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: SN2019(32) **Issue Date: 13th December 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Healthcare	V41975 V41978

ISSUE
Philips has identified two issues with the HeartStart XL+ Defibrillator/Monitor (Model number 861290) that may result in unpredictable device behaviour, resulting in a potential device failure. The issues have been communicated in the two attached field safety notices (FSNs).

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Read the accompanying FSNs carefully. 2 Following the instructions in the FSNs, identify whether you have affected devices in use at your facility. 3 If you identify affected devices that exhibit any of the issues described in the FSNs, remove the devices from use immediately and contact Philips to request service.

4 Acknowledge receipt of the FSNs if you have not already done so.

5 Forward a copy of this Safety Notice and the FSNs to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.

6 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS	
Ambulance Services	Nursing Homes
Clinics	Paramedics / Advanced Paramedics
General practitioners	Private medical practitioners
Hospitals	Risk managers
Medical Directors	Supplies managers
Emergency Departments	

BACKGROUND

Philips issued two FSNs to advise users of the following issues with the HeartStart XL+ Defibrillator/Monitor (Model number 861290):

1 A defect in the memory management software or a malfunction of the System On Module (SOM) installed on the Processor printed circuit assembly (PCA), may result in failure of the device to turn on or unexpectedly attempt to restart.

Two patient deaths have been reported (from outside of Ireland). There have been 588 complaints worldwide relating to this issue. This issue affects all HeartStart XL+ Defibrillator/Monitor (Model number 861290) devices.

2 The rotary therapy selector switch may fail, resulting in unpredictable device behaviour, including; the device may not turn on, may not perform the selected function, and/or may deliver a shock with an energy level different than the setting selected by the user.

Philips has not received any reports of patient deaths associated with this failure. This issue affects all HeartStart XL+ Defibrillator/Monitor (Model number 861290) devices *manufactured prior to 1 May 2017*.

The HPRA is issuing this Safety Notice to raise awareness of this issue. Please see the accompanying manufacturer's FSNs for further information.

The HPRA may issue further communications should additional field actions be undertaken by the manufacturer.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Philips Healthcare UK,
The Philips Centre,
Guildford Business Park,
Guildford
UK.

Telephone: +44 870 532 9741
E-mail: safetynoticeuki@philips.com
Website: https://www.philips.ie/healthcare

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

Cardiac Services Group,
Northern Cross Business Park,
Finglas,
Dublin 11.

Telephone: +353 1 830 7499
E-mail: recall@cardiac-services.com
Website: https://www.cardiac-services.com

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
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie