

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

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.

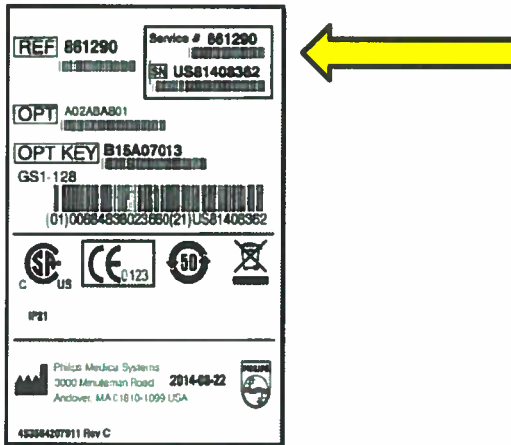
If you have questions regarding this notification or need any further information or support, please contact your local Philips representative. <Philips representative contact details to be completed by the KM / country>

Sincerely,



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

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AFFECTED PRODUCTS	All Philips HeartStart XL+ Defibrillator/Monitor (Model number 861290) 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.  The image shows a rectangular label with the following text and markings: 'REF 861290', 'Service # 861290', 'US81408362', 'OPT A02ABA801', 'OPT KEY B15A07013', 'GS1-128', a barcode, '(01)00884636023660(21)US81408362', regulatory marks (US, CE, 50, IP21), 'Philips Medical Systems', '3000 MinuteMan Road', 'Andover, MA 01810-1099 USA', '2014-08-22', and '453084207911 Rev C'.
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. 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.

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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. If you identify a device that exhibit these behaviors, please remove the device from service and contact Philips to request service. 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>
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. 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>



Philips Healthcare

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FSN86100203A, FCO86100206A
October 2019

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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 the number or email address provided below.

☐ 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 representative contact details to be completed by the KM / country>.

If you are unable to carry out the instructions contained in this communication, please contact your local Philips representative.