



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 40875

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

RE: GE Healthcare A1 Panel for Nuclear scanners

GE Healthcare has identified that a small number of Nuclear systems recently installed with a GE supplied A1 electrical panel may not be properly wired to the partial system UPS (Uninterruptible Power Supply). GE Healthcare will contact you to disconnect the UPS(s) from your system to eliminate the hazard until this situation can be corrected.

This communication is intended to inform you of this potential issue and GE Healthcare's plan to correct all affected systems. Please ensure that the organization that services your system is made aware of this potential hazard until GE Healthcare can correct this situation.

Safety Issue

When your system was installed, the Main disconnect switch, EPO button on the A1 panel, and Remote EPO button(s) (outside of the A1 panel) may not have been wired correctly which could result in these not shutting off all power to the entire system as intended, resulting in a potential electric hazard.

Specifically, power may still be applied by the partial UPS despite turning off the Main disconnect switch, pressing the Emergency Power Off (EPO) button, and pressing Remote EPO button(s) when the system is equipped with a partial UPS. Emergency Stop (E-stop) switches which are used to stop system motion and X-Ray generation, are not affected and will function as intended.

Safety Instructions

GE Healthcare will contact you to disconnect the UPS(s) from your system to eliminate the hazard until this situation can be corrected.

Affected Product Details

The following Nuclear system are potentially affected if they have had a new A1 panel installed since December 2017:

Discovery NM/CT 670 3/8 Pro (model 5376204-70-54 GTIN 00840682121194)

Discovery 670 DR 3-8 16SL (model 5376204-70-56 GTIN 00840682124393)

Discovery 670 ES NMCT 0540+3-8 (model 5376204-70-57 GTIN 00840682123877)

Product Correction

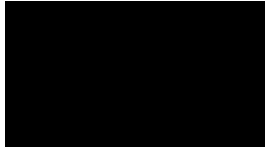
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction to include restoration of UPS function.

**Contact
Information**

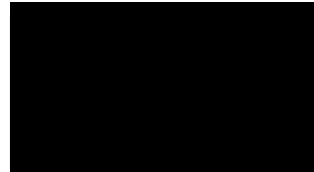
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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