PHILIPS

URGENT - Medical Device Correction
Philips HeartStart MRx Monitor/Defibrillator
Leads ECG Cable Connection Could Experience Accelerated Wear

Dear Customer,

This letter is to inform you of a product correction initiated by Philips Healthcare due to an issue that could occur with the Philips HeartStart MRx Monitor/Defibrillator. Under certain conditions, Leads ECG signals on the HeartStart MRx Monitor/Defibrillator could experience accelerate wear.

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.

When used in hospital transport and pre-hospital (EMS) environments the MRx leads ECG connector block port / trunk cable connection could experience accelerated wear.

Please see the attached Field Safety Notice that provides 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.

To correct this issue, 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 as expeditiously as possible.

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 call us at <Philips representative contact details to be completed by the KM / country>.

Sincerely,

Director QA/RA, Emergency Care and Resuscitation

URGENT - Medical Device Correction
Philips HeartStart MRx Monitor/Defibrillator
Leads ECG Cable Connection Could Experience Accelerated Wear

AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx Monitor/Defibrillator, model numbers M3535A, M3536A, M3536J, M3536M, M3536M5, and M3536MC **Units Affected:** Serial numbers within the range US00100100 - US00550668 Please note: Not every serial number within the listed range is affected by this Medical Device Correction. If you have questions about whether your MRx is affected by this issue, please contact Philips at <Philips representative contact details to be completed by the KM / country>.
PROBLEM DESCRIPTION	The ECG trunk cable and connector block of the MRx could be susceptible to accelerated wear, which could result in an interrupted ECG signal. Interruption of the ECG signal can cause: • Loss of demand mode pacing • Inability to perform synchronized cardioversion with paddles • Disruption of leads ECG monitoring, which could delay appropriate treatment Defibrillation, fixed mode pacing, ECG monitoring via pads/paddles, and other monitoring functions are not impacted by this issue.
HAZARD INVOLVED	When monitoring via leads ECG, there is a potential for: • Loss of demand mode pacing • Inability to perform synchronized cardioversion with paddles • Disruption of ECG monitoring
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Monitors/Defibrillators identified above are affected by the issue. The model and serial number of your HeartStart MRx Monitor/Defibrillator are printed on the primary label on the back of the MRx in battery bay B.

URGENT - Medical Device Correction
Philips HeartStart MRx Monitor/Defibrillator
Leads ECG Cable Connection Could Experience Accelerated Wear

ACTION TO BE TAKEN BY CUSTOMER / USER	You can continue to use your MRx prior to receiving the hardware upgrade, while remaining aware that if the problem were to occur you could experience the following symptoms: • Loss of demand mode pacing • Inability to perform synchronized cardioversion with paddles • Disruption of ECG monitoring or INOP messages If the problem occurs refer to the HeartStart MRx Instructions For Use for troubleshooting assistance. In addition, the following actions can be taken: • **If demand mode pacing is not available,** fixed mode pacing can be used. Change the pacing mode to “fixed” in the Pacer Mode menu. • **If Synchronized cardioversion with paddles is not available,** Sync cardioversion with pads can be used. Switch to pads. • **If leads ECG monitoring is not available,** ECG monitoring via pads/paddles is available. Connect the pads or paddles cable and press the lead select button until the pads or paddles ECG waveform is displayed. • **Connect a spare ECG trunk cable, if available.** Important Note: Defibrillation, fixed mode pacing, ECG monitoring via pads/paddles, and other monitoring functions are not impacted by this issue.
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 hardware upgrade.
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 <Philips representative contact details to be completed by the KM / country>.

PHILIPS

URGENT - Medical Device Correction
Philips HeartStart MRx Monitor/Defibrillator
Leads ECG Cable Connection Could Experience Accelerated Wear

Dear Customer,

This letter is to inform you of a product correction initiated by Philips Healthcare due to an issue that could occur with the Philips HeartStart MRx Monitor/Defibrillator. Under certain conditions, Leads ECG signals on the HeartStart MRx Monitor/Defibrillator could experience accelerate wear.

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.

When used in hospital transport and pre-hospital (EMS) environments the MRx leads ECG connector block port / trunk cable connection could experience accelerated wear.

Please see the attached Field Safety Notice that provides 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.

It is imperative that all end-users with affected MRx monitor/defibrillators as identified in the “AFFECTED PRODUCTS” section of the FSN, receive this Device Correction Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, send a copy of the attached package to any customer to whom you have distributed one of the affected devices. Be sure to include the:

- Customer Letter
- Field Safety Notice

Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the “Ship To” field on the original invoice).

In addition please provide your local Philips organization with the names and addresses of the customers to who you have sold affected devices, so that arrangements can be made to provide the correction.

URGENT - Medical Device Correction
Philips HeartStart MRx Monitor/Defibrillator
Leads ECG Cable Connection Could Experience Accelerated Wear

If you need any further information or support concerning this issue, please contact your local Philips representative at <Philips representative contact details to be completed by the KM / country>.

Sincerely,

Director QA/RA, Emergency Care and Resuscitation