URGENT – Field Safety Notice
Philips HeartStart MRx Monitor/Defibrillator
Incorrect internal software settings could pose a risk for patients

Dear Customer,

We have identified some MRx monitor/defibrillators that were shipped with incorrect internal software settings which could pose a risk for patients. Further details on this issue are 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 correction. A Philips Healthcare representative will contact you to make arrangements for the correction. We appreciate your patience as we work to schedule your service.

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,

[redacted]

Director QA/RA, Emergency Care and Resuscitation

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AFFECTED PRODUCTS

Product: Philips HeartStart MRx Monitor/Defibrillators

Units Affected: MRx units, models M3535A and M3536A, with the following serial numbers:

US00101159	US00533518
US00322848	US00533521 through US00535118
US00326834	US00539526
US00328432	US00540124
US00328439	US00543102
US00328442	US00543104
US00328443	US00543138
US00328446	US00543158
US00328450	US00543161
US00328461	US00543166
US00328464	US00543167
US00328465	US00543187
US00328468	US00543204
US00328473	US00543223
US00328478	US00543239
US00330393	US00546804

PROBLEM DESCRIPTION

The MRx could contain incorrect internal software settings, causing the following two issues:

1. The device will perform the weekly automated tests hourly, which could cause the therapy capacitors to degrade sooner than intended.

2. While connected to AC or DC power and with no battery installed or the battery installed has a charge level of less than 10%, the Ready for Use (RFU) indicator will not provide the expected low battery indication (flashing red X with audible chirp). Instead, the RFU will show a flashing black hourglass, indicating that sufficient battery power is available for device operation.

Note: Once the device is disconnected from AC or DC power, the RFU indicator provides the appropriate low battery indications. In addition, all other battery charge indicators continue to operate normally, including the on-screen battery fuel gauges, low battery messages, and low battery alarms. The LED charge level indicators on the batteries themselves also operate normally.

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HAZARD INVOLVED	1. There is no hazard if the device performs the weekly automated tests hourly. However, the MRx could indicate that service is required sooner than intended due to degradation of the therapy capacitor. 2. There is a potential for a delay in therapy due to insufficient battery power, since the user may not be alerted by the RFU indicator that no battery is installed or that a low battery condition exists prior to disconnecting from AC or DC power.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Monitors/Defibrillators identified above are affected by this 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.

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ACTION TO BE TAKEN BY CUSTOMER / USER	A Philips authorized service provider will service the device and ensure it is operating within specification. Prior to receiving service, you can continue to use your MRx provided that the following steps are followed. These steps will prevent further accelerated degradation of the therapy capacitor, and will eliminate the above described behavior for no/low battery conditions. To correct the problem, set the configuration of the MRx to "factory defaults" in configuration mode by performing the following steps: 1.) Turn the therapy knob to the On/Monitor position. 2.) Press the Menu Select button to activate the Main Menu. 3.) Use the Navigation buttons to select ***Other***, then select ***Configuration***. Press the Menu Select button again to ***Acknowledge***. 4.) Press the ***Change Configuration*** soft key. Use the Navigation buttons to enter the Configuration Password when prompted (387466), select ***Done, and*** press the Menu Select button. Press the ***Factory Defaults*** soft key, and finally the ***Save Changes*** soft key. 5.) If you use custom configurations, make any desired changes to the default configuration choices consistent with your protocols and press ***Save Changes*** again, then press the ***Exit Config*** soft key. 6.) For correcting multiple devices: Once you have reset one unit to the factory defaults and confirmed your desired configuration settings, you can then copy the configuration to a data card for import into your other devices. Importing this good configuration into an affected device will correct the problem. Note: Configuration settings can be printed before resetting to factory defaults. This will provide a record of any customized configuration parameters for reference. Print instructions are available in the "Printing Configuration Settings" section of IFU. **Confirmation that the configuration settings have been corrected:** Perform either of the following to confirm that each device has been corrected. • **If an AC or DC power source is available**, connect the power source and remove the batteries from the back of the MRx. If the RFU indicator flashes a red X and chirps, the problem has been corrected. • **If an AC or DC power source is not available**, view the Auto Test Summary (go to: Main menu, Other, Op Check, Auto Test Summary). If the first listed test is "Hourly", the problem has been corrected. Note: After correcting the problem by setting the configuration settings to factory default, it will typically take up to an hour with the MRx turned off and a battery installed for an Hourly test result to be posted to the Auto Test Summary.

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<table>
<tr><td>ACTION TO BE TAKEN BY CUSTOMER / USER (continued)</td><td>If the therapy capacitor degrades to a level where service may be required, the RFU indicator will show a solid red “x” with a periodic chirp. (Note: The RFU indicator can show this status for reasons other than the issue described in this Field Safety Notice.) If this occurs, follow the instructions in the MRx IFU to troubleshoot:
<table>
<tr><th>RFU Status</th><th>Meaning</th><th>Required Action</th></tr>
<tr><td>Solid red “X” and a periodic chirp</td><td>A failure has been detected that may prevent the delivery of a shock, pacing, or ECG acquisition.</td><td>Turn the Therapy Knob to Monitor. An inop message describing the failure is displayed. See Troubleshooting, for the corrective action. If needed, run an Operational Check for further information. If the condition persists, take the device out of use and call for service.</td></tr>
</table></td></tr>
<tr><td>ACTIONS PLANNED BY PHILIPS</td><td>Philips is initiating a correction to affected devices that will be provided to customers free of charge. The correction will consist of replacement of the therapy capacitor and reset of internal software settings. A Philips Healthcare representative will contact customers with affected devices to arrange for service.</td></tr>
<tr><td>FURTHER INFORMATION AND SUPPORT</td><td>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>.</td></tr>
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