URGENT - Medical Device Correction
Philips HeartStart MRx Monitor/Defibrillator
Therapy Board Failure

Dear Customer,

A problem has been detected in the Philips HeartStart MRx Monitor/Defibrillator that, if it were to occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the issue is and under what conditions it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- the corrective action planned by Philips to address the issue

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instructions for Use.

An internal component on the HeartStart MRx may malfunction potentially affecting the ability to deliver therapy.

Please see the attached Field Safety Notice that provides information on how to identify affected devices and instructions on actions to be taken. Please follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice. To correct this issue Philips will provide a replacement therapy board to customers with affected units free of charge.

This voluntary correction has been reported to the appropriate regulatory agency.

If you need any further information or support concerning this, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

John Pardo

John Pardo
Director QA/RA, Emergency Care and Resuscitation

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AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx Monitor/Defibrillator, model numbers M3535A, M3536A, M3536M,M3536M4,M3536M6,861288,861289,861464,861483,and 861491 **Units Affected:** Serial numbers within the range US00100204 to US00570921
PROBLEM DESCRIPTION	An internal component on the HeartStart MRx therapy board may malfunction potentially affecting the ability to deliver therapy. Specifically, the MRx may be unable to charge and deliver a shock. In addition, when used for external pacing, the malfunction may result in a loss of capture during pacing. The MRx may display a Red X in the Ready For Use (RFU) indicator during automated tests informing the user that a failure has been detected that may prevent the delivery of a shock and pacing.
HAZARD INVOLVED	The MRx may fail to charge, defibrillate or externally pace at the selected output current, causing a delay in therapy. .
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Monitors/Defibrillators identified above are affected by the issue. The model and serial numbers of your HeartStart MRx Monitor/Defibrillator are printed on the primary label on the back of the MRx in battery bay B.
ACTION TO BE TAKEN BY CUSTOMER / USER	You can continue to use your MRx prior to receiving the hardware upgrade, provided that if you observe that the MRx is displaying a Red X in the Ready For Use (RFU) indicator\during automated tests, a failure has been detected that may prevent the delivery of a shock or pacing due to this issue. If this is observed you should turn the Therapy Knob to Monitor. An INOP message describing the failure is displayed. If needed, run an Operational Check for further information. If the condition persists, take the device out of use and call for service. Identify a readily available backup defibrillator to use in the event the affected HeartStart MRx fails to deliver therapy.
ACTIONS PLANNED BY PHILIPS	Philips is initiating a correction to affected devices. The correction will consist of a hardware upgrade. These will be provided free of charge for all units affected by this issue. A Philips Healthcare service representative will contact customers with affected devices to arrange for installation of the hardware upgrade.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.