

Urgent Safety Communication

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

Device/ Product Name:	<p>ECG trunk cable:</p> <ul style="list-style-type: none"> • 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:	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">REF/ Catalog Number</th> <th style="width: 50%;">Description</th> <th style="width: 30%;">GTIN</th> </tr> </thead> <tbody> <tr> <td>2106309-001</td> <td>ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, AHA</td> <td>00840682137928</td> </tr> <tr> <td>2106309-002</td> <td>ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, IEC</td> <td>00840682137829</td> </tr> </tbody> </table>	REF/ Catalog Number	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
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Manufacturer:	GE Healthcare									
Problem:	<p>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.</p> <p>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.</p> <p>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.</p>									
Recommendation/Actions:	<ul style="list-style-type: none"> • Identify the affected Integrated ECG cables by Locating the REF/ Catalog Number and GTIN number on the cable, See Figures. 									

- 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 [National Center for Medical Devices Reporting \(NCMDR\)](#) Or [Saudi Vigilance](#) Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.

Devices/Products photo:



ECG TRUNK CABLE 3-lead leadwires, AHA



ECG TRUNK CABLE 3-lead leadwires, IEC



Figure 1REF/ Catalog Number GTIN

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