



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

Search criteria:

CT	MR	NM	PET	US	XR	Radiopharmacy	Cardiology	CIS	Clinical Systems
IIS	OEC	Sub-Acute	Pre-Clinical	Common	Life Support	Multi-Vendor	PM	AW	
			Interventional	Mammo	Lunar DXA	FAQ			

OR

Search Direction Number or Document Name:

[Search Help](#)

Note: This search method is **case insensitive** (you may enter upper or lower case). If multiple words are entered, the input is considered to be an exact phrase search.

- 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

CT	MR	NM	PET	US	XR	Radiopharmacy	Cardiology	CIS	Clinical Systems	IIS	OEC	Sub-Acute	Pre-Clinical	Common	Life Support	Multi-Vendor	PM	AW
										Interventional	Mammo	Lunar DXA	FAQ					

No selection in a section defaults to searching all criteria for that section.
Multiple selections can be made by holding <ctrl> and clicking on the desired entries.

Select all desired
CT Products

- HiSpeed Dual, ProSpeed FI
- HiSpeed DXi
- LS 1.X (DXi 0,Base, Gan)
- LS 2.X (SDAS Plus/DX)
- LS 3.X (MDAS Ultra/Plus/DX)
- LS 4.X (MDAS 16)
- LS 5.X (Pro16, FI, HPW)
- LS 7.X (VCT 84)
- LS 7.X (VCT ProSD)
- Optima CT160 Series
- Optima CT1640
- Optima CT1660

Select all desired
Manual Types

- Periodic Maintenance
- Pre-Installation
- Product/Manufacturer Matrix
- Quick Step Guide
- Reference Protocol Guide
- Renewal Parts
- Safety Checks
- Safety Guidelines
- Safety Guidelines/EMC
- Schematic Diagrams
- Service Document
- Service Note

Select all desired
Classifications

- General (Class A)
- Advanced (Class C)
- Exclusive (Class M)
- Exclusive/Vendor (Class D)

Select all desired
FWI Types

- Not Applicable
- Mandatory Safety
- Mandatory
- Mandatory on Request

Select all desired
Status

- New
- Updated
- CD
- Obsolete
- Clinical

AND
(additional search term)

Search Direction Number or Document Name:

[Search Help](#)

Note: This search method is **case insensitive** (you may enter upper or lower case). If multiple words are entered, the input is considered to be an exact phrase search.

- For PET Products:

The screenshot shows the 'Common Documentation Library' interface. At the top, there is a navigation bar with tabs for various medical imaging modalities: CT, MR, NM, PET, US, XR, Radiopharmacy, Cardiology, CIS, Clinical Systems, IIS, OEC, Sub-Acute, Pre-Clinical, Common, Life Support, Multi-Vendor, PM, and AW. Below this, there are sub-tabs for 'Interventional', 'Mammo', 'Lunar DXA', and 'FAQ'. The main content area contains four columns of selection options, each with a 'Select all desired' link and a list of items:

- PET Products:** Discovery 610, 710 (64 slice), Discovery 610, 710, D660 (16 s), Discovery 690 Elite, Discovery 690 VCT, Discovery Dimension Series, Discovery C, Discovery LS, Discovery ST, Discovery VCT, DST iPower 60, DST, DSTe, DXH, eNTEGRA.
- Manual Types:** other, Pre-installation, QuickStep Guide, Reference Manual, Release Notes and Errata, Schematics, Service Document, Service Note, Service Note - Class C, Site Planning Manual, Troubleshooting Manual, Upgrade Document.
- Classifications:** General (Class A), Advanced (Class C), Exclusive (Class M), Exclusive/Vendor (Class Q).
- FMI Types:** Not Applicable, Mandatory Safety, Mandatory, Mandatory on Request.

Below these columns is a search section with the text 'AND (additional search term)' and a 'Search Direction Number or Document Name:' input field. A 'Search Help' link is provided. At the bottom, there are 'Search' and 'Clear' buttons. A note at the bottom states: 'Note: This search method is case insensitive (you may enter upper or lower case). If multiple words are entered, the input is considered to be an exact phrase search.'

Note: 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: francois.dubos@ge.com

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,

A handwritten signature in black ink, appearing to read "JDennison".

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

A handwritten signature in black ink, appearing to read "JHersh".

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