HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

HeartStart MRx Monitor/Defibrillator

Priority 2 – Warning

HPRA Safety Notice: SN201715 **Issue Date: 24th March 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Healthcare	V31175

ISSUE
Philips has identified a number of issues with the HeartStart MRx Monitor/Defibrillator, which may affect the performance of the device and could potentially delay monitoring or therapy. Philips has circulated a field safety notice (FSN) advising users of these issues.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1. Refer to the accompanying FSN and follow the instructions provided. 2. Forward a copy of this Safety Notice and the FSN to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred. 3. Acknowledge receipt of the FSN if you have not already done so.

4. Please maintain an awareness of this Safety Notice and actions outlined in the FSN until a correction has been completed for your device.

5. Report any adverse events relating to these devices to the manufacturer and the HPRA as soon as possible.

TARGET GROUPS

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

BACKGROUND

The HeartStart MRx Monitor/Defibrillator is designed to provide professional emergency responders with monitoring and defibrillation technology.

Philips has identified in exceptionally rare circumstances, the device may exhibit the following behaviours:

Behaviour 1: If the pins that connect the battery to the device become damaged or full of debris, this could result in a poor electrical connection that may cause the MRx to either not power on or repetitively reboot when used on battery power only.

Philips has provided an addendum to the instructions for use (IFU), which advises users to check the battery connection pins in order to avoid the device from failing to power on or repetitively reboot.

Behaviour 2: After unplugging the device from AC mains, two abnormal behaviours of the HeartStart MRx Monitor/Defibrillator may occur:

a. After the user depresses the charge button, the device attempts to charge, and, after approximately 20 seconds, generates the "Shock Equipment Malfunction" error message and is unable to deliver shock therapy.
b. Pacing may cease without warning.

These device behaviours continue until the unit is reset (as described in the FSN). Philips has advised that these abnormal device behaviours are very uncommon and two separate events must coincide for the behaviour to occur:

1. When the user unplugs AC power, the MRx inappropriately remains in the "AC mains" operating mode and fails to switch to the "battery only" mode and
2. The battery is at least partially depleted.

Philips has confirmed that these behaviours do not happen when the device is operating on two batteries. There have been no reports of these behaviours when the device is unplugged from DC power.

Philips is evaluating software and hardware upgrades to correct behaviour 2 identified above. In the interim Philips is advising customers to follow the actions outlined in the accompanying FSN.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Mr Michael Turvey,
Q&R Officer Health Systems Philips UK&I
The Philips Centre
Guildford Business Park
Guildford
Surrey. GU2 8XG

Telephone: +44 870 532 9741
E-mail: Michael.Turvey@philips.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

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Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
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