المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Potential reduction of energy during defibrillation

Device/ Product Description:	Cables/Leads, Electrocardiography
Brand Name:	ECG trunk cables and leadwires
Lot numbers/Serials:	<table><tr><th>REF/ Catalog Number</th><th>Description</th></tr><tr><td>2106305-001</td><td>ECG TRUNK CABLE, 3/5-LEAD, AHA, 3.6 M/12 FT.</td></tr><tr><td>2106305-003</td><td>ECG TRUNK CABLE, 3/5-LEAD, IEC, 3.6 M/12 FT.</td></tr><tr><td>2106305-004</td><td>ECG TRUNK CABLE, 3/5-LEAD, IEC, 1.2 M/4 FT.</td></tr><tr><td>2106306-001</td><td>ECG TRUNK CABLE, NEONATAL DIN 3-LEAD, AHA, 3.6 M/12 FT.</td></tr><tr><td>2106389-002</td><td>ECG LEADWIRE SET, 5-LD GROUPED, GRABBER, AHA, 130 CM/ 51 IN</td></tr><tr><td>2106391-001</td><td>ECG LEADWIRE SET, 5-LD, GRABBER, AHA, 74 CM/ 29 IN</td></tr></table>
Manufacturer:	GE Healthcare
Problem:	ECG trunk cables and leadwires may reduce the amount of energy reaching the patient during defibrillation, potentially limiting success of defibrillating the patient's rhythm. If this issue occurs during a defibrillation event, it may not be noticeable to the caregiver and could contribute to an adverse patient outcome.
Recommendation/Actions:	The affected ECG trunk cables and leadwires may continue to be used for monitoring only. Discontinue use of the affected ECG trunk cables and leadwires for patients where an arrhythmia that might require defibrillation is foreseeable, and in these patients use unaffected ECG trunk cables and leadwires. If defibrillation turns out to be unexpectedly needed when the affected ECG trunk cables and leadwires are being used just for monitoring, follow the instructions below: 1) Disconnect ALL ECG leadwires from the patient. 2) Defibrillate the patient per hospital protocol.

	3) If it is possible to monitor the patient's rhythm using defibrillator ECG leadwires or pads, please do so. If this is not possible, reconnect ECG leadwires after the patient's rhythm has been defibrillated. You can read the complete Safety Alert that includes recommendations from (HERE).
Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2995, 2952
Fax: +966 (11) 2757245
Or
Saudi Vigilance

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Sincerely,
NCMDR Team