PHILIPS

Philips
November 19, 2013
MEDICAL DEVICE SAFETY NOTICE
HeartStart FRx, HeartStart Home, and HeartStart OnSite

Dear HeartStart AED Owner,

Your Philips AED tests itself at regular intervals to ensure it is ready for use. A triple-chirp alert (♪♪♪... ♪♪♪... ♪♪♪...) could mean that during self-test a serious problem is detected that could prevent your AED from delivering therapy in an emergency.

(1) Reason for the Voluntary Action:

- Philips is sending this letter to inform customers of a potential hazard associated with the failure of an internal electrical component. Philips found this component can fail in a way, whereby the device may incorrectly indicate it is ready for use. The probability of an AED experiencing this internal component failure in an emergency situation is extremely low. To date, Philips has received no reports of this failure mode during emergency use.

- Beginning in 2005, Philips manufactured over 615,000 AEDS that could be subject to this one failure mode and has received 61 reports from customers that their devices detected the component failure in stand-by mode and alerted them with triple chirps. In 25 of the 61 devices, customers applying one or more Battery Insertion Tests were able to clear the triple chirp alert, indicating that the device was ready for use, when it was not.

If you ever hear a series of triple chirps from your AED

- **In Stand-By Mode**: **Please call Philips immediately for delivery of a replacement unit and receipt of a Return Authorization (RA) number**.

- **In an Emergency**: Press the flashing blue i-button and follow the voice prompts. Removing and reinserting the battery can clear some errors and equip the device to deliver therapy in a rescue. This battery removal and reinsertion procedure should only be done in an emergency situation.

  Once the emergency is over, please call Philips immediately for delivery of a replacement unit and receipt of an RA number.

(2) Risk to Health:

- Removing and reinserting the battery one or more times when an AED emits a series of triple chirps may reset the device and cause it to report it is ready for use, though it may be unable to deliver therapy during a rescue. ***If your device is emitting a series of triple chirps, please remove the AED from service and contact Philips immediately for delivery of a replacement unit and receipt of an RA number.***

- To hear the difference between single chirps and triple chirps emitted by your AED, please visit our website at www.philips.com/heartstartmaintenanceadvisory.

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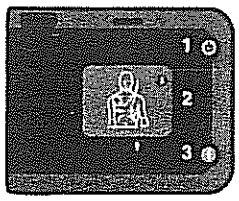
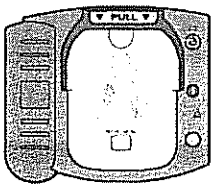
(3) Product Information:

HeartStart FRx, HeartStart Home, and HeartStart OnSite AEDs are affected.



FRx



Home and Onsite

(4) Action Taken by Philips:

Philips began notifying owners of this potential hazard in September, 2012. With this mailing, we are providing our customers with additional information and have created a website supporting this safety notice at www.philips.com/heartstartmaintenanceadvisory. The website includes audio clips to assist you in distinguishing the difference between single and triple chirp patterns.

(5) For Technical Support:

If your Philips AED has ever emitted or begins to emit a pattern of triple chirps, please contact Philips for technical support at 1-800-263-3342, and select option 5. Live technical support is available Monday-Friday, 7:00AM-5:00PM PST. This number is also available 24 hours a day, seven days a week for customer messages that will be promptly returned on the next business day.

Your satisfaction with Philips products is very important to us. For further information or support concerning the use of your AED, please contact your local Philips representative.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Authorized by:

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