

Safety Notice

Medical Devices

HeartStart MRx Monitor/Defibrillator

Priority 2 – Warning



HPRA Safety Notice: SN2015(01)

Issue Date: 30th January, 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Healthcare	V22933

ISSUE

Potential for interrupted pacing or, a delay in defibrillation or cardioversion therapy.

Philips has determined that the MRx could reboot once in any operating mode if the following sequence occurs:

1. In Service Mode, the Status Log* is cleared
2. Prior to exiting Service Mode, the MRx generates an entry in the Status Log
3. Service Mode is exited.

The MRx is then in a state that could trigger a reboot at an indeterminate time, potentially causing therapy to be interrupted or delayed.

Note: If a reboot occurs during clinical use, current device settings and patient records are retained.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

- 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 Philips will provide a software upgrade to affected devices. Contact your local Philips representative should you need further information in relation to this issue.

TARGET GROUPS

Ambulance Services Biomedical Engineering Departments Clinics General practitioners Hospitals Medical Directors	Nursing Homes Paramedics Private medical practitioners Risk Managers Supplies Managers
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BACKGROUND

Philips has identified that under certain circumstances, the MRx monitor/defibrillator could reboot at an indeterminate time, potentially causing therapy to be interrupted or delayed.

Affected models of HeartStart MRx and the serial number ranges are detailed by Philips in the attached Field Safety Notice.

Please be aware of previous IMB/HPRA Safety notices issued for the Philips HeartStart MRx Monitor/Defibrillator in March 2014 (IMB Ref: SN2014(15)) and December 2014 (Ref: SN2014(46)).

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Customer Care Service Centre	Telephone:	0044 (0)870 532 9741
Philips Healthcare	Fax:	
Guildford Business Park	E-mail:	PH.PMUK.Support@philips.com
Guildford	Website:	
Surrey		
GU2 8XH		

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

Cardiac Services	Telephone:	00353 (0)1 830 7499
128 Slaney Road	Fax:	
Glasnevin	E-mail:	recall@cardiacservices.com
Dublin 11	Website:	

HPRA CONTACT INFORMATION

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

Health Products Regulatory Authority	Telephone:	+353-1-6764971
Kevin O'Malley House	Fax:	+353-1-6344033
Earlsfort Centre	E-mail:	devicesafety@hpra.ie
Earlsfort Terrace	Website:	www.hpra.ie
Dublin 2		