URGENT MEDICAL DEVICE CORRECTION

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

June 20, 2018

GEHC Ref# 26860-1

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

RE: GE Healthcare A1 Panel for CT and CT/PET scanners

GE Healthcare has identified that some CT and CT/PET systems recently installed with a GE supplied A1 electrical panel may not be properly wired to the partial system UPS (Uninterruptible Power Supply).

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 CT or CT/PET system is made aware of this potential hazard until GE Healthcare can correct this situation.

Safety Issue

When your system was installed, any remote Emergency Power Off (EPO) buttons that were installed (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 pressing the Remote EPO button(s).

The red EPO button on the A1 panel as well as the main disconnect switch on the A1 panel will power off the system as expected. Emergency Stop (E-stop) buttons which are used to stop system motion and X-Ray generation, are not affected and will function as intended

Safety Instructions

In the unlikely event of a system fire or other event which requires all power to be removed from the system, shut off power at the A1 panel instead of the remote EPO button.
During normal operation, there is no hazard for your patients or your CT and PET/CT Operators/Technicians. You can continue to use your system while waiting for the correction.

Affected Product Details

The following CT system are potentially affected if they have had a new A1 panel installed since December 2017:
Discovery RT (model 2374682-17 GTIN 00840682118699)
Optima CT 520 (model 5439126 GTIN 00840682102568)
Optima CT 540 (model 5144709-3 GTIN 00840682138963)
Revolution EVO (models 5454001-60 GTIN 00840682109796, 5454001-160 GTIN 00840682109796, 5454001-260 GTIN 00840682109796, 5454004-30 GTIN 00840682109796, 7454001-62 GTIN 00840682109796)
Revolution CT (model 5590000-6, 5595000-6 GTIN 00840682118552)
GoldSeal Optima 660 (model 5454001-22)
GoldSeal BrightSpeed 16 Power (model 5143716-2)

The following PET/CT system are potentially affected if they have had a new A1 panel installed since December 2017:
Discovery MI (models 5454001-170, 5990025 GTIN 00840682108218, 5990020 GTIN 00840682108218, 5990015 GTIN 00840682108218)
Discovery MI Digital Ready (model 5986030 GTIN 00840682120975)
Discovery IQ (models 5432539-22, 5900025 GTIN 00840682103107, 5900020 GTIN 00840682103107, 5900015 GTIN 00840682103107, 5900025-20 GTIN 00840682125703)

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,

[redacted]

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

[redacted]

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare