



URGENT MEDICAL DEVICE CORRECTION

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

Date of Letter Deployment

GEHC Ref# 22998

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

RE: **Potential for the CT, PET, or NM table to drop during specific servicing activities**

This document contains important information for your product. Please ensure all potential Users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

GE Healthcare has become aware of an issue regarding the products listed below that can result in the table dropping during a specific service activity if the wrong screws are removed by the service personnel without the appropriate table supports in place. This can result in injury to service personnel. There is no defect in the table itself; this issue is related to unclear guidance in the service manual for a specific service procedure.

The table functions normally during clinical operation. This issue can only occur during specific servicing activities on the table.

Actions to be taken by Customer / User

You can continue to use the system. The system and table will function as designed during clinical use. To avoid this issue, contact GE Healthcare Service at the number listed below prior to any table servicing activities so that GE Healthcare can provide you with guidance.

Please complete and return the attached acknowledgement form to
RecallFMI22998.mailbox@ge.com

Affected Product Details

Tables listed in Appendix A Table 1 are affected. Affected tables are used with CT (Computed Tomography), PET (Positron Emission Tomography) and NM (Nuclear Medicine) systems identified in Appendix A Table 2.

Intended Use:

CT: The systems are intended for head, whole body, cardiac and vascular X-ray CT applications.

PET: The systems are intended for head and whole body attenuation corrected PET imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images

NM: The systems are intended for performing nuclear cardiac imaging procedures for detection and imaging of radioisotope tracer uptake in the patient body for clinical diagnostic purposes as well as performing general Head & Body CT applications

Product Correction

GE Healthcare will provide an updated service manual with specific instructions regarding safe servicing of the impacted CT, PET, and NM tables to all customers at no cost. The service manual updates are planned to be released by the end of June, 2022. Please see Appendix B for instructions on accessing the latest service manuals online.

**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,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



GE Healthcare

GEHC Ref# 22998

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to:
RecallFMI22998.mailbox@ge.com



Appendix A

Table 1 – Affected Table Identification

Table	Part Number	Table GTIN
GT1700/GT1700V/VT1700	5122080	Not Applicable
	5122080-5	Not Applicable
	5122080-3	Not Applicable
	5122080-10	Not Applicable
	5122080-11	Not Applicable
	5122080-12	00840682103541
	5122080-4	00840682103534
	5122080-2	Not Applicable
GT2000/VT2000	5121647	Not Applicable
	5121647-2	Not Applicable
	5121647-3	Not Applicable
	5121647-4	00840682103572
GT2000x/VT2000x	5380966	00840682102674
	5380966-110	Not Applicable
	5380966-120	Not Applicable
High Capacity Table	5272966	Not Applicable
	5272966-2	Not Applicable
	5272966-3	00840682102667
Lite Table	5182488	Not Applicable
	5182488-110	Not Applicable
	5182488-2	Not Applicable
	5182488-3	00840682102575
	5182488-5	Not Applicable
Kunlun Table	5858588	Not Applicable
	5858588-2	00840682136600
	5858588-3	Not Applicable
Global PET-CT Table	5101900	Not Applicable
	5101900-2	Not Applicable
	5101900-20	00840682102582
NP Table	2113694	Not Applicable
	2200192	Not Applicable
	2200290	Not Applicable
	2200291	Not Applicable
	2247800	Not Applicable
	2247801	Not Applicable
	2113694-2	Not Applicable
	2200192-2	Not Applicable
	2200290-2	Not Applicable
	2200291-2	Not Applicable
	2247800-2	Not Applicable
	2247801-2	Not Applicable
P2005AA Table	2244226	Not Applicable
	2244226-3	Not Applicable
LCT Table	2297024	Not Applicable
CTE TWIN Table ASSY	2320315	Not Applicable

Appendix A Table 2 – Affected Systems, Tables and Service manuals.

System	Table Type	Service Manual Identifier	Affected Service Manual Revision	System GTIN
BrightSpeed Elite/Edge/Excel	GT1700	5193754-800	rev23 and prior	Not Applicable
BrightSpeed Elite/Edge/Excel Select	Lite Table	5181178-800	rev24 and prior	Not Applicable
Brivo CT315/CT325	Kunlun Table	5478834-1EN	rev6 and prior	Not Applicable
Brivo CT385	Kunlun Table	5458022-8EN	rev15 and prior	Not Applicable
Revolution Discovery CT Revolution HD Discovery CT750 HD Discovery CT	GT1700 GT2000/GT2000x	5307450-2EN	rev30 and prior	Revolution Discovery CT: 00840682102490 Revolution Discovery CT A: 00840682125574
HiSpeed Dual, ProSpeed FII	CTE TWIN Table	5116374	rev21 and prior	Not Applicable
HiSpeed Series	NP Table	2188543	rev44 and prior	Not Applicable
CTe, ProSpeed AI/FI	P2005AA Table LCT table	2244773	rev36 and prior	Not Applicable
CTe Dual, ProSpeed All/FII	CTE TWIN Table	2326233	rev17 and prior	Not Applicable
Optima CT520 Series	Lite Table	5411810-8EN	rev10 and prior	Optima CT520: 00840682102568
Optima CT520 Series with DoD Optima Advance	Lite Table	5457941-8EN	rev16 and prior	Optima CT520: 00840682102568 Optima Advance: 00840682147415
Optima CT540	GT1700	5350500-8EN	rev28 and prior	Optima CT540: 00840682102551 Optima CT540 N: 00840682138963
Optima CT620	Lite Table GT1700	5836560-8EN	rev2 and prior	00195278563408
Optima CT660	Lite Table GT1700 GT2000/VT2000x	5366080-8EN	rev39 and prior	Optima CT660 Cj2.5 Upgrade: 00840682116510
Optima CT680 Series Optima CT670	Lite Table GT1700	5487410-8EN	rev14 and prior	Not Applicable
Revolution ACT Revolution ACTs Revolution ACT EL Revolution Star Revolution Star ES ACT ACTs	Kunlun Table	5487206-8EN	rev8 and prior	Revolution ACT: 00840682135313 Revolution ACT LMB: 00840682146197 Revolution ACT EL: 00195278568373 Revolution ACTs: 00195278534811
Revolution EVO	VT1700 VT2000/VT2000x	5866660-8EN	rev26 and prior	00840682109796
Revolution Maxima/Ace Optima CT680 Expert Revolution Maxima M	Lite Table GT1700 GT2000	5809950-8EN	rev3 and prior	Revolution Maxima: 00840682146180 Revolution Maxima US: 00840682147392 Revolution Ace: 00840682146159 Optima CT680 Expert: 008406821469372
Revolution ACE ES	GT1700	5848536-8EN	rev1 and prior	00195278420893
Revolution Frontier	GT1700 GT2000/GT2000x	5796213-2EN	rev8 and prior	00840682137553
Discovery RT Discovery CT590RT Optima CT580	GT1700 High Capacity Table	5366638-8EN	rev24 and prior	Discovery RT: 00840682118699 Discovery CT590RT and CT580: Not Applicable
LightSpeed RT ¹⁶ and Xtra	GT1700 GT2000 High Capacity Table	5196837-800	rev12 and prior	Not Applicable

System	Table Type	Service Manual Identifier	Affected Service Manual Revision	System GTIN
Revolution Ascend	GT1700V VT2000/VT2000x	5987660-8EN	rev3 and prior	00840682146173
Revolution Advance / Eagle	Lite Table	5850006-8EN	rev1 and prior	Revolution Advance: 00195278385215 Revolution Eagle: 00195278403087
Discovery MI	Global PET-CT Table / GT2000	5661743-2EN	Rev 9 and prior	00840682143523 00840682108218 00195278098603
Discovery MI-DR	Global PET-CT Table / GT2000	5146686-2EN	Rev 7 and prior	00840682120975 00840682146166
Discovery IQ	Global PET-CT Table / GT2000	5495002-2EN	Rev 11 and prior	00840682125703
Discovery 610 (64 slice) Discovery 710 (64 Slice)	Global PET-CT Table / GT2000	5428822-2EN	Rev 5 and prior	00840682103053 00840682102995
Discovery 610 (16 Slice) Discovery 710 (16 slice) Optima 560	Global PET-CT Table / GT2000	5440658-2EN	Rev 5 and prior	00840682103053 00840682102995
Discovery 600 Discovery 690 Elite (16 slice) Optima 560	Global PET-CT Table / GT2000	5322777-2EN	Rev 12 and prior	00840682143981
Discovery 690 VCT	Global PET-CT Table / GT2000	5266353-2EN	Rev 14 and prior	Not Applicable
Discovery NM/CT 570c	GT1700 GT2000	5193574-800	rev36 and prior	00840682105286
LightSpeed VCT	GT1700 GT2000	5193574-800	rev36 and prior	Not Applicable

Appendix B – Service Manual Access Instructions

Please follow the below instructions to download the desired CT, PET or NM System Service Manual.

The latest versions of Service Manuals are available at:

<https://customer-doc.cloud.gehealthcare.com/#/cdp/dashboard>

Step 1: Enter the Service Manual Identifier from Appendix A Table 2 that corresponds with your device into the search field and select “Search”

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5193754-800

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Document Number	Title	Modality	Products	Document Type	Language	Status	Revision	Publish Date	Actions
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Step 2: Verify the manual revision is higher than the version number listed in Appendix A Table 2, then download the manual. Note - If the manual version is at or before the version listed in Table 2, the instructions related to this table servicing issue have not been updated in that document. Please contact GE Healthcare service before performing servicing underneath the table.

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5193754-800

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Search Results | 1 items found for 5193754-800

Document Number	Title	Modality	Products	Document Type	Language	Status	Revision	Publish Date	Actions
5193754-800	BRIGHTSPEED SERIES SERVICE METHODS_GENERAL	Computed Tomography (CT)	Multiple Products	Service Manual	English (EN)	Current	23	Apr 19, 2022	Download Print

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