URGENT – Field Safety Notice
Philips HeartStart MRx Monitor/Defibrillator
Two Issues with MRx Housing Could Pose Risk to Patients or Caregivers

Dear Customer,

We have identified two issues associated with the housing of the MRx Monitor/Defibrillator that could pose a risk to patients and/or caregivers.

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/users
- 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 hardware upgrade that will be provided to customers free of charge. A Philips Healthcare representative will contact you to arrange for installation of the hardware 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 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 **Units Affected:** MRx units meeting one or both of the conditions described in the "How to Identify Affected Products" section of this letter, **AND** with a serial number within the following ranges: • Model M3535A: US00100100 to US00552845 • Model M3536A: US00100902 to US00552848 • Model M3536M: US00500002 to US00501201 • Model M3536MC: US00500001 to US00500087 • Model M3536M4: US00500003, US00500004, US00552673, US00552678, US00552679 • Model M3536M5: US00500001 to US00552801 **Please note: Not every serial number within the listed ranges are affected by this Field Safety Notice. Please refer to the "How to Identify Affected Products" section for more information.**
PROBLEM DESCRIPTION	The MRx can be susceptible to one or both of the issues described below. 1. The CO2 Inlet Port associated with end-tidal carbon dioxide (EtCO2) monitoring on MRx Monitor/Defibrillators can be pushed into the MRx housing, making it inaccessible. This can occur if the user attempts to push the CO2 FilterLine fitting into the Inlet Port, instead of twisting it clockwise as described in the MRx Instructions for Use. 2. The handle can separate from the MRx housing due to breakage of mounts on the rear case.
HAZARD INVOLVED	1. If the CO2 Inlet Port can no longer be accessed, the user will be unable to initiate EtCO2 monitoring when needed. 2. Separation of the handle from the MRx housing can cause the MRx to fall, potentially injuring the patient or user. In addition, a delay of therapy could occur if the device is damaged by the impact.

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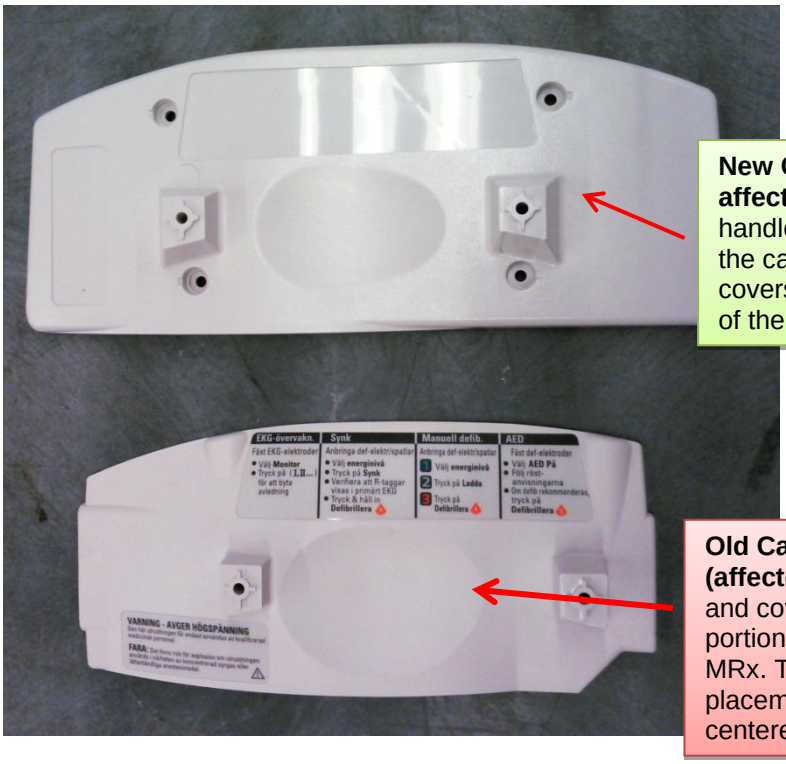
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Monitors/Defibrillators (1) within the identified serial number range **AND** (2) meeting one or both of the conditions below are affected by the issue. **Condition #1: Device has EtCO2 Option** Devices with the EtCO2 option are affected. To determine if an MRx has the EtCO2 option, press the Menu Select button to open the Main Menu. Use the Navigation and Menu Select buttons to select **Other**, followed by **Print Device Info**. Devices with EtCO2 option have 'etCO2' printed under 'Options' on the printed strip. **Condition #2: Device has Old Cap Plate** Devices with the old cap plate, shown below, are affected. Devices with a paddle tray or the new cap plate are not affected.  **New Cap Plate (NOT affected)** positions the handle in the middle of the cap plate and covers the entire top of the MRx. **Old Cap Plate (affected)** is shorter and covers only a portion of the top of the MRx. The handle placement is off-centered on cap plate.

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ACTION TO BE TAKEN BY CUSTOMER / USER	You can continue to use your MRx prior to receiving the hardware upgrade provided that you follow the steps provided below. 1. The CO2 FilterLine fitting should not be forced into the CO2 Inlet Port. Rather, after inserting the FilterLine fitting into the port, the fitting should be turned clockwise to secure into place, per the MRx Instructions for Use. If the Inlet Port becomes inaccessible during use, continue to treat the patient according to your organization's protocol. 2. If one or both sides of the handle are found to have separated from the MRx housing, continue to treat your patient per existing protocols. Do not use the handle to carry the MRx. The MRx can be carried in another manner. For example, the MRx shoulder strap or bed rail hook can be used if available on the unit.
ACTIONS PLANNED BY PHILIPS	Philips is initiating a correction to affected devices. A hardware 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.