

URGENT Field Safety Notice

Brilliance iCT, CT 6000, IQon Spectral CT, Spectral CT, and Spectral CT 7500 on Rails
CT Subsystem Assembly Torque Not to Specification

06-JAN-2026

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Your system did not pass the inspection performed in FCO72800845. A Philips Field Service Engineer (FSE) has implemented a temporary correction. This temporary correction brings the system back into specification and supports continued safe use, in accordance with the Instructions For Use, for a period of two-weeks. During this period, Philips will schedule FCO72800846 to implement a permanent correction.

If the permanent correction (FCO72800846) is not implemented within two weeks of the FCO72800845 inspection date, **please discontinue use of your CT system immediately**. After two-weeks the temporary correction may no longer be effective in maintaining the system within specification and the system may pose a potential safety risk as described below. This URGENT Field Safety Notice letter is intended to inform you about:

1. What the problem is and under what circumstances it can occur

As part of the CT systems sub assembly, thirty-two (32) fasteners are used to attach the rotor to the bearing within the gantry. One or more of these fasteners may not be torqued to specification. If multiple fasteners are not torqued to specification, the rotor or rotor parts may become unsecured or displaced. While there has been no reported or observed event of expelled parts during gantry rotation, unsecured rotor parts may potentially be expelled, resulting in a potential risk of serious injury, including death, to individuals in the scanning room.

As of December 2025, Philips has received two (2) complaints related to this issue. In both instances, no parts were expelled from the gantry, and no injuries or harm occurred.

2. Hazard/harm associated with the issue

The probability of this hazard occurring is very remote. If the first hazardous scenario below occurs, there is a potential risk of bodily injury including death for individuals in the scanning room (e.g., service user, clinical user, or patient). Additionally, in the case of the second hazardous scenario below, a rescan might be required, and the patient may experience radiation effects.

The table below outlines the potential harm associated with each hazardous scenario and the individuals potentially affected by the harm:

Scenario	Hazardous Scenario	Affected	Potential Harm(s)
Scenario 1	An expelled rotor/part contacts the patient, operator, bystander, service personnel, or property.	Users and patients	Bodily injury to the person(s) contacted by the expelled rotor/part, including potential: contusion, laceration, fracture, pain, debilitating injury, traumatic brain injury/concussion, death. Property damage to the scan room and/or neighboring structure or properties.
Scenario 2	The operator may cancel the scan and either rescan the patient following repair or transport the patient to another scanner.	Patients	Radiation effects

3. Affected products and how to identify them

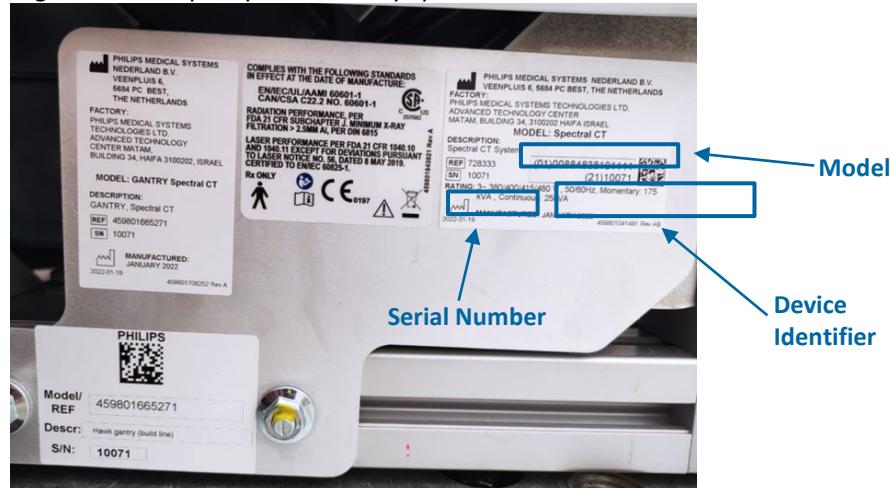
Potentially impacted models are listed below. Appendix A lists the affected serial numbers for each model.

Product Code (REF)	Product Model	Device Identifier
728306	Brilliance iCT	(01)00884838059474
728307	CT 6000	(01)00884838104600
728332	IQon Spectral CT	(01)00884838059542
728333	Spectral CT	(01)00884838101111
728334	Spectral CT 7500 on Rails	(01)00884838103627
728340	Spectral CT 7500 CN	(01)00884838111103
728344	Spectral CT 7500 Plus	(01)00884838117822

To identify if your system is affected:

Locate the Device Identifier, Model, and Serial Number (SN). These are found on a label on the back of the gantry in the bottom-right corner. An example is shown in Figure 1. Your system is affected if your Serial Number is listed in Appendix A.

Figure 1. Example Spectral CT equipment label — 728333



Spectral CT Intended Use: The Spectral CT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Spectral CT on Rails Intended Use: The Spectral CT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Philips CT (Brilliance iCT and IQon Spectral CT) Systems Intended Use:

The Philips CT system is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment support, component parts, and accessories.

4. Actions that should be taken by the customer / user to prevent risks for patients or users

- With the temporary correction implemented during FCO72800845, you may continue to use your system in accordance with the intended use and instructions for use for up to two weeks.
- As a precaution, continue to monitor the gantry for any unusual sounds or vibrations during operation - particularly during air calibration, during tube conditioning, after a Survey and before the Clinical Scan, and at other times, when the rotor comes up to speed. Continue to monitor Exams until they are ended and the gantry spins down. If unusual sounds are heard or vibrations are observed, immediately call your service contact.
- **Identify the two-week deadline by which your system must receive the permanent correction (FCO72800846).** For example, if the temporary correction (FCO72800845) was implemented on 06-Jan-2026, then the two-week deadline will be 20-Jan-2026.
- When contacted, please work with your Philips representative to schedule a time for the permanent correction (FCO72800846) to be performed within the two-week timeframe.
- If the permanent correction is not implemented by the two-week deadline as described above:
 - **Immediately discontinue use of your CT system(s).**
 - Post a “Do not use” notice on or near the impacted CT system(s).
 - Post this letter near the impacted CT system(s) for reference.
- Circulate this letter to all users of this device so that they are aware of the issue and the associated hazard/harm until this issue has been resolved.
- Please complete and return the attached Customer Response Form to Philips **promptly and no later than 5 days from receipt of this letter.**



5. Actions planned by Philips to correct the problem

Philips will contact you to schedule a time for a Philips Field Service Engineer (FSE) to visit your site and perform the permanent correction to resolve the issue (reference FCO72800846).

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative:

Telephone 80 30 30 35
Email philips.service@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Idan Lazar
Head of Quality
Computed Tomography / Advanced Molecular Imaging

Appendix A – Affected Product Code, Model, and Serial Numbers (SN)

Product Code: 728306

Model: Brilliance iCT

87064	87120	87121	87122	87125	87126	87127	87128	87129	87130
87135	87143	87148	87152	87153	87157	87160	87162	87167	87173
87174	87176	87181	87197	87198	87199	87200	87202	87203	87204
87205	87206	87207	87208	87209	87210	87211	87212	87213	87214
87215	87216	87217	87218	87219	87220	87221	390007	390008	390010

Product Code: 728307

Model: CT 6000

87110	87115	87116	87117	87118	87119	87123	87124	87131	87132
87133	87134	87136	87137	87138	87139	87140	87141	87142	87144
87145	87146	87147	87149	87150	87151	87154	87155	87158	87159
87161	87163	87164	87165	87166	87168	87169	87170	87171	87172
87175	87177	87178	87179	87180	87182	87183	87184	87185	87186
87187	87188	87189	87190	87191	87192	87193	87194	87195	87196

Product Code: 728332

Model: IQon Spectral CT

60068	60128	60129	60130	60132	60133	60134	60136	60137	60138
60139	60141	60142	60143	60144	60145	60146	60147	60148	60149
60150	60151	60152	60153	60154	60155	60156	60157	60158	60159
60160	60161	60162	60163	60164	60165	60166	60167	60168	60169
60170	60171	60172	60173	60174	60175	60176	60177	60178	60179
60180	60181	60182	395007	395008	395009	395010	395011	395012	

Product Code: 728333

Model: Spectral CT

10055	10056	10057	10058	10059	10060	10061	10062	10070	10074
10075	10076	10077	10078	10079	10080	10081	10082	10084	10085
10086	10087	10088	10089	10090	10091	10092	10094	10095	10096
10097	10098	10099	10100	10101	10102	10103	10104	10105	10106
10107	10108	10109	10110	10111	10112	10113	10114	10115	10116
10118	10119	10120	10121	10122	10123	10124	10125	10126	10127
10128	10129	10130	10131	10132	10133	10134	10135	10136	10137
10138	10139	10140	10141	10142	10143	10144	10145	10146	10147
10148	10149	10150	10151	10152	10153	10154	10155	10156	10157
10158	10159	10160	10161	10162	10163	10164	10165	10166	10167
10168	10169	10170	10171	10172	10173	10174	10175	10176	10177
10178	10179	10180	10181	10182	10183	10184	10185	10186	10187
10188	10189	10190	10191	10192	10193	10194	10195	10196	10197
10198	10199	10200	10201	10202	10203	10204	10205	10206	10207
10208	10209	10210	10211	10212	10213	10214	10215	10217	10218
10219	10220	10221	10222	10223	10224	10225	10226	10227	10228
10229	10230	10231	10232	10233	10234	10235	10236	10237	10238
10239	10240	10241	10242	10243	10244	10245	10246	10247	10248
10249	10250	10251	10252	10253	10254	10255	10256	10257	10258
10259	10260	10261	10262	10263	10264	10265	10266	10267	10268
10269	10270	10271	10272	10273	10274	10275	10276	10277	10278

10279	10280	10281	10284	10285	10286	10287	10288	10289	10290
10291	10292	10293	10294	10298	10299	10300	10301	10302	10303
10304	10305	10306	10307	10308	10310	10311	10312	10314	12000
12001	12002	12003	12004	12005	12006	12007	12008	12009	12010
12011	12012	12013	12014	12015	12016	12017	12018	12019	12020
12021	12022	12023	12024	12025	12026	12027	12028	12029	12030
12031	12032	12033	396004	396005	396006	396007	396008	396009	396010
396011	396012	396013	398003	398004					

Product Code: 728334

Model: Spectral CT 7500 on Rails

1005	1007	1008
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Product Code: 728340

Model: Spectral CT 7500 CN

397003	397005	397006	397007	397008	397009	397010	397011	397012	397013
397014	397015	397016	397017	397018	397019	397020	397021	397022	397023
397024	397025	397026	397027	397028	397029	397030	397031	397032	397033
397034	397036	397037	397038	397039	397040	397041	397043	397044	397045
397046	397047	397048	397049	397050	397053	397054	397055	397056	397058
397059	397060	397061	397062	397063	397064	397065	397066	397067	397070
397071	397072	397073	397075	397076	397077	397079	397080	397081	397082
397083	397084	397085	397086	397087	397088	397089	397091	397093	397095
397096	397097	397098	397099	397101	397102	397105	397106	397107	397108
397110	397112	397115	397116	397117	397119	397120	397121		

Product Code: 728344

Model: Spectral CT 7500 Plus

397057	397068	397074	397078	397090	397092	397094	397100	397103	397104
397111	397113	397114	397118	397122					

URGENT Field Safety Notice Response Form

Reference: CT Subsystem Assembly Torque Not to Specification on Brilliance iCT, CT 6000, IQon Spectral CT, Spectral CT, and Spectral CT 7500 on Rails, 2025-PD-CTAMI-013 (FCO72800845 and FCO72800846).

Instructions: Please complete and return this form to Philips promptly and **no later than 5 days from receipt**. Completing this form confirms receipt of the Urgent Field Safety Notice letter, your understanding of the issue, and the required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Refer to the instructions provided in Section 4 of the Urgent Field Safety Notice letter.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to: **FCO.Nordic@philips.com**