URGENT – Medical Device Recall
HeartStart XL Defibrillator/Monitor (Model number M4735A)

Rotary therapy selector switch may fail

Dear Valued HeartStart XL Customer,

Philips has identified that the HeartStart XL Defibrillator/Monitor (Model number M4735A) rotary therapy selector switch (Energy Select Knob) may fail, resulting in unexpected device behavior. These behaviors 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 behaviors occur, appropriate therapy delivery may be delayed.

The purpose of this notification is to:

- Describe actions that you should take to mitigate risk to patients
- Inform you that any unit that exhibits these symptoms should be removed from service
- Remind you to remove all other HeartStart XL Defibrillator/Monitors from service as soon as practicable, since it has reached its end of life

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.

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.

In February 2013, Philips announced its intention to discontinue the HeartStart XL; XL devices were discontinued in December 2013. Service and availability of service parts for the HeartStart XL ended in December 2018. The only XL accessory that is still available from Philips is the battery (M3516A), which is being discontinued as of March 31, 2020. As Philips is not able to service your units to resolve this component issue, you should retire your units as soon as practically possible, consistent with the needs of your patients.

If you have questions regarding this notification or need any further information or support, please contact your local Philips representative: **0800 80 3000**

Sincerely,

Tanya DeSchmidt
Director, Quality, Emergency Care and Resuscitation

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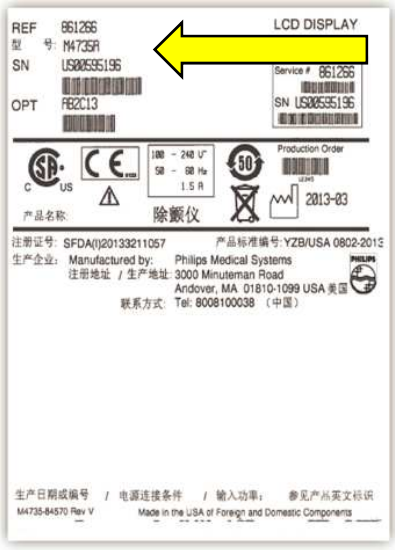
AFFECTED PRODUCTS	**Product:** Philips HeartStart XL Defibrillator/Monitor (Model number M4735A): **Units Affected:** Worldwide
BEHAVIOR DESCRIPTION	The Philips HeartStart XL Defibrillator/Monitor rotary therapy selector switch (Energy Select Knob) may fail, resulting in unexpected device behavior. These behaviors 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 behaviors could result in a delay in therapy or failure to deliver the intended therapy. There have been three reported patient deaths potentially associated with the failure of the HeartStart XL Monitor/Defibrillator rotary therapy selector switch (Energy Select Knob).
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 

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ACTION TO BE TAKEN BY CUSTOMER / USER	As the HeartStart XL Defibrillator/Monitor has been discontinued and has reached its end of life, therefore you should replace and retire your units as soon as practically possible, consistent with the needs of your patients. Continue to perform Shift Checks and Operational checks as recommended in the Instructions for Use (IFU) as this reduces the risk of a failure until your units are safely retired. If you identify a device that exhibit any of the behaviors described above or fails shift or operational checks, immediately remove it from service. **To acknowledge receipt of this notification, please complete and mail the Customer Reply Form to: customercare.ch@philips.com**
ACTIONS PLANNED BY PHILIPS	Philips intends to take no further action beyond this notification and its direction to retire the XL as soon as practically possible: the XL is beyond its support life and is no longer serviceable.
FURTHER INFORMATION AND SUPPORT	If you need further information or support concerning this notification, please contact your local Philips representative: **0800 80 3000**

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Customer Reply for FSN86100213A

Please complete, sign, and return this form at your earliest convenience.

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

I certify that our facility received, read and understand the Field Safety Notification FSN86100213A.

Signature: _____ Date: _____

Please select one method below to return your completed form at your earliest convenience.

Email completed and signed form to **customercare.ch@philips.com**