URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. #16005

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

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

Safety Issue

GE HealthCare has become aware that a diode on the power supply of the Prucka 3 Amplifier could reach elevated temperatures. This could cause the amplifier to fail and consequently power off and become inoperable. The failure of the amplifier results in no ECG/Intracardiac and Invasive Blood Pressure waveforms to be visible on the CardioLab systems. If this issue were to occur during an interventional procedure, it could contribute to an adverse patient outcome.

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

Actions to be taken by Customer/ User

You can continue to use CardioLab/ComboLab systems with the following conditions:

- Ensure the facility has stable power. Lower voltage of the supplied power (e.g., 100V) causes more heat buildup and can cause the amplifier to fail.
- Ensure the room temperature where the device is used is kept at < 30 degrees Celsius/86 degrees Fahrenheit. High temperatures (≥30 degrees Celsius/86 degrees Fahrenheit) can cause the amplifier to fail.
- Ensure additional devices are available to monitor and/or stabilize the patient and/or complete the study (e.g., patient monitor, defibrillator, 3D Mapping system, etc.)
- Ensure that the hospital staff is familiar with utilizing the Direct Stimulator Connections on the CIM Block(s). This allows pacing from the stimulator when the amplifier has no power.

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 ICAR.RecallFMI16005@ge.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.

ComboLab

The 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 plan execution 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 & Safety Officer
GE HealthCare

GE HealthCare

GE HealthCare Ref. # 15146

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

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

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

☐ 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: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: ICAR.RecallFMI16005@ge.com

APPENDIX

List of impacted serial numbers:

SVS22330007SA	SVS22330008SA	SVS22330009SA	SVS22330010SA	SVS22330011SA
SVS22330012SA	SVS22330013SA	SVS22330014SA	SVS22330015SA	SVS22330016SA
SVS22330017SA	SVS22330018SA	SVS22330019SA	SVS22330020SA	SVS22330021SA
SVS22330022SA	SVS22330023SA	SVS22330024SA	SVS22330025SA	SVS22330026SA
SVS22330028SA	SVS22330030SA	SVS22330031SA	SVS22330032SA	SVS22330033SA
SVS22330034SA	SVS22330035SA	SVS22440001SA	SVS22440002SA	SVS22440005SA
SVS22440006SA	SVS22440007SA	SVS22440008SA	SVS22440009SA	SVS22440010SA
SVS22440011SA	SVS22440012SA	SVS22440013SA	SVS22440015SA	SVS22440016SA
SVS22490001SA	SVS22490002SA	SVS22490003SA	SVS22490004SA	SVS22520005SA
SVS22520006SA	SVS22520008SA	SVS22520009SA	SVS22520010SA	SVS22520011SA
SVS22520012SA	SVS22520013SA	SVS22520014SA	SVS22520015SA	SVS23040001SA
SVS23040002SA	SVS23040003SA	SVS23040004SA	SVS23040005SA	SVS23040007SA
SVS23040008SA	SVS23040011SA	SVS23040012SA	SVS23040013SA	SVS23040014SA
SVS23040015SA	SVS23040016SA	SVS23040017SA	SVS23040018SA	SVS23040019SA
SVS23070002SA	SVS23070004SA	SVS23070005SA	SVS23070008SA	SVS23070009SA
SVS23070011SA	SVS23070012SA	SVS23100001SA	SVS23100002SA	SVS23100004SA
SVS23100006SA				