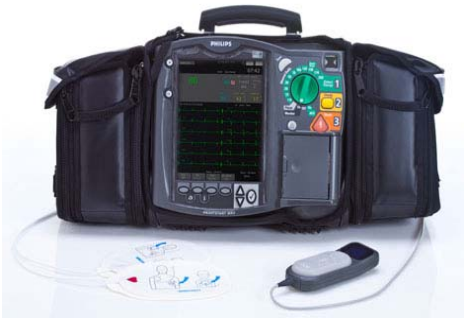
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

HeartStart MRx Monitor/Defibrillator

Philips M1783A and M5526A Sync Cables



Priority 2 – Warning

HPRA Safety Notice: SN2014(46) **Issue Date: 17th December 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Healthcare	V22689 / V22723 / V22725 / V22727

ISSUE

Philips has identified a number of issues with the HeartStart MRxMonitor/Defibrillator and also an issue with the Philips M1783A and M5526A Sync Cables which may affect device performance. Philips has initiated four field safety corrective actions during November and December 2014.

The field safety notices are numbered : FSN86100160A, FSN86100162A , FSN86100163A , FSN86100165A

Full listings of affected products and details of the actions to be taken by users can be found in the attached field safety notices

The Health Products Regulatory Authority (HPRA) is circulating this Safety Notice to ensure that all users of these devices are aware of the issues and to highlight the actions to be undertaken as part of these field safety corrective actions (FSCAs).

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Ensure that all device users are aware of the information provided in the attached field safety notices issued recently by Philips.
2. Forward this Safety Notice and the manufacturer's field safety notices to all those that need to be aware of these actions within your organisation.
3. Work with the local distributor to ensure that your device receives the relevant upgrades as soon as possible.
4. Report any adverse incidents relating to the above devices to the HPRA as soon as possible.

TARGET GROUPS

Paramedics	General practitioners
Ambulance Services	Private medical practitioners
Medical directors	Clinics
Risk managers	Hospitals
Supplies managers	Nursing Homes

Background

FSN86100160A

Issue 1: The MRx can be susceptible to interference from electrical fast transients (EFTs) when connected to AC or DC power, operating with a LAN cable, or operating near a source of EFT interference, which could cause therapy to be delayed or delivered inadvertently.

Issue 2: If a user performs either of the following two atypical clinical workflows, the MRx can exhibit unexpected behaviour.

> *Workflow A:* When using external paddles for defibrillation, the MRx can deliver a shock when only one of the two shock buttons is depressed, if the if the user performs a specific workflow sequence. Further detail of the workflow sequence is provided in the 'Background' section below.
>
> *Workflow B:* When using the Periodic Clinical Data Transmission (PCDT) option on the MRx, the MRx can reboot if the user performs a specific workflow sequence. Further detail of the workflow sequence is provided in the 'Background' section below.

Issue 3:
If electrode-to-skin contact impedance values are outside the ranges for detection during demand mode pacing, pacing could be interrupted, potentially leading to a delay in therapy.

FSN86100162A Incorrect internal software settings could pose a risk for patients

The MRx could contain incorrect internal software settings, causing the following two issues:

1. The device will perform the weekly automated tests hourly, which could cause the therapy capacitors to degrade sooner than intended.

2. While connected to AC or DC power and with no battery installed or the battery installed has a charge level of less than 10%, the Ready for Use (RFU) indicator will not provide the expected low battery indication (flashing red X with audible chirp). Instead, the RFU will show a flashing black hourglass, indicating that sufficient battery power is available for device operation.

Note: Once the device is disconnected from AC or DC power, the RFU indicator provides the appropriate low battery indications. In addition, all other battery charge indicators continue to operate normally, including the on-screen battery fuel gauges, low battery messages, and low battery alarms. The LED charge level indicators on the batteries themselves also operate normally.

FSN86100163A
The MRx can be susceptible to one or both of the issues described below.

1. The CO2 Inlet Port associated with end-tidal carbon dioxide (EtCO2) monitoring on MRx Monitor/Defibrillators can be pushed into the MRx housing, making it inaccessible. This can occur if the user attempts to push the CO2 FilterLine fitting into the Inlet Port, instead of twisting it clockwise as described in the MRx Instructions for Use.

2. The handle can separate from the MRx housing due to breakage of mounts on the rear case.

FSN86100165A When a Philips monitor/defibrillator is receiving an ECG signal from an auxiliary bedside monitor via a sync cable, the following can occur if the monitor/defibrillator experiences interference from electrical fast transients (EFTs) while connected to AC power:

1. On the HeartStart MRx and HeartStart XL, EFT noise can be misinterpreted as an R-wave

2. On the HeartStart XL+, EFT noise can disable ECG monitoring, and potentially interrupt demand mode pacing*.

*Note: It is contrary to the instructions in the XL+ Instructions for Use (IFU) to perform demand mode pacing while using the sync cable to provide the ECG signal from a beside monitor. The XL+ IFU includes the following warning: "When pacing in Demand Mode, the ECG cable from the patient must be directly connected to the HeartStart XL+." If the user follows this warning, this problem cannot occur on the XL+.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Customer Care Service Centre
0870 532 9741
Philips Healthcare
Guildford Business Park
Guildford
Surrey
GU2 8XH
E-mailPH.PMUK.Support@philips.com

Enquiries in relation to this action may be addressed to the Irish distributor::

Cardiac Services
128 Slaney Road
Glasnevin
Dublin 11

Telephone: +353-1-8307499
Email: recall@cardiacservices.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
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie