Philips Healthcare

Field Safety Notice

Philips Healthcare

Therapeutic Care

FSN86100119A

January 2013

URGENT - Medical Device Recall
Philips HeartStart XL+ Defibrillator/Monitor

Device May Become Locked Out of Clinical Use

Dear Customer,

A problem has been detected in the Philips HeartStart XL+ Defibrillator/Monitor that, if it were to occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

If the Philips HeartStart XL+ Defibrillator/Monitor is first powered on and then there is disconnection or an interruption in AC power, the device may be locked out of clinical mode until the user enters the service mode password and performs an Operational Check.

Please see the attached Field Safety Notice that provides information on how to identify affected devices and instructions on actions to be taken. Please follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice.

The source of the problem has been identified and addressed in new production. To correct this issue Philips will provide a software upgrade to customers with affected units free of charge.

If you need any further information or support concerning this issue, please contact your local Philips representative:

< Bitte Kontaktinformationen ergänzen>

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Vernon Trimble,
Sr. Director QA/RA, Patient Care and Clinical Informatics, Therapeutic Care

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 Instruction for Use.
### AFFECTED PRODUCTS

<table>
<thead>
<tr>
<th>Product: Philips HeartStart XL+ Defibrillator/Monitor, model number 861290.</th>
<th>Units Affected: Units manufactured by Philips from October, 2011 to January 2013, and shipped worldwide with serial numbers within the ranges below:</th>
</tr>
</thead>
<tbody>
<tr>
<td>USO1100100 – USO1100372</td>
<td>US61201722 – US61201924</td>
</tr>
<tr>
<td>USN1100376 – USN1100960</td>
<td>US71201925 – US71202048</td>
</tr>
<tr>
<td>USD1100961 – USD1101095</td>
<td>US81202049 – US81202168</td>
</tr>
<tr>
<td>US21201187 – US21201239</td>
<td>USO1202515 – USO1202990</td>
</tr>
<tr>
<td>US31201240 – US31201537</td>
<td>USN1202991 – USN1203537</td>
</tr>
<tr>
<td>US41201538 – US41201585</td>
<td>USD1203538 – USD1203968</td>
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</tbody>
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**Manufactured and Distributed by:** Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.

### PROBLEM DESCRIPTION

The Philips HeartStart XL+ Defibrillator/Monitor may fail to power on in clinical mode and instead, power on in service mode displaying an “Equipment Disabled: Therapy” prompt, requiring the user to enter a password and perform an Operational Check to clear the condition. The device will not return to clinical mode until an Operational Check is performed.

### HAZARD INVOLVED

A delay in therapy may occur if the Philips HeartStart XL+ Defibrillator/Monitor is locked out of clinical mode until the user enters the service mode password and performs an Operational Check.

### HOW TO IDENTIFY AFFECTED PRODUCTS

Philips HeartStart XL+ Defibrillator/Monitors with the serial numbers identified above are affected by the issue. To identify an affected unit, locate the serial number on the bottom of the Philips HeartStart XL+ Defibrillator/Monitor.

### ACTION TO BE TAKEN BY CUSTOMER / USER

Until your device is repaired, you may continue to use it by following any one of these three conditions (1, 2, or 3)

1. When turning the Philips HeartStart XL+ Defibrillator/Monitor on, wait for a clinical mode screen to appear before removing AC power

   ![Example of a clinical mode screen](image)

2. Remove AC power before turning the Philips HeartStart XL+ on

3. Do not disconnect the HeartStart XL+ Defibrillator/Monitor from AC power when in clinical use

A Philips Healthcare representative will contact you regarding repair of your device once the software is available.
### ACTIONS PLANNED BY PHILIPS

Philips is voluntarily initiating a correction to affected devices. Philips considers this correction to be required for all affected units and will perform the upgrade free of charge. A Philips Healthcare representative will contact customers with devices on the Units Affected List to arrange for a software upgrade. A Philips Healthcare representative will contact you regarding repair of your device once the software is available.

### FURTHER INFORMATION AND SUPPORT

If you need any further information or support concerning this issue, please contact

< Bitte Kontaktinformationen ergänzen>