

URGENT - Medical Device Removal HeartStart MRx Monitor/Defibrillators

**HeartStart MRx Monitor/Defibrillators may
not have been included in prior field actions**

Dear Valued HeartStart MRx Customer,

Philips has determined that there are certain HeartStart MRx Monitor/Defibrillator devices, including devices that may have originally shipped to your facility, that may have been erroneously excluded from previous field actions. As a result, the defibrillators may not have received a number of required corrections. Philips is notifying customers of the Serial Numbers affected (please see Appendix A) to recommend that these devices be removed from service immediately for further evaluation.

The purpose of this notification is to:

- Describe the problem and actions that you should take to mitigate risk to patients.
- Describe 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 via telephone number: +31 (0)40 7001210

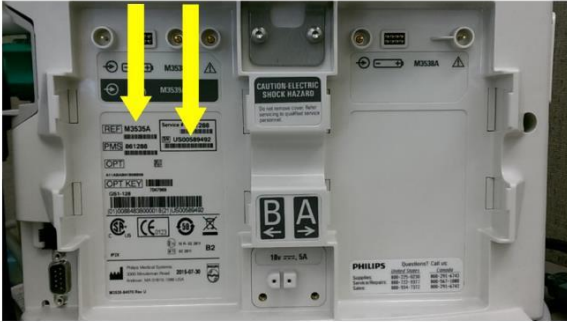
Sincerely,

.....

URGENT - Medical Device Removal HeartStart MRx Monitor/Defibrillators

**HeartStart MRx Monitor/Defibrillators may
not have been included in prior field actions**

Director, Quality, Emergency Care and Resuscitation

<p>AFFECTED PRODUCTS</p>	<p>HeartStart MRx Monitor/Defibrillators with model numbers M3535A, M3536A, and M3536M. The affected devices are listed on page 3, Appendix A, of this notification.</p> <p>Affected Countries: China, Republic of Korea, Netherlands, Norway, United Kingdom and United States.</p>
<p>PROBLEM DESCRIPTION</p>	<p>Philips has identified HeartStart MRx Monitor / Defibrillator devices that were erroneously excluded from previous field actions.</p>
<p>HAZARD INVOLVED</p>	<p>The identified devices were not included in Philips' list of distributed devices that Philips uses to send notices of medical device corrections. As a result, the defibrillators may not have received a number of required corrections.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>The model and serial number of a HeartStart MRx Monitor/Defibrillator is printed on the primary label on the back of the MRx in battery bay B.</p> <div style="text-align: center;">  </div>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>Upon receipt of this notification, promptly locate the affected MRx M3535A, M3536A, and M3536M devices listed on page 3, Appendix A, of this notification and remove them from clinical use immediately.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>A Philips representative will contact you to arrange removal of the affected devices for evaluation.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need further information or support concerning this notification, please contact your local Philips representative via telephone number: +31 (0)40 7001210</p>

URGENT - Medical Device Removal HeartStart MRx Monitor/Defibrillators

HeartStart MRx Monitor/Defibrillators may
not have been included in prior field actions

Appendix A

AFFECTED PRODUCTS	<p>Our records indicate that Philips shipped the following affected devices to your facility:</p> <table border="1" data-bbox="532 737 1065 867"><thead><tr><th>Model Number</th><th>Serial Number</th></tr></thead><tbody><tr><td>M3536A</td><td>US00320726</td></tr><tr><td>M3536A</td><td>US00320747</td></tr></tbody></table>	Model Number	Serial Number	M3536A	US00320726	M3536A	US00320747
Model Number	Serial Number						
M3536A	US00320726						
M3536A	US00320747						