PHILIPS

URGENT - Medical Device Correction
Philips HeartStart XL+ Defibrillator/Monitor
Hardware and Software Issues

Dear Customer,

Philips has identified several issues that could impact the safety and/or performance of certain HeartStart XL+ defibrillator/monitors. These issues are further detailed in the attached Field Safety Notice.

This Field Safety Notice is intended to inform you about:

- what the issues are and under what conditions they can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- 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 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 Instructions for Use.

Please see the following pages, which also 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.

Philips is initiating an upgrade which will address the software and hardware issues described in the Field Safety Notice. This upgrade will be provided to customers free of charge. A Philips Healthcare representative will contact you to arrange for installation. We appreciate your patience as we work to schedule your upgrades.

This voluntary correction has been reported to the appropriate regulatory agencies.

Philips sincerely apologizes for any inconvenience this may cause you. 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,

John Pardo
Director QA/RA, Emergency Care and Resuscitation

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AFFECTED PRODUCTS	**Product:** Philips HeartStart XL+ Defibrillator/Monitor **Units Affected**: XL+ units with a serial number within the following ranges: • USO1100100 to USD1101095 • US11201096 to USD1203968 • US11303969 to USD1309471 • US11409472 to US61414022
PROBLEM DESCRIPTION	**Through internal testing and customer complaint investigations, the following XL+ software and hardware issues have been identified:** **Software:** • The XL+ may fail to complete the power on sequence and continuously reboot. • The XL+ may either fail to power up or may shut down unexpectedly. • The XL+ may have a software version that did not reset a fail-safe monitoring component which could delay of therapy or pacing interruption. • The XL+ may fail to generate verbal prompts in AED mode. **Hardware:** • The XL+ may have been manufactured with a speaker that may fail. • The battery may not seat properly causing the XL+ to shut down unexpectedly or remain powered on and not acknowledge or charge the battery. • The XL+ exceeds the allowable radiated emissions level for Class B CISPR11. • The XL+ ECG signal from leads could be lost and unrecoverable. • The XL+ SpO2 signal may lose communication and cause the device to reboot. • The XL+ battery detection system may be disrupted and cause a false low battery alarm.
HAZARD INVOLVED	**Associated with Software:** • If the XL+ continuous reboot occurs, therapy could be delayed until there is sufficient space reclaimed in the file system and the reboot stops. • If the XL+ software error occurs and the XL+ fails to power up or shuts down unexpectedly, therapy could be delayed or not delivered. • Software upgrades B.00.02 or earlier can interfere with the reset of a fail-safe monitoring component and the device might be unable to deliver therapy, start pacing or continue pacing. • If the XL+ loses audible voice prompts, the user will not receive direction in AED mode and may be unable to provide defibrillation. **Associated with Hardware:** **XL+ speaker:** • If the XL+ speaker housing shorts to ground during use there could be a delay in therapy if the speaker is unable to provide audible voice prompts and alarms.

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	XL+ battery: • If the XL+ shuts down unexpectedly, or remains on without acknowledging and charging the battery therapy could be delayed or pacing could be interrupted. **XL+ radiated emissions:** • Radiated emissions from the XL+ may exceed allowable limits and impact/impair other medical devices in the vicinity with insufficient immunity, potentially causing them to fail. **XL+ ECG lost signal:** • Loss of the ECG signal could cause an ECG leads off alarm that may result in the inability to monitor ECG or interrupts or delays demand mode pacing and sync cardioversion. **XL+ SpO2 communication loss and reboot:** • When the XL+ is connected to AC power and exposed to Electrical Fast Transients (EFT), the SpO2 communication my fail and causes the device to reboot and interrupt pacing or delay therapy. **XL+ battery detection:** • When the XL+ is connected to AC power and exposed to Electrical Fast Transients (EFT), the battery detection system can be disrupted and cause a false latching low battery alarm condition. The XL+ therapy and monitoring functionality are unaffected and the XL+ will continue to operate until the condition is cleared.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart XL+ Defibrillator/Monitors identified in the Affected Products section above are affected by these issues. The serial number of the HeartStart XL+ Defibrillator/Monitor is printed on the primary label on the bottom of the XL+.  ← XL+ serial number

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ACTION TO BE TAKEN BY CUSTOMER / USER	Philips is initiating a correction to affected devices. An upgrade consisting of both software and hardware will be scheduled to address this issue. In the interim, Philips recommends that a backup defibrillator be made available for immediate use by your facility. Pending the completion of the correction, the affected device should not be used for clinical purposes.
ACTIONS PLANNED BY PHILIPS	An upgrade consisting of both software and hardware will be provided free of charge for all units affected by these issues. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the upgrades.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or call us at 1-800-722-9377.