PHILIPS

URGENT – Medical Device Removal
Two HeartStart MRx Monitor/Defibrillators may not have been included in prior field actions

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

Philips has identified two HeartStart MRx Monitor/Defibrillator devices, with serial numbers US00539461 and US00539462, may not have been included in previous field actions. Philips is removing these devices rather than performing any corrections that were not previously completed.

The purpose of this notification is to:

- Describes the problem and actions that you should take to mitigate risk to patients.
- The actions planned by Philips to correct the problem.

This document contains important information for the removal of the identified devices.

Please review the following information with all members of your staff who should be aware of the contents of this communication.

The following pages 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.

If you have questions regarding this notification or need any further information or support, please contact your local Philips representative or call us at 1-800-722-9377.

Sincerely,

[redacted]

Greg Ayers, MD, PhD, FACC, FHRS
Head of Post Market Surveillance
Associate Chief Medical Officer
Monitoring & Analytics and Therapeutic Care

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AFFECTED PRODUCTS	**Product:** HeartStart MRx Monitor/Defibrillators with model number M3535A and serial numbers [redacted] and [redacted]
HOW TO IDENTIFY AFFECTED PRODUCTS	The model of the HeartStart MRx Monitor/Defibrillator is printed on the primary label on the back of the MRx in battery bay B. 
HAZARD INVOLVED	These devices were not included in the list of distributed devices that Philips used to send notices of medical device corrections. As a result, the defibrillators may not have had a number of corrections, applicable to these devices, performed on them.
ACTION TO BE TAKEN BY CUSTOMER / USER	Upon receipt of this notification, promptly locate the MRx devices M3535A with the serial numbers [redacted] and [redacted], remove them from clinical use and quarantine these two devices in a secure location.
ACTIONS PLANNED BY PHILIPS	A Philips representative will contact you to arrange for the removal of the affected HeartStart MRx devices and return them to the factory.
FURTHER INFORMATION AND SUPPORT	If you need further information or support concerning this notification, please contact your local Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number). Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax.