Philips
Healthcare

February 16, 2018
FSN86100186

Medical Device Recall/Notification
HeartStart FRx, HeartStart Home, and Heartstart OnSite AEDs

Dear HeartStart AED Owner,

We are contacting you because our records show you are the owner of one or more Philips HeartStart FRx, HeartStart OnSite, or HeartStart Home automated external defibrillators (AEDs) manufactured between 2002 and 2013. Philips is voluntarily issuing this recall notification due to awareness of isolated failures with one of the device's electrical components (a resistor).

1. Reason for This Recall Notification:

Your Philips AED is used to treat ventricular fibrillation (VF), a common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). These Philips AEDs have a low failure rate of less than ½ % per year.

To help ensure your AED will perform in the event of an emergency, Philips AEDs include self-tests that run automatically when the AED is not being used. Various tests occur at daily, weekly, and monthly intervals. These self-tests have been effective at catching over 99% of critical performance issues and alerting users through a series of audible chirps. However, isolated failures can occur that are not detected by these self-tests, and occur during use, putting patients at risk of not receiving adequate therapy for their VF or VT, potentially resulting in serious injury, or even death.

Philips has become aware of a specific issue with one of the electric components (a resistor) in approximately 660,000 AEDs that were manufactured between 2002-2013. Virtually all of these resistor-related failures were detected through the device's automatic self-testing, alerting the user by issuing audible chirps. The in-use reliability of these AEDs is greater than 99.9% when the AED determines a cardiac arrest victim is in need of shock therapy.

However, in rare instances, self-tests might not identify a problem and the device might not deliver a shock when needed. To date, Philips is aware of 13 instances in which this component failed during treatment, out of more than 45,000 uses in which shock therapy was delivered. In all these instances, the device delivered at least one shock before failure. Among the cases for which the patient outcome is known, 5 patients died and 2 patients were successfully resuscitated and survived.
Importantly, when AEDs are used on patients suffering sudden cardiac arrest, not all patients survive. In published studies of public access defibrillation to treat sudden cardiac arrest, the typical indicated survival rates are approximately 25% when an AED is used by a bystander versus 10% if an AED is not used.

2. Risk to Health

Philips is sending this letter to remind customers about the nature and meaning of audible chirps, and to notify customers what to do ***in the extremely rare circumstances the automated tests fail to detect the AED's inability to function normally, and fail to deliver a shock when one is needed.***

3. Actions To Be Taken By Customer/User

Understanding Audible Chirps from Your AED:

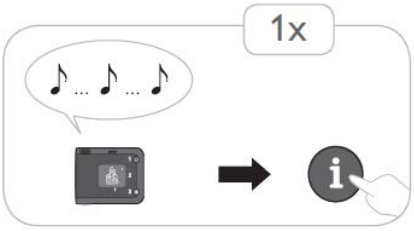
Your Philips AED tests itself at regular intervals to ensure it is ready for use. Issues identified during self- tests result in the sounding of audible single chirps or triple chirps. When an error is detected, the AED continues to chirp until the error is cleared. To help you better understand the difference between single and triple chirps, please view the instructional video on our website at:

www.philips.com/aedaudiblechirps

As stated in your HeartStart manual:

If your AED emits a series of single chirps (♪... ♪... ♪...):

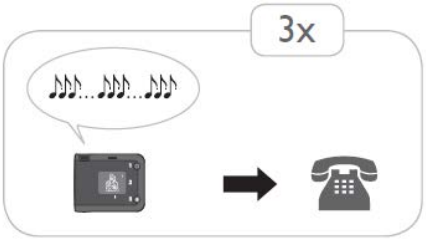
- ☐ Press the flashing blue i-button for information. Your AED will tell you what actions to take (such as replacing expired battery or pads).



If your AED emits a series of triple-chirps (♪♪♪... ♪♪♪... ♪♪♪...), this could mean that a potentially serious problem was detected during self-test that could prevent your AED from delivering therapy in an emergency.

If you ever hear your AED emit a series of triple chirps:

- ☐ <u>During Stand-By Mode:</u> ***Please call Philips immediately*** for technical support including delivery of a replacement unit and receipt of a Return Authorization (RA) number in accordance with the eligibility criteria described in the "Replacement or Rebate Opportunity" section below.



During an Emergency Rescue: 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. ***The battery removal and reinsertion procedure should only be done in an emergency situation. Once the emergency is over, call Philips immediately*** for technical support including delivery of a replacement unit and receipt of a Return Authorization (RA) number.

WARNING: 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. Removing and reinserting the battery when your AED is emitting a pattern of triple chirps should only be done during an emergency. *If your device is emitting a series of triple chirps in stand-by mode, or after an emergency, please remove the AED from service and contact Philips immediately.*

In the rare event that an AED fails during use and is unable to deliver shock therapy, you should:

- ***Ensure that 911 has been called.***
- ***Continue CPR while waiting for Emergency Medical Services to arrive.***
- ***If an additional bystander is available, send him/her to locate another nearby AED.***

4. Specific Products Covered by This Notification

Philips AED Models: HeartStart FRx, HeartStart Home, and HeartStart OnSite AEDs manufactured from September 2002 through February 2013 are included within the scope of this notification because they may contain the type of resistor that has previously been associated with a failure. The year of manufacture can be identified by the 2nd and 3rd characters in the serial number on the back of the AED in the range:

Home/Onsite: A02I-xxxxx *through* A 13B-xxxxx

FRx: B04L-xxxxx *through* B13B-xxxxx

However, if your device was manufactured in 2013 and the 4th digit is the letter "C" or later (D, E, F…), it is not covered by this recall. For example, A13G-02375 is not covered by this recall because it does not contain the resistor associated with this recall notification.

Examples:

Serial number A07C-01002 was manufactured in 2007. It falls within this range and ***is*** covered by this notification.

Serial number A13C-00773 was manufactured after February 2013. It does ***not*** fall within this range and ***is not*** covered by this notification because it does not contain the resistor associated with this recall notification.

Serial number A13B-02375 is covered by this recall because it may contain the resistor associated with this recall notification, but A13G-02375 is not covered by this recall because it does not contain the resistor associated with this recall notification.

Some of the AEDs within the date ranges covered by this recall notification do not contain the resistor associated with the reported failures. Where Philips determined, based on its records, that a device within the date range covered by the notification does not contain a resistor previously associated with a failure, we did not send a notification. Nonetheless, if you wish to confirm whether your device contains the resistor at issue, please contact Philips at <Philips representative contact details to be completed by the KM / country>.

5. Action Taken by Philips

Philips began notifying owners of this potential hazard in September 2012. With this mailing, we are providing additional information and have created an instructional video available at www.philips.com/aedaudiblechirps.

Philips carefully monitors the reliability of our AED products. If you experience an issue with your AED or if it is emitting triple chirps, please contact Technical Support (refer to following section).

6. For Technical Support

As noted above, and in your HeartStart AED owner's manual, if your Philips AED has ever emitted or begins to emit a pattern of triple chirps, please contact Philips for technical support at <Philips representative contact details to be completed by the KM / country>.

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

7. Replacement or Rebate Opportunity

Your continued satisfaction with Philips AEDs is very important to us and we want to ensure your confidence in the reliability of our products. If your device is covered by this notification and is still under warranty, you are entitled to receive a refurbished exchange unit at no cost, in accordance with our standard warranty terms. If your device is no longer under warranty or if you desire to purchase a newer model replacement for your present AED, as an owner of a Philips HeartStart FRx, HS1 OnSite, and HS1 Home AED manufactured prior to 2013, you may be eligible for a trade-in rebate. Philips is offering trade-in rebates ranging from $50 to $625, depending on the age and model of your AED.

To request a warranty exchange unit or a trade-in rebate, or to obtain additional information, please contact your local Philips representative or contact Philips directly at <Philips representative contact

details to be completed by the KM / country>. Further information about the trade-in rebate program may be found at: www.philips.com/aedsupport.

Additionally, to help you get the most out of your AED and to help you ensure it is ready for use if needed, please refer to the online instructional video on AED pads and batteries:

www.philips.com/padsandbatteries

Philips
Healthcare

Customer Reply for FSN86100186A:

HeartStart FRx, HeartStart Home, and Heartstart OnSite AEDs

Field Action for R92 Resistor Issue

Please complete and fax to: <Philips representative contact details to be completed by the KM/country>.

CUSTOMER ID:

Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address City, State, Zip:	

Please fax or email this completed form to the number or email address provided above.

CUSTOMER ACKNOWLEDGEMENT

The letter and instructional video was read/viewed and understood by staff/customers who may use the HeartStart FRx, HeartStart Home, and Heartstart OnSite AEDs.

_____ _____

CUSTOMER NAME (please print) **TITLE**

_____ _____

CUSTOMER SIGNATURE **DATE**

Please email the completed reply form to <Philips representative contact details to be completed by the KM/country>. If you experience difficulty carrying out the instructions contained in this communication, contact your local Philips representative.

PHILIPS

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the <product name> due to FCO XXXXXXXX . Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: XXXXXX, XXXXXX, XXXXXXX, XXXXXX

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:

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