



Urgent Field Safety Notice

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 or your local Service Representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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 blue ink, appearing to read 'Laila', followed by a long horizontal flourish.

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

A handwritten signature in blue ink, appearing to read 'JH', followed by a long horizontal flourish.

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 Urgent Field Safety 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



| 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 AII/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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Search By: Modality, Products, Document Type, Language, Current Revisions

Search Results | 0 items found

| Document Number | Title | Modality | Products | Document Type | Language | Status | Revision | Publish Date | Actions |
|-----------------|-------|----------|----------|---------------|----------|--------|----------|--------------|---------|
|-----------------|-------|----------|----------|---------------|----------|--------|----------|--------------|---------|

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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Search By: Modality, Products, Document Type, Language, Current Revisions

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] |

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