Voluntary Recall of Philips Automated External Defibrillators

U.S. Food & Drug Administration

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Audience:

- First responders who use Philips HeartStart FRx AED
- Consumers who have purchased Philips HeartStart HS1 Home or HeartStart HS1 OnSite AEDs

Medical Specialty: Cardiology, Electrophysiology, Internal Medicine, Family Medicine

Device:
An automated external defibrillator (AED) is a device that analyzes the heart rhythm in victims of sudden cardiac arrest, and delivers an electrical shock to restore normal rhythm.

The Philips HeartStart FRx AED may be used by first responders including Emergency Medical Services (EMS) and fire departments.

The Philips HeartStart HS1 Home AED may be used in the home.

The Philips HeartStart HS1 OnSite AED may be used in public locations including airports, community centers, schools and government buildings.

Purpose:
The FDA is alerting all users of the Philips HeartStart FRx, HS1 Home and HS1 OnSite AEDs manufactured between 2005 and 2012 that these devices may fail to deliver a shock in the event of an emergency. If you have this device, please contact Philips Healthcare immediately for a replacement unit.

Summary of Problem and Scope:
In September 2012, Philips Healthcare initiated a Voluntary Medical Device Recall of HeartStart Frx, HeartStart HS1 Home, and HeartStart HS1 OnSite AEDS after determining that an internal electrical component in the AED could fail, and the device could incorrectly indicate it is ready for use. This recall affects approximately 700,000 devices.

In a Medical Device Safety Notice dated Nov. 19, 2013, Philips provided customers with updated information about the failure of an electrical component that could cause the AEDs to fail to deliver appropriate shock. The notification also directed

consumers to a Maintenance Advisory [1].

Recommendations:
All owners of the Philips HeartStart AEDs should contact Philips Healthcare immediately at 1-800-263-3342, and select option 5 for technical support. Live technical support is available Monday – Friday, 7:00 am – 5:00 pm Pacific Time.

Keep the recalled HeartStart AED in service until Philips Healthcare replaces the device or you can obtain another working AED. Despite current manufacturing and performance problems, the FDA considers the benefits of attempting to use an AED in a cardiac arrest emergency greater than the risk of not attempting to use the defibrillator.

If you are unsure if your Philips HeartStart AED is affected by this recall or you received a replacement unit after the September 2012 recall notification, please contact Philips Healthcare for additional information.

Please be aware that the Philips HeartStart AEDs are designed to automatically test themselves at regular intervals to ensure they are ready for use. The HeartStart AED should emit a triple chirp sound and have a flashing “i-button” if it detects a serious problem that could prevent the HeartStart AED from delivering an electrical shock.

- If your Philips HeartStart AED is emitting a series of triple chirps while in stand-by-mode, please contact Philips Healthcare immediately for a replacement unit. Keep the recalled HeartStart AED in service until Philips Healthcare replaces the device or you can obtain another working AED.
- If your Philips HeartStart AED is emitting a series of triple chirps during an emergency situation, and you are unable to locate another working AED:

1. Call Emergency Medical Services (EMS) or 911 and start cardiopulmonary resuscitation (CPR)
2. Press the flashing “i-button” and follow the voice prompts.
3. If there is an error message, remove and reinsert the battery to attempt to clear some errors and equip the device to deliver an electrical shock if needed. ***(Note: This step should be followed ONLY during an emergency situation.)***
4. If an advised electrical shock is not delivered, continue CPR while you wait for the EMS.
5. After the emergency is resolved, contact Philips Healthcare for a replacement unit.

FDA Actions
The FDA continues to closely monitor all AED manufacturers’ quality system design practices and device malfunctions that have persistently contributed to AED recall and Medical Device Reports.

In September 2012, the FDA classified Philips’ recall of HeartStart AED devices as a Class II recall after determining that the chance of serious adverse consequences or

death due the device failure is remote. In this current situation, the FDA believes that because the patients who need these devices are in a life threatening situation, the chance of serious adverse consequences or death directly related to AED failure is very difficult to conclusively determine.

In March 2013, the FDA issued a Proposed Order [2] requiring manufacturers of AEDS and accessories to submit premarket approval (PMA) applications. The FDA is currently reviewing and considering the comments provided by the public, and will take them into consideration when issuing a final order.

Reporting Problems to the FDA
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect that an AED has malfunctioned, the FDA encourages you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [3].

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements [4] should follow the reporting procedures established by their facilities.

Contact Information:
If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at industry.devices@fda.hhs.gov [5], 1-800-638-2041, or 301-796-7100.

Additional Resources:

- FDA press release [6]
- Philips Maintenance Advisory: HeartStart FRx and Onsite (HS1) AEDs [1] [7]

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[1] http://www.healthcare.philips.com/us_en/products/resuscitation/products/aeds/support/heartstart-maintenance-advisory.wpd
[2] http://www.gpo.gov/fdsys/pkg/FR-2013-03-25/html/2013-06723.htm
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