Safety Communication رسالة سلامة

Combined Cable 3 or 5 Lead sets may cause possible reduction of defibrillation energy delivered or failure to deliver defibrillation energy and possible electric shock hazard

Device/ Product Description:	ECG Cables/Lead sets
Brand:	Efficia Combined Cable/Leadsets
AFFECTED PRODUCTS:	

Part Number	Part Description
989803160731	Efficia Combined Cable/3-Leadset Grabber, AAMI
989803160741	Efficia Combined Cable/3-Leadset Grabber, IEC
989803160751	Efficia Combined Cable/3-Leadset Snap, AAMI
989803160761	Efficia Combined Cable/3-Leadset Snap, IEC
989803160771	Efficia Combined Cable/5-Leadset Grabber, AAMI
989803160781	Efficia Combined Cable/5-Leadset Grabber, IEC
989803160791	Efficia Combined Cable/5-Leadset Snap, AAMI
989803160801	Efficia Combined Cable/5-Leadset Snap, IEC

Manufacturer:	Philips Healthcare
Problem:	During use of the device, if the patient required electrical energy for defibrillation or cardioversion, it is possible for some of the energy to be diverted away from the patient's thoracic cavity through the ECG cable. This could result in reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient. During defibrillation, there is also a possibility of an unintentional electrical shock hazard to the patient and/or clinician. For the patient, this hazard may be present if the Efficia Combined Cable/Leadset remains connected to the electrodes on the patient during the delivery of therapy. For the clinician, this hazard may be present if the clinician is touching the cable during defibrillation. The issue is present due to manufacturing variability during assembly of the cables.

Recommendation/ Actions:	1. Review this notice and ensure that affected personnel are aware of the contents. 2. If you have affected product at your facility, contact the authorized representative to arrange for replacement. 3. Make sure to use the affected cables **only for monitoring** until replacement cables are received. 4. Dispose of all affected Efficia Combined Cable/Leadsets in your inventory once replacement cables are received. Please do not return any affected product to Philips. For more information, Please click here.
Devices/Products photo:	

Authorized Representative Details	AR name:	Philips Healthcare Saudi Arabia Ltd.
	Assigned Contact Person:	Mohammed AlSamhan
	Mobile/Phone:	0558685708
	Email:	sfda.sa.met@philips.com