

CAPA 305 DISTRIBUTOR LETTER

January 28, 2005

Customer Name Address Address Address

Re: Powerheart AED model 9300 Recall Notification

Dear Customer,

In addition, we are giving notification of a recall of the <u>Powerheart AED model 9300 Recall</u>. Please be advised that Cardiac Science has determined that Powerheart AED G3s delivered to customers in the late September/October 2004 timeframe may contain an electronic component that does not meet its full range of operating specifications.

Our records indicate that your organization received one or more of these AED device(s) that may contain the aforementioned component. Attached is a serial number listing of the device(s) subject to the recall.

Background on the model 9300 recall:

Cardiac Science has determined that a limited number of Powerheart AED G3's may contain an electronic component that does not meet its full range of operating specifications. This is a voluntary recall and CSI has effectively completed field testing all of the recalled AEDs in the United States and we are currently evaluating and replacing the units outside of the United States.

Therefore, we will require your immediate assistance to facilitate the replacement of the <u>Powerheart AED model 9300</u> devices.

Enclosed with this letter you will find the following attachments:

- i. List of Model and Serial numbers of the affected <u>Powerheart AED model 9300</u> devices your organization has received according to our records.
- ii. Shipping schedule for your replacement devices and estimated time of arrival to your location

What Cardiac Science is doing:

1. Cardiac Science is coordinating with the Area Sales Management, the distribution of replacement AED's. Cardiac Science is shipping replacement product to your location to facilitate a rapid change out of product.

2. Cardiac Science will pay for all shipping costs so you and or your customer will not incur any additional shipping costs.

What we are requesting you to do:

- 1) Please closely review the serial number listing attached to this letter and identify by serial number the exact location of the end user customers who have received one of these model 9300 that is on the list.
- 2) Begin the immediate removal of the Powerheart 9200, 9210, and 9300 AEDs listed from service.

Call, fax or email your area sales management, Mr. Holger Friedrich, with the model and serial numbers as they are replaced. They can be contacted as follows:

Holger Friedrich, Regional Manager

Central Europe

hf@curative.net

Phone: +49 351 450 4505 Fax: +49 351 450 4522 Mobile: +49 171 140 3462

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3) Please package the ALD(s) for shipment and call your regional manager for return institutions. Cardiac Science will pay for all shipping costs so you and or your customer will not incur any additional shipping costs.

While it is regrettable to have to recall product at any time, be assured the management and employees of Cardiac Science are committed to ensuring our customers and distribution partners are fully supported. We apologize for this inconvenience and sincerely appreciate your continued support and commitment to saving lives.

Sincerely,

Mac McKeen, RAC

Director Regulatory Affairs

Cardiac Science, Inc.