HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

HeartStart FRx, HeartStart HS1 (Home) and HeartStart HS1 (OnSite) AEDs

Priority 2 – Warning

HPRA Safety Notice: SN2018(37)

Issue Date: 24th October 2018

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Medical Systems	V35048

ISSUE
Philips Medical Systems has become aware of an issue affecting a resistor component in approximately 660,000 **HeartStart FRx, HeartStart HS1 (Home) and HeartStart HS1 (OnSite) AEDs** manufactured between 2002-2013. Philips Medical Systems has distributed a field safety notice (FSN) to highlight this issue, emphasise the purpose and meaning of audible chirps to users and to notify users of steps to take in the rare event that a shock is not delivered when needed. Users of devices affected by this notification and whose devices are still under warranty, can receive a replacement AED as detailed in the accompanying FSN.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Read the accompanying Field Safety Notice (FSN) carefully.

2 Acknowledge receipt of the FSN if you have not already done so.

3 Forward a copy of this safety notice and FSN to all relevant personnel within your organisation and to any other organisations or persons where these devices have been transferred.

4 Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

5 Contact Philips and/or your distributor to determine whether you are eligible for a replacement device.

TARGET GROUPS

A&E departments	EBME departments
All clinical departments	Health and safety managers
All clinical staff	Maintenance staff
All wards	Medical directors
Ambulance services directors	Nursing directors
Ambulance staff	Risk managers
Biomedical engineering staff	Volunteer Ambulance Services
Cardiology departments	First Aid Organisations
Cardiothoracic departments	Sport Centres
Nursing Homes	Schools
Work Places/Employers	Gyms
Retailers	Dental Clinics
Medical Centres	

BACKGROUND

Philips Medical Systems issued this Field Safety Notice (attached) following identification of a resistor component failure in certain AEDs. Typically, AEDs perform various self-tests at daily, weekly and monthly intervals and alert users though audible chirps if an issue is identified. For AEDs effected by this issue, these self-tests are effective at catching the vast majority of issues and alerting users through a series of audible chirps. However, failures have occurred that were not previously detected by these self-tests.

This FSN aims to remind users about the nature and meaning of audible chirps and to provide additional information on the steps to take should audible chirps occur. Further information on these triple chirps and their meaning can be found in the accompanying FSN.

Users can also view an instructional video available on the Philips website at www.philips.com/aedaudiblechirps.

At the time of FSN distribution, Philips Medical Systems was aware of 13 incidents where this component failed during treatment. On these occasions 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.

The FSN also informs users with affected AEDs of their eligibility for a replacement HeartStart FRx, HeartStart HS1 (Home) and HeartStart HS1 (OnSite) AEDs. Please see the associated FSN for further details. Please contact Philips Medical Systems using the contact details below to determine if you are eligible for a replacement device.

MANUFACTURER

Enquiries to the **manufacturer** should be addressed to:

Philips Healthcare UK,
The Philips Centre,
Guildford Business Park,
GU2 8XG

Telephone: 00 44 0870 532 9741
Fax: 00 44 01483 369 037
E-mail: devicevigilanceuki@phillips.com
Website: www.philips.co.uk

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie