



14000 NW 57th Ct
Miami Lakes, Florida 33014 USA
T + 1 (305) 818-4100
F + 1 (305) 364-2665
Email: quality@heartwareinc.com

Date

Distributor
Address

RE: Distribution of Urgent Field Safety Notice

Dear Distributor,

Please be advised that HeartWare has initiated an Urgent Field Safety Notice related to the HeartWare® Controller. As a result, we will disseminate the attached letter to your affected customers. Our records indicate that the following customers are affected:

Clinical Institution/Hospital	Physician and/or VAD Coordinator Name	Mailing Address

We request your assistance to confirm the accuracy of the customer contact and mailing information within forty-eight (48) hours of receipt of this notice. If we do not receive a request from you for modifications to the list above within this timeframe, we will distribute the letters to these addresses. It is your responsibility to ensure that you provide HeartWare with your customer list so that we may appropriately send notifications.

Kindly confirm that you have received and understand the actions required to comply with this field notification by completing the attached 'Distributor Acknowledgment Form' and returning it to HeartWare via fax or email: quality@heartwareinc.com.

We regret any inconvenience caused and thank you in advance for your prompt attention and co-operation.

Sincerely,

Ramon Paz
VP, Quality Assurance

Attachments:

- "Urgent Field Safety Notice" and Acknowledgment Form
- Distributor Acknowledgment Form



Distributor Acknowledgment Form

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

Distributor Name	
------------------	--

The undersigned hereby acknowledges receipt and understanding of actions required to comply with HeartWare's Field Safety Notice FSCA APR2013.

Position/ Title

Name

Signed/ Date

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

Quality Compliance Manager

F: + 1 (305) 364-2665

Email: quality@heartwareinc.com