PHILIPS

URGENT – Field Safety Notice
Philips HeartStart MRx Monitor/Defibrillator

Dear Customer,

Philips has identified issues that could impact the safety and/or performance of certain MRx monitor/defibrillators. These issues are further detailed in the attached Field Safety Notice.

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.

Please see the following pages, which 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.

Philips is initiating a software upgrade that will be provided to customers free of charge. A Philips Healthcare representative will contact you to arrange for installation of the software upgrade. We appreciate your patience as we work to schedule your upgrade.

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

Philips sincerely 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 <Philips representative contact details to be completed by the KM / country>.

Sincerely,

Director QA/RA, Emergency Care and Resuscitation

URGENT – Field Safety Notice
Philips HeartStart MRx Monitor/Defibrillator

AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx Monitor/Defibrillators **Units Affected:** MRx units with a serial number within the following ranges: • Model M3535A: US00100100 to US00576623 • Model M3536A: US00100902 to US00576650 • Model M3536J: US00209838 to US00332675 • Model M3536M: US00500002 to US00553553 • Model M3536MC: US00500001 to US00500087 • Model M3536M2: US00554176, US00554177, US00554178 • Model M3536M4: US00500003 to US00574869 • Model M3536M5: US00500001 to US00562935 • Model M3536M6: US00554358 to US00576619
PROBLEM DESCRIPTION	**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 behavior. **These workflows do not correspond to instructions in the *MRx Instructions for Use* (IFU) and are not expected to be performed by trained clinicians.** In addition, these device behaviors have only been observed during internal testing, and have not been reported during clinical use. The workflows and associated device behaviors are as follows: **Workflow A:** When using external paddles for defibrillation, the MRx can deliver a shock when only one of the two shock buttons are depressed if the user performs the following sequence: 1. MRx in use with external paddles and turned on in Manual Defib mode 2. User presses and holds a single button on the external paddle “Apex” and turns the Therapy Knob to any other Clinical Mode (Monitor, Pacer, AED) 3. User releases the button being held on the external paddles 4. User turns the MRx back to any Manual Defib setting and presses charge 5. User inadvertently presses the button on the other external paddle “Sternum”. The MRx will deliver a shock with this single button press. The ability to shock with a single button press will continue until the device is shut off. *Note: Paddles Apex and Sternum can be interchanged to reproduce the issue.*

URGENT – Field Safety Notice
Philips HeartStart MRx Monitor/Defibrillator

PROBLEM DESCRIPTION (continued)

Workflow B: When using the Periodic Clinical Data Transmission (PCDT) option on the MRx, the MRx can reboot if the user performs the following sequence:

1. In Monitor mode with PCDT turned on and transmitting, the user switches from Monitor Mode to Manual Defib mode.
2. While the display is transitioning from Monitor mode to Manual Defib mode, the user presses the Sync button.
3. The MRx reboots, restarting in 6 to 8 seconds.

Issue 3:

The MRx could stop demand mode pacing due to an ECG leads-off condition when electrode-to-skin contact impedance values are outside design ranges for detection.

Note: Philips has previously improved the MRx's ability to maintain ECG monitoring in the presence of high skin contact impedance. However, these improvements are not available on devices with Revision B.06.XX software.

HAZARD INVOLVED

Issue 1:

If EFT interference occurs:

- The MRx shock function could disarm, causing a delay in defibrillation therapy.
- The MRx pacing function could pause, causing a delay in pacing therapy
- The MRx could deliver an inadvertent discharge when using switched internal paddles, causing an unintended shock to patient or users.

Note: If the MRx disarms unexpectedly due to this issue, the user can press the charge button to continue operation. Likewise, if the MRx pauses pacing due to this issue, the user can resume pacing to continue operation.

Issue 2:

Workflow	Hazard if specific workflow is followed
A	When using external paddles for defibrillation, the MRx can deliver an inadvertent shock when only one of the two shock buttons are depressed, potentially causing an unintended shock to patient or users.
B	When using the PCDT option on the MRx, the MRx can reboot. If a patient is in need of emergent cardioversion, the reboot could potentially lead to a delay in therapy.

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.

URGENT – Field Safety Notice
Philips HeartStart MRx Monitor/Defibrillator

<table>
<tr><td>HOW TO IDENTIFY AFFECTED PRODUCTS</td><td>Philips HeartStart MRx Monitors/Defibrillators identified above are affected by one or more of these issues.

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.</td></tr>
<tr><td>ACTION TO BE TAKEN BY CUSTOMER / USER</td><td>You can continue to use your MRx prior to receiving the software upgrade, provided that you follow the guidance provided below.

Issue 1:
If interference were to occur:

• Users could experience the symptoms described below, and can take the listed actions to resume operation. (Note: these symptoms can occur for other clinical reasons unrelated to electrical interference.)

<table>
<tr><th>Symptom</th><th>Action to resume operation</th></tr>
<tr><td>When charged, the MRx disarms unexpectedly, and displays a “Defib Disarmed” message and audio tone.</td><td>To recharge the device, press the Charge button.</td></tr>
<tr><td>When pacing, the MRx displays a “Pacing Stopped” message, displays a “Pads Off” or “Pads Cable Off” message, and enunciates an alarm.</td><td>Check that the pads are applied correctly to the patient. Check cable connections. Press the “Resume Pacing” soft key to continue pacing.</td></tr>
</table>

• There is a potential for inadvertent discharge when using switched internal paddles. To mitigate the risk associated with this, users should ensure that, prior to charging the MRx, the internal paddles are correctly applied to the patient and the user is not touching the patient or paddle contacts.

Issue 2:

Ensure that users are aware that the two workflows described in the “Problem Description” section of this Field Safety Notice can lead to unexpected device behavior, and therefore should not be performed.</td></tr>
</table>

URGENT – Field Safety Notice
Philips HeartStart MRx Monitor/Defibrillator

ACTION TO BE TAKEN BY CUSTOMER / USER (continued)	**Issue 3:** The MRx will display the "Pacing Stopped. Leads Off" message when pacing has stopped due to detection of a leads-off condition or an ECG cable disconnection. (Note: this message can display for clinical reasons unrelated to the issue described in this Field Safety Notice.) If this message appears during demand mode pacing, users can choose either of the following options to resume pacing, if desired: • Troubleshoot the leads-off condition as described in the MRx Instructions for Use: "Check that the monitoring electrodes are applied properly to the patient. Check cable connections. Press the "Resume Pacing" soft key to continue pacing." • Change the pacing mode to "fixed" using the following steps: 1. With the therapy knob in the Pacer position, press the Menu Select button to activate the Main Menu. 2. Use the Navigation buttons to select ***Pacer Mode*** and press the Menu Select button to confirm. 3. Use the Navigation buttons to select ***Fixed***, and press the Menu Select button to confirm.
ACTIONS PLANNED BY PHILIPS	Philips is initiating a correction to affected devices. A software upgrade will be provided free of charge for all units affected by one or more of these issues. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the upgrade.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>