



URGENT FIELD SAFETY NOTICE

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 39001-ROW

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

RE: ECG trunk cables and leadwires - Potential reduction of energy during defibrillation

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

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. There have been no injuries reported due to this issue.

Safety Instructions

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.

Affected Product Details

See [Appendix A](#) for list of affected ECG trunk cables and [Appendix B](#) for list of affected ECG leadwires. The ECG trunk cables and leadwires can be used with Patient Monitors, Cath Labs, and Ultrasound equipment.

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

Figure 1: Location of the REF/ Catalog Number and GTIN number on the affected trunk cables & leadwires.

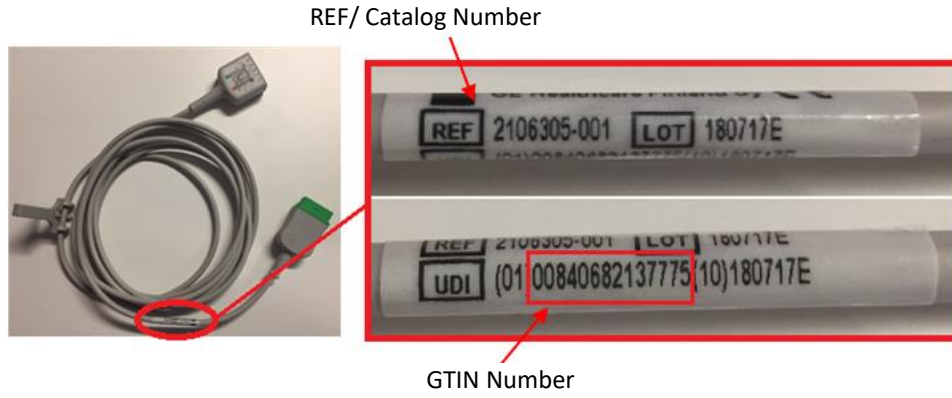
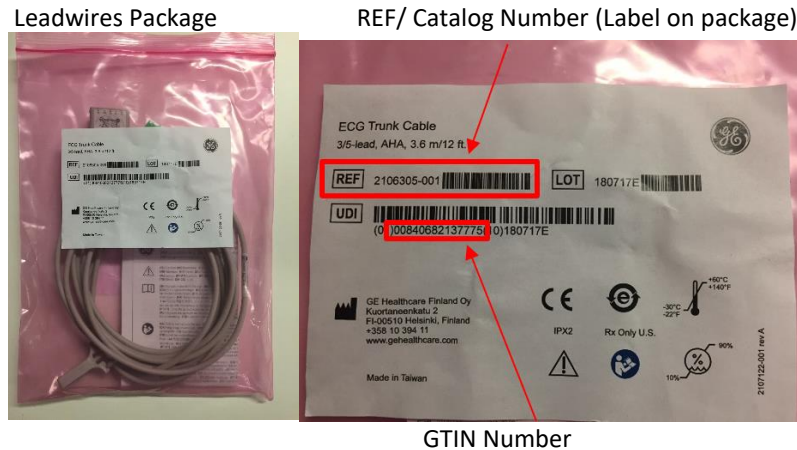


Figure 2: Location of the REF/ Catalog Number and GTIN number on the affected trunk cables and leadwires package label.

ECG Trunk cables and
Leadwires Package

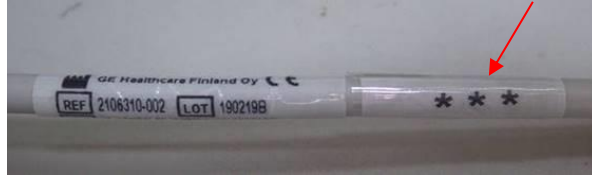


Note: Identification of Not affected products:

Some of the ECG Trunk cables and Leadwires shipping since April 2019 have been inspected by GE Healthcare prior to shipment and are not affected. The safety instructions above do not apply to these unaffected products and they can be used during defibrillation. They have additional identification to distinguish them from the products affected by this correction.

- 1) Not affected ECG Trunk cables & lead wires include an additional wrap label with three asterisks to identify they are inspected and not impacted by this correction.

Not Affected ECG Trunk cables & lead wires



- 2) Not affected ECG trunk cables & lead wires packaged with a green circle sticker are inspected and not impacted by this correction.

Not Affected packaged ECG Trunk cables & lead wires



**Product
Correction**

GE Healthcare will replace all affected trunk cables and leadwires at no cost to you. Complete and return the attached "Customer Response" form via e-mail to Recall39001.ECGCable@ge.com and GE Healthcare will provide replacement parts at no cost to you.

**Contact
Information**

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

Oxygen Care Ltd.
2 Holfeld Business Park,
Kilmacanogue, Co. Wicklow
Ireland
T: +353 1 276 9700

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,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

APPENDIX A – ECG Trunk Cables

REF/ Catalog Number	Description	GTIN
2106305-001	ECG Trunk Cable, 3/5-lead, AHA, 3.6 m/12 ft.	00840682137775
2106305-002	ECG Trunk Cable, 3/5-lead, AHA, 1.2 m/4 ft.	00840682137898
2106305-003	ECG Trunk Cable, 3/5-lead, IEC, 3.6 m/12 ft.	00840682137799
2106305-004	ECG Trunk Cable, 3/5-lead, IEC, 1.2 m/4 ft.	00840682137720
2106306-001	ECG Trunk Cable, Neonatal, DIN 3-lead, AHA, 3.6 m/12 ft.	00840682137843
2106306-002	ECG Trunk Cable, Neonatal, DIN 3-lead, AHA, 1.2 m/4 ft.	00840682137737
2106306-003	ECG Trunk Cable, Neonatal, DIN 3-lead, IEC, 3.6 m/12 ft.	00840682137690
2106306-004	ECG Trunk Cable, Neonatal, DIN 3-lead, IEC, 1.2 m/4 ft.	00840682137706
2106307-001	ECG Trunk Cable, 6-lead, AHA, 3.6 m/12 ft.	00840682137836
2106307-002	ECG Trunk Cable, 6-lead, AHA, 1.2 m/4 ft.	00840682137751
2106307-003	ECG Trunk Cable, 6-lead, IEC, 3.6 m/12 ft.	00840682137744
2106307-004	ECG Trunk Cable, 6-lead, IEC, 1.2 m/4 ft.	00840682137874
2106308-001	ECG Trunk Cable, 12-lead, AHA, 3.6 m/12 ft.	00840682137713
2106308-002	ECG Trunk Cable, 12-lead, AHA, 1.2 m/4 ft.	00840682137812
2106308-003	ECG Trunk Cable, 12-lead, IEC, 3.6 m/12 ft.	00840682137881
2106308-004	ECG Trunk Cable, 12-lead, IEC, 1.2 m/4 ft.	00840682137867
2106310-001	ECG Trunk Cable, 3/5-lead w/ESU filter, AHA, 3.6 m/12 ft.	00840682137935
2106310-002	ECG Trunk Cable, 3/5-lead w/ESU filter, IEC, 3.6 m/12 ft.	00840682137805
2106311-001	ECG Trunk Cable, 3/5-lead, AHA, 6 m/20 ft.	00840682137676
2106311-002	ECG Trunk Cable, 3/5-lead, IEC, 6 m/20 ft.	00840682137911

APPENDIX B - ECG Lead wires

B.1 Lead wire sets with Grabber Ends

REF/ Catalog Number	Description	GTIN
2106389-001	ECG Leadwire set, 5-lead, grouped, grabber, AHA, 74 cm/ 29 in	00840682139960
2106389-002	ECG Leadwire set, 5-lead, grouped, grabber, AHA, 130 cm/ 51 in	00840682139779
2106389-003	ECG Leadwire set, 5-lead, grouped, grabber, IEC, 74 cm/ 29 in	00840682139700
2106389-004	ECG Leadwire set, 5-lead, grouped, grabber, IEC, 130 cm/ 51 in	00840682140089
2106389-005	ECG Leadwire set, 5-lead, grouped, grabber, AHA, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682139786
2106389-006	ECG Leadwire set, 5-lead, grouped, grabber, IEC, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682139984
2106390-001	ECG Leadwire set, 3-lead, grabber, AHA, 74 cm/ 29 in	00840682139687
2106390-002	ECG Leadwire set, 3-lead, grabber, AHA, 130 cm/ 51 in	00840682140232
2106390-003	ECG Leadwire set, 3-lead, grabber, IEC, 74 cm/ 29 in	00840682140058
2106390-004	ECG Leadwire set, 3-lead, grabber, IEC, 130 cm/ 51 in	00840682140317
2106391-001	ECG Leadwire set, 5-lead, grabber, AHA, 74 cm/ 29 in	00840682140799
2106391-002	ECG Leadwire set, 5-lead, grabber, AHA, 130 cm/ 51 in	00840682139830
2106391-003	ECG Leadwire set, 5-lead, grabber, IEC, 74 cm/ 29 in	00840682140003
2106391-004	ECG Leadwire set, 5-lead, grabber, IEC, 130 cm/ 51 in	00840682139601
2106391-005	ECG Leadwire set, 5-lead, grabber, AHA, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682140348
2106391-006	ECG Leadwire set, 5-lead, grabber, IEC, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682140133
2106393-001	ECG Leadwire set, 5-lead V2-6, grabber, AHA, 130 cm/ 51 in	00840682140287
2106393-002	ECG Leadwire set, 5-lead C2-6, grabber, IEC, 130 cm/ 51 in	00840682139922
2106393-003	ECG Leadwire set, 5-lead V2-6, grabber, AHA, 74 cm/ 29 in	00840682139885
2106393-004	ECG Leadwire set, 5-lead C2-6, grabber, IEC, 74 cm/ 29 in	00840682139823
2106397-001	ECG Leadwire set, 6-lead, grouped, grabber, AHA, 74 cm/ 29 in	00840682140522
2106397-002	ECG Leadwire set, 6-lead, grouped, grabber, AHA, 130 cm/ 51 in	00840682140461
2106397-003	ECG Leadwire set, 6-lead, grouped, grabber, AHA, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682140041
2106398-001	ECG Leadwire set, 6-lead, grouped, grabber, IEC, 74 cm/ 29 in	00840682140072

2106398-002	ECG Leadwire set, 6-lead, grouped, grabber, IEC, 130 cm/ 51 in	00840682140256
2106398-003	ECG Leadwire set, 6-lead, grouped, grabber, IEC, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682139717

B.2 Replacement Lead wires with Grabber Ends

REF/ Catalog Number	Description	GTIN
2106388-001	Replacement ECG Leadwire, grabber, LL , AHA, 74 cm/ 29 in	NA
2106388-002	Replacement ECG Leadwire, grabber, RA, AHA, 74 cm/ 29 in	NA
2106388-003	Replacement ECG Leadwire, grabber, GRN RL, AHA, 74 cm/ 29 in	NA
2106388-004	Replacement ECG Leadwire, grabber, BLK LA, AHA, 74 cm/ 29 in	NA
2106388-005	Replacement ECG Leadwire, grabber, BRN V, AHA, 74 cm/ 29 in	NA
2106388-006	Replacement ECG Leadwire, grabber, YEL L, IEC, 74 cm/ 29 in	NA
2106388-007	Replacement ECG Leadwire, grabber, BLK N, IEC, 74 cm/ 29 in	NA
2106388-008	Replacement ECG Leadwire, grabber, RED R, IEC, 74 cm/ 29 in	NA
2106388-009	Replacement ECG Leadwire, grabber, GRN F, IEC, 74 cm/ 29 in	NA
2106388-010	Replacement ECG Leadwire, grabber, WHT C, IEC, 74 cm/ 29 in	NA
2106388-101	Replacement ECG Leadwire, grabber, LL , AHA, 130 cm/ 51 in	NA
2106388-102	Replacement ECG Leadwire, grabber, RA, AHA, 130 cm/ 51 in	NA
2106388-103	Replacement ECG Leadwire, grabber, GRN RL, AHA, 130 cm/ 51 in	NA
2106388-104	Replacement ECG Leadwire, grabber, BLK LA, AHA, 130 cm/ 51 in	NA
2106388-105	Replacement ECG Leadwire, grabber, BRN V, AHA, 130 cm/ 51 in	NA
2106388-106	Replacement ECG Leadwire, grabber, YEL L , IEC, 130 cm/ 51 in	NA
2106388-107	Replacement ECG Leadwire, grabber, BLK N, IEC, 130 cm/ 51 in	NA
2106388-108	Replacement ECG Leadwire, grabber, RED R, IEC, 130 cm/ 51 in	NA
2106388-109	Replacement ECG Leadwire, grabber, GRN F, IEC, 130 cm/ 51 in	NA
2106388-110	Replacement ECG Leadwire, grabber, WHT C, IEC , 130 cm/ 51 in	NA
2106392-001	Replacement ECG Leadwire, grabber, YEL V, AHA, 74 cm/ 29 in	NA
2106392-002	Replacement ECG Leadwire, grabber, GRN V, AHA, 74 cm/ 29 in	NA
2106392-003	Replacement ECG Leadwire, grabber, BLU V, AHA, 74 cm/ 29 in	NA
2106392-004	Replacement ECG Leadwire, grabber, ORG V, AHA, 74 cm/ 29 in	NA
2106392-005	Replacement ECG Leadwire, grabber, VIO V, AHA, 74 cm/ 29 in	NA

B.3 Lead wire sets with Snap Ends

REF/ Catalog Number	Description	GTIN
2106381-001	ECG Leadwire set, 5-lead, snap, AHA, 74 cm/ 29 in	00840682139953
2106381-002	ECG Leadwire set, 5-lead, snap, AHA, 130 cm/ 51 in	00840682140201
2106381-003	ECG Leadwire set, 5-lead, snap, IEC, 74 cm/ 29 in	00840682139847
2106381-004	ECG Leadwire set, 5-lead, snap, IEC, 130 cm/ 51 in	00840682139939
2106381-005	ECG Leadwire set, 5-lead, snap, AHA, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682139854
2106383-001	ECG Leadwire set, 5-lead, grouped, snap, AHA, 74 cm/ 29 in	00840682140126
2106383-002	ECG Leadwire set, 5-lead, grouped, snap, AHA, 130 cm/ 51 in	00840682140096
2106383-003	ECG Leadwire set, 5-lead, grouped, snap, IEC, 74 cm/ 29 in	00840682139618
2106383-004	ECG Leadwire set, 5-lead, grouped, snap, IEC, 130 cm/ 51 in	00840682140171
2106383-005	ECG Leadwire set, 5-lead, grouped, snap, AHA, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682140034
2106383-006	ECG Leadwire set, 5-lead, grouped, snap, IEC, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682139816
2106385-001	ECG Leadwire set, 3-lead, snap, AHA, 74 cm/ 29 in	00840682139588
2106385-002	ECG LEADWIRE SET, 3-LD GROUPEd, SNAP, AHA, 130 CM/ 51 IN	00840682140119
2106385-003	ECG LEADWIRE SET, 3-LD GROUPEd, SNAP, IEC, 74 CM/ 29 IN	00840682139724
2106385-004	ECG LEADWIRE SET, 3-LD GROUPEd, SNAP, IEC, 130 CM/ 51 IN	00840682140508
2106394-001	ECG Leadwire set, 5-lead V2-6, snap, AHA, 130 cm/ 51 in	00840682139892
2106394-002	ECG Leadwire set, 5-lead C2-6, snap, IEC, 130 cm/ 51 in	00840682140478
2106394-003	ECG Leadwire set, 5-lead V2-6, snap, AHA, 74 cm/ 29 in	00840682140102
2106394-004	ECG Leadwire set, 5-lead C2-6, snap, IEC, 74 cm/ 29 in	00840682140393
2106395-001	ECG Leadwire set, 6-lead, grouped, snap, AHA, 74 cm/ 29 in	00840682139649
2106395-002	ECG Leadwire set, 6-lead, grouped, snap, AHA, 130 cm/ 51 in	00840682139656
2106395-003	ECG Leadwire set, 6-lead, grouped, snap, AHA, mix 74 cm/ 29 in, 130 cm/ 51 in	00840682139663
2106396-001	ECG Leadwire set, 6-lead, grouped, snap, IEC, 74 cm/ 29 in	00840682140379
2106396-002	ECG Leadwire set, 6-lead, grouped, snap, IEC, 130 cm/ 51 in	00840682140409

B.4 – Replacement ECG Leadwires with Snap Ends

REF/ Catalog Number	Description	GTIN
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2106386-001	Replacement ECG Leadwire, snap, LL, AHA, 74 cm/ 29 in	NA
2106386-002	Replacement ECG Leadwire, snap, RA, AHA 74 cm/ 29 in	NA
2106386-003	Replacement ECG Leadwire, snap, RL, AHA, 74 cm/ 29 in	NA
2106386-004	Replacement ECG Leadwire, snap, LA, AHA, 74 cm/ 29 in	NA
2106386-005	Replacement ECG Leadwire, snap, V, AHA, 74 cm/ 29 in	NA
2106386-101	Replacement ECG Leadwire, snap, LL, AHA, 130 cm/ 51 in	NA
2106386-102	Replacement ECG Leadwire, snap, RA, AHA, 130 cm/ 51 in	NA
2106386-103	Replacement ECG Leadwire, snap, RL , AHA, 130 cm/ 51 in	NA
2106386-104	Replacement ECG Leadwire, snap, LA, AHA, 130 cm/ 51 in	NA
2106386-105	Replacement ECG Leadwire, snap, V, AHA, 130 cm/ 51 in	NA



GE Healthcare

GEHC Ref# 39001-ROW

**MEDICAL DEVICE NOTIFICATION 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# 39001-ROW.

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:

Recall39001.ECGCable@ge.com

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

