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.

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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,

John Pardo
Director QA/RA, Emergency Care and Resuscitation