



## URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 12269

To: Director of Clinical/Radiology  
Risk Manager/Hospital Administrator  
Director of Biomedical Engineering

**RE: Power cord failure and replacement on Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems**

**Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Your safety and the safety of your patients is of our utmost concern.**

### **Safety Issue**

The system side of the power cord may break and expose the electrical conductors leading to the risk of shock. This can lead to injuries up to and including cardiac arrhythmia or cardiac arrest.

### **Safety Instructions**

You may continue to use your system. If you need to remove the power cord from the rear of the unit (see picture of location below), before doing so be sure to do the following:

1. Turn the system off
2. **Unplug it from the wall**

If the system end of the power cord (see picture below) is damaged, discontinue use of the system until a replacement cord is provided. If you experience any power issues with your unit, discontinue use of the system and contact GEHC Service.



*Location of power cord in rear of unit.*

### **Affected Product Details**

Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording systems which have been installed or received a power cord replacement having **product catalogue # P1009NN (P/N 401855-049) or product catalogue # P1009NL (P/N 405535-101)**, refer to attached Appendix for Serial Number details

**Product  
Correction**

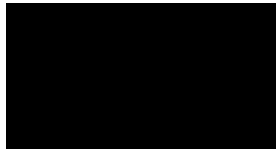
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

**Contact  
Information**

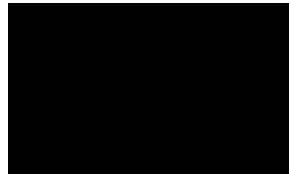
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



James W. Dennison  
Vice President - Quality Assurance  
GE Healthcare



Jeff Hersh, PhD MD  
Chief Medical Officer  
GE Healthcare

## Appendix

Associated system serial number list which uses **product catalogue # P1009NN (P/N 401855-049) or product catalogue # P1009NL (P/N 405535-101).**

SG411061097GA	SJS16246551TA	SKP17208220TA	SKP17258486TA
SJS13463938TA	SKP16366961TA	SKP17208238TA	SKP17258504TA
SJS14154502TA	SKP16366962TA	SKP17218256TA	SKP17278563TA
SJS14164531TA	SKP16366963TA	SKP17218277TA	SKP17278580TA
SJS15025242TA	SKP16397103TA	SKP17248439TA	SKP17278592TA
SJS15455982TA	SKP16407123TA	SKP17248451TA	SKP17278594TA
SJS15516025TA	SKP16437248TA	SKP17258471TA	SKP17278597TA
SJS16086176TA	SKP16457334TA	SKP17258477TA	SKP17469114TA
SJS16086178TA	SKP16467368TA	SKP17258481TA	SPH17358709TA
SJS16086182TA	SKP17017673TA	SKP17258483TA	SPH18049347TA
SJS16196416TA	SJS15516028TA	SKP17258484TA	SPH18089461TA
SJS16246549TA	SKP17027710TA	SKP17258485TA	SPH18109485TA
			SPH18139565TA

,