PHILIPS



# URGENT –Field Safety Notice
## Philips HeartStart MRx Monitor/Defibrillator Could Reboot

Dear Customer,

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.

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 softwareupgrade. We appreciate your patience as we work to schedule your upgrade.

This voluntary correctionhas 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 or the UK Philips Customer Care Service Centre on 0870 532 9741.

Sincerely,

John Pardo
Director QA/RA, Emergency Care and Resuscitation

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| **AFFECTED PRODUCTS** | **Product:** Philips HeartStart MRx Monitor/Defibrillators<br><br>**Units Affected:**MRx units with a serial number within the following ranges:<br><br>• Model M3535A: US00100100 to US00578696<br>• Model M3536A: US00100902 to US00576650<br>• Model M3536J: US00209838 to US00332675<br>• Model M3536M: US00500002 to US00553553<br>• Model M3536MC: US00500001 to US00500087<br>• Model M3536M2: US00554176, US00554177, US00554178<br>• Model M3536M4: US00500003 to US00574869<br>• Model M3536M5: US00500001 to US00562935<br>• Model M3536M6: US00554358 to US00576619 |
| **PROBLEM DESCRIPTION** | The MRx could reboot once in any operating modeif the following sequence occurs:<br><br>1. In Service Mode, the Status Log* is cleared<br>2. Prior to exiting Service Mode, the MRx generates an entry in the Status Log.<br>3. Service Mode is exited.<br><br>The MRx is then in a state that could trigger a reboot at an indeterminate time, potentially causing therapy to be interrupted or delayed.The MRx will restart within 8 seconds.<br><br>Note: If a reboot occurs during clinical use, current device settings and patient record are retained.<br><br>*The Status Log is a tool accessed by service personnel. It includes entries for all messages logged during normal operating mode, Automated tests, Service and Configuration Mode, and Operational Checks. The MRx Service Manual instructs service personnel to clear the status log after successful completion of an Operational Check. |
| **HAZARD INVOLVED** | Ifthe MRx reboots during the application of therapy or pacing, there is the potential for:<br>• Interrupted pacing<br>• A delay of defibrillation or cardioversion therapy |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | Philips HeartStart MRx Monitors/Defibrillators identified above are affected by this issue.<br><br>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 software upgrade.<br><br>If the MRx reboots during clinical use, continue to treat the patient according to your organization’s protocol, reinitiating therapy if necessary. |

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| **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 this issue.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 or the UK Philips Customer Care Service Centre on 0870 532 9741. |