



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 12286

To: Healthcare Administration/Risk Manager
Director of Clinical / Biomedical Engineering
Chief of Nursing
Chairman Medical Board and relevant Head of Departments

RE: **Certain CLab II Plus Amplifiers used with CardioLab/ComboLab Systems failed patient leakage current test**

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

GE has become aware that certain CLab II Plus Amplifiers used with CardioLab/ComboLab systems have failed the patient leakage current test. There is a potential that if another device with electrical connectivity (e.g., ablation device, ECG monitor) fails, then the CLab II Plus Amplifier will not prevent an electric current from completing a circuit, which could cause an electrical shock to a patient. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use your system by following these instructions:

- 1) Test all equipment used in conjunction with CardioLab/ComboLab per manufacturer instructions on electrical safety to ensure that all equipment is in good operating condition and performs per manufacturer specifications.
Note: Due to the potential safety risks of other devices used in conjunction with CLab II Plus Amplifiers in Electrophysiology Procedures, all equipment that can electrically contact the patient during a procedure should be checked against each device's safety conformances in manufacturer specifications.
- 2) If you suspect another connected device is or may be malfunctioning, discontinue use of the CLab II Plus Amplifier until all nonconforming equipment is corrected. If nonconforming equipment is used in conjunction with the CLab II Plus Amplifier, the CLab II Plus Amplifier will not provide necessary mitigation to prevent patient shock.

Affected Product Details

Certain CLab II Plus Amplifiers used with CardioLab/ComboLab Systems - see below for affected part numbers and serial numbers.

Amplifier part numbers:

2088700-002 CLAB II PLUS64 AMP 110-240V 50/60HZ (GTIN 00840682119634)
2088700-004 CLAB II PLUS128 AMP 110-240V 50/60HZ (GTIN 00840682119603)

List of impacted serial numbers (continued on next page):

RXJ19122001TA	RXJ19194002TA	RXJ19224004TA	RXJ19232009TA
RXJ19122002TA	RXJ19194003TA	RXJ19224005TA	RXJ19232010TA
RXJ19122003TA	RXJ19194004TA	RXJ19224006TA	RXJ19232011TA
RXJ19122004TA	RXJ19194005TA	RXJ19224007TA	RXJ19232012TA
RXJ19122005TA	RXJ19194006TA	RXJ19224008TA	RXJ19244001TA

RXJ19122006TA	RXJ19194007TA	RXJ19224009TA	RXJ19244002TA
RXJ19122007TA	RXJ19194008TA	RXJ19224010TA	RXJ19244003TA
RXJ19122008TA	RXJ19194009TA	RXJ19224011TA	RXJ19244004TA
RXJ19122009TA	RXJ19194010TA	RXJ19224012TA	RXJ19244005TA
RXJ19122010TA	RXJ19194011TA	RXJ19224013TA	RXJ19244006TA
RXJ19154001TA	RXJ19204001TA	RXJ19224014TA	RXJ19244007TA
RXJ19154002TA	RXJ19204002TA	RXJ19224015TA	RXJ19244008TA
RXJ19154003TA	RXJ19204003TA	RXJ19224016TA	RXJ19284001TA
RXJ19154004TA	RXJ19204004TA	RXJ19224017TA	RXJ19284002TA
RXJ19154005TA	RXJ19204005TA	RXJ19232001TA	RXJ19284004TA
RXJ19154006TA	RXJ19204006TA	RXJ19232002TA	RXJ19284005TA
RXJ19154007TA	RXJ19204007TA	RXJ19232003TA	RXJ19284007TA
RXJ19154008TA	RXJ19204008TA	RXJ19232004TA	RXJ19284008TA
RXJ19154009TA	RXJ19204009TA	RXJ19232005TA	RXJ19284009TA
RXJ19154010TA	RXJ19224001TA	RXJ19232006TA	RXJ19284010TA
RXJ19154011TA	RXJ19224002TA	RXJ19232007TA	RXJ19284011TA
RXJ19194001TA	RXJ19224003TA	RXJ19232008TA	RXJ19284014TA

**Product
Correction**

GE Healthcare will correct all affected GE products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

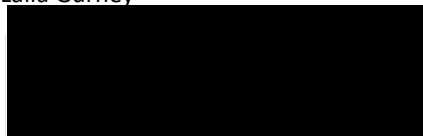
**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative

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.

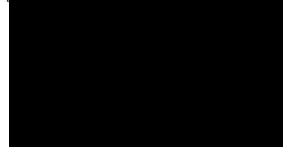
Sincerely,

Laila Gurney



Senior Executive, Global Regulatory and Quality
GE Healthcare

1



Chief Medical Officer
GE Healthcare