betreft een gevoelig onderwerp (nog door PtO te formuleren).

ie, versie 1 september 2015

Overal 10.2.e, tenzij anders aangegeven.

[redacted]

Van: meldpunt@igz.nl
Verzonden: vrijdag [redacted] 2015 8:45
Aan: _Dienstpostbus IGZ Utrecht
Onderwerp: [redacted], [WARNING: MESSAGE ENCRYPTED]Melding zorgaanbieder-[redacted]
Bijlagen: IGZ_MF_ZVO_report_[redacted].pdf

Bijgaand bericht inboeken svp.

Nieuwe melding Afdeling Meldpunt - team msz

Met vriendelijke groet,

Mw. [redacted] <meldpunt@igz.nl>

[redacted]2015 17:09 _dienstpostbus IGZ meldpunt,:
Date sent: [redacted] 2015 5:08 PM
To: Meldpunt@igz.nl
Subject: [WARNING: MESSAGE ENCRYPTED]Melding zorgaanbieder-[redacted]

Nieuwe melding zorgaanbieder [redacted]

Op welke datum heeft de gebeurtenis waarover u meldt plaatsgevonden? *	Datum:

Heeft de gebeurtenis waarover u wilt melden plaatsgevonden bij een andere zorgaanbieder/zorginstelling/beroepsbeoefenaar/bedrijf?	Nee

Naam van de locatie/het bedrijf waar de gebeurtenis zich heeft voorgedaan *	LUMC
Afdeling *(Indien van toepassing)*	Hartziekten
Straat *	Albinusdreef
Huisnummer (+ eventuele toevoeging) *	2
Postcode *	2333ZA
Plaats *	Leiden
Telefoonnummer	
E-mailadres	@lumc.nl
De Raad van Bestuur/directie/individuele beroepsbeoefenaar is ook op dit adres gevestigd	Ja

Achternaam melder *	
Titel	
Tussenvoegsel	
Voorletter(s) *	
Geslacht *	
Wat is uw functie binnen de organisatie? *	
De IGZ correspondeert altijd met de Raad van Bestuur of de directie van een zorginstelling. **Indien u niet namens een zorginstelling meldt en daarom de ontvangstbevestiging zelf wenst te ontvangen kruis a.u.b. het vakje rechts aan.**	nee

Zijn er patiënten betrokken bij de gebeurtenis waarover u meldt?	Ja

Wat zijn de gegevens van de direct bij de gebeurtenis betrokken patiënt(en)/cliënt(en) waarover u meldt?	1

Achternaam of initialen patiënt/cliënt een *	Doc. 169
Geboortedatum (dd-mm-jjjj) *	
Geslacht *	

10.1.d, 10.2.d, 10.2.g

BEKNOPTE BESCHRIJVING GEBEURTENIS Geef hier een feitelijke omschrijving van de situatie waar de melding betrekking op heeft. * (maximaal 1024 tekens).	
Kruis onderstaand vakje aan als er een geneesmiddel of een medisch hulpmiddel bij de melding betrokken is	ja
Indien u niet genoeg ruimte heeft om uw melding te omschrijven dan kunt u extra informatie over uw melding in onderstaand veld invullen (maximaal 1024 tekens).	Productnaam: HVAD Producent: HeartWare Contact gegevens HeartWare: HeartWare UK Ltd. 500 Old Connecticut Path Framingham, MA 0170 USA De alarmen zijn gecommuniceerd met de producent
Indien van toepassing: Wat is aan nazorg gedaan voor de patiënt/cliënt/familie/andere betrokkenen?	Patient heeft uitleg gekregen over de bevindingen en adviezen van de fabrikant.

U geeft aan dat er een geneesmiddel of een medisch hulpmiddel bij de gebeurtenis is betrokken.

Wilt u in de beschrijving van de melding de productnaam en de naam van de fabrikant van het geneesmiddel/medisch hulpmiddel vermelden.
Ook verzoeken wij u vriendelijk te vermelden of u de gebeurtenis al aan de fabrikant heeft gemeld.

Zijn er andere zorgaanbieders/zorginstellingen/beroepsbeoefenaren/bedrijven bij de gebeurtenis betrokken?	Nee
E-mailadres	@lumc.nl
Tijdstip melding:	
Referentienummer	

Overal 10.2.e, tenzij anders aangegeven.

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal Address: P.O. Box 2680, NL - 3500BS Utrecht, Visitors address: St. Jacobsstraat 16, NL	

Date of this report
2015-

Reference number assigned by the manufacturer
CMP-

Reference number assigned by NCA

Type of report
- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1	**Fax** 1-
E-mail @heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Barnett Way, Barnwood	
Postcode GL43RT	**City** Gloucester
Phone 44(0	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1
E-mail @heartware.com	**Country** US - USA

Doc. 175

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977
Nomenclature text	
Artificial heart, temporary	
Commercial name/ brand name / make	
HeartWare® Ventricular Assist System	
Model number	**Catalogue number**
	1104
Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
Unknown - Pump	
Software version number (if applicable)	
Device Mfr Date	**Expiry date**
Implant date (For implants only)	**Explant date (For implants only)**
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d +	10.2.g
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable)	
BAT[redacted]_Battery BAT[redacted]_Battery BAT[redacted]_Battery BAT[redacted]_Battery BAT[redacted]_Battery	
Notified Body (NB) ID-number	
0086 BSI Product Services	

7 Incident Information

Date the incident occurred

[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative

[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable	
Manufacturer's awareness date 2015	
Number of patients involved (if known) 1	**Number of medical devices involved (if known)** 6
Medical device current location/disposition (if known) Batteries were replaced and received by the manufacturer for evaluation. 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

Batteries were exchanged.

Gender, if applicable

Age of the patient at the time of incident, if applicable	**units**
	◉ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility

UMC Utrecht

Contact person within the facility

Address

Heidelberglaan 100

Postcode	**City**
3584	Utrecht
Phone	**Fax**
	UNK
E-mail	**Country**
@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

Initial corrective actions/preventive actions implemented by the manufacturer

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

The HeartWare VAD is used for treatment not diagnosis. The batteries were returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the devices in relation to the reported event. Thorough external visual inspection of the devices revealed no signs of physical damage or contamination. The reported event was confirmed via review of the controller log files, which revealed a premature power switching event the day prior to the reported event date. Analysis of BAT and BAT revealed that the batteries failed to meet specifications; the batteries exhibited a high max error, indicative that the batteries were out of calibration. This finding is considered an incidental finding and not related to the reported power switching event. Analysis of BAT and BAT revealed that the batteries met specifications; the batteries passed visual examination and functional testing. Analysis of BAT revealed that the battery failed to meet specifications. Initial testing revealed abnormal noise in the functional plots. Improper soldering was observed after internal inspection. After connections were re-soldered, the battery once again failed functional testing as it was observed that the battery had a faulty cell pair. The confirmed malfunction is related to the reported event. The most likely root cause of the reported event is a combination of a battery with a faulty internal cell pair and a communication error between the controller and batteries. HeartWare has opened an internal investigation to evaluate these types of issues.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

On April 30, 2014, HeartWare issued a Field Safety Notice (FSCA APR2014) and patient letter to physicians; the sites delivered the letter to patients currently on device. The Field Safety Notice and patient letter were intended to enable patients to recognize abnormally behaving batteries and to specify actions to take when a battery needs to be replaced. The communications outlined general power management requirements and focused on recognizing the alarms and message displays related to the specific failure modes. Instructions were given in the field safety notice to provide advice to patients and sites on how to respond in the event of premature battery switching, rapid capacity change, or rapid switching back and forth.

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

The most likely root cause of the reported event is a combination of a battery with a faulty internal cell pair and a communication error between the controller and batteries.

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

Number of similar incidents

691

If yes, state in which countries and the report reference numbers of the incidents.

Power Switching with Communication Error
Power Switching with Faulty Cell
7/1/2012 to 7/1/2015

10.1.c + 10.2.g

Austria
Belgium
Czech Republic
Denmark
Estonia
Finland
France
Germany
Italy
Luxembourg
Netherlands
Norway
Poland
Spain
Sweden
Switzerland
Turkey
United Kingdom
Grand Total 691

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, India (Continued in Section 12 Comments)

12 Comments

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

Any additional information received will be submitted in a Supplemental Report when the manufacturer's investigation has been completed.

Updated sections on 28-Sep-15:
Section 7: Medical device current location/disposition updated to include latest information available.
(Continued from Section 11 Distributed Countries) Israel, Chile, Singapore, South Africa, Kazakhstan, South Korea, Lebanon, Kuwait, Serbia, Japan, Egypt, United Arab Emirates and Canada.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? MHRA Devices Federal Office for Safety in Healthcare - (BASG) Norwegian Directorate for Health AFMPS - Agence Fédérale des Medicaments et des Produits de Santé Dr. Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Valvira - National Supervisory Authority for Welfare and Health Swissmedic, Swiss Agency for Therapeutical Products Agence nationale de sécurité du médicament et des produits de santé (ANSM) The State Health Care Accreditation Agency Medical Products Agency´ 'Läkemedelsverket'Medical Devices National Organization for Medicines Federal Institute for Drugs and Medical Devices Danish Health and Medicines Authority Dutch Healthcare Inspectorate Ministry of Health, Department of Medical Device Services, Market Surveillance Section
Type of report ○ Initial report ○ Follow-up report ◉ Final report
Date of this report 2015-
Reference number assigned by the manufacturer FSCA APR2013.1
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable) US-FDA; MHRA

2 Information on submitter of the report
Status of submitter ○ Manufacturer ◉ Authorised Representative within EEA and Switzerland ○ Others: (identify the role)

3 Manufacturer information	new

Name HeartWare, Inc.	
Contact Name	
Address 14420 NW 60th Avenue	
Postcode FL 33014	**City** Miami Lakes
Phone +	**Fax** +1
E-mail FSCA@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International, Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 National contact point information

new

National contact point name MedPass International, Ltd.	
Name of the contact person	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpassar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text

Circulatory Assist System, Artificial Heart, Tempo

Commercial name/ brand name / make

HeartWare Ventricular Assist System

Model number	**Catalogue number**
1400 and 1401XX	
Serial number(s)	**Lot/batch number(s)**
CON [redacted] through CON [redacted]	
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0086 BSDI PRODUCT, SERVICES CE marked: 2009-01-29

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

In 2013, HeartWare distributed an Urgent Field Safety Notice (FSCA APR2013) following two incidents of patient deaths where the electrostatic discharge (ESD) was suspected to cause or contribute to data corruption in the pump motor Controller resulting in a loss of commutation. In these circumstances, the Controller software was no longer driving the pump's motor Controller circuit which led to a pump stop. HeartWare has not demonstrated conclusively that ESD caused the events in the field; only that symptoms are consistent with an ESD challenge replicated in the laboratory.

The 2013 Urgent Field Safety Notice indicated that ESD is a known risk for electronic equipment and identified techniques to reduce exposure to ESD. The HeartWare® Ventricular Assist System Instructions for Use (IFU) and Patient Manual also address ESD awareness and Controller alarm management. As stated in the 2013 Urgent Field Safety Notice, patients can reduce the risk of ESD by avoiding dry environments, certain fabrics and materials such as silk clothing and carpeting, electronic devices prone to static electricity and certain activities such as vacuuming and removing clothes from a dryer. Patients are instructed to carry backup Controllers at all times and are trained on how to perform a Controller exchange in emergency situations.

Following further analysis of complaint data and ongoing risks, HeartWare is expanding its voluntary Field Safety Corrective Action, FSCA APR2013, by initiating a Medical Device Recall of older HeartWare Controllers (product codes [redacted] and [redacted]) with Serial Numbers CON[redacted] through CON[redacted]

Using cumulative ESD complaint data between January 1, 2010 and July 31, 2014, a re-assessment was completed on November 26, 2014 to re-evaluate the risk benefit analysis related to Controller design changes potentially affecting the probability of Electrostatic Discharge (ESD) and the risk of Controller exchange (and consequent pump stop). The affected Controllers exhibit a higher susceptibility to ESD than enhanced Controllers. The recent analysis of the complaint data has conclusively shown that the enhanced Controller demonstrates improved performance when compared to the original Controller (see Attachment 1, Health Hazard Evaluation).

*XX represents country designation.

Description and justification of the action (corrective / preventive)

HeartWare has made design enhancements to the Controller to improve the Controller's immunity to ESD. This recall only applies to the Controllers (product codes [redacted]) with Serial Numbers CON[redacted] through CON[redacted]. Although HeartWare introduced the enhanced design prior to the 2013 Field Safety Corrective Action, HeartWare only recently accumulated sufficient complaint data to quantify and support the conclusion that enhanced Controllers reduce ESD risk to a level that potentially justifies an intentional pump stop inherent in the exchange of an older Controller.

HeartWare recommends that all affected Controllers be exchanged. It is the treating physician's responsibility to assess a patient's status and determine if the risk of a pump stop due to a Controller exchange is greater than the risk of a pump stop due to an ESD event. Controller exchanges may not be suitable for all patients. It is recommended that Controller exchanges be performed in a controlled setting under medical supervision.

Risks to Health

- Affected Controllers have a probability of an ESD event of 4% after twelve months of use according to analyzed complaint data. For comparison, the newer Controllers have a probability of an ESD event of 0.1% after twelve months of use. No serious adverse health consequences have been reported in connection with the newer Controllers.

- The risk of injury associated with ESD includes the interruption of circulatory support due to a pump stop. According to analyzed complaint data with respect to affected Controllers, approximately 25% of ESD events may cause or contribute to a pump stop requiring a Controller exchange.

- As described in the HeartWare IFU and Patient Manual, an ESD event may necessitate a Controller exchange. A brief pump stop during a Controller exchange poses a risk of injury in some patients, ranging from minimal temporary symptoms of hypoperfusion to cardiopulmonary arrest or death. In patients with a high risk of catastrophic cardiovascular collapse (e.g. patients with a fused aortic valve, patients with an aortic valve that has been sewn shut due to aortic valve regurgitation, patients with very poor endogenous ventricular function, etc.), ESD poses an elevated risk due to the patients' low tolerance of even a temporary pump stop. For reference, when looking at complaint data, only 2.9% of patients who underwent a brief pump stop (not necessarily related to ESD) experienced a serious adverse event or required additional intervention such as inotropic therapy.

Advice on actions to be taken by the distributor and the user

Actions to be Taken by the Clinician:

1. Quarantine Affected Controllers. Immediately review and quarantine all affected Controllers (product codes [redacted] and [redacted] Serial Numbers CON[redacted] through CON[redacted] in your possession, including "hospital training" Controllers. The serial number is located on the white label on the back of the Controller.

2. Acknowledgement Form. Complete and return the attached "Acknowledgement Form" no later than 30 days from the date of this letter to your HeartWare representative or to email address FSCA@heartware.com (even if you have no affected patients or Controllers).

3. Identify Affected Patients. Review your current patients' equipment records and identify those patients who may possess affected Controllers (both primary and backup).

4. Primary Controllers. For each current patient using an affected Controller as their primary Controller, review the applicable

risks with the patient as soon as reasonably possible and, if medically advisable, exchange the affected Controller under medical supervision with a new Controller (serial number CON [redacted] or higher).

5. Backup Controllers. For each patient using an affected Controller as their backup Controller, contact the patient and arrange to have the backup Controller replaced with a new Controller (serial number CON [redacted] or higher).

6. Return Controllers to HeartWare. Return all quarantined, affected Controllers to HeartWare. Your HeartWare representative will contact you to assist with this process and to help replace affected Controllers as may be necessary.

7. Completion Form. Complete and return the attached "Completion Form" no later than 6 months from the date of this letter to your HeartWare representative (or to email address FSCA@heartware.com) with the assistance of your HeartWare representative, as needed.

Forward the notice to individuals within their organization who need to be aware of the notice, or to any other organization to which affected controllers were transferred.

**If a site objects to the removal of affected Controllers used for training purposes only, the HeartWare Representative will mark those Controllers with a "Not For Human Use" sticker and document that the Controllers will not be returned to HeartWare.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

HeartWare has achieved 100% effectiveness monitoring success. The attached FSCA APR2013.1 - Action Effectiveness document provides further conclusion details per country.

Time schedule for the implementation of the different actions

HeartWare will distribute FSN letters in English to the UK on December 29, 2014 (see Attachment 2, FSCA APR2013.1 Field Safety Notice). Language translations for remaining EU countries may take two weeks to fully obtain from international translators for distribution to remaining EU countries. HeartWare targets to complete reconciliation of all actions of this FSCA within 9 months of initiation of distribution.

Attached please find

☐ Field Safety Notice (FSN) in English

☐ FSN in national language

☒ Others (please specify)

Action Effectiveness document

FSN Status

○ Draft FSN

◉ Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☐ CZ	☒ DE	☒ DK
☐ EE	☐ ES	☒ FI	☒ FR	☒ GB	☒ GR	☐ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☐ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☐ RO	☒ SE	☐ SI	☐ SK	☒ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Updated Section: Progress of FSCA , together with reconciliation data and attached Action Effectiveness document.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e.

[redacted]

Van: meldpunt@igz.nl
Verzonden: donderdag 19 november 2015 10:58
Aan: [redacted]@medpass.org
Onderwerp: [redacted] Our reference [redacted]_Your reference [redacted]

Dear Mr/Mrs [redacted],

We herewith acknowledge receipt of your e-mail of 6 October 2015, by which you inform the Dutch Healthcare Inspectorate about an incident with your reference [redacted].
This incident involves the HeartWare® Ventricular Assist System and is registered under our reference number [redacted].

Risk-analysis
The information provided has been analysed on potential risks. Based on the results of this analysis the Dutch Healthcare Inspectorate will not start an investigation with regard to this issue. Should problems related to this incident (re)occur in the future it is possible that the inspectorate reopens this case on behalf of an investigation.

Procedure
The Healthcare Inspectorate already received the final incident report, I consider this case closed.

Any further questions?
I hope this provides you with sufficient information. If you have any further questions, do not hesitate to contact us. We are available from Monday until Friday, from 9.00 to 17.00 at +31 (0)88 ? 120 50 00. You can also send an e-mail to meldpunt@igz.nl. Please mention the reference number of this e-mail when you contact us.

Yours sincerely,

Ms [redacted]
Head of IGZ Information and Notification Centre (Meldpunt IGZ)
.....
Healthcare Inspectorate
IGZ Central Information Office
Postbus 2680 | 3500 GR | Utrecht
The Netherlands
.....
T 088 1205000
meldpunt@igz.nl
http://www.igz.nl
.....
.....

06-10-2015 09:22 Mailimport,:
Sender: [redacted]@medpass.org
Date sent: Oct 6, 2015 9:21 AM
To: "'meldpunt@igz.nl'" <meldpunt@igz.nl>
CC: MedpassAR <medpass.ar@medpass.org>
Subject: HeartWare - NL - Initial Incident report - [redacted]

Our Reference: Initial Incident report [redacted]

Sponsor: HeartWare Inc.

Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding initial incident report in pdf and xml format.

Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

[redacted]
Regulatory Affairs Assistant

[cid:image001.jpg@01CCFD48.7FCB3C00]

Tel:

[redacted]

MedPass International

95 bis Boulevard Pereire

Fax:

+33 (0)1 40 53 81 11

75017 Paris - France

E:

[redacted]@medpass.org<mailto:[redacted]@medpass.org>

+33 (0)1 42 12 83 30

W:

www.medpass.org<http://www.medpass.org/>

[redacted]

Van: [redacted] [redacted]@medpass.org]
Verzonden: dinsdag 17 november 2015 13:55
Onderwerp: HeartWare - NL - Final Incident report - [redacted]
Bijlagen: [redacted]_Final MDV_Signed.pdf; [redacted]_Final MDV_Signed_data.xml

Our Reference: Final Incident report [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding final incident report in pdf and xml format.
Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

[redacted]
Regulatory Affairs Assistant

MEDPASS

Tel: [redacted]
Fax: +33 (0)1 40 53 81 11
E: [redacted]@medpass.org
W: www.medpass.org

MedPass International
95 bis Boulevard Pereire
75017 Paris - France
+33 (0)1 42 12 83 30

From: [redacted]
Sent: mardi 6 octobre 2015 09:22
To: 'meldpunt@igz.nl'
Cc: MedpassAR
Subject: HeartWare - NL - Initial Incident report - [redacted]

Our Reference: Initial Incident report [redacted]
Sponsor: HeartWare Inc.
Medical Device: HeartWare Ventricular Assist System

Dear Sir/Madam,

On behalf of HeartWare Inc., the manufacturer of the abovementioned medical device, and acting as European Authorized Representative, we would like to notify you of an incident that occurred in the Netherlands.

Please find attached the corresponding initial incident report in pdf and xml format.
Please do not hesitate in contacting us for any further information you may require.

Yours faithfully,

[redacted]
Regulatory Affairs Assistant

MEDPASS

Tel: [redacted]

Fax: +33 (0)1 40 53 81 11
E: [redacted]@medpass.org
W: www.medpass.org

MedPass International
95 bis Boulevard Pereire
75017 Paris - France
+33 (0)1 42 12 83 30

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal address: P.O. Box 2680, NL - 3500 BS Utrecht	
Date of this report 2015-	
Reference number assigned by the manufacturer CMP-	
Reference number assigned by NCA	
Type of report ○ Initial report ○ Follow-up report ○ Combined initial and final report ◉ Final report	
Does the incident represent a serious public health threat? ○ yes ◉ no	
Classification of incident ◉ Death ○ Unanticipated Serious Deterioration in State of Health ○ All other reportable incidents	
Identify to what other NCA's this report was also sent US Food and Drug Administration (FDA), Pharmaceutical and Medical Device Agency (PMDA)	

2 Information on submitter of the report

Status of submitter

○ Manufacturer
◉ Authorised Representative within EEA and Switzerland and Turkey
○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail productquality@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	Catalogue number
	1104

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
[redacted]	

Software version number (if applicable)

Device Mfr Date	Expiry date
2015-06-27	2017-06-30

Implant date (For implants only)	Explant date (For implants only)
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted]

Incident description narrative
[redacted]

24 lid 4 + 25 lid 3 + 10.2.d + 10.2.e + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2015[redacted]

Number of patients involved (if known)	Number of medical devices involved (if known)
1	1

Medical device current location/disposition (if known)
[redacted] The site declined to return the product to HeartWare for further analysis.

24 lid 4 + 25 lid 3 + 10.2.d + 10.2.e + 10.2.g

Operator of the medical device at the time of incident (select one)

- (•) Healthcare Professional
- ( ) Patient
- ( ) Other

Usage of the medical device (select from list below)

- (•) initial use
- ( ) reuse of a single use medical device
- ( ) reuse of a reusable medical device
- ( ) re-serviced/refurbished
- ( ) other
- ( ) problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.2.d + 10.2.e + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

UNK

Gender, if applicable

( ) Female ( ) Male

Age of the patient at the time of incident, if applicable	**units** ( ) Years ( ) months ( ) days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility

Leiden University Medical Center

Contact person within the facility

Address

Albinusdreef 2

Postcode	**City**
2333ZA	leiden
Phone	**Fax**
E-mail	**Country**
@lumc.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

none

Remedial action/corrective action/preventive action / Field Safety Corrective Action

none

Time schedule for the implementation of the identified actions

none

Final comments from the manufacturer

This event was reported as a MDV event in error. complaint information has found this event does not meet the definition of a reportable incident per Med Dev 5.1.3.5 EXPECTED AND FORESEEABLE SIDE EFFECTS

Further investigations

none

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

○ Yes ◉ No

Number of similar incidents

0

If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒AT	☒BE	☒BG	☒CH	☒CY	☒CZ	☒DE	☒DK
☒EE	☒ES	☒FI	☒FR	☒GB	☒GR	☒HU	☒IE
☐IS	☒IT	☐LI	☒LT	☒LU	☒LV	☐MT	☒NL
☒NO	☒PL	☐PT	☒RO	☒SE	☒SI	☒SK	☒TR

Candidate Countries

☒HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, Canada, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Afri+

12 Comments

Updated sections on 2016:
Section 1: Type of report, Reference number assigned by NCA
Section 11: Results of manufacturers final investigation (Final report)

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The Instructions for Use (IFU) states: The LVAD System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage heart failure. Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. These surgical procedures are associated with numerous risks and adverse events including, Respiratory Failure, Neurological disorders and also Death. As stated in IFU, that right heart failure is common in patients receiving LVADs. Also that the etiology of late right heart failure may be a progression of chronic heart disease.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e, tenzij anders aangegeven.

Doc. 191

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)

Stamp box

Address of National Competent Authority

Dutch Healthcare Inspectorate
Postal address: P.O. Box 2680, NL - 3500 BS Utrecht

Date of this report

2015

Reference number assigned by the manufacturer

CMP-

Reference number assigned by NCA

Not Received

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter

- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail productquality@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	Catalogue number

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
BAT [redacted] - Battery BAT [redacted] - Battery	

Software version number (if applicable)

Device Mfr Date	Expiry date

Implant date (For implants only)	Explant date (For implants only)

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]

User facility report reference number, if applicable

Manufacturer's awareness date
2015-[redacted]

Number of patients involved (if known)	Number of medical devices involved (if known)
1	2

Medical device current location/disposition (if known)
It was reported that the two batteries would be sent to the manufacturer for evaluation; however, they have not been received as of the date of this report.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ○ initial use
- ○ reuse of a single use medical device
- ◉ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility
Leiden University Medical Center

Contact person within the facility

Address
Albinusdreef 2

Postcode	**City**
2333	Leid
Phone	**Fax**
E-mail	**Country**
@lumc.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

Based on the results of the previous manufacturer's internal investigation, field actions and changes to the battery internal cell supplier, no additional investigation of this event is required at this time. The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

FSCA APR2014.1

Time schedule for the implementation of the identified actions

None

Final comments from the manufacturer

Based on the results of the previous manufacturer's internal investigation, field actions and changes to the battery internal cell supplier, no additional investigation of this event is required at this time. The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack.

Further investigations

HeartWare has opened an internal investigation to address this issue.

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

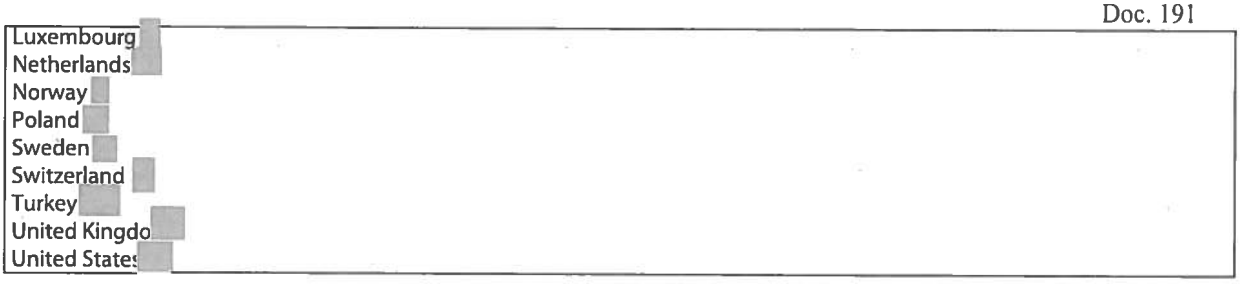
Number of similar incidents

482 from 10/1/2012 to 9/30/2015

If yes, state in which countries and the report reference numbers of the incidents.

Austria [redacted]
Belgium [redacted]
Denmark [redacted]
Estonia [redacted]
France [redacted]
Germany [redacted]
Israel [redacted]
Italy [redacted]

10.1.c + 10.2.g


Luxembourg
Netherlands
Norway
Poland
Sweden
Switzerland
Turkey
United Kingdo
United State

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒AT	☒BE	☒BG	☒CH	☒CY	☒CZ	☒DE	☒DK
☒EE	☒ES	☒FI	☒FR	☒GB	☒GR	☒HU	☒IE
☐IS	☒IT	☐LI	☒LT	☒LU	☒LV	☐MT	☒NL
☒NO	☒PL	☐PT	☒RO	☒SE	☒SI	☒SK	☒TR

Candidate Countries

☒HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Africa, Kazak

12 Comments

Updated sections on 16-Nov-15:
Section 1: Date of this Report, Reference number assigned by NCA, Type of report.
Section 3: Manufacturer information
Section 4: Authorised Representative Information
Section 5: Submitter's Information
Section 7: Incident Information
Section 10: Expected date of next report
Section 11: Results of manufacturers final investigation, Remedial action, Final Comments, Further investigations and number of similar incidents

The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate P.O. Box 2680, NL - 3500 BS Utrecht	

Date of this report
2015-

Reference number assigned by the manufacturer
CMP-

Reference number assigned by NCA
None received.

Type of report
- ○ Initial report
- ○ Follow-up report
- ◉ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail productquality@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN) GMDN	**Nomenclature code** 16977
Nomenclature text Artificial heart, temporary	
Commercial name/ brand name / make HeartWare® Ventricular Assist System	
Model number	**Catalogue number** 1650DE
Serial number(s) (if applicable) BAT [redacted] - Battery BAT [redacted] - Battery	**Lot/batch number(s) (if applicable)**
Software version number (if applicable)	
Device Mfr Date	**Expiry date** 2013-04-30
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable)	
Notified Body (NB) ID-number 0086 BSI Product Services	

7 Incident Information

Date the incident occurred [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
Incident description narrative [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
User facility report reference number, if applicable
Manufacturer's awareness date 2014-[redacted]

Number of patients involved (if known) 1	**Number of medical devices involved (if known)** 2

Medical device current location/disposition (if known) The batteries are currently at HeartWare.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

The batteries were removed from service

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility

UMC Utrecht

Contact person within the facility

Address

Heidelberglaan 100

Postcode	**City** Utrecht
Phone	**Fax**
E-mail @umcutrecht.nl	**Country** NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

The HVAD is used for treatment not diagnosis. [redacted]

Based on the results of the previous manufacturer's internal investigation, field actions and changes to the battery internal cell supplier, no additional investigation of this event is required at this time. The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

Z- [redacted] 2014
Field Safety Notice (FSCA APR2014) was issued to provide patients and healthcare providers with information to recognize batteries with less than two hours of run time, as well as reemphasize instruction on actions to take when battery alarms occur and reinforce proper power management
Field Safety Notice was then expanded (FSCA APR2014.1) in order to remove batteries from the field that were released prior to the implementation of enhanced battery screening process to address and prevent battery failures.

Time schedule for the implementation of the identified actions

None.

Final comments from the manufacturer

The mostly likely root cause of the reported event can be attributed to faulty Lishen internal cells within the HVAD Battery Pack.

Further investigations

None

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

Number of similar incidents

2 from 2012-10-01 -to- 2015-09-30

If yes, state in which countries and the report reference numbers of the incidents.

Germany 1
Netherlands 1

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒AT	☒BE	☒BG	☒CH	☒CY	☒CZ	☒DE	☒DK
☒EE	☒ES	☒FI	☒FR	☒GB	☒GR	☒HU	☒IE
☐IS	☒IT	☐LI	☒LT	☒LU	☒LV	☐MT	☒NL
☒NO	☒PL	☐PT	☒RO	☒SE	☒SI	☒SK	☒TR

Candidate Countries

☒HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Africa, Kazakh

12 Comments

BAT [redacted] - Expiry Date. 2014-06-30

The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The Instructions for Use (IFU), Patient Manual, and training material provide clear instructions to the user on proper usage and care of power sources. The IFU provides instruction to further educate the patient about product safety, visual and audible alarm management, and device management; additional guidelines instruct the user on how to detect and react to a power source malfunction. Additionally there is a warning to keep spare, fully charged batteries and back up controller available at all time. The steps for exchange of batteries and controllers are outlined.

Missing information from this report is identified as a Blank, Unknown and as No Information (NI); this information was not provided in the reported event or available at the time of report submission.

HeartWare will submit a Supplemental Report when new facts arises which materially alters information submitted in a previous MDV report.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature [redacted]

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e.

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Luxembourg, Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden, Switzerland, Turkey, and United Kingdom
Type of report (•) Initial report ( ) Follow-up report ( ) Final report
Date of this report 2015-
Reference number assigned by the manufacturer FSCA DEC2015B (Previously submitted as APR2014.2)
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable) MHRA

2 Information on submitter of the report
Status of submitter ( ) Manufacturer (•) Authorised Representative within EEA and Switzerland ( ) Others: (identify the role)

3 Manufacturer information	new

Name HeartWare, Inc.	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode FL 33014	**City** Miami Lakes
Phone +1	**Fax** +1
E-mail FSCA@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International, Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 National contact point information

new

National contact point name MedPass International, Ltd.	
Name of the contact person	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpassar@medpass.org	**Country** GB - Great Britain

Doc. 202

6 Medical device information	new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977
Nomenclature text	
Circulatory Assist System, Artificial Heart, Tempo	
Commercial name/ brand name / make	
HeartWare Ventricular Assist System	
Model number	**Catalogue number**
1650, 1650-DE & A00035	
Serial number(s)	**Lot/batch number(s)**
BAT [redacted] to BAT [redacted]	
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number
0086 BSDI PRODUCT, SERVICES CE marked: 2009-01-29
Accessories / associated devices (if applicable)
Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

On April 10, 2013, HeartWare opened CAPA00243 to investigate an increase in complaints associated with battery switching. "Battery switching" generally describes a built-in safety precaution in which the controller's internal automated power management system detects a power interruption signal emanating from the battery's firmware and automatically switches to the second battery. Specifically, the investigation targeted identification of the root cause(s) of reports of premature battery switching. Initially, cell failure was identified as a contributing root cause of battery switching.

The investigation phase of CAPA00243 was conducted over several months and included the involvement of the battery manufacturer (Cirtec) and the battery cell manufacturer (Lishen). Cirtec and HeartWare also employed two independent outside Lithium ion battery experts (Exponent and the University of Maryland) to help determine the root cause of these complaints.

It was determined that a faulty cell may be a causal factor of battery switching. For example, the battery is designed to open an internal field effect transistor (FET) when a cell's output voltage drops below 2.7 volts,, interrupting power flow. This is a safety precaution to prevent damage to the battery from over discharge which could cause cell overheating. When the FET opens, the controller's internal automated power management system detects the power interruption and automatically switches to the second battery. In the event of a faulty cell, the FET may open prematurely and initiate the switching sequence.

HeartWare developed and implemented a more robust battery screening process at Cirtec during battery manufacture to increase the level of detection of potential cell failures in order to root out potentially susceptible cells. This test screens batteries by drawing current at 2.5 times the historical load. Upon qualification, the screening test was released on July 23, 2013.

Investigation continued and included the utilization of external laboratories to conduct failure analysis on the Lishen cells as well as the FET that are used to manufacture the battery packs. Based on these analyses, the primary underlying cause of the Lishen cell failure was determined to be poorly assembled cells.

Description and justification of the action (corrective / preventive)

A risk reduction and containment action was taken in April 2014 by issuing a field corrective action communication (HeartWare Reference FSCA APR2014) informing users of this condition and reinstructing users on proper power management procedures.

To address the battery cell failures, the following corrective actions were implemented:
1. Cell manufacturing process improvements for winding and alignment of the electrode material were validated and implemented by Lishen.
2. X-ray inspection for the cell winding and alignment was validated and implemented at Lishen.
3. Improved and validated the welding process of the internal cells at Cirtec.
4. Validated and implemented a solder inspection process at Cirtec.

Following corrective actions at the cell and battery manufacturers and implementation of the enhanced battery screening process, a decision was taken to remove the unscreened batteries from the field. The Field Correction initiated in April of 2014 (HeartWare Reference FSCA APR2014) was expanded to recall all unscreened batteries from the field. This action was reported to BSI on August 12, 2014 (HeartWare Reference FSCA APR2014.1). HeartWare concluded that this Field Safety Corrective Action (which included additional training on power management and the recall of unscreened batteries), coupled with the battery screening testing, proved adequate containment actions to support continued release of the "screened" batteries.

HeartWare also pursued an alternate supplier of the internal cells as an additional battery cell source. Panasonic cells were submitted as an alternate component supplier based on the qualification of the supplier and continuation of the enhanced process controls implemented at Cirtec per corrective action in CAPA00243. BSI authorized a Design Dossier Amendment allowing for an additional battery cell supplier for the HeartWare HVAD Battery. Following this approval, HeartWare has been shipping batteries with internal cells manufactured by the new supplier to customers in the EU since November 2014.

HeartWare initiated a study to evaluate the effectiveness of the containment actions described above. An investigation of battery switching complaints which were associated with a pump stop was performed for the period between January 1, 2014 and July 17, 2015. Based on this analysis, it was determined there were 62 complaints involving screened batteries. It was not possible to confirm the pump stops were associated with battery failure; however, evidence was insufficient to completely disassociate the occurrence of battery failure from a subsequent pump stop. Among the 62 complaints, there were 4 events involving patient deaths that could not be disassociated from cell failures.

In addition to the study described above, reliability estimation was completed comparing the performance, based on reported complaints, of unscreened Screened Lishen versus Panasonic cells. This analysis concluded that the Panasonic cell failure calculates to be 0.066 failures per million hours while Lishen cell failure calculates to 1.077 failures per million hours.

Accordingly, HeartWare will be expanding the replacement of batteries with Lishen cells when a sufficient supply of batteries with Panasonic cells are available in January 2016.

Advice on actions to be taken by the distributor and the user

See Attachment 1 - FSCADEC2015 INTL Field Safety Notice for detailed information.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

HeartWare will distribute FSCA Notification to Competent Authorities in the EU (in English) beginning on December 18th, 2015. HeartWare will then begin distributing the Field Safety Notice (FSN) to clinical sites beginning January 07th, 2016 (see Attachment, FSCADEC2015 INTL Field Safety Notice). The Completion of Actions by the consignees is due 9 months. HeartWare targets to complete reconciliation of all actions of this FSCA within 12 months of initiation of distribution.

Attached please find

☒ Field Safety Notice (FSN) in English

☐ FSN in national language

☒ Others (please specify)

FSN Status

○ Draft FSN

◉ Final FSN

Attachment 1 - FSCADEC2015 INTL Field Safety Notice; Attachment 2 - FSCA DEC2015B_HHE_RADP00101

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☐ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e, tenzij anders aangegeven.

Doc. 208

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal address: P.O. Box 2680, NL - 3500 BS Utrecht	

Date of this report
2015

Reference number assigned by the manufacturer
CMP-

Reference number assigned by NCA

Type of report
- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail CAReporting@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	Catalogue number
	1650DE

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
BAT [redacted] - Battery	

Software version number (if applicable)

Device Mfr Date	Expiry date
	2015-04-30

Implant date (For implants only)	Explant date (For implants only)

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2015-[redacted]

Number of patients involved (if known)	Number of medical devices involved (if known)
1	1

Medical device current location/disposition (if known)
The involved battery is available for return for further evaluation but has not yet been received.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ○ initial use
- ○ reuse of a single use medical device
- ◉ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility
Leiden University Medical Center

Contact person within the facility

Address
Albinusdreef 2

Postcode	**City**
2333ZA	Leiden
Phone	**Fax**
	UNK
E-mail	**Country**
@lumc.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

The HVAD is used for treatment not diagnosis. It was reported that the battery changed to the other power source earlier than expected. Log files were analyzed and the battery was replaced. [redacted] Investigation is ongoing.
Based on the results of the previous manufacturer's internal investigation, field actions and changes to the battery internal cell supplier, no additional investigation of this event is required at this time. The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

FSCA APR2014.1
Field Safety Notice was then expanded (FSCA APR2014.1) in order to remove batteries from the field that were released prior to the implementation of enhanced battery screening process to address and prevent battery failures.

Time schedule for the implementation of the identified actions

None

Final comments from the manufacturer

The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack.

Further investigations

HeartWare has opened an internal investigation to address this issue.

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

Number of similar incidents

487 from 10/1/2012 to 9/30/2015

If yes, state in which countries and the report reference numbers of the incidents.

Austria [redacted]
Belgium [redacted]
Denmark [redacted]
Estonia [redacted]
France [redacted]
Germany [redacted]
Israel [redacted]

10.1.c + 10.2.g

Italy
Luxembourg
Netherlands
Norway
Poland
Sweden
Switzerland
Turkey
United Kingdom
United States

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒AT	☒BE	☒BG	☒CH	☒CY	☒CZ	☒DE	☒DK
☒EE	☒ES	☒FI	☒FR	☐GB	☒GR	☒HU	☒IE
☐IS	☒IT	☐LI	☒LT	☒LU	☒LV	☐MT	☒NL
☒NO	☒PL	☐PT	☒RO	☒SE	☒SI	☒SK	☒TR

Candidate Countries

☒HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Africa, Kazak

12 Comments

Updated sections on 29-DEC-15:
Section 1: Date of this Report, Reference number assigned by NCA, Type of report.
Section 3: Manufacturer information
Section 4: Authorised Representative Information
Section 5: Submitter's Information
Section 6: Medical device information
Section 7: Medical device current location/disposition
Section 10: Expected date of next report
Section 11: Results of manufacturers final investigation, Remedial action, Final Comments, Further investigations and number of similar incidents

The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The HeartWare System Instructions for Use (IFU), Patient Manual, and training material provide clear instructions to the user on proper usage and care of HVAD power sources. Moreover, the IFU provides instruction to further educate the patient about product safety, alarm management, and device management; additional guidelines instruct the user on how to detect and react to a power source malfunction.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)

Stamp box

Address of National Competent Authority

Dutch Healthcare Inspectorate
Postal address: P.O. Box 2680, NL - 3500 BS Utrecht,
Visitors address: St. Jacobsstraat 16, NL - 3511 BS Utrecht

Date of this report

2016-

Reference number assigned by the manufacturer

CMP-

Reference number assigned by NCA

Not Received

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter

- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail CAReporting@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
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Phone 44(0)	**Fax** 44(0)
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E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	Catalogue number
	A00035

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
Battery - BAT [redacted]	

Software version number (if applicable)

Device Mfr Date	Expiry date
	2015-07-31

Implant date (For implants only)	Explant date (For implants only)

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)
None

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2015-[redacted]

Number of patients involved (if known)	Number of medical devices involved (if known)
1	1

Medical device current location/disposition (if known)
The Battery will be returned to HeartWare for further evaluation.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ○ initial use
- ○ reuse of a single use medical device
- ◉ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility

UMC Utrecht

Contact person within the facility

Address

Heidelberglaan 100

Postcode	**City**
UNK	utrecht
Phone	**Fax**
E-mail	**Country**
@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

The HVAD is used for treatment not diagnosis. It was reported by the ventricular assist device (VAD) coordinator from the Netherlands

Based on the results of the previous manufacturer's internal investigation, field actions and changes to the battery internal cell supplier, no additional investigation of this event is required at this time. The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

FSCA APR2014.1
Field Safety Notice was then expanded (FSCA APR2014.1) in order to remove batteries from the field that were released prior to the implementation of enhanced battery screening process to address and prevent battery failures.

Time schedule for the implementation of the identified actions

None

Final comments from the manufacturer

The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack.

Further investigations

HeartWare has opened an internal investigation to address this issue.

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

Number of similar incidents

487 from 10/1/2012 to 9/30/2015

If yes, state in which countries and the report reference numbers of the incidents.

Austria
Belgium
Denmark
Estonia
France
Germany

10.1.c + 10.2.g

Israel
Italy
Luxembourg
Netherlands
Norway
Poland
Sweden
Switzerland
Turkey
United Kingdom
United States

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Africa, Kazak

12 Comments

Updated sections on 06-JAN-16:
Section 1: Date of this Report, Reference number assigned by NCA, Type of report.
Section 3: Manufacturer information
Section 4: Authorised Representative Information
Section 5: Submitter's Information
Section 6: Medical device information
Section 7: Medical device current location/disposition
Section 10: Expected date of next report
Section 11: Results of manufacturers final investigation, Remedial action, Final Comments, Further investigations and number of similar incidents

The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The HeartWare System Instructions for Use (IFU), Patient Manual, and training material provide clear instructions to the user on proper usage and care of HVAD power sources. Moreover, the IFU provides instruction to further educate the patient about product safety, alarm management, and device management; additional guidelines instruct the user on how to detect and react to a power source malfunction.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal address: P.O. Box 2680, NL - 3500 BS Utrecht, Visitors address: St. Jacobsstraat 16, NL	

Date of this report
2016-

Reference number assigned by the manufacturer
CMP-

Reference number assigned by NCA

Type of report
- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1
E-mail CAReporting@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

Doc. 222

new

6 Medical device information

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	**Catalogue number**
	1407DE

Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
Controller-CON [redacted]	

Software version number (if applicable)

Device Mfr Date	**Expiry date**
2015-01-28	2015-10-31
Implant date (For implants only)	**Explant date (For implants only)**

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)
None

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
It was reported from the Netherlands by the Ventricular Assist Device (VAD) coordinator that [redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2015 [redacted]

Number of patients involved (if known)	**Number of medical devices involved (if known)**
1	1

Medical device current location/disposition (if known)
[redacted] Controller is currently at HeartWare. 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

Trouble shooting of the monitor and cables, the controller was exchanged

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility

UMC Utrecht

Contact person within the facility

Address

Heidelberglaan 100

Postcode	**City** UMCU
Phone	**Fax**
E-mail	**Country** NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None

Initial corrective actions/preventive actions implemented by the manufacturer

None

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

CON [redacted] was returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the device/devices in relation to the reported event. The reported event could not be confirmed.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

None

Time schedule for the implementation of the identified actions

None

Final comments from the manufacturer

. The device was related to the reported event; however there is no evidence to suggest that a device malfunction caused or contributed to the reported event. With review of the reported information and analysis of the returned device with no confirmed malfunction, a root cause cannot be determined.

Further investigations

None

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

○ Yes ◉ No

Number of similar incidents

0

If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, Canada, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Afri+

12 Comments

Updated sections on 23JAN2016:
Section 1: Type of report, Reference number assigned by NCA
Section 3: Manufacturer Information.
Section 5: Submitter's information
Section 7: Medical device current location/disposition updated to include latest information available.
Section 11: Results of manufacturers final investigation (Final report)

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The system is designed for in-hospital and out-of-hospital settings.

Information For Use states: The controller is a microprocessor unit that controls and manages the system operation. It sends power and operating signals to the blood pump and collects information from the pump. When connected to a controller, the monitor receives continuous data from the controller and displays real-time and historical pump information. Do not force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e, tenzij anders aangegeven.

Doc. 225

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)

Stamp box

Address of National Competent Authority

Dutch Healthcare Inspectorate
Postal address: P.O. Box 2680, NL - 3500 BS Utrecht

Date of this report

2016-

Reference number assigned by the manufacturer

CMP-

Reference number assigned by NCA

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter

- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail CAReporting@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

Doc. 225

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	**Catalogue number**
	1650DE
Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
BAT - Battery	

Software version number (if applicable)

Device Mfr Date	**Expiry date**
	2015-11-30
Implant date (For implants only)	**Explant date (For implants only)**

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)
None.

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2015-

Number of patients involved (if known)	**Number of medical devices involved (if known)**
1	1

Medical device current location/disposition (if known)
The battery was returned on 2015-

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

The battery was removed from service.

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility

UMC Utrecht

Contact person within the facility

Address

Heidelberglaan 100

Postcode	**City** Utrecht
Phone	**Fax**
E-mail @umcutrecht.nl	**Country** NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

Battery BAT [redacted] was returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the battery in relation to the reported event. However, the problem could not be replicated in bench testing. Analysis of the battery revealed that it met specifications; it passed visual examination and functional testing. Premature power switching events were confirmed in the logs on the day of the reported event and on prior days, which confirmed the reported event. However, no problem with the batteries could be confirmed in bench testing. The battery was in use when the reported event occurred. The circumstances of the event and the controller log files are consistent with an internal investigation, which is a controller communications error with the battery.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

Heartware has opened an internal investigation to address this issue.

Time schedule for the implementation of the identified actions

Unknown.

Final comments from the manufacturer

The probable cause for the power switching is controller communication error with the battery.

Further investigations

Heartware has opened an internal investigation to address this issue.

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

Number of similar incidents

442 from 2013/1/1 to 2015/12/31.

If yes, state in which countries and the report reference numbers of the incidents.

Austria [redacted]
Belgium [redacted]
Czech Republic [redacted]
Finland [redacted]
France [redacted]
Germany [redacted]

10.1.c + 10.2.g

Italy
Netherlands
Norway
Poland
Spain
Sweden
Switzerland
Turkey
United Kingdom

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒AT	☒BE	☒BG	☒CH	☒CY	☒CZ	☒DE	☒DK
☒EE	☒ES	☒FI	☒FR	☒GB	☒GR	☒HU	☒IE
☐IS	☒IT	☐LI	☒LT	☒LU	☒LV	☐MT	☒NL
☒NO	☒PL	☐PT	☒RO	☒SE	☒SI	☒SK	☒TR

Candidate Countries

☒HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

Australia, Argentina, Belarus, Bosnia, New Zealand, Malaysia, Hong Kong, India, Israel, Turkey, Chile, Singapore, South Africa, Ja

12 Comments

Updated Sections as of 2016/03/07:
Section 1: Date of this report
Section 1: Reference number assigned by NCA
Section 1: Type of report
Section 3: Manufacturer information
Section 4: Authorised Representative Information
Section 5: Submitter's information
Section 6: Catalogue number
Section 6: Device Mfr Date
Section 6: Accessories / associated devices
Section 7: Medical device current location/disposition
Section 10: Expected date of next report
Section 11: Results of manufacturers final investigation
Section 12: Comments

LVAD implantation [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The device has not been returned to the manufacturer for analysis. The Instructions for Use and Patient Manual include a reference guide for normal battery behavior and both visual and tone alarms including potential causes and actions to take. Additionally there is a warning to keep spare, fully charged batteries and back up controller available at all time. If there is a controller failure, the controller should be switched to the back-up controller. The steps for exchange of batteries and controllers are outlined.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature [redacted]

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA) Law Enforcement (a.o. vigilance and market surveillance)	Stamp box
Address of National Competent Authority Law Enforcement (a.o. vigilance and market surveillance) Dutch Healthcare Inspectorate, IGZ information office (Meldpunt) Dutch Healthcare Inspectorate Postal Address: P.O. Box 2680, NL - 3500BS Utrecht	

Date of this report
2016-

Reference number assigned by the manufacturer
CMP-

Reference number assigned by NCA

Type of report
- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1	**Fax** 1-
E-mail CAReporting@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN) GMDN	**Nomenclature code** 16977
Nomenclature text Artificial heart, temporary	
Commercial name/ brand name / make HeartWare® Ventricular Assist System	
Model number	**Catalogue number** 1407DE
Serial number(s) (if applicable) CON [redacted] - Controller	**Lot/batch number(s) (if applicable)**
Software version number (if applicable)	
Device Mfr Date	**Expiry date** 2014-09-30
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable) None.	
Notified Body (NB) ID-number 0086 BSI Product Services	

7 Incident Information

Date the incident occurred

[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative

[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date

2015[redacted]

Number of patients involved (if known) 1	**Number of medical devices involved (if known)** 1

Medical device current location/disposition (if known)

Controller was received on 2015[redacted].

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility
UMC Utrecht

Contact person within the facility

Address
Heidelberglaan 100

Postcode	**City**
3584	Utrecht
Phone	**Fax**
E-mail	**Country**
@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None

Initial corrective actions/preventive actions implemented by the manufacturer

None

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

One controller was returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the device in relation to the reported event. The reported event was confirmed via functional testing. Analysis of the device revealed that the device failed to meet specifications; the device passed visual examination but failed functional testing due to the right side of the controller display gradually diminishing in intensity. The confirmed malfunction is related to the reported event.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

None

Time schedule for the implementation of the identified actions

Unknown.

Final comments from the manufacturer

The most likely root cause of the failure is a faulty LCD display module, which likely contributed to the event.

Further investigations

None

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

Number of similar incidents

20 from 2013/1/1 to 2015/12/31.

If yes, state in which countries and the report reference numbers of the incidents.

Austria [redacted]
Germany [redacted]
Italy [redacted]

10.1.c + 10.2.g

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, Canada, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Afri

12 Comments

Updated Sections as of 2016/03/08:
Section 1: Date of this report
Section 1: Reference number assigned by NCA
Section 1: Type of report
Section 3: Manufacturer information
Section 4: Authorised Representative Information
Section 5: Submitter's information
Section 6: Serial number(s)
Section 6: Accessories / associated devices
Section 7: Medical device current location/disposition
Section 7: Operator of the medical device at the time of incident
Section 7: Usage of the medical device
Section 10: Expected date of next report
Section 11: Results of manufacturers final investigation
Section 12: Comments

LVAD implanted on [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The Instructions for Use and Patient Manual warns that if there is a controller failure, the controller should be switched to the back-up controller.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature [redacted]

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e, tenzij anders aangegeven.

Doc. 237

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)
The Instructions for Use (IFU) provides instructions for properly connecting the power so

Stamp box

Address of National Competent Authority
Dutch Healthcare Inspectorate
Postal address: P.O. Box 2680, NL - 3500 BS Utrecht

Date of this report
2016

Reference number assigned by the manufacturer
CMP-

Reference number assigned by NCA

Type of report
- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter
- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name	
HeartWare	
Contact Name	
[redacted]	
Address	
14400 NW 60th Avenue	
Postcode	**City**
33014	Miami Lakes
Phone	**Fax**
1 [redacted]	1- [redacted]
E-mail	**Country**
CAReporting@heartware.com	US - USA

4 Authorised Representative Information

new

Name	
MedPass International Limited	
Contact Name	
[redacted]	
Address	
Windsor House, Bretforton, Evesham	
Postcode	**City**
WR11 7JJ	Worcestershire
Phone	**Fax**
44(0 [redacted]	44(0) [redacted]
E-mail	**Country**
medpass.ar@medpass.org	GB - Great Britain

5 Submitter's Information

new

Name	
MedPass International Limited	
Contact Name	
[redacted]	
Address	
Windsor House, Bretforton, Evesham	
Postcode	**City**
WR11 7JJ	Worcestershire
Phone	**Fax**
44(0) [redacted]	44(0) [redacted]
E-mail	**Country**
medpass.ar@medpass.org	GB - Great Britain

new

6 Medical device information

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text
Artificial heart, temporary

Commercial name/ brand name / make
HeartWare® Ventricular Assist System

Model number	**Catalogue number**
	1407DE
Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
CON [redacted] - Controller	

Software version number (if applicable)

Device Mfr Date	**Expiry date**
	2015-11-30
Implant date (For implants only)	**Explant date (For implants only)**

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)
None.

Notified Body (NB) ID-number
0086 BSI Product Services

7 Incident Information

Date the incident occurred
[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative
[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date
2015 [redacted]

Number of patients involved (if known)	**Number of medical devices involved (if known)**
1	1

Medical device current location/disposition (if known)
The controller was returned to the manufacturer on [redacted] 2015.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ○ initial use
- ○ reuse of a single use medical device
- ◉ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

Gender, if applicable

Age of the patient at the time of incident, if applicable	**units** ◉ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility
UMC Utrecht

Contact person within the facility

Address
Heidelberglaan 100

Postcode	**City** Utrecht
Phone	**Fax**
E-mail @umcutrecht.nl	**Country** NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

One controller was returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the device in relation to the reported event. Analysis of the device revealed that the device met specifications; the device passed visual examination and functional testing.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

None.

Time schedule for the implementation of the identified actions

None.

Final comments from the manufacturer

The reported event could not be duplicated at the bench level.

Further investigations

None.

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

○ Yes ◉ No

Number of similar incidents

0

If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒AT	☒BE	☒BG	☒CH	☒CY	☒CZ	☒DE	☒DK
☒EE	☒ES	☒FI	☒FR	☒GB	☒GR	☒HU	☒IE
☐IS	☒IT	☐LI	☒LT	☒LU	☒LV	☐MT	☒NL
☒NO	☒PL	☐PT	☒RO	☒SE	☒SI	☒SK	☒TR

Candidate Countries

☒HR

☐All EEA, candidate countries and Switzerland and Turkey

Others:

USA, Australia, Argentina, Belarus, Bosnia, Canada, New Zealand, Malaysia, Hong Kong, India, Israel, Chile, Singapore, South Afri

12 Comments

Updated sections on 07/APR/2016:
Section 1: Administrative information (Date of this report, Reference number assigned by NCA, Type of Report).
Section 3: Manufacturer Information(E-mail)
Section 11: Results of manufacturers final investigation (Final report).

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The Instructions for Use (IFU) provides instructions for properly connecting the power sources. It instructs to line up the solid white arrow on the connector with the white dot. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A successful connection will result in an audible click. The IFU cautions, "DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors." If both power sources are disconnected from the controller, a loud, continuous alarm will sound and there will be NO message on the controller display. The pump is NOT pumping and power sources should be connected immediately. If this action does not resolve the alarm condition replace the controller."

The Instructions for Use (IFU) and Patient Manual include a reference guide for both visual and tone alarms including potential causes and actions to take. Additionally there is a warning to keep spare, fully charged batteries and back up controller available at all time. The steps for exchange of batteries and controllers are outlined.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

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print | check | send XML-data by E-Mail

Overal 10.2.e.

Doc. 241

import XML | fix + save

fill with test data #1

new case, keep base data

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.7en
2012-12-03

1 Administrative information

To which NCA(s) is this report being sent?

Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Luxembourg, Netherlands, Norway, Poland, Romania,Slovakia, Spain, Sweden, Switzerland, and United Kingdom

Type of report

- (•) Initial report
- ( ) Follow-up report
- ( ) Final report

Date of this report

2016-05-24

Reference number assigned by the manufacturer

FSCA APR2016

FSCA reference number assigned by NCA

Incidence reference number assigned by NCA

Name of the co-ordinating NCACompetent Authority (if applicable)

MHRA

2 Information on submitter of the report

Status of submitter

- ( ) Manufacturer
- (•) Authorised Representative within EEA and Switzerland
- ( ) Others: (identify the role)

3 Manufacturer information | new

Name

HeartWare, Inc.

Contact Name

Address

14400 NW 60th Avenue

Postcode	**City**
FL 33014	Miami Lakes
Phone	**Fax**
+1	+1
E-mail	**Country**
FSCA@heartware.com	US - USA

4 Authorised Representative Information

new

Name MedPass International, Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 National contact point information

new

National contact point name MedPass International, Ltd.	
Name of the contact person	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpassar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977
Nomenclature text	
Circulatory Assist System, Artificial Heart, Tempo	
Commercial name/ brand name / make	
HeartWare Ventricular Assist System	
Model number	**Catalogue number**
1407XX	
Serial number(s)	**Lot/batch number(s)**
HeartWare® Controllers Manufactured September 2014 and after.	
Device Mfr Date	**Expiry date**
2014-09-01	

Notified Body (NB) ID-number
0086 BSI PRODUCT, SERVICES CE marked: 2009-01-29
Accessories / associated devices (if applicable)
Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

In mid-January 2016, HeartWare launched a software maintenance release update for Controllers outside of the US that included, in some jurisdictions, a functional inspection of each Controller following the update. In the course of conducting these inspections, HeartWare has opened an increased number of complaints for loose connector ports within the Controller body. In parallel, there has been an increasing trend of customer reports of loose connectors. On February 29, 2016, an escalation was initiated to evaluate the loose connectors to determine if a field corrective action might be necessary. A loose connector may affect the Controller's IPX 7 rating potentially allowing for fluid ingress into the Controller. Loss of IPX 7 integrity and failure to protect the Controller per the instructions for use could result in fluid ingress into the electronics. If fluid ingress were to occur, this could lead to lead to internal corrosion, electrical issues, reduced speaker volume and connection failures.

Description and justification of the action (corrective / preventive)

HeartWare has initiated a corrective action with the Controller supplier to investigate and establish root cause. This ongoing investigation has attributed the following as potential causes to the loose port connectors:

1. Port gasket materials.
2. Manufacturing processes for thread lock application processes and workmanship issues.
3. Design requirements for torqueing the port fastener and the material properties of the connectors.

Actions to be taken:
A) Communicate the potential occurrence of this issue to clinicians.
B) Units identified as having loose connectors will be replaced and processed via the HeartWare handling process. The communication and replacement plan will be determined and documented in a Field Action Implementation Plan (FM00927).
C)Regulatory bodies and competent authorities where affected controllers have been distributed will be notified.
D)Products identified as affected during routine inspection will be removed from service & processed via HeartWare's Return & Complaint process.

Advice on actions to be taken by the distributor and the user

See Attachment 2 - FSCA APR2016 Urgent Field Safety Notice for detailed information.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

HeartWare will distribute FSN letters in English beginning the week of May 23, 2016 (FSCA APR2016 Urgent Field Safety Notice). Language translations for remaining EU countries may take two weeks to fully obtain from international translators for distribution to remaining EU countries. The Acknowledgement is due 30 days from distribution of the Field Safety Notice. HeartWare targets to complete this action 90 days from initiation of distribution.

Attached please find

- ☒ Field Safety Notice (FSN) in English
- ☐ FSN in national language
- ☒ Others (please specify)

FSN Status

- ○ Draft FSN
- ◉ Final FSN

Attachment 1 - Health Hazard Evaluation; Attachment 2 - FSCA APR2016 Urgent Field Safety Notice; Attachment 3- F

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK
☐ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☐ SI	☒ SK	☐ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Overal 10.2.e.

Doc. 243

[redacted]

Van: [redacted]@medpass.org]
Verzonden: dinsdag 21 juni 2016 11:27
Onderwerp: RE: 1605 3569, Our reference [redacted]_Your reference FSCA APR2016
Bijlagen: HeartWare FSCA APR2016 Urgent Field Safety Notice_EU.NL.PDF

Your reference number [redacted]

Dear Sir/Madam,

On behalf of HeartWare Inc., and acting as the European Authorized Representative, please find attached the following document:

- Field Safety Notice in Dutch language

Kind Regards

[redacted]
Regulatory Affairs Assistant
Tel: [redacted]
[redacted]@medpass.org

MedPass International
95 bis Boulevard Pereire
75017 Paris - France
Tel : +33 (0)1 42 12 83 30
Fax: +33 (0)1 40 53 81 11
www.medpass.org

The Full Service Medical Device CRO
Strategic Consulting - Market Access & Reimbursement Clinical Evaluations and Investigations - Regulatory Affairs Clinical Operations - Data Management & Biostatistics Authorized Representative - Legal Representative

-----Original Message-----
From: meldpunt@igz.nl [mailto:meldpunt@igz.nl]
Sent: mardi 7 juin 2016 09:27
To: [redacted]
Subject: 1605 3569, Our reference [redacted]_Your reference FSCA APR2016

Dear Mrs [redacted],

We herewith acknowledge receipt of your e-mail of 24 may 2016, by which you inform the Dutch Healthcare Inspectorate about a Field Safety Corrective Action with your reference FSCA APR2016.
This corrective action concerns the HeartWare Ventricular Assist System and is registered under our reference number [redacted].

Risk-analysis
The information provided has been analysed on potential risks. Based on the results of this analysis the Dutch Healthcare Inspectorate will not start an investigation with regard to this issue. Should problems related to this FSCA (re)occur in the future it is possible that the inspectorate reopens this case on behalf of an investigation.

Procedure

We kindly request you to send us a confirmation when this FSCA has been completed in the Netherlands. You can send this by e-mail to meldpunt@igz.nl or by letter to the address mentioned below. Please mention the reference number of this e-mail when you contact us. On receipt of your confirmation that this FSCA has been completed in the Netherlands, I consider this case closed. You will not receive a separate message to confirm this.

Any further questions?
I hope this provides you with sufficient information. If you have any further questions, do not hesitate to contact us. We are available from Monday until Friday, from 9.00 to 17.00 at +31 (0)88 ? 120 50 00. You can also send an e-mail to meldpunt@igz.nl. Please mention the reference number of this e-mail when you contact us.

Yours sincerely

Ms [redacted]

Head of IGZ Information and Notification Centre (Meldpunt IGZ)
.....
Healthcare Inspectorate
IGZ Central Information Office
Postbus 2518| 6401 DA | Heerlen
The Netherlands
.....
T 088 1205000
meldpunt@igz.nl
http://www.igz.nl
.....
.....

24-05-2016 17:31 Mailimport,:
Sender: [redacted]@medpass.org
Date sent: May 24, 2016 5:18 PM
To: [redacted]
CC: MedpassAR <medpass.ar@medpass.org>
Subject: Heartware- Initial FSCA APR2016

Identifier: FSCA APR2016
Manufacturer: HeartWare, Inc.
Product Name: HeartWare(r) Ventricular Assist System

Coordinating National Competent Authority: MHRA

Dear NCA contact,

As part of ongoing product performance monitoring, HeartWare has received reports of loose power and data connectors on the HeartWare Controller, and is therefore conducting this Field Safety Corrective Action to reduce the occurrence of avoidable injuries as patients remain on the device for increasingly long periods of time.

Please see attached the following documents:

* FSCA APR2016 Initial FSCA form

* FSCA APR2016 Urgent Field Safety Notice

* FSCA APR2016 Health Hazard Evaluation

The FSCA Report explains HeartWare's strategy and timeline for customer notification, implementation of actions and completion of actions.

Please note that translation of the FSN into your national language(s) is currently underway and you will be formally notified of this FSCA as soon as these translations are available. As soon as the translations are available, the affected customers will also be notified of this FSCA.

Should you need further information, please do not hesitate to contact MedPass at medpass.ar@medpass.org<mailto:medpass.ar@medpass.org> .

Kind Regards

[redacted]
Regulatory Affairs Assistant

Tel: [redacted]
[redacted]@medpass.org<mailto:[redacted]@medpass.org>

[cid:image001.jpg@01D168D0.FCE72CB0]

MedPass International
95 bis Boulevard Pereire
75017 Paris - France
Tel : +33 (0)1 42 12 83 30
Fax: +33 (0)1 40 53 81 11
www.medpass.org<http://www.medpass.org/>

[cid:image002.jpg@01D168D0.FCE72CB0]

The Full Service Medical Device CRO
Strategic Consulting - Market Access & Reimbursement Clinical Evaluations and Investigations - Regulatory Affairs Clinical Operations - Data Management & Biostatistics Authorized Representative - Legal Representative

20/06/2016

DRINGEND VEILIGHEIDSBULLETIN

HeartWare® controller

Identificatie:	FSCA APR2016
Type actie:	Veiligheidsbulletin
Productcodes:	1407XX
Reeks serienrs.:	HeartWare® controllers

Beste HeartWare clinicus,

Als onderdeel van de voortdurende bewaking van de prestaties van haar producten, heeft Heartware meldingen ontvangen van loszittende stroom- en dataconnectoren. We verspreiden dit vrijwillige veiligheidsbulletin om de kans op mogelijke problemen te verkleinen.

Gezondheidsrisico's

HeartWare controllers worden nu zo gemaakt dat ze toch in zekere mate beschermd zijn tegen blootstelling aan water. Indien een stroom- of dataconnector los komt te zitten, bestaat de kans dat controllers kwetsbaarder worden voor waterschade.

In het bijzonder zou een loszittende connector er kunnen voor zorgen dat vocht door het oppervlak van een controller dringt. Dit kan leiden tot interne corrosie, elektrische storingen, verminderd volume van de luidspreker en verbindingsfouten. Mogelijke risico's in deze scenario's zijn:

- Onderbreking van de ondersteuning van de bloedsomloop wegens een gestopte pomp; dit kan leiden tot ernstige kwetsuren of de dood;
- Mogelijkheid om alarmen op te sporen is verminderd; en
- Verlies van communicatie tussen de controller en de HeartWare monitor.

We hebben gemerkt dat bij gebruik van de controller, connectoren mettertijd los kunnen komen te zitten. Heartware heeft een groei in het aantal meldingen van loszittende connectoren vastgesteld, bij controllers die langer dan een jaar in gebruik zijn.

Acties voor de clinicus

HeartWare vraagt dat u, na het lezen van dit bulletin, volgende acties uitvoert:

1. Blijf uw patiënten, die op dit moment gebruik maken van het HVAD® systeem, eraan herinneren alle instructies in hun Patiënthandleidingen goed op te volgen, zoals alert zijn voor alarmen, uit de buurt houden van water en voorzichtig zijn bij aansluiten aan, of loskoppelen van, stroom- en gegevensbronnen.

2. Wanneer de patiënt op vaste afspraak komt, kijk dan de controller na op loszittende connectoren door zachtjes op elke connector te duwen en aandacht te hebben voor ongewone bewegingen. Duw niet te hard op de connectoren want dan zouden ze kapot kunnen gaan. Als u een loszittende connector opmerkt, stellen wij voor dat u de betrokken controller vervangt door een controller uit

voorraad, en dat u uw lokale Heartware-vertegenwoordiger contacteert. Indien de betrokken controller de primaire controller van de patiënt is, bepaal dan naar eigen goeddunken of de risico's om de controller te vervangen opwegen tegen de risico's van een controller met een loszittende connector.

3. Gelieve het "Bevestigingsformulier" in bijlage, binnen de **30 dagen**, ondertekend terug te sturen naar Heartware. Stuur dit bulletin naar alle personen in uw organisatie die zich bewust moeten zijn van de inhoud.

Vragen

Gelieve uw lokale Heartware-vertegenwoordiger te contacteren indien u vragen of bezorgdheden heeft.

Dank bij voorbaat voor uw medewerking. HeartWare verspreidt dit vrijwillige veiligheidsbulletin met goedkeuring van uw lokale regelgevende instantie en de Medicines and Healthcare products Regulatory Agency (MHRA).

Hoogachtend,

Mark Jackson,
Vice President, Quality and Design Assurance

Bijlage:

1. Bevestigingsformulier

Bevestigingsformulier

DRINGEND VEILIGHEIDSBULLETIN

(in te vullen door de vertegenwoordiger van de site)

Identificatie:	FSCA APR2016
Type actie:	Veiligheidsbulletin
Productcodes:	1407XX
Reeks serienrs.:	HeartWare® controllers

Naam Klinische instelling / Hospitaal	

Ondergetekenden bevestigen hierbij ontvangst en begrip van het Dringend veiligheidsbulletin van HeartWare, FSCA APR2016.

Functie / Titel	Naam in hoofdletters	Handtekening	Datum

Gelieve ons het "Bevestigingsformulier" in bijlage, binnen de 30 dagen, ondertekend terug te bezorgen op een van volgende manieren:

- ***Stuur een e-mail met een elektronische kopie van het ondertekende formulier naar het emailadres van het HeartWare Quality Compliance team FSCA@heartware.com ; of***
- ***Fax het ondertekende formulier naar +1 (305) 364-2665***

Overal 10.2.e, tenzij anders aangegeven.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority Dutch Healthcare Inspectorate Postal Address: P.O. Box 2680, NL - 3500BS Utrecht,	
Date of this report 2016	
Reference number assigned by the manufacturer CMP-	
Reference number assigned by NCA	
Type of report ○ Initial report ○ Follow-up report ○ Combined initial and final report ◉ Final report	
Does the incident represent a serious public health threat? ○ yes ◉ no	
Classification of incident ○ Death ○ Unanticipated Serious Deterioration in State of Health ◉ All other reportable incidents	
Identify to what other NCA's this report was also sent US Food and Drug Administration (FDA)	

2 Information on submitter of the report

Status of submitter ○ Manufacturer ◉ Authorised Representative within EEA and Switzerland and Turkey ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone	**Fax**
E-mail CAReporting@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name HeartWare	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

Doc. 247

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN) GMDN	**Nomenclature code** 16977
Nomenclature text Artificial heart, temporary	
Commercial name/ brand name / make HeartWare® Ventricular Assist System	
Model number	**Catalogue number** 1407DE
Serial number(s) (if applicable) Controller - CON	**Lot/batch number(s) (if applicable)**
Software version number (if applicable)	
Device Mfr Date	**Expiry date** 2015-07-31
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable)	
Notified Body (NB) ID-number 0086 BSI Product Services	

7 Incident Information

Date the incident occurred 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	
Incident description narrative 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	
User facility report reference number, if applicable	
Manufacturer's awareness date 2015-	
Number of patients involved (if known) 1	**Number of medical devices involved (if known)** 1
Medical device current location/disposition (if known) The controller was returned to the manufacturer for evaluation.	

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

The Controller was replaced.

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ◉ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility

Leiden University Medical Center

Contact person within the facility

Address

Albinusdreef 2

Postcode	**City**
2333	Leiden
Phone	**Fax**
E-mail	**Country**
@lumc.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None

Initial corrective actions/preventive actions implemented by the manufacturer

None

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

One controller was returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the device in relation to the reported event. The reported event could not be confirmed since log file analysis did not reveal any anomalies during the analyzed period. Analysis of the device revealed that the device met specifications; the device passed visual examination and functional testing. The reported event could not be duplicated at the bench level. When both external power supplies were disconnected from the controller, the ensuing No Power alarm met specification for duration

Remedial action/corrective action/preventive action / Field Safety Corrective Action

None

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

No failure detected, the reported event could not be duplicated at the bench level.

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

○ Yes ◉ No

Number of similar incidents

0

If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Updated sections on 13 JUL 2016:
Section 1: Type of report- Final
Section 7: Medical device is currently at Heartware.
Section 11: Manufacturer's comments of investigation..

Implanted with Ventricular Assist Device (VAD) on [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The Instructions for Use (IFU) and Patient Manual include a reference guide for both visual and tone alarms including potential causes and actions to take. Additionally there is a warning to keep spare, fully charged batteries and back up controller available at all time. The steps for exchange of batteries and controllers are outlined.

The Instructions for Use and Patient Manual include a warning to keep a spare back up controller available at all times and outlines that if there is a controller failure, the controller should be switched to the back-up controller. The steps for exchange of devices are also outlined. It further warns that damaged equipment should be reported to the manufacturer and inspected.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature [redacted]

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e, tenzij anders aangegeven.

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)

Stamp box

Address of National Competent Authority

Dutch Healthcare Inspectorate
Postal address: P.O. Box 2680, NL - 3500 BS Utrecht, Visitors address: St. Jacobsstraat 16, NL 3511 BS Utrecht

Date of this report

2016-

Reference number assigned by the manufacturer

CMP-

Reference number assigned by NCA

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

US Food and Drug Administration (FDA)

2 Information on submitter of the report

Status of submitter

- ○ Manufacturer
- ◉ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name HeartWare	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode 33014	**City** Miami Lakes
Phone 1-	**Fax** 1-
E-mail productquality@heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0)
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 Submitter's information

new

Name MedPass International Limited	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcestershire
Phone 44(0)	**Fax** 44(0
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN) GMDN	**Nomenclature code** 16977
Nomenclature text Artificial heart, temporary	
Commercial name/ brand name / make HeartWare® Ventricular Assist System	
Model number	**Catalogue number** A00036
Serial number(s) (if applicable) BAT [redacted] Battery	**Lot/batch number(s) (if applicable)**
Software version number (if applicable)	
Device Mfr Date	**Expiry date** 2016-02-29
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable) None	
Notified Body (NB) ID-number 0086 BSI Product Services	

7 Incident Information

Date the incident occurred

[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Incident description narrative

[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

User facility report reference number, if applicable

Manufacturer's awareness date

2016 [redacted]

Number of patients involved (if known) 1	**Number of medical devices involved (if known)** 1

Medical device current location/disposition (if known)

Battery has been returned to HeartWare for evaluation.

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

[redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

[redacted]

Gender, if applicable

○ Female ○ Male

Age of the patient at the time of incident, if applicable	**units** ○ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

Name of the healthcare facility

UMCU Utrecht

Contact person within the facility

[redacted]

Address

Heidelberglaan 100

Postcode	**City**
3584 CX	Utrecht
Phone	**Fax**
[redacted]	
E-mail	**Country**
[redacted]@umcutrecht.nl	NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

None.

Initial corrective actions/preventive actions implemented by the manufacturer

None.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

One battery was returned for evaluation. Various analyses were conducted and reviewed in order to evaluate the performance of the device in relation to the reported event. Analysis of the device revealed that the device failed to meet specifications; the device passed visual inspection but failed functional testing as a result of the battery received in an inactive mode. However, once the battery was connected to the charger, the battery was reset to an active/present mode and operated as intended afterward. This observation is considered not related to the reported event. The reported event was confirmed via review of the controller log files, which revealed several instances of premature power switching events prior to the 25% threshold involving battery BAT [redacted]. These premature switching events were most likely caused by a communication error between the controller and batteries. HeartWare has opened an internal investigation to evaluate communication errors between the controller and batteries.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

A Field Safety Notice (FSCA APR2015A) was issued to clinicians to be delivered to patients currently on device. It provided awareness, warnings, and safety mitigations regarding potential communication issues between the controller and battery power sources.

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

The most likely root cause of the reported event may be attributed to a communication error between the controller and the battery

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

(●) Yes ( ) No

Number of similar incidents

481

If yes, state in which countries and the report reference numbers of the incidents.

Power Switching with Communication Error
AUSTRIA [redacted]
BELGIUM [redacted] 10.1.c + 10.2.g
FINLAND [redacted]

FRANCE [redacted]
GERMANY [redacted]
ITALY [redacted]
LUXEMBOURG [redacted]
NETHERLANDS [redacted]
NORWAY [redacted]
POLAND [redacted]
SPAIN [redacted]

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Updated sections on 26 JUL 2016:
Section 1: Type of report- Final
Section 7: Medical device is currently at Heartware.
Section 11: Manufacturer's comments of investigation..

LVAD Implanted on [redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

This device is used for treatment not diagnosis. The Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The System is designed for in-hospital and out-of-hospital settings.

The Instructions for Use (IFU) and Patient Manual include a reference guide for both visual and tone alarms including potential causes and actions to take. Additionally there is a warning to keep spare, fully charged batteries and back up controller available at all time. The steps for exchange of batteries and controllers are outlined.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature [redacted]

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge

Overal 10.2.e, tenzij anders aangegeven.

Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 2518 6401 DA Heerlen

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T.a.v. [redacted]
[redacted]
Postbus 9600
2300 RC LEIDEN

Stadsplateau 1
3521 AZ Utrecht
Postbus 2518
6401 DA Heerlen
T 088 120 50 00
F 088 120 50 01
www.igz.nl

Inlichtingen bij
Meldpunt IGZ
meldpunt@igz.nl

Ons kenmerk
[redacted]

Datum 8 november 2016
Onderwerp Melding [redacted]

Geachte [redacted]

Op [redacted] ontving de Inspectie voor de Gezondheidszorg een melding van MedPass International Limited over [redacted] na het plaatsen van een HeartWare® Ventricular Assist System. Patiënt gegevens werden niet verstrekt. 24 lid 4 + 25 lid 3 + 10.2.d + 10.2.e 10.2.g

De fabrikant gaf aan dat [redacted]

Procedure
Wij hebben deze melding opgenomen in ons centrale registratiesysteem onder nummer [redacted]. Mogelijk is hier sprake geweest van een calamiteit volgens artikel 11, eerste lid onder a, van de Wet kwaliteit, klachten en geschillen zorg (Wkkgz). Indien, naar uw mening, sprake is van een calamiteit dan vraag ik u om deze nader te onderzoeken en te analyseren. Vervolgens verzoek ik u een schriftelijke rapportage op te stellen volgens de bijgevoegde '*Richtlijn calamiteitenrapportage*'. Ook verneem ik graag uw mening over de aanbevolen maatregelen van de calamiteitencommissie en de wijze waarop u deze maatregelen gaat implementeren.

U wordt verzocht de rapportage binnen acht weken toe te sturen naar bovenstaand adres. Indien deze termijn voor eigen onderzoek te kort is, kunt u beargumenteerd uitstel vragen bij de inspectie. U moet dit wel binnen de genoemde termijn van acht weken doen.

Ketenzorg
Indien bij de door u gemelde calamiteit meerdere zorginstellingen/zorgaanbieders betrokken zijn geweest, verzoek ik u om naast een interne analyse ook de overgang tussen de schakels in de keten te analyseren. U kunt dit samen of in goede onderlinge afstemming met de andere zorginstellingen/zorgaanbieders uitvoeren.

Ons kenmerk
[redacted]

Datum
8 november 2016

Geen calamiteit
Mocht u van mening zijn dat geen sprake is van een calamiteit volgens artikel 11, eerste lid onder a, van de Wkkgz zorginstellingen dan verzoek ik u ons daarvan binnen twee weken gemotiveerd mededeling te doen.

Beoordeling inspectie
Na ontvangst van uw rapportage beoordeelt de inspectie of er aanleiding is om verder onderzoek naar uw melding in te stellen. Wij informeren u binnen vier weken over ons standpunt. Als uw rapportage geen aanleiding geeft tot vragen of verder onderzoek, dan informeren wij u schriftelijk dat de inspectie het dossier van deze melding afsluit.

Vragen?
Ik hoop dat ik u met deze brief voldoende heb geïnformeerd. Heeft u toch nog vragen, neem dan contact op met het Meldpunt IGZ.

Met vriendelijke groet

[redacted]

Bijlage: Richtlijn calamiteitenrapportage

Richtlijn calamiteitenrapportage

Ons kenmerk
[redacted]

Datum
8 november 2016

In deze richtlijn calamiteitenrapportage zet de Inspectie voor de Gezondheidszorg uiteen wat zij van een zorginstelling verwacht ten aanzien van de rapportage die de zorginstelling aan de inspectie stuurt naar aanleiding van een calamiteit. Op basis van de calamiteitenrapportage kijkt de inspectie zowel naar de inhoud van de calamiteit als naar de onderzoeksmethode. Verloopt het onderzoeksproces adequaat en zorgvuldig en kan geconcludeerd worden dat tekortkomingen leiden tot SMART[1] geformuleerde verbetermaatregelen die worden geborgd door de bestuurder[2].

De inspectie hecht veel belang aan de inbreng van de betrokken patiënt, cliënt, bewoner, wettelijk vertegenwoordiger of nabestaande bij het vaststellen van de feiten en het beschrijven van de gebeurtenissen. Uw analyse geschiedt door een commissie die voldoende deskundig is en bij voorkeur bestaat uit onafhankelijke personen. Waar mogelijk wordt deze analyse uitgevoerd door een team dat is samengesteld uit vertegenwoordigers van alle betrokken disciplines. Vervolgens is het de verantwoordelijkheid van de bestuurder om ervoor te zorgen dat de zakelijke inhoud van de rapportage met de betrokken burgers wordt gedeeld.

Deze richtlijn is geen in te vullen format maar een handleiding waarin de inspectie de aspecten benoemt die in de rapportage aan de orde moeten komen, tenzij die niet van toepassing zijn.

1. Gegevens van de patiënt/cliënt/bewoner: naam, geboortedatum, geslacht, juridische status, zorgzwaarte.

2. Datum calamiteit, datum van melden bij de bestuurder, referentienummer van de ontvangstbevestiging.

3. Samenstelling van de calamiteitencommissie:
- Functie en achtergrond van de leden.
- Mate van betrokkenheid bij de calamiteit.

4. Betrokken zorgverleners bij de calamiteit:
- Functies van alle betrokkenen.
- Indien de bestuurder zorgen heeft over het individueel functioneren van een betrokkene, dan wil de inspectie ook de naam en het BIG-nummer van deze betrokkene ontvangen.

5. Wijze waarop het onderzoek is verricht:
- Welke medewerkers zijn gehoord en op welke wijze?
- Is de betrokken patiënt, cliënt, bewoner, wettelijk vertegenwoordiger of nabestaande gehoord? Zo ja, op welke wijze? Zo nee, geef een toelichting.
- Welke informatiebronnen zijn geraadpleegd?
- Welke literatuur, richtlijnen en protocollen zijn bij het onderzoek betrokken?
- Is er een externe deskundige geraadpleegd? Zo ja, op welke wijze?
- Welke analysemethode is toegepast (bijvoorbeeld PRISMA, SIRE. Tripod, DAM)?

6. Beschrijving van de feiten, met bijbehorend tijdschema, zodanig dat het verloop van de calamiteit inzichtelijk is voor de lezer. Betrek daarbij, voor zover bij deze calamiteit van toepassing, de volgende aspecten:
- Opname-indicatie en behandeling.

[1] SMART: Specifiek, Meetbaar, Acceptabel, Realistisch, Tijdgebonden
[2] Indien er geen bestuurder is kunt u dit lezen als zijnde de eigenaar/hoofdverantwoordelijke van de zorginstelling

- Locatie, setting en context van de zorgverlening.
- Voorgeschiedenis en comorbiditeit.
- Risicotaxatie, bijvoorbeeld bij suïcide, delier, valcalamiteiten.
- Toezicht op patiënt, cliënt, bewoner.
- Gehanteerde landelijke of interne richtlijnen en protocollen c.q. motivatie ter afwijking.
- Bevoegd- en bekwaamheid van betrokken medewerkers en een reflectie daarop.
- Betrokkenheid farmacotherapie.
- Betrokkenheid medische hulpmiddelen en eventuele melding bij de fabrikant.
- Beschrijving van toegepaste vrijheidsbeperkende maatregelen.
- Beschrijving van de communicatie tussen de zorgverleners, zowel intern als extern.
- Beschrijving van de communicatie met de patiënt, cliënt, bewoner, wettelijk vertegenwoordiger en familie.
- Betrokkenheid ketenpartners; benoem en beschrijf de betrokkenheid en samenwerking in onderhavige casus.
- Bij overlijden: afgifte natuurlijke dood verklaring.
- Betrokkenheid Openbaar Ministerie met beschrijving.
- Aangifte bij de politie met wijze, datum en plaats.

7. Analyse tot basisoorzaken met behulp van de aangegeven methode. Classificatie in technische, organisatorische en/of menselijke basisoorzaken.

8. Hoe luiden de conclusies van de calamiteitencommissie?

9. Wat zijn de verbetermaatregelen en sluiten die aan op de basisoorzaken? Welke verbetermaatregelen zijn al getroffen en welke moeten nog geëffectueerd worden?

10. Beschrijving van de nazorg die is verleend aan de betrokkenen en aan de betrokken zorgverleners. Geef eveneens aan wat de reactie is van de cliënt, bewoner, wettelijk vertegenwoordiger of nabestaande op de wijze waarop de calamiteit is afgehandeld en op de nazorg die is geboden.

11. Acties van de bestuurder:
- Op welke wijze onderschrijft de bestuurder de analyse, conclusies en verbetermaatregelen?
- Sluiten de verbetermaatregelen in de ogen van de bestuurder aan bij de conclusies? Zo nee, geef een toelichting.
- De inspectie verwacht dat de verbetermaatregelen SMART zijn geformuleerd. Hoe gaat de bestuurder de verbetermaatregelen implementeren? Is het duidelijk voor wie deze zijn bestemd en hoe deze worden geborgd?

Overal 10.2.e, tenzij anders aangegeven.

Doc. 263

[redacted]

Van: [redacted]
Verzonden: donderdag 24 november 2016 15:39
Onderwerp: Herziene brief - Br a [redacted] -IGZ - reactie op melding [redacted]
Bijlagen: 7335 - brf a [redacted] -IGZ - reactie op melding [redacted] .pdf

Geachte heer/mevrouw,

Vanmiddag stuur ik u een brief voor [redacted] (inzake melding [redacted]). In deze brief stond een storende typefout.
Wilt u de brief uit de bijlage vervangen voor de brief die ik u eerder stuurde ?

Hartelijk dank,
met vriendelijke groet,

[redacted]
I LUMC I
I Postbus 9600 – H1-Q I
I 2300 RC Leiden I
I Tel: 071 - [redacted] I
I Email [redacted] @lumc.nl I
[redacted]

Van: [redacted]
Verzonden: donderdag 24 november 2016 12:41
Aan: meldpunt@IGZ.nl
Onderwerp: Br a [redacted] -IGZ - reactie op melding [redacted]

Geachte heer/mevrouw,

Op verzoek van mevr. [redacted], [redacted], stuur ik u deze brief voor [redacted], inzake melding [redacted].

Met vriendelijke groet,

[redacted]
I LUMC I
I Postbus 9600 – H1-Q I
I 2300 RC Leiden I
I Tel: 071 - [redacted]
I Email [redacted] @lumc.nl I
I [redacted] I

Leids Universitair
Medisch Centrum

Doc. 263

afdeling [redacted]
postzone
afzender
bezoekadres Albinusdreef 2, 2333ZA Leiden
telefoon 071 [redacted]

aan [redacted]
IGZ
Postbus 2518
6401 DA Heerlen

onze referentie [redacted]
uw referentie
datum 24 november 2016
onderwerp Reactie op melding [redacted]
aantal pagina's 2

Via: meldpunt@igz.nl

Geachte mevrouw [redacted],

Op 8 november 2016 ontving het LUMC uw brief met de melding [redacted]. MedPass International Limites had de IGZ geïnformeerd over [redacted] nadat er een HeartWare® Ventricular Assist System was geplaatst.

24 lid 4 + 25 lid 3 + 10.2.d + 10.2.e + 10.2.g

De melding is intern onderzocht. [redacted]

Er werd overlegd met HeartWare waarbij de diagnose werd bevestigd. [redacted]

24 lid 4 + 25 lid 3 + 10.2.d + 10.2.e + 10.2.g

De conclusie:

1. [redacted]
2. [redacted]

24 lid 4 + 25 lid 3 + 10.2.d + 10.2.e +10.2.g

Ondanks dat de gebeurtenis voor patiënt en familie een dramatische uitkomst heeft zijn wij van mening dat dit geen calamiteit is in het kader van de Wet kwaliteit, klachten en geschillen zorg (Wkkgz). De casus wordt binnen de afdeling geëvalueerd tijdens de complicatiebespreking. Uiteraard is er voldoende aandacht voor de familie geweest.

Ik hoop u hierbij voldoende geïnformeerd te hebben.

Met vriendelijke groet,

[redacted]

[redacted]

Overal 10.2.e, tenzij anders aangegeven.

Doc. 265

Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 2518 6401 DA Heerlen

Leids Universitair Medisch Centrum
T.a.v. [redacted]
[redacted]
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3521 AZ Utrecht
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6401 DA Heerlen
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F 088 120 50 01
www.igz.nl

Inlichtingen bij
Meldpunt IGZ
meldpunt@igz.nl

Datum 13 december 2016
Onderwerp Melding [redacted]

Ons kenmerk
[redacted]

Geachte [redacted],

Op [redacted] ontving de Inspectie voor de Gezondheidszorg een e-mail waarmee de inspectie werd geïnformeerd over een mogelijke calamiteit in uw ziekenhuis. Het betreft een incident met HeartWare® Ventricular Assist System.

Naar aanleiding van de bovengenoemde melding heeft de inspectie u verzocht een intern onderzoek in te stellen. Op 25 november 2016 heeft de inspectie uw reactie ontvangen. In deze afrondende brief is de conclusie van de inspectie weergegeven.

U heeft beargumenteerd dat geen sprake was van een calamiteit in de zin van artikel 11, eerste lid onder a, van de Wet kwaliteit, klachten en geschillen zorg (Wkkgz).

Conclusie inspectie
Op basis van uw toegestuurde informatie stelt de inspectie vast dat geen sprake was van een calamiteit in de zin van artikel 1, eerste lid en 11, eerste lid onder a van de Wkkgz. Gelet op artikel 8.23 tweede lid van het Uitvoeringsbesluit Wkkgz, sluit de inspectie deze melding af.

Vragen?
Ik ga ervan uit dat ik u met deze brief voldoende heb geïnformeerd. Heeft u toch nog vragen, neem dan contact op met Meldpunt IGZ.

Met vriendelijke groet,
[redacted]

Overal 10.2.e

Doc. 267

[redacted]

Van: [redacted]@medpass.org]
Verzonden: woensdag 1 maart 2017 16:28
Onderwerp: Heartware (now a part of Medtronic) - Initial FSCA JAN 2017
Bijlagen: FSCA JAN2017_MEDDEV Form_03-01-2017_signed.pdf; Medtronic FCA JAN2017 OUS Clinician Letter and Ack.pdf; Medtronic FCA JAN2017 OUS Clinician Letter and Ack_Dutch.pdf

Identifier: FSCA JAN 2017
Manufacturer: HeartWare, Inc. now a part of Medtronic
Product Name: HeartWare® Ventricular Assist System

Coordinating National Competent Authority: MHRA

Dear Sir/Madam,

On behalf of HeartWare Inc, now a part of Medtronic, and acting as the European Authorized Representative, we would like to provide you with the Initial Field Safely Notification related to the abovementioned medical device.

Please see attached the following documents:

- FSCA JAN 2017 Initial FSCA form
- FSCA JAN2017 Clinician Letter (FSN) in English and Dutch

Should you need further information, please do not hesitate to contact MedPass at medpass.ar@medpass.org .

[redacted]
Regulatory Affairs Assistant

MEDPASS

Tel: +33 [redacted]
Fax: +33 (0)1 40 53 81 11
E: [redacted]@medpass.org
W: www.medpass.org

MedPass International
95 bis Boulevard Pereire
75017 Paris - France
+33 (0)1 42 12 83 30

import XML | fix + save

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new case, keep base data

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.7en
2012-12-03

1 Administrative information

To which NCA(s) is this report being sent?

Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Luxembourg, Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

Type of report

- (•) Initial report
- ( ) Follow-up report
- ( ) Final report

Date of this report

2017-02-28

Reference number assigned by the manufacturer

FSCA JAN2017

FSCA reference number assigned by NCA

Incidence reference number assigned by NCA

Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report

Status of submitter

- ( ) Manufacturer
- (•) Authorised Representative within EEA and Switzerland
- ( ) Others: (identify the role)

3 Manufacturer information | new

Name Medtronic	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode FL 33014	**City** Miami Lakes
Phone	**Fax** +1
E-mail FSCA@Heartware.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International, Ltd.	
Contact Name	
Address Windsor House, Bretforton, Evesham	
Postcode WR117JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 National contact point information

new

National contact point name MedPass International, Ltd.	
Name of the contact person	
Address Windsor House, Bretforton, Evesham	
Postcode WR11 7JJ	**City** Worcs
Phone +44	**Fax** +44
E-mail medpassar@medpass.org	**Country** GB - Great Britain

6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text

Circulatory Assist System, Artificial Heart, Temp

Commercial name/ brand name / make

HeartWare Ventricular Assist System

Model number	**Catalogue number**
1400, 1401 and 1407	
Serial number(s)	**Lot/batch number(s)**
This action covers all HeartWare HVAD System Controllers with serial numbers lower than CON[redacted], and all HeartWare DC Adapters, product code [redacted].	
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0086 BSI Product, Services CE marked: 2009-01-29

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

In April 2015 and April 2016, HeartWare released customer communications that discussed the risks of the following issues associated with the current generation HVAD System Controller:
• Worn alignment guides, which could allow connectors to rotate or move, potentially resulting in damaged connector pins (FSCA APR2015A).
• Internal "double disconnect (no power) alarm" battery failure, which could prevent the controller from sounding an alarm in the event of a complete interruption of power (FSCA APR2015A).
• Software Power Management Software Upgrade to address transient losses of communication between the Controller and batteries (FSCA APR2015A).
• Loose power and data connectors, which could allow the ingress of fluid, resulting in controller malfunction (FSCA APR2016).
Since release of these original communications, HeartWare has developed a new HVAD System Controller and Power Management Software Update that includes design changes to address these issues and is initiating procedures for the removal and exchange for previous generation HeartWare Controllers and associated DC Adapters, which are incompatible with the new HVAD Controller.

Description and justification of the action (corrective / preventive)

With the introduction of the updated HVAD Controller, also referred to as Controller 2.0, HeartWare is initiating removal procedures for previous generation HeartWare HVAD Controllers with serial numbers lower than CON[redacted], and all HeartWare DC Adapters, product code[redacted] (all serial numbers), which are incompatible with the new HVAD Controller. The removal of these HVAD Controllers and DC Adapters will occur concurrently with the introduction of the new HVAD Controller.

As described in the previous Urgent Field Safety Notices from April 2015 and April 2016, there was the potential for the following safety issues associated with the current HeartWare® HVAD System Controller, including:

1. Worn alignment guides, which could allow connectors to rotate or move, potentially resulting in damaged connector pins.
2. Internal "double disconnect (no power) alarm" battery failure, which could prevent the controller from sounding an alarm in the event of a complete interruption of power.
3. Loose power and data connectors, which could allow the ingress of fluid, resulting in controller malfunction.

The new HVAD Controller includes enhancements to address these potential safety issues, including:

1. Strengthened power and serial port alignment guides to reduce the incidence of wear that could lead to damaged connector pins.
2. Functionality that monitors internal battery performance and sounds an alert when the internal battery is nearing its end of life.
3. Redesigned connectors and housing to prevent the risk of connectors loosening and moisture ingress.

In addition, the new HVAD Controller introduces upgraded internal circuitry designed to improve overall device reliability.

Advice on actions to be taken by the distributor and the user

Hospital and Clinician Actions (to be executed in the following order):

1) Review the enclosed notice and forms, and forward the notice to those individuals within your organization who need to be aware of its contents.

2) Complete, sign, and return the "Acknowledgement Form" to HeartWare within thirty (30) days of receipt of this letter.

3) Complete Training. Training will cover the new product labeling including the Instructions for Use and Patient Manual. This training will be scheduled and conducted by your HeartWare Representative and is required before new HVAD Controllers will be distributed to your hospital. There may be a period of weeks to months between receipt of this letter and the date individuals at your site are trained.

Patients must be educated on using the new HVAD Controller by hospital staff who have received training from a HeartWare representative. Do not exchange current HVAD Controllers and DC Adapters until after your site is trained.

4) Quarantine and replace affected HVAD Controllers, DC Adapters, Instructions for Use, Emergency Responder Guides and Patient Manuals in hospital inventory after training is complete.

For every patient, quarantine and replace the following under clinical supervision in an environment where appropriate support equipment is readily available:
- Primary and Backup HVAD Controller;
- Affected DC Adapters; and
- Patient Manual and Emergency Responder Guide.

Clinicians are reminded not to perform an HVAD Controller exchange during an active electrical fault alarm as the HVAD Pump will be running a single stator. If an electrical fault is present, download patient log files and contact your HeartWare representative to resolve the electrical fault before executing the controller exchange.

5) Return all quarantined HVAD Controllers and DC Adapters to HeartWare. Your HeartWare representative will assist you with this process.

6) Completion Form. Once affected product in inventory has been identified and returned, complete and return the attached "Completion Form" to CON2.0@Medtronic.com or your Medtronic representative no later than twelve (12) months from the date of this letter according to the instructions on the form.

See Attachment 2 - FSCA JAN2017 Clinician Letter for detailed information.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

Internationally, beginning 1-Mar-2017, a Field Safety Notice communication will be sent to consignees in geographies that have received regulatory approval of the new HVAD Controller, using international mail services.

Customers must be trained on the use of the new HVAD Controller before they may begin use. Medtronic representatives will be responsible for training HVAD sites on the use of the new HVAD Controller. This training must be scheduled with the HVAD site and will be executed in phases. Until an HVAD site is trained, they will continue to receive the previous generation HVAD Controller. A product hold will be used to control the distribution of the appropriate Controller based on the status of training. As part of this training, Medtronic representatives will also apply a monitor software update to select Controller Monitors that allow them to utilize features of the new Controller.

Once training is complete, HVAD sites will be instructed to quarantine and return impacted product in hospital inventory and in use by patients (where deemed clinically appropriate).

The Acknowledgement is due 30 days from distribution of the Field Safety Notice. The completion of Actions by the consignees is due 12 months from distribution of the Field Safety Notice.

Attached please find

☒ Field Safety Notice (FSN) in English

☒ FSN in national language

☐ Others (please specify)

Attachment - FSCA JAN2017 OUS Clinician Letter;

FSN Status

○ Draft FSN

◉ Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK
☐ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☒ RO	☒ SE	☐ SI	☒ SK	☐ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Medtronic

March 1, 2017

URGENT FIELD SAFETY NOTICE

HeartWare® Ventricular Assist Device (HVAD) System

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Medical Device Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Dear HeartWare Clinician,

This communication is to inform you that HeartWare, now a part of Medtronic, has developed an updated HeartWare® HVAD System Controller as part of our continuous improvement initiatives following two previously communicated Urgent Field Safety Notices that occurred in April 2015 and April 2016.

With the introduction of the updated HVAD Controller, also referred to as Controller 2.0, HeartWare is initiating removal procedures for previous generation HeartWare HVAD Controllers with serial numbers lower than CON300000, and all HeartWare DC Adapters, product code 1435 (all serial numbers), which are incompatible with the new HVAD Controller. The removal of these HVAD Controllers and DC Adapters will occur concurrently with the introduction of the new HVAD Controller.

As described in the previous Urgent Field Safety Notices from April 2015 and April 2016, there was the potential for the following safety issues associated with the current HeartWare® HVAD System Controller, including:

1. Worn alignment guides, which could allow connectors to rotate or move, potentially resulting in damaged connector pins.
2. Internal "double disconnect (no power) alarm" battery failure, which could prevent the controller from sounding an alarm in the event of a complete interruption of power.
3. Loose power and data connectors, which could allow the ingress of fluid, resulting in controller malfunction.

The new HVAD Controller includes enhancements to address these potential safety issues, including:

1. Strengthened power and serial port alignment guides to reduce the incidence of wear that could lead to damaged connector pins.
2. Functionality that monitors internal battery performance and sounds an alert when the internal battery is nearing its end of life.
3. Redesigned connectors and housing to prevent the risk of connectors loosening and moisture ingress.

In addition, the new HVAD Controller introduces upgraded internal circuitry designed to improve overall device reliability.

With the introduction of the HVAD Controller modifications described above, HeartWare requires that your site be trained by your local HeartWare representative on the new HVAD Controller prior to allowing distribution and use to occur at your hospital and with your patients. Your HeartWare Representative will work with you to identify a time that is best for your facility. HeartWare requests that you complete the following actions in the order noted in the Hospital and Clinician Actions section below.

> While HeartWare recommends that all patient HVAD Controllers be exchanged, clinicians should weigh the benefits of the updated HVAD Controller against the risks of a controller exchange procedure. Based on data reported to HeartWare, 0.2% of patients who underwent a controller exchange experienced a serious adverse event that required additional intervention. Serious adverse events reported were inclusive of neurological event, events requiring resuscitative efforts, and death due to pump failing to re-start after the controller exchange.

As a reminder, as with all HVAD Controllers, continue to reinforce the following with your patients and staff at all opportunities:

- Patients should continue to have a backup HVAD Controller ready at all times in the event of a primary HVAD Controller failure.
- *Staff only*: The driveline extension cable is to be used during the pre-implant test only. It is not intended to be used after the pump is implanted in the patient.

Hospital and Clinician Actions (to be executed in the following order):

1) **Review** the enclosed notice and forms, and **forward** the notice to those individuals within your organization who need to be aware of its contents.

2) **Complete, sign,** and **return** the "Acknowledgement Form" to HeartWare within thirty (30) days of receipt of this letter.

3) **Complete Training.** Training will cover the new product labeling including the Instructions for Use and Patient Manual. This training will be scheduled and conducted by your HeartWare Representative and is required before new HVAD Controllers will be distributed to your hospital. There may be a period of weeks to months between receipt of this letter and the date individuals at your site are trained.

   Patients must be educated on using the new HVAD Controller by hospital staff who have received training from a HeartWare representative. Do not exchange current HVAD Controllers and DC Adapters until after your site is trained.

4) **Quarantine and replace** affected HVAD Controllers, DC Adapters, Instructions for Use, Emergency Responder Guides and Patient Manuals in hospital inventory after training is complete.

   For every patient, quarantine and replace the following under clinical supervision in an environment where appropriate support equipment is readily available:
   - Primary and Backup HVAD Controller;
   - Affected DC Adapters; and
   - Patient Manual and Emergency Responder Guide.

   Clinicians are reminded not to perform an HVAD Controller exchange during an active electrical fault alarm as the HVAD Pump will be running a single stator. If an electrical fault is present, download patient log files and contact your HeartWare representative to resolve the electrical fault before executing the controller exchange.

5) **Return** all quarantined HVAD Controllers and DC Adapters to HeartWare. Your HeartWare representative will assist you with this process.

6) **Completion Form.** Once affected product in inventory has been identified and returned, complete and return the attached "Completion Form" to con2.0@medtronic.com or your HeartWare representative no later than twelve (12) months from the date of this letter according to the instructions on the form.

Please contact your local HeartWare Representative with questions. We regret any inconvenience that this action may cause and appreciate your understanding as we take action to ensure patient safety and customer satisfaction. Thank you in advance for your cooperation.

Sincerely,

Medtronic

Attachments
Attachment 1: Acknowledgement Form
Attachment 2: Completion Form

Medtronic

Al openbaar

Acknowledgement Form

URGENT FIELD SAFETY NOTICE

(To be completed by site representative)

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Clinical Institution / Hospital Name:

The undersigned hereby acknowledges receipt and understanding of HeartWare's Urgent Field Safety Notification, FSCA JAN2017.

Position / Title	**Printed Name**	**Signature**	**Date**

No later than 30 days from the date of this notification, please:

- Return this signed form to your HeartWare representative; or
- Email an electronic copy of this signed form to con2.0@medtronic.com.

Medtronic

Product Return Completion Form

URGENT FIELD SAFETY NOTICE

(To be completed by site representative)

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Clinical Institution / Hospital Name:

_____

The undersigned hereby acknowledges:

- That all affected controllers and DC adapters in inventory and from current patients (if any) have been identified, quarantined, and replaced (or not replaced due to clinician judgment), and
- That quarantined controllers have been returned to HeartWare.

Position / Title	**Printed Name**	**Signature**	**Date**
_____	_____	_____	_____

Please provide this form upon return of all impacted hospital and patient controllers. Please:

- Return this signed form to your HeartWare representative; or
- Email an electronic copy of this signed form to con2.0@medtronic.com.

Medtronic

Januari 2017

Reeds openbaar

URGENTE VEILIGHEIDSWAARSCHUWING

HeartWare®-ondersteuningsapparaat voor de hartkamer (HVAD)

Identificatienummer	FSCA JAN2017
Soort actie	Veiligheidsmelding en verwijdering van medisch apparaat
Productcodes/reeks serienummers	Alle HeartWare® HVAD-controllers met serienummers lager dan CON300000 en alle HeartWare® 1435-gelijkstroomadapters (alle serienummers)

Geachte arts-gebruiker van HeartWare,

Met dit bericht willen wij u op de hoogte stellen van het volgende. HeartWare, nu onderdeel van Medtronic, heeft een bijgewerkte HeartWare® HVAD-systeemcontroller ontwikkeld als onderdeel van onze voortdurende verbeteringsinitiatieven als reactie op twee eerder gecommuniceerde urgente veiligheidswaarschuwingen van april 2015 en april 2016.

Met de introductie van de bijgewerkte HVAD-controller, ook Controller 2.0 genoemd, start HeartWare verwijderingsprocedures voor HeartWare HVAD-controllers van eerdere generaties met serienummers lager dan CON300000, en alle HeartWare-gelijkstroomadapters, productcode 1435 (alle serienummers), die niet compatibel zijn met de nieuwe HVAD-controller. De verwijdering van deze HVAD-controllers en gelijkstroomadapters wordt tegelijkertijd met de introductie van de nieuwe HVAD-controller uitgevoerd.

Zoals vermeld in de vorige urgente veiligheidswaarschuwingen van april 2015 en april 2016, bestond het risico op de volgende veiligheidsproblemen met betrekking tot de huidige HeartWare® HVAD-systeemcontroller:

1. Versleten geleiders, waardoor de connectoren konden draaien of bewegen, wat mogelijk leidt tot beschadigde connectorpennen.
2. Interne batterijstoring 'dubbel ontkoppelingsalarm (geen stroom)', waardoor de controller mogelijk geen geluidsalarm afspeelt als de stroom volledig wordt onderbroken.
3. Losse stroom- en gegevensconnectoren, waardoor vloeistof kan binnendringen en een storing kan veroorzaken in de controller.

De nieuwe HVAD-controller bevat verbeteringen om deze mogelijke veiligheidsproblemen op te lossen. Enkele verbeteringen zijn:

1. Versterkte stroomgeleiders en geleiders voor seriële poorten om slijtage te verminderen die kan leiden tot beschadigde connectorpennen.
2. Functie waarmee interne batterijprestaties worden bijgehouden en een geluidsalarm wordt afgespeeld als de interne batterij bijna is opgebruikt.
3. Connectoren en behuizing met nieuw ontwerp om te voorkomen dat connectoren losraken en vloeistof kan binnendringen.

Bovendien bevat de HVAD-controller een geüpgraded intern circuit om de algehele betrouwbaarheid van het apparaat te verbeteren.

Met de introductie van de hierboven genoemde wijzigingen aan de HVAD-controllers vereist HeartWare dat trainingen worden uitgevoerd op uw locatie. Deze trainingen moeten worden geleid door uw lokale HeartWare-vertegenwoordiger en betrekking hebben op de nieuwe HVAD-controller, zodat deze kan worden verspreid en gebruikt in uw ziekenhuis en met uw patiënten. Uw HeartWare-vertegenwoordiger spreekt met u af wanneer deze training het beste kan worden gegeven. HeartWare verzoekt dat u de

volgende acties uitvoert in de volgorde die in het onderstaande gedeelte 'Acties van ziekenhuis en artsen' staat vermeld.

HeartWare raadt aan dat alle HVAD-controllers bij patiënten worden vervangen, maar artsen moeten zelf de voordelen van de bijgewerkte HVAD-controller afwegen tegen de risico's van de vervangingsprocedure. Op basis van aan HeartWare verstrekte gegevens, heeft maar 0,2% van de patiënten die een controllervervanging ondergingen een ernstige bijwerking ervaren waardoor aanvullende interventie nodig was. Ernstige bijwerkingen die gemeld zijn, zijn onder andere neurologische gebeurtenissen, gebeurtenissen waardoor reanimatie moest worden uitgevoerd, en overlijden doordat de pomp na het verwisselen van de controller niet meer startte.

Let op: net zoals bij alle HVAD-controllers moet u te allen tijde het volgende benadrukken voor patiënten en personeel:

- Patiënten moeten te allen tijde een reserve HVAD-controller beschikbaar hebben voor het geval dat de primaire HVAD-controller stopt met werken.
- *Alleen personeel:* Het verlengsnoer van de aandrijflijn moet alleen gebruikt worden tijdens de pre-implantatietest. Deze is niet bedoeld voor gebruik na implantatie van de pomp in de patiënt.

Acties van ziekenhuis en artsen (uit te voeren in de volgende volgorde):

1) **Bekijken** van de bijgesloten waarschuwing en formulieren en **doorsturen** van de waarschuwing naar de personen binnen uw organisatie die zich bewust moeten zijn van deze inhoud.

2) **Invullen, ondertekenen en terugsturen** van het 'Bevestigingsformulier' aan HeartWare binnen dertig (30) dagen na ontvangst van deze brief.

3) **Voltooien van training.** In de training worden de nieuwe productlabels besproken, inclusief de Gebruikersinstructies en Patiëntenhandleiding. Deze training wordt gepland en gegeven door uw HeartWare-vertegenwoordiger en is verplicht voordat nieuwe HVAD-controllers kunnen worden verstrekt aan uw ziekenhuis. Er kunnen weken tot maanden zitten tussen de ontvangst van deze brief en de datum waarop personen op uw locatie worden getraind.

   Patiënten moeten van het ziekenhuispersoneel instructies krijgen over het gebruik van de nieuwe HVAD-controller. Dit ziekenhuispersoneel moet zijn getraind door een HeartWare-vertegenwoordiger. Vervang huidige HVAD-controllers en gelijkstroomadapters pas als personeel op uw locatie is getraind.

4) Plaats betrokken HVAD-controllers, gelijkstroomadapters, Gebruikersinstructies, Richtlijnen voor noodgevallen en Patiëntenhandleidingen in ziekenhuisvoorraad in **quarantaine** en **vervang** deze als de training is voltooid.

   Plaats voor elke patiënt het volgende in quarantaine en vervang dit onder toezicht van een arts in een omgeving waar de juiste ondersteuningsapparatuur beschikbaar is:
   - Primaire en reserve HVAD-controller;
   - Betrokken gelijkstroomadapters; en
   - Patiëntenhandleiding en Richtlijn voor noodgevallen.

   Artsen worden eraan herinnerd HVAD-controllers niet te vervangen tijdens een actief alarm voor elektrische storing, omdat de HVAD-pomp draait op een enkele stator. Als zich een

elektrische storing voordoet, downloadt u de patiëntlogboekbestanden en neemt u contact op met uw HeartWare-vertegenwoordiger om de elektrische storing op te lossen voordat u de controller vervangt.

5) **Retourneer** alle in quarantaine geplaatste HVAD-controllers en gelijkstroomadapters aan HeartWare. Uw HeartWare-vertegenwoordiger helpt u bij dit proces.

6) **Voltooiingsformulier.** Als een betrokken product in de voorraad is geïdentificeerd en geretourneerd, vult u het bijgesloten 'Voltooiingsformulier' in en stuurt u dit naar con2.0@medtronic.com of uw HeartWare-vertegenwoordiger. Doe dit binnen twaalf (12) maanden na de datum van deze brief en volgens de instructies op het formulier.

Neem bij vragen contact op met uw lokale HeartWare-vertegenwoordiger. Onze excuses voor enige ongemakken die door deze actie kunnen worden veroorzaakt en wij waarderen uw begrip dat wij actie ondernemen om de veiligheid van de patiënt en klanttevredenheid te verzekeren. Bij voorbaat hartelijk dank voor uw samenwerking.

Hoogachtend,

Tim Samsel
Vice President, Quality, CRHF
Medtronic

Bijlagen
Bijlage 1: Bevestigingsformulier
Bijlage 2: Voltooiingsformulier

Medtronic

Bevestigingsformulier

URGENTE VEILIGHEIDSWAARSCHUWING

(In te vullen door de locatievertegenwoordiger)

Identificatienummer	FSCA JAN2017
Soort actie	Veiligheidsmelding en verwijdering
Productcodes/reeks serienummers	Alle HeartWare® HVAD-controllers met serienummers lager dan CON300000 en alle HeartWare® 1435-gelijkstroomadapters (alle serienummers)

Naam kliniek/ziekenhuis:

_____

Hierbij bevestigt ondergetekende ontvangst en begrip van de urgente veiligheidswaarschuwing, FSCA JAN2017 van HeartWare.

Functie/Titel	**Naam in drukletters**	**Handtekening**	**Datum**
_____	_____	_____	_____

Binnen 30 dagen na de datum van deze waarschuwing doet u het volgende:

- Retourneer dit ondertekende formulier aan uw HeartWare-vertegenwoordiger; of
- Stuur een digitaal exemplaar van dit ondertekende formulier via e-mail naar con2.0@medtronic.com

Medtronic

Voltooiingsformulier voor productretournering

URGENTE VEILIGHEIDSWAARSCHUWING

(In te vullen door de locatievertegenwoordiger)

Identificatienummer	FSCA JAN2017
Soort actie	Veiligheidsmelding en verwijdering
Productcodes/reeks serienummers	Alle HeartWare® HVAD-controllers met serienummers lager dan CON300000 en alle HeartWare® 1435-gelijkstroomadapters (alle serienummers)

Naam kliniek/ziekenhuis:

_____

De ondertekende bevestigt hierbij:

- Dat alle betrokken controllers en gelijkstroomadapters in de voorraad en van huidige patiënten (indien van toepassing) zijn geïdentificeerd, in quarantaine zijn geplaatst en zijn vervangen (of niet vervangen na beoordeling van een arts), en
- Dat in quarantaine geplaatste controllers zijn geretourneerd aan HeartWare.

Functie/Titel	**Naam in drukletters**	**Handtekening**	**Datum**
_____	_____	_____	_____

Stuur dit formulier op bij de retournering van alle betrokken controllers van het ziekenhuis en patiënten.
Doe het volgende:

- Retourneer dit ondertekende formulier aan uw HeartWare-vertegenwoordiger; of
- Stuur een digitaal exemplaar van dit ondertekende formulier via e-mail naar con2.0@medtronic.com

Overal 10.2.e, tenzij anders aangegeven.

Werkprocesnummer	Meldingsnummer fabrikant	Datum	Advies/Besluit
		14-11-2013	Maatregelen afgerond d.m.v. afsluitende brief MHRA en IGZ.
	CMP-	24-10-2013	melding beoordelen door lmo 10
	CMP-	13-11-2013	Kan afgesloten worden, maar nog even reactie afwachten.
	CMP-	13-11-2013	Geen vervolgactie.
	CMP-	19-12-2013	Inbrengen in LMO als level III
	CMP-	7-4-2014	Geen aanvullende vragen voor het ziekenhuis. tzt misschien eens om tafel over communicatie en scholing eerste lijnszorg en mantelzorgers. (telefoonnummer op device zou al een hele vooruitgang zijn) wachten is nu op het eindrapport van Heartware.
	CMP-	8-8-2014	Wachten tot volgende rapport.
	CMP-	10-10-2014	Melding afsluiten, nu uitvoerig onderzoek van de fabrikant is afgerond.
	CMP-	14-2-2014	Afsluiten samen met : standaard afsluitmail onder .
	CMP-	14-2-2014	Meldingen en zijn vrijwel identiek en worden beide met mail onder deze melding afgesloten (zie overweging).
	FSCA DEC2013	14-2-2014	Aanvullende vragen gesteld (zie overweging).
	FSCA DEC2013	28-2-2014	Afsluiten
	FSCA DEC2013	10-5-2014	afsluiten middels ovb
	CMP-	14-2-2014	Aanvullende vragen (zie overweging).
	CMP-	8-7-2014	Open houden in verband onderzoek, zoals ook onder
	CMP-	2-9-2014	Melding sluiten en de actie die de fabrikant in de Telcon heeft aangekondigd (vervangen batterijen) volgen onder melding
	CMP-	25-2-2014	Meer vragen over risico's voor patient.
	CMP-	17-3-2014	Zeer tevreden met antwoord: afsluiten
		10-1-2014	bijzonderheid voorleggen lmo
1002099		1-4-2014	Besluit: akkoord met afsluiten. Actie: verstuurt brief.
	CMP-	25-2-2014	Afhandelen onder melding
	CMP-	28-2-2014	Deze individuele melding kan gesloten worden, maar het probleem van de batterijen volgen onder melding
	CMP-	14-3-2014	Vraag voorleggen in LMO10.
	CMP-	18-3-2014	eens met benadering :beschreven risico's bij apparaten accepteren en op dit moment geen actie ondernemen naar fabrikanten
	CMP-	18-3-2014	Conform besluit LMO10 geen verdere actie ondernemen.
	CMP-	13-6-2014	Afsluiten

[redacted]	CMP-[redacted]	7-8-2014	Volgen onder melding [redacted]
[redacted]	CMP-[redacted]	2-7-2014	Risicoscore: trend. Geaggregeerd volgen, maar deze individuele melding sluiten.
[redacted]	FSCA APR2014	8-7-2014	Nieuwe vragen gesteld naast / ter aanvulling op melding [redacted]. Tevens bij MHRA voorstel doen voor vigilance enquiry.
[redacted]	FSCA APR2014	1-10-2014	Melding sluiten
[redacted]	CMP-[redacted]	8-7-2014	Conform procedure afsluiten
[redacted]	CMP-[redacted]	8-7-2014	Individuele melding sluiten, maar geaggregeerd volgen onder melding [redacted].
[redacted]	CMP-[redacted]	26-9-2014	FIR afwachten conform Level I incident
[redacted]	CMP-[redacted]	27-2-2015	valt onder fsc van april 2014 ook aan europa gestuurd afsluiten
[redacted]	CMP-[redacted]	3-11-2014	Afsluiten zodra FIR binnen is. FSCA tbv vervanging batterijen al gestart. hierin: Boxed instructions were provided in the field safety notice to provide advice to patients and sites on how to respond in the event of premature battery switching, rapid capacity change, or rapid switching back and forth.
[redacted]	CMP-[redacted]	3-11-2014	Melding Level trend, als zodanig afsluiten
[redacted]	CMP-[redacted]	28-11-2014	Melding Level Trend, afhandelen conform procedure
[redacted]	CMP-[redacted]	28-11-2014	Medling level trend
[redacted]	CMP-[redacted]	12-12-2014	afsluiten als trend melding
[redacted]	CMP-[redacted]	22-12-2014	opvragen FIR
[redacted]	CMP-[redacted]	28-5-2015	geen conclusie mogelijk afsluiten
[redacted]	CMP-[redacted]	22-12-2014	afsluten als trend
[redacted]	FSCA APR2013.1	12-1-2015	aan heartware cijfers opvragen hoeveel óude controlers'nog in gebruik in Nederland, bij welke instellingen. en hoeveel controlers wel al zijn gewisseld.
[redacted]	FSCA APR2013.1	3-4-2015	afwachten einde fsca daarna bepalen of overleg met de ziekenhuizen nodig is
[redacted]	FSCA APR2013.1	12-10-2015 10.1.c + 10.2.g	[redacted] devices zijn geimplanteerd in Nederland, daarvan is niet bekend bij de fabrikant hoeveel er daadwerkelijk nog in gebruik zijn. de beide implantsites hebben aangegeven bij de fabrikant dat zij de benodigde acties okk richting de patienten hebben uitgevoerd. afsluiten
[redacted]	CMP-[redacted]	16-1-2015	afsluiten
[redacted]	CMP-[redacted]	6-3-2015	afwachten fir level 1
[redacted]	CMP-[redacted]	12-10-2015	afsluiten
[redacted]	CMP-[redacted]	23-3-2015	afwachten FIR

[redacted]	CMP-[redacted]	15-10-2015	afsluiten, naast matig contact door losse contact ook een slechte cel in de batterij fsn is al een suitgegaan om gebruikers op problemen met batterijen t ewijzen geen andere aanwijzingen van defecte cellen in ander batterijen
[redacted]	CMP-[redacted]	5-6-2015	afwachten FIR
[redacted]	CMP-[redacted]	26-2-2016	defect niet aangetoond afsluiten
[redacted]	FSCA APR2015B	5-6-2015	tweedelige fsca 1 informeren artsen en gebruikers met extra aandacht voor omgaan met product. 2 nieuwe repair kid die grotere krachten aankan ontwikkelen en implementeren aanvullende vragen hoeveel van de [redacted] waren er in NL en hoeveel van de [redacted] zijn er in NL, welke instellingen betrokken.
[redacted]	FSCA APR2015B	10-7-2015	NL FSN is ook binnen 1 patient in Nl di evalt onder de fsca afwachten FSCA
[redacted]	FSCA APR2015B	12-10-2015	afsluiten basis oorzaak, verbetermaatregelen en implementatie zijn duidelijk
[redacted]	FSCA APR2015A	12-6-2015	fsca over veel gebruikers gerelateerde problemen met de LVAD . plus een software update over patient management systeem. is eigenlijk een fsca van kleine issues die wel ernstige gevolgen kunnen hebben. afwachten einde fsca (ivm product type en het informeren van patienten)
[redacted]	FSCA APR2015A	14-9-2015	iedereen is geinformeerd binnen europa, afsluiten
[redacted]	CMP-[redacted]	12-6-2015	afwachten FIR
[redacted]	CMP-[redacted]	3-12-2015	afsluiten
[redacted]	CMP-[redacted]	12-6-2015	afwachten FIR
[redacted]	CMP-[redacted]	29-12-2015	afsluiten incident kan niet bevestigd worden , geen fout geen letsel
[redacted]	CMP-[redacted]	22-8-2015	Level: II MO: vooralsnog niet nodig Vervolgrapportage: 06-11-15 Gerelateerde meldingen: vooralsnog onbekend Conclusie fabrikant:- Analyse IGZ:- Ovb/Afsluit-email naar fabrikant: ovb naar fabrikant met verzoek om FIR uiterlijk 06-11-15 en antwoord op enkele aanvullende vragen (sex, age, outcome, duration implantation). Vragen voor betrokken instelling via MSZ: vooralsnog niet nodig.

10.1.c + 10.2.g

[redacted]	CMP-[redacted]	22-12-2015	Level: II LMOMT: niet nodig Vervolgrapportage: 06-11-15 Gerelateerde meldingen: vooralsnog onbekend Conclusie fabrikant: Based on the results of the previous manufacturer's internal investigation, field actions (FSCA APR2014.1) and changes to the battery internal cell supplier, no additional investigation of this event is required at this time. The most likely cause of the reported event can be attributed to faulty internal cells within the Battery Pack. Heartware has open an internal investigation to address this issue. Analyse IGZ: Eens met de fabrikant, vooraslnog voldoende actie middels hun eerdere fsca/fsn over de batterijen. Wel benieuwd naar het resultaat van hun verder onderzoek in deze. Ik verwacht in het vervolg wel meer inspanning van hen om achter gegevens patiënt, duur implantatie en uiteindelijk letsel te komen. Afsluit-email naar fabrikant: ja LMOMSZ: niet nodig.
[redacted]	CMP-[redacted]	3-8-2015	Het meldpunt verzoeken OVB te sturen aan fabrikant en FIR op te vragen
[redacted]	CMP-[redacted]	12-2-2016	Melding sluiten.
[redacted]	CMP-[redacted]	13-8-2015	Trend: OVB en afsluiten
[redacted]	CMP-[redacted]	13-8-2015	Trend; OVB en afsluiten
[redacted]	CMP-[redacted]	4-9-2015	afsluiten als trend
[redacted]	CMP-[redacted]	4-9-2015	afsluiten als trend
[redacted]	CMP-[redacted]	9-10-2015	afsluiten als level 1
[redacted]	CMP-[redacted]	9-10-2015	afsluiten als level 1
[redacted]	CMP-[redacted]	9-10-2015	afsluiten als trend
[redacted]	CMP-[redacted]	2-11-2015	bekend probleem afsluiten als level 1
[redacted]	CMP-[redacted]	6-11-2015	afsluiten als trend melding
[redacted]	CMP-[redacted]	9-11-2015	afsluiten als trend
[redacted]	CMP-[redacted]	9-11-2015	geen letsel afsluiten als trend melding
[redacted]	CMP-[redacted]	20-11-2015	afsluiten als trend melding
[redacted]	CMP-[redacted]	20-11-2015	batterij issue bekend bij heartware aktie al ondernomen afsluiten als level 1
[redacted]	CMP-[redacted]	20-11-2015	afwachten FIR. voor nu geen vragen aan de fabrikant. vraag aan MO: kunnen wij iets met de weigering van het LUMC om het product te retourneren aan de fabrikant?
[redacted]	CMP-[redacted]	24-11-2015	MO10 dd 24 november 2015: Melding ter kennisgeving doorgeven aan MSZ. Voorstel aan MSZ waarom ziekenhuis geen info wil verstrekken. antword MSZ: Geen aanwijzingen voor calamiteit, geen reden om zh te vragen device te delen
[redacted]	CMP-[redacted]	1-4-2016	afsluiten

[redacted]	CMP-[redacted]	20-11-2015	afsluiten als level 1
[redacted]	CMP-[redacted]	20-11-2015	afsluiten als level1
[redacted]	CMP-[redacted]	20-11-2015	afsluiten, 42 gelijksoortige meldingen in 5 jaar in Europa
[redacted]	CMP-[redacted]	30-11-2015	[redacted] afsluiten als level 1 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
[redacted]	CMP-[redacted]	30-11-2015	afsluiten, lijkt meer een patient gererelateerd probleem dan een device gerelateerd probleem
[redacted]	CMP-[redacted]	30-11-2015	afsluiten als level 1
[redacted]	CMP-[redacted]	17-12-2015	afsluiten als trend
[redacted]	CMP-[redacted]	17-12-2015	afsluiten als trend
[redacted]	CMP-[redacted]	29-12-2015	afsluiten als trend
[redacted]	CMP-[redacted]	29-12-2015	afsluiten als trend
[redacted]	CMP-[redacted]	29-12-2015	afsluiten als trend melding
[redacted]	CMP-[redacted]	29-12-2015	afsluiten bekend probleem fabrikant heeft al aktie ondernomen trend melding
[redacted]	CMP-[redacted]	31-12-2015	afsluiten volgens afspraken level 1
[redacted]	CMP-[redacted]	31-12-2015	afsluiten trend melding 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
[redacted]	CMP-[redacted]	11-1-2016	[redacted] 6 incidenten kbekend in Europa complicatie die kan voorkomen. afsluiten
[redacted]	CMP-[redacted]	11-1-2016	afsluiten hoort bij fsca
[redacted]	CMP-[redacted]	11-1-2016	afsluiten level 1
[redacted]	FSCA DEC2015B	11-1-2016	Voluntary Battery Recall, Voluntary AC Adapter Recall, Controller Software Update producten op voorrad direct in quarantaine , Arrange for current patients to bring their Controllers, AC Adapters, and Batteries to a clinic appointment as soon as possible, (at least within the next three months), oorzaak en verbetermaatregel plus recall plan opvragen aantal producten in NL voor defintief overzicht
[redacted]	FSCA DEC2015B	18-1-2016	voldoende info binnen basisoorzaak en implementatie volledig en duidelijk Vervroegd afsluiten
[redacted]	CMP-[redacted]	15-1-2016	afsluiten
[redacted]	CMP-[redacted]	15-1-2016	afsluiten
[redacted]	CMP-[redacted]	1-2-2016	level 1 afsluiten
[redacted]	CMP-[redacted]	18-2-2016	afsluiten las level 1
[redacted]	CMP-[redacted]	26-2-2016	batterijen die niet goed zijn met serie nummer boven nummers die gerecalled zijn. echter nieuwe batterijen zouden pas in januari aanwezig zijn even afwachten of we meldingen blijven krijgen afsluiten al level 1
[redacted]	CMP-[redacted]	14-3-2016	afsluiten als level 1

[redacted]	CMP-[redacted]	25-3-2016	ziekenhuis meldt dat er een 10 sec LVAD stop was tijdens de update, dit wordt niet vernoemd door de fabrikant navragen hoe dit zit
[redacted]	CMP-[redacted]	25-4-2016	afsluiten OVB aanvullende vragen plus afsluiten met extra zin: Risk-analysis The information provided has been analyzed based on potential risks. Following this analysis, the Dutch Health Care Inspectorate will not start an investigation with regard to this issue. Therefore, I consider this case as closed. The hospital has send an incident report too, if their analysis raises new questions, then we can reopen this case. Futhermore, should problems related to this incident (re)occur the inspectorate might reopen this case on behalf of an additional investigation
[redacted]	CMP-[redacted]	1-4-2016	afsluiten als trend, wel geregistreerd in overzicht heartmate
[redacted]	CMP-[redacted]	1-4-2016	afsluiten trend melding
[redacted]	CMP-[redacted]	11-4-2016	afsluiten
[redacted]	CMP-[redacted]	11-4-2016	afsluiten als level 1
[redacted]	CMP-[redacted]	20-5-2016	afsluiten als trend
[redacted]	CMP-[redacted]	20-5-2016	afsluiten als trend
[redacted]	FSCA APR2016	3-6-2016	connectoren kunnen los komen, gebruik is ook veel intensiever, komt rek en trek op, wel risico's van verlies connectie, niet meer waterdicht etc oplossing: extra controle en bewustwording risicos's patienten
[redacted]	CMP-[redacted]	8-7-2016	lijkt een heel specifiek probleem, nog geen andere meldingen over trend
[redacted]	CMP-[redacted]	4-8-2016	Melding sluiten
[redacted]	CMP-[redacted]	26-8-2016	op basis van IR geen conclusie te maken, niet duidelijk of de LVAD niet goed werkte, ofdat behandeling niet aansloeg, overweging tot operatie is niet helemaal duidelijk, gezien gebruik van [redacted] kort ervoor, afwacten FIR, daarna indien nodig evt vragen stellen aan het zkh voor nu geen aanvullende vragen 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g
[redacted]	CMP-[redacted]	28-10-2016	product niet retour, geen melding van het ziekenhuis, overweging tot operatie is niet helemaal duidelijk, gezien gebruik van [redacted] kort ervoor. Voorleggen aan MSZ. afsluiten richting fabrikant. MSZ kan behandeling evt overnemen.
[redacted]	CMP-[redacted]	28-10-2016	L63 ziekenhuis, motivatie waarom niet gemeld als calamiteit of calonderzoek
[redacted]	CMP-[redacted]	7-12-2016	afsluiten op 8.23 brief door MT sturen
[redacted]	CMP-[redacted]	26-8-2016	afsluiten

[redacted]	FSCA JUL2016	2-9-2016	root cause is bekend, tussentijdse oplossing: terughalen van alle betrokken producten definitieve oplossing: aanpassen van productie proces. risico: laag evt klachten ontstaan in eerste 30 dagen, procedure schoonmaken driveline kan probleem daarna oplossen level 1 FSN is ook binnen afsluiten
[redacted]	CMP-[redacted]	2-9-2016	trend melding afsluiten
[redacted]	CMP-[redacted]	2-9-2016	afsluiten
[redacted]	CMP-[redacted]	9-9-2016	geen letsel, gemakkelijk te herkennen afsluiten level I
[redacted]	CMP-[redacted]	2-9-2016	afsluiten trend
[redacted]	CMP-[redacted]	26-9-2016	afsluiten level 1
[redacted]	CMP-[redacted]	26-9-2016	afsluiten trend
[redacted]	CMP-[redacted]	14-10-2016	geen letsel, probleem wordt duidelijk herkend afsluiten level I
[redacted]	CMP-[redacted]	9-12-2016	afsluiten
[redacted]	CMP-[redacted]	27-12-2016	termijnbewaking fir
[redacted]	CMP-[redacted]	24-3-2017	melding sluiten
[redacted]	CMP-[redacted]	17-2-2017	afsluiten trend
[redacted]	FSCA JAN2017	10-3-2017	HeartWare raadt aan dat alle HVAD-controllers bij patiënten worden vervangen, maar artsen moeten zelf de voordelen van de bijgewerkte HVAD-controller afwegen tegen de risico's van de vervangingsprocedure. Op basis van aan HeartWare verstrekte gegevens, [redacted] Moeilijk om het risicos formulier in tevullen, verbeteracties zijn goed, omruilactie is echter risicovol. patienten en staff moet heel goed getraind worden in het gebruik van de nieuwe controller, het vervangen en verwisselen. Is een leven ondersteunend apparaat , waar de meeste zoniet alle patienten niet zonder kunnen. vragen aan fabrikant: hoeveel producten op de markt, uitleg specifieke verschillen oude en nieuwe (ingebruik en bij wissel), voorstel hoe personeel en patienten geschoold gaan worden (zie FSCA 1004322 van concurent waaruit blijkt dat vervangen van materiaal kan leiden tot levensbedreigende situaties)
[redacted]	FSCA JAN2017	14-3-2017	MO Medtech dd 14-3-2017: eens met voorstel
[redacted]	FSCA JAN2017	17-3-2017	melding doorgeleiden naar team acchouders , [redacted] en [redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

[redacted]	FSCA JAN2017	27-3-2017	Afgestemd oordeel MSZ: voor nu geen actie IGZ, graag MSZ informeren bij informatie over onvoldoende reactie ziekenhuizen.
[redacted]	CMP-[redacted]	17-3-2017	afsluiten level trend
[redacted]	CMP-[redacted]	27-3-2017	afsluitel level 1 geen letsel

Overal 10.2.e, tenzij anders aangegeven.

Werkprocesnummer	Meldingsnummer fabrikant	Datum	Betreft	Aantekening
[redacted]		7-1-2012	FSCA	Beste [redacted], Bijgaand een melding. OVB met verzoek om ons te informeren wanneer de FSCA is voltooid in Nederland is vandaag digitaal verzonden. Gaarne deze melding in behandeling nemen. Met vriendelijke groet, [redacted]
[redacted]		3-2-2012	10.1.c + 10.2.g	[redacted] producten in Nl waarvan [redacted] in [redacted] en [redacted] in UMCu, rest lijkt nog bij Medpass Nl te zijn. onderdeel in de LVAD wat als deze in de uitmodes staat de reden is dat er in bepaalde omstandigheden niet gealameerd wordt. instructie voor artsen en verpleegkundigen , na te gaan of de Lavare Cycle aan staat. Als dit niet zo is patienten oproepen en Lavare Cycle aan zetten. Niet duidelijk wat het risico is bij niet alarmeren. OVB is uit met verzoek te melden als fsca compleet, [redacted]: contact opnemen met beroepsbroep? of 14 feb even na vragen als we in overleg zijn met nvvc en nhra?
[redacted]		6-2-2012		antwoord [redacted]: FSCA is voldoend naar zijn mening geen LMO afsluiten als fsca afgerond
[redacted]		6-3-2013	Beoordeling melding [redacted]	06-03-2013 ([redacted]) - Initial incident report Medpass. - HeartWare Ventricular Assist System. - LUMC. - 10 maanden na implementatie bleek de controller geen geluid meer te produceren. - Bij uitlezen bleek dat de controller meerdere alarmsignalen moet hebben afgegeven, deze zijn door de patiënt niet gehoord. - Controller is vervangen zonder verdere problemen/consequenties voor de patiënt. - Fabrikant doet onderzoek en verwacht rond half april een eindrapport. - Risicoscore is Level I, zie activiteit richting Meldpunt.

		22-3-2013	Beoordeling melding	22-03-2013 ( ) - FSCA Heartware (gemeld door Medpass, AR). - Betreft HeartWare Ventricular Assist System. - Bij een onderzoek naar klachten van klanten is een klein aantal voorvallen ( ) vastgesteld waarbij het achterste gedeelte van de behuizing van de aandrijflijnconnector van de HVAD®-pomp gedeeltelijk of volledig is losgekomen van het voorste gedeelte van de aandrijflijnconnector. - In het (onwaarschijnlijke) geval dat deze delen worden gescheiden, kan reparatie nodig zijn. Indien niets wordt gedaan, kan de elektrische verbinding met de controller verstoord worden met mogelijk een VAD-stopalarm als gevolg. - Er wordt op gewezen dat geen van de bevestigde voorvallen tot schade aan de getroffen patiënten heeft geleid. - Momenteel worden veranderingen aan het fabricageproces ingevoerd om dergelijke voorvallen te voorkomen. - Alle klanten zijn geïnformeerd met instructies rondom controle. Deze moet worden uitgevoerd tijdens de routine controles. - 10.1.c +10.2.g 10.1.c +10.2.g
		26-3-2013	BT 26/3:	BT 26/3: -Nagaan of deze melding in verband staat met meldingen en -Aan FSN voorleggen (of dit afdoende in thuissituaties).
		1-5-2013		In FIR dat is binnengekomen (om welke melding dit gaat is niet bekend) wordt wel naar deze FSCA verwezen, het verband is mij niet geheel duidelijk. Overleg gepland met om deze meldingen en FSCA naast elkaar te leggen.

[redacted]		22-5-2013	Wachten met afronding FSCA	Niet duidelijk is de connectie tussen deze FSCA en de verschillende incidenten bij ons bekend. [redacted] hebben we in het LMO van 22 mei voorgesteld Medpass uit te nodigen voor een gesprek. Maandag 27-05-2013 een voorstel uitwerken met [redacted] voor LMO+.
[redacted]		26-6-2013	Afronden na ontvangst final report	26-06-2013 ([redacted]) - Final incident report ontvangen. - Heartware kan het product niet onderzoeken, omdat dit niet retour is gezonden (waarschijnlijk nog in gebruik). - Diverse analyses en uitlezen van gegevens tonen niets aan dat het gemelde incident kan bevestigen, er zouden geen alarmen zijn geweest. - Er zijn geen soortgelijke incidenten bekend bij Heartware. - Vandaag op basis van het final incident report deze melding afgesloten richting fabrikant en in WPM>
[redacted]		23-8-2013	Samenhang met [redacted], termijnbewaking voor overbrugging naar zelfde antwoorden	Deze FSCA hangt erg samen met alle vragen en documenten aan MedPass en HeartWare onder melding [redacted]. Wanneer die vragen allemaal beantwoord zijn, kunnen zowel de FSCA als die meldingen gesloten worden.
[redacted]	CMP-[redacted]	19-12-2013	Inbrengen in LMO 10: [redacted] 10.2.d, 10.2.e	Gaarne deze casus inbrengen in het behandelteam zodra dat weer plaats gaat vinden. Mag 2014, want duurt nog wel even voordat fabrikant apparaat heeft beoordeeld.

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[redacted]	CMP-[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	7-1-2014	Verzoek of jullie verslag onderzoek ziekenhuis willen opvragen	Beste, bij deze melding betreft het [redacted] Betrokkenheid van het medisch hulpmiddel zou goed kunnen en wij wachten met zeer veel belangstelling op analyse van fabrikant. We kunnen echter niet uitsluiten dat het apparaat gewoon gefunctioneerd heeft, [redacted]. Vandaar dat wij graag zouden willen weten of het ziekenhuis hier onderzoek naar heeft gedaan en wat de uitkomst is. Zouden jullie dat voor ons op kunnen vragen, of willen jullie dat wij dat zelf doen? Met vriendelijke groet, [redacted]

[redacted]	CMP-[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	7-1-2014	Verzoek of jullie verslag onderzoek ziekenhuis willen opvragen	Beste, bij deze melding betreft het [redacted] Betrokkenheid van het medisch hulpmiddel zou goed kunnen en wij wachten met zeer veel belangstelling op analyse van fabrikant. We kunnen echter niet uitsluiten dat het apparaat gewoon gefunctioneerd heeft, [redacted]. Vandaar dat wij graag zouden willen weten of het ziekenhuis hier onderzoek naar heeft gedaan en wat de uitkomst is. Zouden jullie dat voor ons op kunnen vragen, of willen jullie dat wij dat zelf doen? Met vriendelijke groet, [redacted]
[redacted]		10-1-2014	beoordelen bijzonderheid melding	bijzonderheid: medisch hulpmiddel betrokken, huisarts en ambulance ook betrokken? Standaard L13 versturen? Het UMCU verzoekt om uitstel van rapportage (terwijl ze nog niet weten wanneer ze de rapportage moeten sturen), zie doc nr. [redacted]. Voorstel om in de brief te zetten dat ze hem 8 weken na dagtekening moeten versturen.

[redacted]	CMP-[redacted]	27-3-2014	Verzoek LMO 4: Beoordelen rapportage	Beste collega's, De rapportage van het ziekenhuis is binnen. Ik heb het rapport beoordeeld ter voorbereiding van het LMO van 1 april en zal adviseren af te sluiten richting het ziekenhuis (dat gaat dan om hun eigen melding melding [redacted]). Als er vanuit LMO10 toch nog aanvullende vragen zijn voor het ziekenhuis nav de vragen vernemen we dat graag. gr [redacted]
[redacted]	CMP-[redacted]	27-3-2014	Verzoek LMO 4: Beoordelen rapportage	Beste collega's, De rapportage van het ziekenhuis is binnen. Ik heb het rapport beoordeeld ter voorbereiding van het LMO van 1 april en zal adviseren af te sluiten richting het ziekenhuis (dat gaat dan om hun eigen melding melding [redacted]). Als er vanuit LMO10 toch nog aanvullende vragen zijn voor het ziekenhuis nav de vragen vernemen we dat graag. gr [redacted]
[redacted]	24 lid 4 + 25 lid 3 + 10.1.d	27-3-2014	Voorstel LMO 1-4: Afsluiten + 10.2.d + 10.2.g	Probleem: [redacted] (gelijk aan melding [redacted] vanuit de fabrikant) Voorstel: [redacted]

10.2.d , 11.1

[redacted]	CMP-[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	1-4-2014	Zie aantekening	Hai [redacted], hier graag bekwame collega goed naar laten kijken. Betrof [redacted]
[redacted]	CMP-[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	1-4-2014	Zie aantekening	Hai [redacted], hier graag bekwame collega goed naar laten kijken. Betrof [redacted]
[redacted]	CMP-[redacted]	1-4-2014	Doorzetten naar [redacted] zie aantekening	Kort geleden met [redacted] gesproken over assist-devices en deze fabrikant. Is ook een apparaat waar hij belangstelling voor heeft. Onder andere gesproken over procedures van de fabrikant. Nu er reactie van fabrikant is binnengekomen ben ik zeer benieuwd naar zijn reactie en invalshoek. Wellicht ziet hij er wel iets in deze melding verder op te pakken.

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[redacted]		1-4-2014	actie nav LMO 1 april 2014	Besluit: akkoord met afsluiten. Actie: [redacted] verstuurt brief. aanvulling [redacted]: Nieuwe rapportage beoordeeld, wijzigingen met name tekstueel, score veranderd niet. Wel is de brief in de BANnene map gewijzigd.
[redacted]	CMP-[redacted]	7-4-2014	afwachten follow up of final report	rapportage van het ziekenhuis is binnen geen nadere vragen nodig. [redacted]. UMCU heeft deze opmerkingen ook gemaakt.
[redacted]	CMP-[redacted]	7-4-2014	afwachten follow up of final report	rapportage van het ziekenhuis is binnen geen nadere vragen nodig. [redacted]. UMCU heeft deze opmerkingen ook gemaakt.
[redacted]	CMP-[redacted]	13-6-2014	Termijnbewaken	Batterij issues --> moet breder opgepakt worden, niet op niveau van individuele melding. Desalniettemin level II en wachten op FIR.
[redacted]	CMP-[redacted]	28-8-2014	Aanvullende info	FIR is nog niet binnen? Melding is wel afgesloten.
[redacted]	CMP-[redacted]	24-10-2014	FUR ontvangen, zie document [redacted]	FUR ontvangen, zie document [redacted]
[redacted]	CMP-[redacted]	12-1-2015	Overnemen	Hai [redacted], bij de lusten horen ook de lasten :). Je krijgt mijn ontzettend leuke en spannende onderwerpen, maar dan ook de vraag of je misschien het regelen van deze FIR in de gaten kan houden. Bij voorbaar dank :)...

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[redacted]		17-9-2015	geen calamiteit , msz kan afsluiten	Willen jullie deze info beoordelen: verder actie van jullie kant nodig? ziekenhuis geeft aan contact met de fabrikant te hebben gehad maar niet of de fabrikant eigen onderzoek doet en of dit meer voorkomt...
[redacted]		17-9-2015	[redacted]	graag ovb naar lumc: geen calamiteit voor behandeling msz, maar ik heb wel nog act voor p10 gemaakt om de info te beoordelen.
[redacted]	CMP-[redacted] 24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g	7-12-2015	zkh wil betrokken device niet afgeven aan fabrikant? kan MSZ hierin iets betekenen? zie aantekening	15 dagen na implant: [redacted] It was also stated that the cause of the onset of flow decrease is still not known. Log Files have been sent to manufacturer for analysis. Investigation is ongoing. No additional information available at this time [redacted] The site declined to return the product to HeartWare for further analysis geen melding van zkh, mi ook geen calamiteit.
[redacted]	CMP-[redacted]	8-12-2015	zie aant	Geen aanwijzingen voor calamiteit, geen reden om zh te vragen device te delen
[redacted]	CMP-[redacted]	22-12-2015	afsluiten richting fabrikant	Zie beoordeling 22-12-15 Eens met de fabrikant, vooralsnog voldoende actie middels hun eerdere fsca/fsn over de batterijen. Wel benieuwd naar het resultaat van hun verder onderzoek in deze. Ik verwacht in het vervolg wel meer inspanning van hen om achter gegevens patiënt, duur implantatie en uiteindelijk letsel te komen.

[redacted]	CMP-[redacted]	25-4-2016	svp OVB aanvullende vragen , plus bericht van afsluiten, par. risk-analysis vervangen voor onderstaande.	Afsluitbericht is verzonden, [redacted] Risk-analysis The information provided has been analyzed based on potential risks. Following this analysis, the Dutch Health Care Inspectorate will not start an investigation with regard to this issue. Therefore, I consider this case as closed. The hospital has send an incident report too, if their analysis raises new questions, then we can reopen this case. Futhermore, should problems related to this incident (re)occur the inspectorate might reopen this case on behalf of an additional investigation
[redacted]	CMP-[redacted]	28-10-2016	Graag jullie oordeel, is dit een incident wat het zkh zou moeten melden? medtech heeft geen vragen meer aan fabrikant, MSZ kan melding overnemen.	[redacted] de fabrikant heeft onderzoek gedaan en ziet op basis van de door hem ontvangen informate geen aanleiding aan te nemen dat de LVAD niet goed werkte of de oorzzaak is van de uiteindelijk fatale afloop:Though the root cause of the reported event cannot be conclusively determined clinical factors that may have contributed to the patient's outcome related to the event are multi factorial and may be attributed to the patient's past [redacted], and
	24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g			
	24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g			

[redacted]	CMP-[redacted]	29-11-2016	Screening: Reactie LUMC ontvangen, geen calamiteit. S.v.p. beoordelen en voorstel doen t.b.v. MO 13 december 2016 Medtech betrekken!	Reactie LUMC ontvangen, geen calamiteit. S.v.p. beoordelen en voorstel doen t.b.v. MO 13 december 2016 Medtech betrekken!
[redacted]	CMP-[redacted] 24 lid 4 + 25 lid	5-12-2016 3 + 10.1.d +	VOA voorstel - 8.23 route 10.2.d + 10.2.g	Zkh motiveert geen signalen voor tekortkomingen in zorg. Melding komt van fabrikant. Nav rapportage fabrikant is in triage besloten zkh om aanvullende info te vragen. Triage: "[redacted] Zkh motiveert summier en gaat niet in op bovenstaande punt uit de triage. Dit hebben we ook niet gevraagd, standaard L63 is gestuurd. Zkh heeft een signalen voor tekortkomingen in zorg daarom voorstel: afsluiten op 8.23
[redacted]	CMP-[redacted]	9-12-2016	svp med techn ([redacted]) inseinen als brief naar LUMC weg is dan sluiten zij de melding (brief bij AL)	zie act coll [redacted]: medtech heeft geen aanvullende vragen, beweegredenen zijn duidelijk. na jullie brief aan het zkh zal ik de melding sluiten

[redacted]	FSCA JAN2017	17-3-2017	graag jullie beoordeling of meer actie nodig is, achten jullie het noodzakelijk dat de IGZ zelf contact opneemt met betrokken zkh?	2017-[redacted] is een nederlnadstalige FSN te vinden die duidelijk omschrijft wat er aan de hand is. [redacted] patienten en staff moeten heel goed getraind worden in het gebruik van de nieuwe controller, het vervangen en verwisselen. Is een leven ondersteunend apparaat , waar de meeste zoniet alle patienten niet zonder kunnen. vragen
[redacted]	FSCA JAN2017	17-3-2017	graag overnemen melding/vraag van med techn	zie beoordeling/vraag van med technologie, is het nodig ziekenhuizen die hiermee werken te bevragen zie ook mail aan jou/[redacted]

10.1.d, 10.2.d, 10.2.g, 11.1

Overal 10.2.e.

Doc. 270

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? MHRA
Type of report (•) Initial report ( ) Follow-up report ( ) Final report
Date of this report
Reference number assigned by the manufacturer FSCA DEC2013
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable) U.S.: Food and Drug Administration; Europe: MHRA

2 Information on submitter of the report
Status of submitter ( ) Manufacturer (•) Authorised Representative within EEA and Switzerland ( ) Others: (identify the role)

3 Manufacturer information	new

Name HeartWare, Inc.	
Contact Name	
Address 14400 NW 60th Avenue	
Postcode FL 33014	**City** Miami Lakes
Phone	**Fax** +1 305 364 2665
E-mail @heartwareinc.com	**Country** US - USA

4 Authorised Representative Information

new

Name MedPass International Ltd	
Contact Name	
Address Windsor House, Barnet Way, Barnwood	
Postcode GL4 3RT	**City** Gloucester
Phone	**Fax** +44 14 52 619 222
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

5 National contact point information

new

National contact point name MedPass International Ltd	
Name of the contact person	
Address Windsor House, Barnet Way, Barnwood	
Postcode GL4 3RT	**City** Gloucester
Phone	**Fax** +44 14 52 619 222
E-mail medpass.ar@medpass.org	**Country** GB - Great Britain

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6 Medical device information

new

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	16977

Nomenclature text

Circulatory Assist System

Commercial name/ brand name / make

HeartWare Ventricular Assist System

Model number	**Catalogue number**
1100, 1101, 1102, 1103, 1104, and 1205	
Serial number(s) HeartWare HVAD® Pumps HW [redacted] to HW [redacted] and HW [redacted] to HW [redacted]	**Lot/batch number(s)**
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0086 BSI PRODUCT SERVICES CE marked: 2009-01-29

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

In early 2013, HeartWare notified customers via FSCA JAN2013 / MHRA Ref [redacted] of complaints of a small number of events (11 of approximately 2900 implants) where the rear portion of the HVAD® Pump's driveline connector housing became partially or fully separated from the front portion of the driveline connector. In the unlikely event of a separation, we advised that repair is necessary. If left unattended, electrical connection to the controller could be affected and a VAD stop alarm could result. Please note that none of the 11 confirmed events resulted in harm to the patients affected. In the notice, we recommended the inspection of the driveline connection at routine patient visits. Recently, we have discovered an alternate failure mechanism arising from the same root cause (improper thread locking technique). In 8 cases, customers have reported that the locking mechanism of the driveline connector has failed to engage. Of these 8 reports, none has resulted in any injury.

Description and justification of the action (corrective / preventive)

If the device is affected, the connector can become disengaged from the controller when the white protective cover is pulled back in a routine inspection. This issue is highly detectable. However, to assure recognition by the user, we have updated the Technical Bulletin previously distributed to include this alternate failure mode. If the device is affected, the field repair is simple, quick, and performed with minimal risk by a HeartWare Clinical Engineer. Please see attached Health Hazard Evaluation for further details.

Advice on actions to be taken by the distributor and the user

As stated in the Instructions For Use, during the implant procedure, the physician should ALWAYS check for an audible click when connecting the driveline to the controller or driveline extension. In the rare event the locking mechanism fails to engage and the driveline disconnects, the controller will generate a high priority alarm, alerting the patient and healthcare providers to take immediate action to reconnect. At implant and at each routine clinic visit, please inspect the patient's driveline connector as described in the attached Technical Bulletin (TB00001 Rev02) for proper locking and to ensure that the connector assembly remains secure. For already implanted patients, please arrange a follow up visit at the earliest convenience to check the patient's driveline connector. If the locking mechanism of the driveline connector is found to have failed to engage, please push the connector back into the controller immediately and arrange for a HeartWare Clinical Engineer to perform the needed field repair.

HeartWare is notifying you of a potential condition in a small number of driveline connectors and reiterating instructions for equipment handling stated in the IFU and recognized practices prior to implant to ensure proper connection.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

HeartWare expects to begin international distribution of the Urgent Medical Device Correction letter in English on 13-December-2013, unless otherwise instructed by MHRA. Language translations will be thereafter requested and may take around 10-14 business days to fully obtain from international translators.

Attached please find

- ☒ Field Safety Notice (FSN) in English
- ☐ FSN in national language
- ☒ Others (please specify)

Health Hazard Evaluation, Urgent Medical Device Correction Letter, Acknowledgment Form, Technical Bulletin TB00

FSN Status

- ○ Draft FSN
- ◉ Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK
☐ EE	☐ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☐ PT	☐ RO	☒ SE	☐ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Ontvangstdatum	melder
16-12-2011	Medpass als AR
19-4-2012	Medpass als AR
21-11-2012	Medpass als AR
7-2-2013	Medpass als AR
19-2-2013	Medpass als AR
10-6-2013	Medpass als AR
15-10-2013	Medpass als AR
16-10-2013	Medpass als AR
25-11-2013	Medpass als AR
28-11-2013	Medpass als AR
12-12-2013	Medpass als AR
12-12-2013	Medpass als AR
13-12-2013	Medpass als AR
13-12-2013	Medpass als AR
19-12-2013	Zorginstelling
24-12-2013	Medpass als AR
10-1-2014	Medpass als AR
6-2-2014	Medpass als AR
21-2-2014	Medpass als AR
4-4-2014	Medpass als AR
15-4-2014	Medpass als AR
12-5-2014	Medpass als AR
12-5-2014	Medpass als AR
19-5-2014	Medpass als AR
28-8-2014	Medpass als AR
15-10-2014	Medpass als AR
16-10-2014	Medpass als AR
21-10-2014	Medpass als AR
21-10-2014	Medpass als AR
27-11-2014	Medpass als AR
8-12-2014	Medpass als AR
15-12-2014	Medpass als AR
30-12-2014	Medpass als AR
7-1-2015	Medpass als AR
25-2-2015	Medpass als AR
10-3-2015	Medpass als AR
11-5-2015	Medpass als AR
15-5-2015	Medpass als AR
15-5-2015	Medpass als AR
18-5-2015	Medpass als AR
20-5-2015	Medpass als AR
13-7-2015	Medpass als AR
23-7-2015	Medpass als AR
29-7-2015	Medpass als AR
29-7-2015	Medpass als AR
19-8-2015	Medpass als AR
20-8-2015	Medpass als AR
11-9-2015	Medpass als AR
11-9-2015	Zorginstelling
14-9-2015	Medpass als AR

14-9-2015	Medpass als AR
6-10-2015	Medpass als AR
22-10-2015	Medpass als AR
27-10-2015	Medpass als AR
27-10-2015	Medpass als AR
4-11-2015	Medpass als AR
5-11-2015	Medpass als AR
9-11-2015	Medpass als AR
12-11-2015	Medpass als AR
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4-12-2015	Medpass als AR
8-12-2015	Medpass als AR
8-12-2015	Medpass als AR
10-12-2015	Medpass als AR
15-12-2015	Medpass als AR
16-12-2015	Medpass als AR
18-12-2015	Medpass als AR
21-12-2015	Medpass als AR
21-12-2015	Medpass als AR
23-12-2015	Medpass als AR
23-12-2015	Medpass als AR
5-1-2016	Medpass als AR
6-1-2016	Medpass als AR
12-1-2016	Medpass als AR
19-1-2016	Medpass als AR
5-2-2016	Medpass als AR
15-2-2016	Medpass als AR
26-2-2016	Medpass als AR
17-3-2016	Medpass als AR
18-3-2016	Medpass als AR
22-3-2016	Medpass als AR
1-4-2016	Medpass als AR
4-4-2016	Medpass als AR
29-4-2016	Medpass als AR
13-5-2016	Medpass als AR
24-5-2016	Medpass als AR
17-6-2016	Medpass als AR
22-6-2016	Medpass als AR
10-8-2016	Medpass en Zorginstelling
12-8-2016	Medpass als AR
18-8-2016	Medpass als AR
19-8-2016	Medpass als AR
22-8-2016	Medpass als AR
23-8-2016	Medpass als AR
26-8-2016	Medpass als AR
9-9-2016	Medpass als AR
14-9-2016	Medpass als AR

27-9-2016	Medpass als AR
30-11-2016	Medpass als AR
15-12-2016	Medpass als AR
9-2-2017	Medpass als AR
1-3-2017	Medpass als AR