PHILIPS

URGENT - Field Safety Notification Medical Device Correction

Philips HeartStart MRx Monitor/Defibrillator on exceptionally rare occasions may exhibit abnormal behavior when operating using a single battery as the sole source of power.

Dear Customer,

Philips has identified the possibility of abnormal device behaviors on the HeartStart MRx Monitor/Defibrillator. Under exceptionally rare circumstances, the device may exhibit the following behaviors:

1. If the pins that connect the battery to the device have become damaged or full of debris, it could result in a poor electrical connection. The device may not power on or may repetitively reboot when on battery power only.
2. After unplugging the device from AC mains, when operating with a single battery as the sole source of power, there are two abnormal behaviors of the HeartStart MRx Monitor/Defibrillator that 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 behaviors continue until the unit is reset.

Either potential problem could potentially delay monitoring or therapy.

The purpose of this Field Safety Notice is to inform you about the:

- Issues and under what conditions they can occur
- Actions that you should take to prevent risks for patients
- Corrective actions planned by Philips to address the issues

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 should be aware of the contents of this communication.

Please retain a copy with the equipment Instructions for Use.

The following pages provide information on how to identify affected devices and instructions on actions to be taken. Follow the “ACTION TO BE TAKEN BY CUSTOMER / USER” section of the notice. To address this correction, Philips is:

1. Providing an Instructions for Use (IFU) Addendum. This Addendum describes how users can check the battery connection pins in order to avoid the device from failing to power on or repetitively reboot.
2. Providing measures to prevent, or methods to allow the user to correct, the abnormal device behavior related to charging and pacing after disconnecting the device from AC mains.

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

Philips apologizes for any inconvenience this may cause you. If you have questions regarding this notification or need any further information or support, please contact your local Philips representative: **0800 80 3000**

Sincerely,

Thomas Fallon
Director QA/RA, Emergency Care and Resuscitation

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AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx Monitor/Defibrillator model numbers M3535A, M3536A, and military bundles. **Units Affected:** M3535A M3535ATZ M3536A M3536ATZ M3536M M3536MC M3536M2 M3536M3 M3536M4 M3536M5 M3536M6 M3536M7 M3536M8 M3536M9
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Monitors/Defibrillators identified above are affected by this notification. The model and serial numbers of HeartStart MRx Monitor/Defibrillators are printed on the primary label on the back of the MRx in battery bay B.

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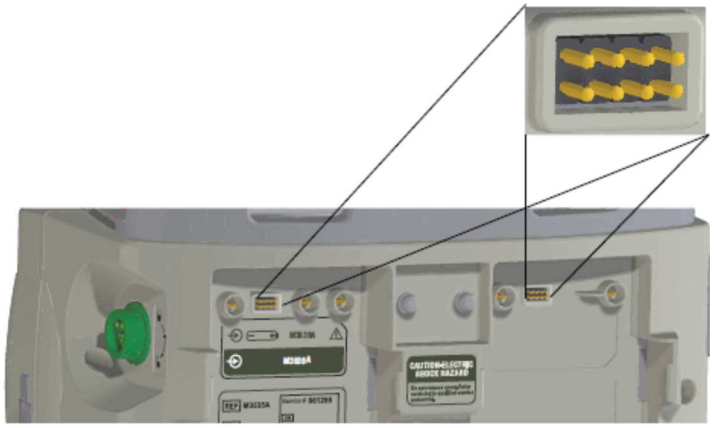
Philips HeartStart MRx Monitor/Defibrillator on exceptionally rare occasions may exhibit abnormal behavior when operating using a single battery as the sole source of power.

BEHAVIOR DESCRIPTION 1	If the battery connecting pins (in the battery compartment of the HeartStart MRx Monitor/Defibrillator) become damaged or contaminated, it could result in a poor electrical connection that may cause the MRx to either (i) not power on or (ii) repetitively reboot, when used on battery power only.
HAZARD INVOLVED 1	HeartStart MRx Monitor/Defibrillator may, on exceptionally rare occasions, either (i) not power on or (ii) repetitively reboot. Either situation would make the device inoperative, delaying therapy to a patient in need of defibrillation, cardioversion, pacing, or monitoring.
ACTION TO BE TAKEN BY CUSTOMER / USER – 1	When inspecting the device, inspect the HeartStart MRx battery compartment connections. Include this step as part of a routine Operational Check to verify that the battery connector pins are clean, fully extended, not bent, and without residue. **Figure A: Battery Connector Pins**  Battery Connector pins, eight in each compartment
ACTIONS PLANNED BY PHILIPS - 1	Philips is voluntarily initiating this correction and is providing an Instructions for Use (IFU) Addendum entitled, HeartStart MRx Battery Connector Pins, for all customers with affected units.

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Philips HeartStart MRx Monitor/Defibrillator on exceptionally rare occasions may exhibit abnormal behavior when operating using a single battery as the sole source of power.

BEHAVIOR DESCRIPTION 2	After unplugging the device from AC mains, there are two abnormal behaviors of the HeartStart MRx Monitor/Defibrillator that may occur: 1. 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. 2. Pacing may cease without warning. These device behaviors continue until the unit is reset (as described in the section "Actions to be Taken by the Customer/User"). These abnormal device behaviors are very uncommon and are difficult to consistently reproduce. Two separate events must coincide for the behavior 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. These behaviors do not happen when the device is operating on two batteries. There have been no reports of these behaviors when the device is unplugged from DC power.
HAZARD INVOLVED 2	The HeartStart MRx Monitor/Defibrillator may, on exceptionally rare occasions, exhibit abnormal behavior during charging. Because the MRx is unable to charge, it cannot deliver defibrillation shock therapy to a patient in need. While never observed to date, pacing may stop without warning. Therefore, the patient might experience a delay in pacing therapy.

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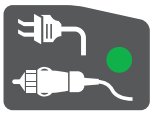
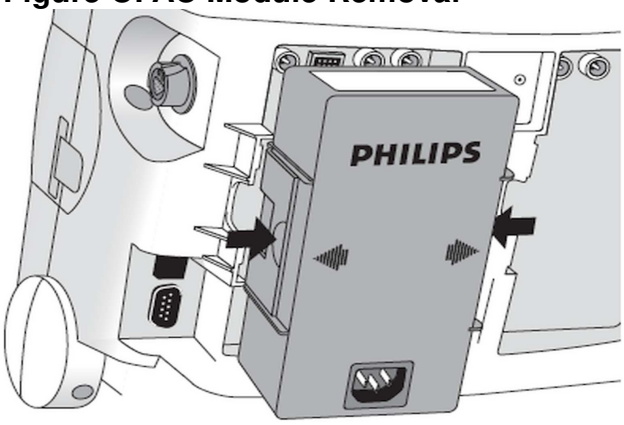
ACTION TO BE TAKEN BY CUSTOMER / USER – 2	After the device is unplugged from AC mains power, if the External Power Indicator light above the MRx display (see Figure B) continues to be illuminated, the device did not appropriately switch to battery power and is at risk of abnormal charging and pacing behaviors. **Figure B: External Power Indicator**  When unplugging the MRx from AC mains, observe the External Power Indicator. If it remains lit, take the following actions to reset the unit: 1. Leave the device unplugged, 2. Remove and reinsert the battery, and 3. Confirm that the Indicator has turned off. There are two ways to prevent this power switching. The user can either: a. Remove the AC module from the MRx, rather than unplugging the cord from AC mains (see Figure C). **Figure C: AC Module Removal**  b. Turn on the MRx using the rotary knob and allow it to complete the start-up before unplugging the device from AC mains.

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	Philips also reminds you to keep batteries fully charged before use, as per the instructions in the HeartStart MRx Monitor/Defibrillator Instructions for Use (IFU).
ACTIONS PLANNED BY PHILIPS - 2	Philips is voluntarily initiating this correction and is providing measures to prevent, or methods to allow the user to correct, the abnormal device behavior related to charging and pacing after disconnecting the device from AC mains. Philips is evaluating both software and hardware changes to prevent this abnormal device behavior. Once the solution is available, you will be contacted by Philips if you have a device that is at risk of exhibiting this issue.
FURTHER INFORMATION AND SUPPORT	If you need further information or support concerning this notification, please contact your local Philips representative: **0800 80 3000**