URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 16008

To: Healthcare Administration/Risk Manager
Director of Clinical / Biomedical Engineering
Director of Cardiology
Chief of Nursing

RE: **Certain Prucka 3 Amplifiers used with CardioLab / ComboLab systems.**

Safety Issue

GE HealthCare has become aware that capacitors in certain Prucka 3 Amplifiers used with CardioLab / ComboLab systems could fail resulting in transient oscillations on the display and inability to view surface and intracardiac ECG waveforms. In the unlikely event that this occurs during an interventional electrophysiologic procedure without alternate equipment to display the waveforms, it could result in delay of treatment. Refer to Figure 1a for normal signal and Figure 1b for signal issue.

Figure 1a

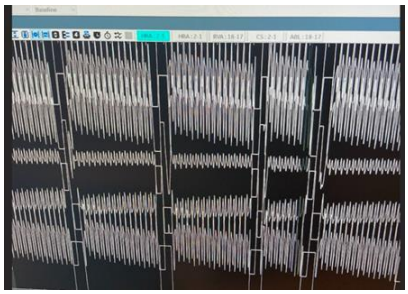

Figure 1b

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

Actions to be taken by Customer /User

You can continue to use the Prucka 3 Amplifiers with your CardioLab/ComboLab systems with the following conditions:

- Ensure additional devices are immediately available to monitor surface and intracardiac ECG waveforms in order to complete the study (e.g., patient monitor, 3D Mapping system, etc.) until your device is corrected.
- In the event the Prucka 3 Amplifier malfunction occurs during the case with the loss of ECG waveforms, use an alternate device.
- Ensure that hospital staff are familiar with utilizing the Direct Stimulator Connections on the CIM Block(s). This allows pacing from the stimulator if the amplifier is not functioning properly.

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.FMI16008@gehealthcare.com.

Affected Product Details

Prucka 3 Amplifier (P1801PA) used with CardioLab and ComboLab Systems (GTIN 00195278507044 and 00195278507051)

The following Field Replacement Units: 5875569 (ASSY CLABIII AMP 128CH 100-240V 50-60HZ)

See attached Appendix for a list of affected serial numbers.

Intended Use:
CardioLab
The CardioLab system is intended for recording electrophysiology clinical data, and may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations.

ComboLabThe ComboLab system is the combination of both the Mac-Lab and CardioLab systems intended for recording hemodynamic and electrophysiology clinical data, respectively and may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations.

Product Correction

GE HealthCare will correct all affected 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 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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare Ref. # 16008

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.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

☐ By completing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: recall.FMI16008@gehealthcare.com

APPENDIX

List of impacted serial numbers:

SVS23210005SA	SVS23280002SA	SVS23280005SA	SVS23280008SA	SVS23280009SA
SVS23290001SA	SVS23290002SA	SVS23290003SA	SVS23290004SA	SVS23320002SA
SVS23330003SA	SVS23330004SA	SVS23330005SA	SVS23330006SA	SVS23330007SA
SVS23330008SA	SVS23330009SA	SVS23350001SA	SVS23350002SA	SVS23350003SA
SVS23350004SA	SVS23350005SA	SVS23350006SA	SVS23350007SA	SVS23350008SA
SVS23350009SA	SVS23350011SA	SVS23350012SA	SVS23350013SA	SVS23350014SA
SVS23350015SA	SVS23350016SA	SVS23350017SA	SVS23350018SA	SVS23350019SA
SVS23350020SA	SVS23350021SA	SVS23350022SA	SVS23350023SA	SVS23350024SA
SVS23350025SA	SVS23360002SA	SVS23360003SA	SVS23360004SA	SVS23360005SA
SVS23360006SA	SVS23360007SA	SVS23360008SA	SVS23360010SA	SVS23360011SA
SVS23360012SA	SVS23360013SA	SVS23360014SA	SVS23360015SA	SVS23360016SA
SVS23360017SA	SVS23360018SA	SVS23360019SA	SVS23360020SA	SVS23400002SA
SVS23400003SA	SVS23400004SA	SVS23400005SA	SVS23400006SA	SVS23400007SA
SVS23400008SA	SVS23400009SA	SVS23400010SA	SVS23400011SA	SVS23400015SA
SVS23400018SA	SVS23400019SA	SVS23400020SA	SVS23400021SA	SVS23400022SA
SVS23400023SA	SVS23400024SA	SVS23400025SA	SVS23400026SA	SVS23400028SA
SVS23400029SA	SVS23400030SA	SVS23400031SA	SVS23400032SA	SVS23400033SA
SVS23400034SA	SVS23400035SA	SVS23400036SA	SVS23400037SA	SVS23400038SA
SVS23400039SA	SVS23460001SA	SVS23460002SA	SVS23460003SA	SVS23460004SA
SVS23460005SA	SVS23460006SA	SVS23460007SA	SVS23460008SA	SVS23460013SA
SVS23460014SA	SVS23460016SA	SVS23460017SA	SVS23460020SA	SVS23470001SA
SVS23470002SA	SVS23470003SA	SVS23470004SA	SVS23470005SA	SVS23470006SA
SVS23470007SA	SVS23470008SA	SVS23470009SA	SVS23470010SA	SVS23470011SA
SVS23470012SA	SVS23470013SA	SVS23470016SA	SVS23470017SA	SVS23470018SA
SVS23470019SA	SVS23470020SA	SVS23470022SA	SVS23480002SA	SVS23480003SA
SVS23480004SA	SVS23480005SA	SVS23480007SA	SVS23480010SA	SVS23480011SA
SVS23480012SA	SVS23480013SA	SVS23480015SA	SVS23480016SA	SVS23520012SA
SVS23520018SA	SVS23520020SA	SVS23520022SA	SVS24020002SA	SVS24020004SA
SVS24020005SA	SVS24020006SA	SVS24020007SA	SVS24020011SA	SVS24020016SA