PHILIPS



# URGENT – Medical Device Correction
# Philips HeartStart XL+ Defibrillator/Monitor may fail to turn on or may unexpectedly attempt to restart

<Hospital/Clinic Name>
cc: Chairman Medical Board and relevant Head of Departments
Dear Customer,

Philips has identified that the HeartStart XL+ Defibrillator/Monitor (Model number 861290) may fail to turn on or unexpectedly attempt to restart, rendering it unable to return to a ready for use state. Although the device indicates to the user that it is not ready for use, a failed restart may result in a delay in therapy if the defibrillator/monitor is needed for immediate use. This device behavior may be caused in some cases by a defect in the HeartStart's memory management software and in other cases by a malfunction of the System On Module (SOM) installed on the Processor printed circuit assembly (PCA). Since 2011, two complaints attributed to these issues on the HeartStart XL+ have involved a patient death.

As a remedy, Philips will perform a system software upgrade and replace the Processor PCA that contains the SOM module that is subject to failure. Until the required parts are available and this service is performed, please inform all users that any XL+ that is observed to reboot itself or fail to start should be removed from service, regardless of whether it is subsequently restarted successfully.

The purpose of this notification is to:

- Describe actions that you should take to mitigate risk to patients
- Recommend that units be removed from service if they exhibit these symptoms
- Describe 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 should be aware of the contents of this communication.

Please retain a copy with the equipment Instructions for Use.

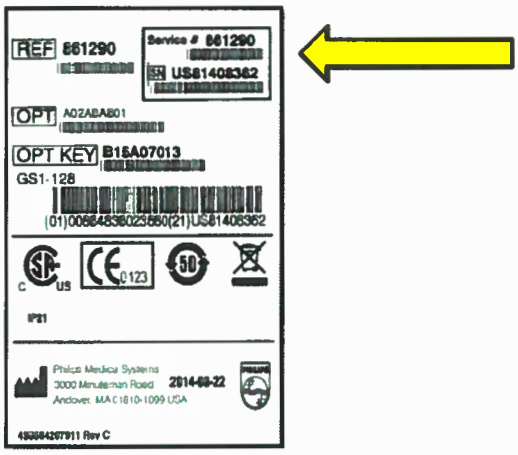
Follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice until your HeartStart XL+ has been repaired.

If you have questions regarding this notification or need any further information or support, please contact your local Philips representative. <Philips representative contact details to be completed by the KM / country> Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

[redacted]

Thomas J Fallon
Senior Director QA/RA, Emergency Care and Resuscitation

# URGENT – Medical Device Correction
# Philips HeartStart XL+ Defibrillator/Monitor may fail to turn on or may unexpectedly attempt to restart

| | |
|---|---|
| **AFFECTED PRODUCTS** | All Philips HeartStart XL+ Defibrillator/Monitor (Model number 861290)<br><br>Unit Affected: World Wide except United States and Canada |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | The model of the HeartStart XL+ Defibrillator/Monitor is printed on the primary label on the back of the device.<br><br>  |
| **BEHAVIOR DESCRIPTION** | The HeartStart XL+ Defibrillator/Monitor may fail to turn on or unexpectedly attempt to restart, rendering it unable to return to a ready for use state. Additionally, this issue may occur when the device is in standby mode, when attempting to power on to run a self-test. If this occurs, the device will indicate that it is not ready for use. |
| **HAZARD INVOLVED** | These device behaviors could result in a delay of therapy being delivered to a patient if the defibrillator/monitor is needed for immediate use.<br><br>Since 2011, Philips has received approximately 588 complaints that have been attributed to this issue on the HeartStart XL+; 2 of these complaints involved a patient death. |

## URGENT – Medical Device Correction
## Philips HeartStart XL+ Defibrillator/Monitor may fail to turn on or may unexpectedly attempt to restart

| | |
|---|---|
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | The device is safe to use and can remain in service if it does not exhibit any of these behaviors described in this notice.<br><br>If you identify a device that exhibit these behaviors, please remove the device from service and contact Philips to request service.<br><br>To acknowledge receipt of this notification, please complete and fax the Customer Reply Form to: <Philips representative contact details to be completed by the KM / country> Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number). |
| **ACTIONS PLANNED BY PHILIPS** | Philips will contact you to arrange for repair of your unit once parts are available. Philips will install a replacement SOM module and perform a software upgrade for the affected devices at no charge to the customer.<br><br>Philips will contact you when the parts are available. |
| **FURTHER INFORMATION AND SUPPORT** | If you need further information or support concerning this notification, please contact your local Philips representative. <Philips representative contact details to be completed by the KM / country><br>Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number). |

**URGENT – Medical Device Correction**
**Philips HeartStart XL+ Defibrillator/Monitor may fail to turn on or may unexpectedly attempt to restart**

## Customer Reply for FSN86100203A

| | |
|---|---|
| Customer ID: | |
| Contact Name: | |
| Telephone Number: | |
| Email Address: | |
| Facility Name: | |
| Street Address | |
| City, State, Postal Code: | |
| Country: | |

***Please E-mail or Fax this completed form to Philips.***

☐ I certify that our facility received, read and understand the Medical Device Correction document FSN86100203A.

Signature: _____ Date: _____ __

Please email the completed reply form to Philips.

If you are unable to carry out the instructions contained in this communication, please contact your local Philips representative. Healthcare Representative /Modality Engineer: 1800__744__5477 or (Overseas Number).