URGENT - Medical Device Correction
Philips HeartStart MRx Defibrillator/Monitor
RFU Indicator shows undocumented pattern

Dear Customer,

Philips has identified an issue that could impact the performance of certain HeartStart MRx defibrillator/monitors. This issue is further detailed in the attached Field Safety Notice.

This Field Safety Notice is intended to inform you about:

- what the issues are and under what conditions they 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 also 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 an upgrade which will address the software issue described in the Field Safety Notice. This upgrade will be provided to customers free of charge. A Philips Healthcare representative will contact you to arrange for installation. We appreciate your patience as we work to schedule your upgrades.

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,

John Pardo
Director QA/RA, Emergency Care and Resuscitation

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AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx Defibrillator/Monitor **Units Affected**: MRx unit types with software versions F.03.06 (M3535A) and T.00.05 (M3536A) and earlier and the following part numbers:

PMS Number:	Part Number:
861288	M3535A
989803132391	M3535ATZ
861289	M3536A
989803132401	M3536ATZ
861314	M3536J
861464	M3536M
861481	M3536M2
861483	M3536M4
861484	M3536M5
861491	M3536M6
861465	M3536MC

PROBLEM DESCRIPTION

Through internal testing and customer complaint investigations, the following MRx software issue has been identified:

MRx model M3535A with software version F.03.06 and earlier, and model M3536A with version T.00.05 and earlier may stop the automated Ready-For-Use (RFU) test in an abnormal state when the device is turned off. If this occurs, the RFU indicator window displays a pattern (pictured below) that is not documented in the Instructions For Use or Service Manual.

If this pattern appears and the device is turned on, it will revert the RFU back to an hourglass, indication that it is fully functional in all monitoring and therapy modes. There is no clinical risk if the device that has displayed this RFU pattern is turned on and put into service.

A device experiencing this issue will continue to run automated RFU test hourly and report a 0x00C000A4 code in the Status Log summary (pictured below) each time:

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	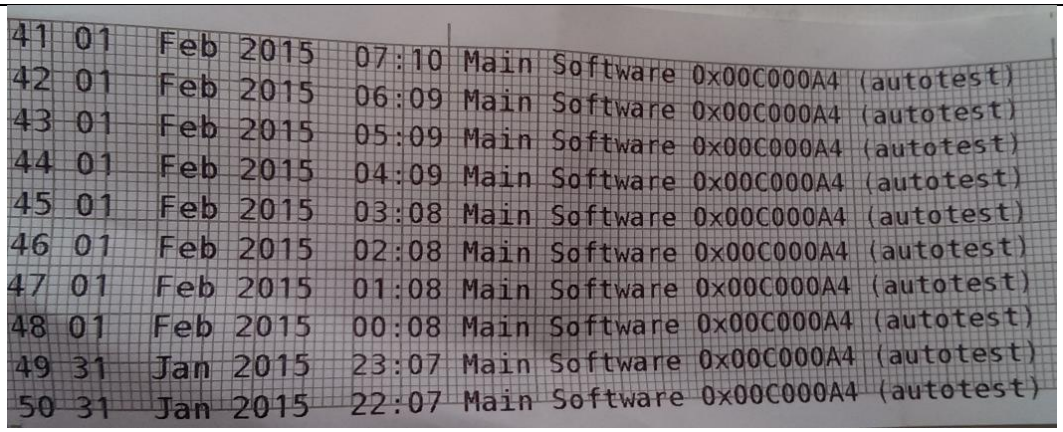 Note that while an MRx experiencing this issue will reliably report this code in the Status Log, existence of the C000A4 code in the Status Log does not necessarily mean that the device is experiencing this issue.
HAZARD INVOLVED	If the issue were to occur the user may unnecessarily remove the MRx from service. However, the performance of the device in use is unaffected by this issue.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Defibrillator/Monitors identified in the Affected Products section above are affected by this issue. The part number of the HeartStart MRx Defibrillator/Monitor is printed on the primary label on the bottom of the MRx  ← MRx part number To print detailed information on software versions, use the **Print Device Info** menu option. To print the device information: 1. Make sure a battery charged to 20% is in place, or that external power is connected. 2. Turn the Therapy Knob to **Monitor**.

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	3. Press the Menu Select button to access the Main menu. 4. From the Main menu, select **Other**. From the **Other** menu, select **Print Device Info**. Detailed information about the device is printed.
ACTION TO BE TAKEN BY CUSTOMER / USER	All MRx users should be informed that if the pattern appears, they can continue to use the device. Once the MRx is turned on, the pattern will disappear and the device will function normally in all monitoring and therapy modes.
ACTIONS PLANNED BY PHILIPS	Philips will provide a software upgrade – for M3535A (software version F.03.07 or higher) and M3536A (software version T.00.06 or higher) – to correct this issue. A software upgrade will be provided free of charge for all affected products. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the upgrades.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or call us at 1-800-722-9377.