



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
 9900 Innovation Drive
 Wauwatosa, WI 53226
 USA

<Date of Letter Deployment>

GEHC Ref# 25463

To: Hospital Administrators / Risk Managers
 Managers of Radiology/Cardiology
 Radiologists/Cardiologists

RE: Potential expulsion of gantry power supply

GE Healthcare has recently become aware of a safety issue due to the potential for an expulsion of the Power Supply on your Lightspeed CT scanner or Discovery ST PET CT or Discovery LS PET CT scanner. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue GE Healthcare has become aware that the Service Procedure used to replace a power supply on the rotating side of the gantry specifies the wrong torque for the mounting hardware. Because of this error, the three mounting bolts securing the power supply could have been over-torqued when the component was replaced on your system. In the unlikely event that the component becomes loose on the CT gantry during operation, it could result in serious bodily injury if the component were to be expelled. There have been no incidents or injuries reported as a result of this procedure error.

Safety Instructions You can continue to use your GE Healthcare Lightspeed CT, Discovery ST PET CT or Discovery LS PET CT scanner. If an error message is displayed during the daily FastCal test, this may indicate that your system failed the balance test due to a possible over-torqued bolt. Should this occur; stop using the system and call your service representative to bring the system back into proper operation.

Affected Product Details GE Healthcare systems listed below which had the MDAS 16 5V Power Supply (part number 2334455) replaced are affected.

The following CT Scanners, manufactured from 2003 – 2006:

- LightSpeed Ultra (8-slice MDAS)
- LightSpeed Plus (4-slice MDAS)
- LightSpeed QX/i (4-slice MDAS)
- LightSpeed 16 (MDAS Only)

The following PET CT Scanners, manufactured from 2003 – 2005:

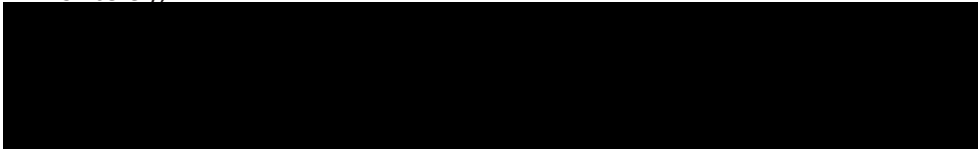
- Discovery ST
- Discovery LS

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 Devices
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer – Medical Solutions
GE Healthcare