# 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 need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

Sincerely,

John Pardo
Director QA/RA, Emergency Care and Resuscitation

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

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

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

| | |
|---|---|
| | **XL+ battery:**<br>• If the XL+ shuts down unexpectedly, or remains on without acknowledging and charging the battery therapy could be delayed or pacing could be interrupted.<br><br>**XL+ radiated emissions:**<br>• 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.<br>**XL+ ECG lost signal:**<br>• 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.<br><br>**XL+ SpO2 communication loss and reboot:**<br>• 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.<br><br>**XL+ battery detection:**<br>• 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.<br><br>The serial number of the HeartStart XL+ Defibrillator/Monitor is printed on the primary label on the bottom of the XL+.<br><br>  <br><br>← XL+ serial number |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | You can continue to use your XL+ prior to receiving the software and hardware upgrades; however you should identify a readily available backup defibrillator to use in the event the affected HeartStart XL+ exhibits any of these issues. |

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

| | |
|---|---|
| | **Software Issues:**<br>• Ensure the Ready for Use Indicator has a flashing hour glass prior to use. If the XL+ Ready for Use Indicator displays a Red X remove the device from service. Take the following actions depending upon the issue:<br>  • If the system is rebooting, perform an Operational Check as described in the Instructions for Use once the rebooting has subsided.<br>  • If the system displays a Red X and is not rebooting, remove all power (AC and battery) from the XL+ for at least 10 seconds. Once power is restored the XL+ should function properly. If the XL+ fails to power up or shuts down, remove the device from service.<br>• If audio prompts are not delivered in AED mode, the XL+ screen prompts should be followed.<br><br>**Hardware Issues:**<br><br>**XL+ Speaker**:<br>• The XL+ speaker failure can be detected during an Operational Check.<br>• Alarms and message prompts are visible on the display if the XL+ speaker fails to deliver audible prompts.<br>• If the XL+ speaker fails during use, follow the XL+ screen prompts.<br><br>**XL+ Battery:**<br>• Connect the XL+ to AC power.<br><br>**XL+ Radiated Emissions:**<br>• As per the XL+ Instructions for Use, Electromagnetic compatibility with surrounding devices should be assessed prior to using the XL+ in the same vicinity.<br>• Attempt to reduce the emissions path by distancing the surrounding devices from the XL+.<br><br>**XL+ ECG Lost Signal:**<br>• The ECG signal can be restored by cycling the power on the XL+.<br><br>**XL+ SpO2 Communication Loss and Reboot:**<br>• The XL+ can recover from a reboot caused by EFT. The device will return to its previous settings activated by the Continued Use feature. Patient treatment can continue with the same settings.<br><br>**XL+ Battery Detection and False Low Battery Alarm:**<br>• The XL+ will continue to operate regardless of the false low battery alarm. The false low battery alarm can be cleared by removing and restoring all power from/to the XL+ for at least 10 seconds. |
| **ACTIONS PLANNED BY PHILIPS** | Philips is initiating a correction to affected devices. 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. |

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

| | |
|---|---|
| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741. |