



URGENT FIELD SAFETY NOTICE

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 39000

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **Stop Use** of Integrated ECG cables with 3-lead leadwires

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

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. There have been no injuries reported as a result of this issue.

Safety Instructions

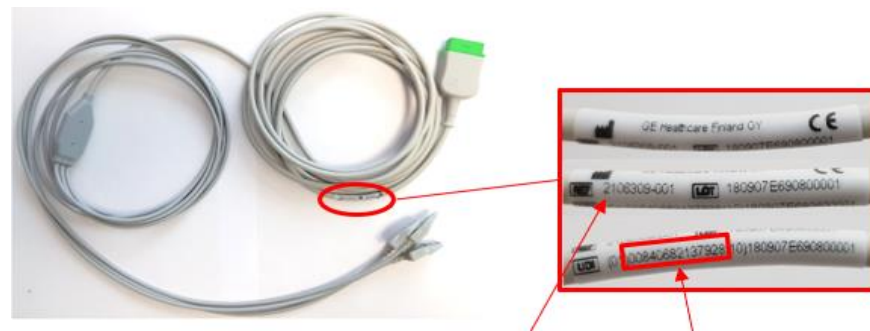
Stop use and quarantine affected Integrated ECG cables immediately.

Affected Product Details

REF/ Catalog Number	Description	GTIN
2106309-001	ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, AHA, 3.6 M/12 FT	00840682137928
2106309-002	ECG TRUNK CABLE, 3-LD W/ INTEGRATED GRABBER LEAD WIRE, IEC, 3.6 M/12 FT	00840682137829

See Figures 1 and 2, below, for instructions on where to locate GTIN number on cables and packaging.

Figure 1: Integrated ECG cable with 3-lead leadwires
Location of the REF/ Catalog Number and GTIN number on the affected cable.



REF/ Catalog Number GTIN Number

Figure 2: Packaged Integrated ECG cable with 3-lead leadwires
 Location of the REF/ Catalog Number and GTIN number on the affected cable package label.

REF/ Catalog Number



GTIN Number

Product Correction

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.

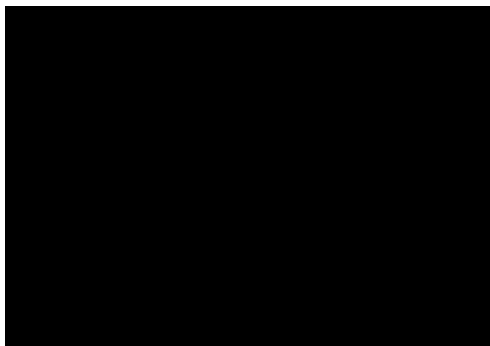
Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

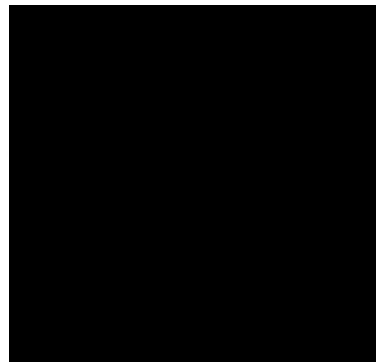
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



GE Healthcare



GE Healthcare



GE Healthcare

GEHC Ref# 39000

**FIELD SAFETY NOTICE ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice Ref# 39000.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:

Recall39000.ECGCable@ge.com

You may obtain this e-mail address through the QR code below:

