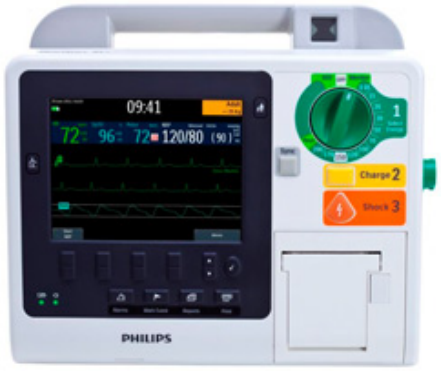
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Philips HeartStart XL+ Defibrillator/Monitor



Priority 2 – Warning

HPRA Safety Notice: SN2015(21)
Philips Reference Number: FCO86100172

Issue Date: 06 April 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Medical Systems GmbH	V24898

ISSUE

The Health Products Regulatory Authority (HPRA) wishes to inform users/owners of HeartStart XL+ defibrillators/monitors of a new FSCA that Philips is releasing which will address the following issues:

Software:

- *The XL+ may fail to complete the power on sequence and continuously reboot.*
- *The XL+ may either fail to power up or may shut down unexpectedly.*
- *The XL+ may have a software version that did not reset a fail-safe monitoring component which could delay of therapy or pacing interruption.*
- *The XL+ may fail to generate verbal prompts in AED mode.*

Hardware:

- *The XL+ may have been manufactured with a speaker that may fail.*
- *The battery may not seat properly causing the XL+ to shut down unexpectedly or remain powered on and not acknowledge or charge the battery.*
- *The XL+ exceeds the allowable radiated emissions level for Class B CISPR11.*
- *The XL+ ECG signal from leads could be lost and unrecoverable.*
- *The XL+ SpO2 signal may lose communication and cause the device to reboot.*
- *The XL+ battery detection system may be disrupted and cause a false low battery alarm*

ACTION OR RECOMMENDATIONS

The HPRA advises the following:

1 Follow the advice given by the manufacturer in the attached Field Safety Notice.

2 Forward this HPRA Safety Notice to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred. Please maintain an awareness of this notice for an appropriate time period.

3 Report all complaints and/or incidents with this device to the manufacturer and the HPRA.

4 Contact your local Philips representative should you need further information in relation to these issues.

TARGET GROUPS

All owners and users of these devices	

BACKGROUND

Philips has identified a number of issues with these devices through internal testing and complaints monitoring.

The expected timeframe for completion is approximately January 2015. There are 106 of these devices in Irish Healthcare institutions. All were supplied to the Irish market via Cardiac Services, who will also be performing the upgrades.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Philips Healthcare UK
The Philips Centre,
Guilford Business Park,
Guilford,
United Kingdom,
GU2 8XH

Telephone: (01) 8307499
E-mail: co-ordinator@cardiac-services.com
Website:
http://www.philips.co.uk/healthcare

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