REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨/ ٢٥
رقم الصادر: ٢٠١٢/٧/٥٢٤
بيروت، في: ٢٠ تموز ٢٠١٢

## جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي مغروس

Implantable ventricular assist devices, ventricular – pump. HeartWare controller

**الجهاز المعني بالمتابعة:**

- Implantable ventricular assist devices, ventricular – pump. HeartWare controller
- Trade Mark: HeartWare Inc
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في طريقة استعمال الصنف الوارد اعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

**مرفق ربطاً:**

- التوصية الصادرة عن الشركة المصنعة

**يبلغ:**

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
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HeartWare

XX May 2013

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URGENT FIELD SAFETY NOTICE

| | |
|---|---|
| **Identifier:** | FSCA APR2013 |
| **Type of Action:** | Safety Notification |
| **Product Name:** | HeartWare® Controller |
| **Product Code:** | 1400, 1401XX, 1407XX, 1408 |
| **Range of Serial #s:** | All HeartWare® Controller Serial Numbers |

Dear XX,

HeartWare wishes to inform you of a recent incident involving a patient death thirty-four months post HeartWare® Ventricular Assist System implantation. The patient was found alone and unresponsive with the controller alarming approximately three hours post event. Log file analysis confirmed that the pump had stopped. Functional testing of the returned controller showed that the device (including motor control circuits) performed all functions as intended within specification and with no fault alarms or errors. The exact cause of the event cannot be conclusively determined; however, we suspect that an electrostatic discharge (ESD) through the exposed controller power ports during battery replacement caused or contributed to data corruption in the pump motor controller resulting in a loss of commutation in which the motor control software was no longer driving the pump's motor controller circuit and leading to a pump stop.

## Circumstances contributing to fatal events.

ESD is a known risk for electronic equipment. During the US IDE BTT clinical trial, a controller lost commutation following a suspected ESD event and the patient subsequently expired. Like this most recent event, the patient was found alone with the controller alarming hours after the event. In both cases, the patients had underlying conditions (the first patient had a sewn-over aortic valve and the second patient had Ehlers-Danlos syndrome with significant aortic and mitral valve insufficiency) which greatly increased the risk of mortality in the event of a pump stop.

In both incidents, the patients were alone and unresponsive with controller fault alarms activated. No controller exchange had been performed as a back-up controller was not nearby, nor was a care giver present as recommended in product labeling. In both incidents, the patients' uncommon underlying medical condition put them at extreme risk of death from pump stop.

Static electricity is widely present and more so in certain conditions such as in drier environments and in the vicinity of certain materials and fabrics such as silk clothing and carpeting. Discharge of static electricity commonly referred to as electrostatic discharge (ESD) may interfere with electronic equipment. The HeartWare® Controller, as a piece of electronic equipment, is susceptible to ESD.

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In patients who may be at risk of catastrophic cardiovascular collapse associated with a pump shutdown (fused aortic valve, aortic valve that has been sewn shut due to aortic valve regurgitation, or patients with very poor endogenous ventricular function) ESD education is extremely important and controller exchanges should be performed in a controlled clinical setting whenever possible.

**Actions You Should Take.**

Please educate your patients on the following, stressing (particularly with susceptible patients as described above) the importance of having a backup controller handy and a caregiver nearby when changing power sources or controllers:

**Be aware of Electrostatic Discharge (ESD) and its potential to cause disruptive and possibly fatal faults.**

The controller may alarm in certain situations as a result of electrostatic discharge (ESD). These alarms include a Controller Failed or a high priority audible alarm without accompanying alarm text on the controller screen. If either of these alarms occurs, the controller should be switched to the backup controller.

In the event of a Controller Fault alarm, it should be treated as directed in the IFU ("Medium Alarms, Controller Fault" section), since there are a number of potential causes for this alarm. In the case of a Controller Fault alarm and the alarm will not clear, a controller exchange should be performed.

**Avoid devices and conditions that may induce strong static discharges** (for example, television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the LVAD to perform improperly or stop.

**Always have a backup controller handy and a caregiver nearby when changing power sources or controllers.** Be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.

**In order to avoid or minimize the potential for ESD occurrence, follow good power/battery connection techniques as described in the patient manual.**

Do not touch the controller connector pins or let foreign objects or material come near a disconnected controller power port. Always utilize 2 power sources and do not leave the controller power port unconnected for extended periods when changing power sources.

When changing batteries, have the new battery within arm's reach before disconnecting the depleted battery and have a caregiver in the vicinity should an alarm occur.

Ensure that the driveline cover is in place and firmly positioned against the controller. Be careful around materials (e.g. carpeted floors, silk clothing, etc.) and electronic devices (TV screens, microwaves when in operation, and laptop or computer screens) prone to static electricity and avoid changing power sources in these areas. Avoid vacuuming and removing clothes from the dryer and always use anti-static dryer sheets and fabric softener and consider using a humidifier in the house.

**Please be aware that no return or exchange of equipment is required.**

**HeartWare is notifying you of an unfortunate outcome and reiterating instructions for equipment handling stated in the IFU and recognized practices to avoid electrostatic discharge.**

Please acknowledge you have received this notification. Please scan and return the signed form via fax or email to: Quality Compliance Manager F: + 1 (305) 364-2665 or by email to: quality@heartwareinc.com.

Should you have any concerns or if you require further clarification, please contact your HeartWare Representative or HeartWare Customer Service.

**Transmission of this Field Safety Notice**

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

**Contact Details**

**Europe:** Please contact your Local Field Representative or the Corporate Customer Service Department in the USA, on +1 (305) 818 4090. Alternatively, you can contact HeartWare via the European Authorized Representative, MedPass International Ltd., on +44 (0) 1452 619 222 (phone and fax).

**Company Address**

HeartWare, Inc.
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Miami Lakes, Florida 33014
USA

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T: + 1 (305) 818-4090
F: + 1 (305) 364-2665
Email: quality@heartwareinc.com

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

Sincerely,

Ramon Augusto Paz
VP, Quality Assurance

**Attachment:**

- Acknowledgment of Medical Device Correction

File: FSCA APR2013_EU