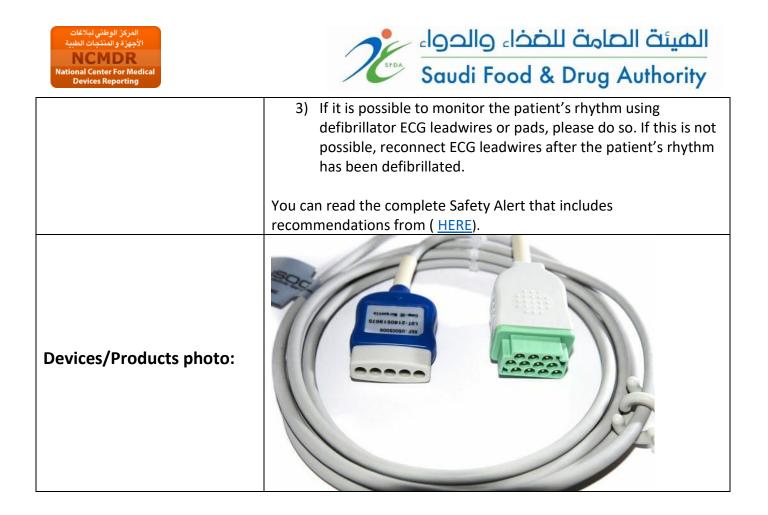




## **Safety Communication**

## Potential reduction of energy during defibrillation

Device/ Product Description:	Cables/Leads, Electrocardiography	
Brand Name:	ECG trunk cables and leadwires	
Lot numbers/Serials:	REF/ Catalog Number	Description
	2106305-001	ECG TRUNK CABLE, 3/5-LEAD, AHA, 3.6 M/12 FT.
	2106305-003	ECG TRUNK CABLE, 3/5-LEAD, IEC, 3.6 M/12 FT.
	2106305-004	ECG TRUNK CABLE, 3/5-LEAD, IEC, 1.2 M/4 FT.
	2106306-001	ECG TRUNK CABLE, NEONATAL DIN 3-LEAD, AHA, 3.6 M/12 FT.
	2106389-002	ECG LEADWIRE SET, 5-LD GROUPED, GRABBER, AHA, 130 CM/ 51 IN
	2106391-001	ECG LEADWIRE SET, 5-LD, GRABBER, AHA, 74 CM/ 29 IN
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.	
	<ul> <li>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:</li> <li>1) Disconnect ALL ECG leadwires from the patient.</li> <li>2) Defibrillate the patient per hospital protocol.</li> </ul>	



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 <u>report any adverse events</u> 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

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

Sincerely, NCMDR Team

