PHILIPS

URGENT – Medical Device Correction
HeartStart XL+ Defibrillator/Monitor (Model number 861290)

Dear Customer,

Philips has identified that the HeartStart XL+ Defibrillator/Monitor (Model number 861290) rotary therapy selector switch may fail, resulting in unpredictable device behaviour. These behaviours include:

- The device may not turn on
- The device may not perform the selected function
- The device may deliver a shock with an energy level different than the setting selected by the user

Should one of these behaviours occur, appropriate therapy delivery may be delayed. To date, Philips has not received any reports of deaths resulting from this switch failure.

As a remedy, Philips will install a replacement switch in affected devices at no charge to the customer.

The purpose of this notification is to:

- Describe actions that you should take to mitigate risk to patients
- Recommend that unit 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.

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,

Gregory M Ayers, MD, PhD
Head of Post Market Surveillance
Associate Chief Medical Officer
Monitoring & Analytics and Therapeutic Care

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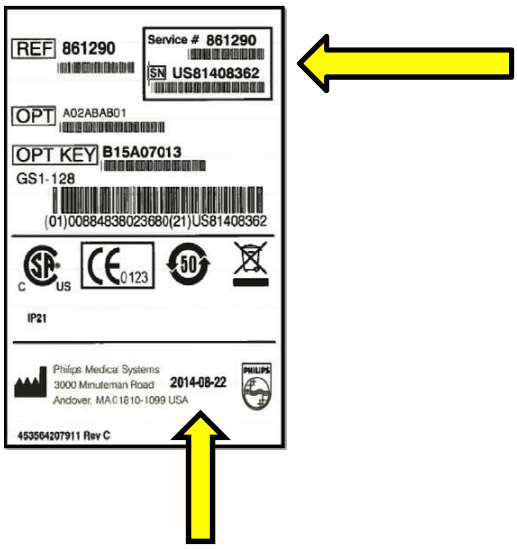
AFFECTED PRODUCTS	All Philips HeartStart XL+ Defibrillator/Monitor (Model number 861290) manufactured prior to 1 May 2017
HOW TO IDENTIFY AFFECTED PRODUCTS	The model number of the Philips HeartStart XL+ is printed on the primary label on the bottom of the device  The date of manufacture of the Philips HeartStart XL is printed on the primary label on the bottom of the device
BEHAVIOUR DESCRIPTION	The Philips HeartStart XL Defibrillator/Monitor rotary therapy selector switch may fail, resulting in unexpected device behaviour. These behaviours include: • The device may not turn on • The device may not perform the selected function • The device may deliver a shock with an energy level different from the setting selected by the user
HAZARD INVOLVED	These device behaviours could result in a delay in therapy or failure to deliver the intended therapy. Philips has not received any reports of patient deaths associated with this failure of an HeartStart XL Monitor/Defibrillator.

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ACTION TO BE TAKEN BY CUSTOMER / USER	The device can continue to be used if it does not exhibit any of these behaviors described in this Notice. Continue to perform Shift Checks and Operational checks as recommended in the Instructions for Use (IFU) as this reduces the risk of a failure during use. If you have a defibrillator other than the target device, you could consider using it as a backup. Each customer must determine the best approach for their institution. If you identify a device that exhibit any of these behaviors, please remove it from service and contact Philips to request service.
ACTIONS PLANNED BY PHILIPS	Philips will contact you to arrange for repair of your unit once parts are available. Philips will install a replacement switch in affected devices at no charge to the customer.
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>.

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Customer Reply for FSN86100208A

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

Please E-mail this completed form to the email address provided below.

☐ I certify that our facility received, read and understand the Medical Device Correction document FSN86100208A.

Signature: _____ Date: _____

Please email the completed reply form <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.