

URGENT FIELD SAFETY NOTICE

GE Healthcare Healthcare Systems 9900 Innovation Drive Wauwatosa, WI 53226 USA

<Date of Letter Deployment>

GEHC Ref# 25467

To: Hospital Administrators / Risk Managers Managers of Radiology/Cardiology Radiologist/Cardiologist

RE: GE Healthcare CT and PET Service Manual Update Notice

GEHC has updated the Service Manuals for the products listed below to update an incorrect torque value. This communication is intended to inform you of this change.

Safety Issue

The Service Procedure describing replacement of 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 be over-torqued if the component is replaced on your system. In the unlikely event that the bolts fail on the CT gantry during operation, it could result in serious bodily injury if the component were to be expelled. There have been no reports of this issue.

Safety Instructions

Please ensure that the organization that services your equipment uses the latest version of the Service Manual to maintain the safe and proper performance of your medical device. You can continue to use your GE Healthcare Lightspeed CT, Discovery ST PET CT or Discovery LS PET CT scanner.

If your scanner is serviced by GE Healthcare, GE Healthcare has confirmed that no further action is needed on your power supply; however, please update your Service Manual per the instructions in the product correction below.

Affected Product Details

The following CT Scanners:

- 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:

- Discovery ST
- Discovery LS

You are being contacted because you have been identified as an owner of one or more of these systems.

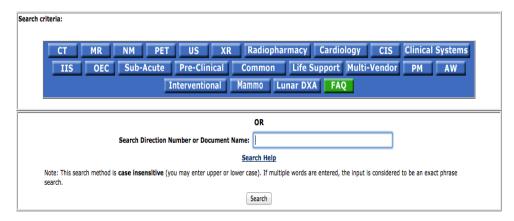
Product Correction

The latest versions of the Service Manuals are available on the Internet at: http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library

- On the home page select CT or PET and click on [Search] to launch the search.

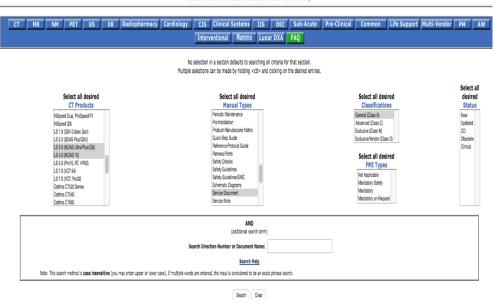
Common Documentation Library

Locate documents in the Common Documentation Library via



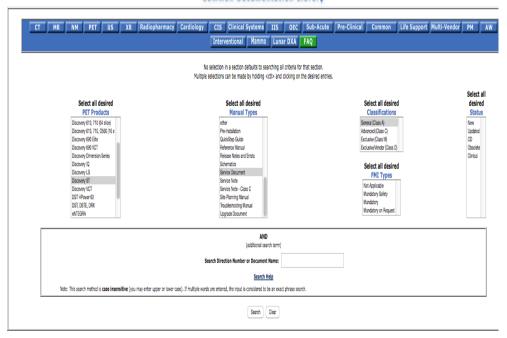
- Select your product from the list and choose Service Manual from the Manual Type and click on [Search] to launch the search to bring up the proper service manual.
- For CT Products:

Common Documentation Library



For PET Products:

Common Documentation Library



<u>Note:</u> The Service Manual is in written English language and not directed to end users but to qualified and trained Service personnel. This safety notice instructs the user/owner if the affected system to make sure, that the most recent version of the service manual will be used for the performance to the maintenance activities.

Contact Information

If you have any questions or concerns regarding this notification, please contact your local GE Healthcare Service Representative.

You can also contact:

Francois Dubos NE CT Modality Leader T: +46 702661865

E: <u>francois.dubos@ge.com</u>

Paul Mardle RA Manager UK/Ireland Phone: +44 1494 498169 e-mail: paul.mardle@ge.com

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 & Regulatory GE Healthcare

Jeff Hersh, M.D. Chief Medical Officer

GE Healthcare