

URGENT – Field Safety Notice Philips M1783A and M5526A Sync Cables Electrical Interference Could Pose a Risk for Patients

Dear Customer,

Philips has identified an issue when using M1783A and M5526A sync cables with some Philips monitor/defibrillators, which could pose a risk for patients. Further details on this issue are provided in the attached Field Safety Notice.

This Field Safety Notice is intended to inform you about:

- what the issue is and under what conditions it 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 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 will replace affected sync cables with a new cable free of charge. A Philips Healthcare representative will contact you to make arrangements for this replacement. We appreciate your patience as we work to schedule your replacement.

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 or the UK Philips Customer Care Service Centre on 0870 532 9741.

Sincerely,



John Pardo
Director QA/RA, Emergency Care and Resuscitation

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AFFECTED PRODUCTS	<p>Product: Philips Sync Cables, models M1783A and M5526A</p> <p>Units Affected: All Philips sync cables, models M1783A and M5526A, are affected.</p>
PROBLEM DESCRIPTION	<p>When a Philips monitor/defibrillator is receiving an ECG signal from an auxiliary bedside monitor via a sync cable, the following can occur if the monitor/defibrillator experiences interference from electrical fast transients (EFTs) while connected to AC power:</p> <ul style="list-style-type: none"> • On the HeartStart MRx and HeartStart XL, EFT noise can be misinterpreted as an R-wave • On the HeartStart XL+, EFT noise can disable ECG monitoring, and potentially interrupt demand mode pacing*. <p>*Note: It is contrary to the instructions in the XL+ Instructions for Use (IFU) to perform demand mode pacing while using the sync cable to provide the ECG signal from a bedside monitor. The XL+ IFU includes the following warning: “When pacing in Demand Mode, the ECG cable from the patient must be directly connected to the HeartStart XL+.” If the user follows this warning, this problem cannot occur on the XL+.</p>
HAZARD INVOLVED	<p>When using a sync cable with the HeartStart MRx or HeartStart XL, EFT noise can be mistaken as an R-wave. If this occurs when performing synchronized cardioversion, there is a potential for inducing ventricular fibrillation if shocks are synchronized to EFT noise instead of the patient’s actual R-wave.</p> <p>When using a sync cable with the HeartStart XL+, EFT noise can disable ECG monitoring, and potentially interrupt demand mode pacing, leading to a possible delay in therapy. A power cycle is required to resume ECG monitoring. (Note: fixed mode pacing is not impacted by this issue.)</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Philips M1783A and M5526A sync cables identified above are affected by this issue.</p> <p>The model number is printed on the outside of the cable, near the end with the ¼” phone plug, as shown below:</p> 

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Electrical Interference Could Pose a Risk for Patients

ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Prior to receiving a replacement sync cable, you can continue to use affected sync cables, provided that they are only used to connect the ECG Out jack on the monitor/defibrillator to the ECG (input) port on a bedside monitor. The issues described in this letter do not impact this application of the sync cable.</p> <p>Affected sync cables should not be used to connect the ECG Out jack of a bedside monitor to the ECG (input) port on the monitor/defibrillator.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips will replace all affected sync cables with a new sync cable free of charge. A Philips Healthcare representative will contact customers with affected devices to arrange for your replacement.</p>
FURTHER INFORMATION AND SUPPORT	<p>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.</p>