



Urgent Safety Communication

URGENT FIELD SAFETY NOTICE for Integrated ECG cables with 3-lead leadwires manufactured by GE Healthcare

Device/ Product Name:	 ECG trunk cable: ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, AHA, 3.6 M/12 FT ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, IEC, 3.6 M/12 FT 		
Lot numbers/Serials:	REF/ Catalog Number	Description Description	GTIN
	2106309-001	ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, AHA	00840682137928
	2106309-002	ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, IEC	00840682137829
Manufacturer:	GE Healthcare		
Problem:	SFDA would like to bring your attention to URGENT FSN issued by GE Healthcare regarding ECG trunk cable for the two models: 3-lead leadwires, AHA and 3-lead leadwires, IEC. The Integrated ECG cable with 3-lead leadwires can short circuit during defibrillation and conduct 25% of the defibrillation energy away from the patient. If this issue occurs during a defibrillation event, it is not noticeable to the caregiver and could contribute to an adverse patient outcome. This Safety Communication is being issued to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate potential risk to the patients.		
Recommendation/Actions:	 Identify the affected Integrated ECG cables by Locating the REF/ Catalog Number and GTIN number on the cable, See Figures. 		

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- Stop use and quarantine affected Integrated ECG cables immediately.
- GE Healthcare will replace all affected cables at no cost to you. A GE Healthcare representative will contact you to arrange for the collection of the affected cables and replacement of new cables.
- Report to SFDA any adverse events suspected to be associated
 with affected ECG trunk cable through <u>National Center for Medical Devices Reporting (NCMDR)</u> Or <u>Saudi Vigilance</u>
 Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.



ECG TRUNK CABLE 3-lead leadwires, AHA

Devices/Products photo:



ECG TRUNK CABLE 3-lead leadwires, IEC

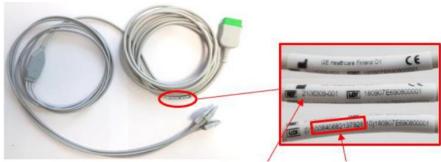


Figure 1REF/ Catalog Number GTIN

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Authorized Representative Details	Company name:	GE Healthcare
	Phone:	+966 (011) 4600530
	Email:	ksa.ra@ge.com

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above to:

National Center for Medical Devices Reporting.

Medical Devices Sector

Saudi Food and Drug Authority

Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)

North Ring Road - Al Nafal Unit (1)

Riyadh 13312 - 6288

Tel: +966 (11) 2038222 Ext: 2406, 2412

Fax: +966 (11) 2757245

SFDA committed to keep the identities of the reporter and the patient confidential.

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely, NCMDR Team



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