Update to Medical Device Correction
Philips M1783A/M5526A Sync Cables & 989803195641 ECG Out Cables
Electrical Interference Could Pose a Risk to Patients

Dear Customer,

Philips notified customers via a Field Safety Notice in March 2016 that using M1783A/M5526A sync cables with certain Philips monitor/defibrillators could pose a risk to patients.

That Field Safety Notice instructed users on how to avoid the risk when using affected cables, but also informed users that cables would be replaced free of charge. Philips now recommends that users stop using sync cables (Models M1783A/M5526A) or ECG out cable (Model 989803195641). (Philips had distributed the ECG out cables to replace the sync cables). This update directs customers to stop using and destroy their sync cables and their ECG out cables.

Please follow the instructions below to destroy your old cables, dispose of them, and document this destruction and disposal:

1. Cut the sync cables and ECG out cable(s) in half.
2. Following the protocol defined by your institution, dispose of the cut cables.
3. Complete the enclosed customer reply form and send it to Philips, retaining a copy for your records.

Do not return any sync cables or ECG out cable(s) to Philips.

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,

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AFFECTED PRODUCTS	**Product:** Philips sync cables, models M1783A and M5526A, and Philips ECG out cables, model 989803195641. **Units Affected:** All units of the above models are affected.
PROBLEM DESCRIPTION	When a Philips monitor/defibrillator is receiving an ECG signal from an auxiliary bedside monitor via a sync cable or ECG out cable, the following can occur if the monitor/defibrillator experiences interference from electrical fast transients (EFTs): • On the HeartStart MRx and HeartStart XL, EFT noise may be misinterpreted as an R-wave. • On the HeartStart XL+, EFT noise can disable ECG monitoring and potentially interrupt demand mode pacing*. *Note: It is contrary to the XL+ Instructions for Use to perform demand mode pacing while using the ECG out cable or obtaining the ECG signal from a bedside monitor. The XL+ Instructions for Use 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+.
HAZARD INVOLVED	When using a sync cable or ECG out cable with the HeartStart MRx or HeartStart XL, EFT noise may 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 R-wave of the patient's actual ECG. When using a sync cable or ECG out 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.)

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HOW TO IDENTIFY AFFECTED PRODUCTS	Philips M1783A/M5526A sync cables and 989803195641 ECG out cable identified above are affected by this issue. The model numbers are printed on the outside of the cable, near the end with the ¼" phone plug and on the bag label.  
ACTION TO BE TAKEN BY CUSTOMER / USER	Customers should remove affected sync cables and ECG out cables from service and destroy them, documenting such action on the attached reply form, which should be returned to Philips. Customers should retain a copy of the reply form. The customer should follow the Instructions for Use that describe the recommended approach for performing cardioversion with the XL+ and MRx monitor/defibrillators. The ECG trunk cable can be disconnected from the Philips bedside monitor and connected to the monitor/defibrillator before delivering therapy; this is the preferred source of an ECG waveform for synchronization.
ACTIONS PLANNED BY PHILIPS	Philips is distributing this notice to inform you that these cables are no longer available or supported for use with the XL, XL+, and MRx monitor/defibrillators. Philips will follow up with customers who do not return the enclosed reply card.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or call Philips at 1-800-722-9377.