PHILIPS

URGENT Field Safety Notice

Incisive CT/CT 3500/CT 5300 System

Potential for System Shutdown and Expelled Parts

15-Apr-2024

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,

Philips has identified an issue with Incisive CT/CT3500/CT5300 systems which could pose a risk for patients, operators, or bystanders. This URGENT Field Safety Notice is intended to inform you about:

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

Philips has identified a hardware issue with a metal mounting box on the rotating scanner on rotor (heat change box) located within the Incisive CT/CT 3500/CT 5300 system. This component's structural integrity may become compromised, resulting in potential contact with other gantry components located within the Incisive CT/CT 3500/CT 5300 system during rotation. Other components could be damaged due to the contact with the detached component.

If this issue occurs, a loud noise will be emitted and the system will shut down.
The cover may become displaced if the following sequence occurs:

- Damaged component(s) come loose
- The damaged component(s) contact other components in the system and cause them to break
- A broken component makes contact with the top right gantry cover

The displaced cover could create a small gap allowing a fragment of a damaged component to be expelled at a low velocity. The maximum weight of a fragment that could be expelled is 60g (2.12 ounces).

This issue was discovered internally by Philips. As of Mar-2024, Philips has not received any customer complaints related to this issue.

2. Hazard/harm associated with the issue

If the Incisive CT/CT 3500/CT 5300 system shut down during clinical scanning, the operator may decide to rescan the patient on another CT system or utilize a different type of imaging

If a broken fragment is expelled from the system and comes into contact with an operator or a bystander in the room, it could cause injury, such as pain (body or neck), laceration, or eye injury.

3. Affected products and how to identify them

Identification of Impacted CT Systems:
This issue affects certain CT systems, which have the Device Identifier as shown in table 1.
A listing of impacted systems is provided in Appendix A. Impacted systems can be identified by the Device Identifier, model number (REF) and system serial number (SN).

To determine if your product is impacted, refer to the system label (Figure 1) located on the back left corner of the gantry.

Table1. Device Identifier

REF	Device Identifier
728143	00884838085015
728144	00884838105508
728146	NA
728148	00884838103467
728149	00884838103474
728151	00884838103481
728134	00884838111318
728138	00884838105522
728139	00884838105539
728285	00884838113237

Figure 1. System Label Example

Intended Use:
Incisive CT & CT 3500
Philips Incisive CT & CT 3500 system produces cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment support, components, and accessories.

CT 5300
Philips CT is a Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of Xray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment support, components, and accessories.

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

- Please continue to use your system in accordance with its intended use. If you need to remain in the room for the duration of a scan, Philips recommends using protective eyewear.
- Circulate this URGENT Field Safety Notice Letter to all users of this device so that they are aware of the issue. Please retain this letter with your system(s) until a solution is installed on your system; ensure the letter is in a place likely to be seen/viewed.
- Place this URGENT Field Safety Notice Letter with your system documentation.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

5. Actions planned by Philips to correct the problem

Philips will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site and install a solution to address the issue (reference FCO72800819 and FCO72800820).

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: <When a Philips representative is required, contact details to be provided by the Market>

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

LI Xin

Li Xin
Quality Leader
Philips Precision Diagnostics (PD) China

Appendix A – Affected Serial Numbers

Serial Numbers for Incisive CT (REF: 728143) Unique Device Identifier Rule: (01)00884838085015(21) + Serial number Applied to FCO72800819								
500001	500002	500003	500004	500005	500006	500007	500008	500010
500011	500012	500013	500014	500017	500018	500019	500020	500021
500022	500023	500024	500025	500026	500027	500028	500029	500030
500031	500032	500033	500034	500035	500036	500037	500038	500039
500040	500041	500042	500043	500044	500045	500047	500048	500049
500050	500051	500052	500053	500054	500055	500056	500057	500058
500059	500060	500061	500062	500063	500065	500066	500067	500068
500069	500070	500071	500072	500073	500075	500076	500077	500078
500079	500080	500081	500082	500083	500087	500089	500090	500091
500092	500093	500094	500095	500096	500097	500098	500099	500100
500103	500104	500105	500106	500107	500108	500109	500112	500113
500114	500115	500116	500117	500118	500119	500120	500121	500122
500123	500124	500125	500126	500127	500128	500129	500130	500131
500132	500133	500134	500135	500136	500137	500138	500139	500141
500142	500143	500144	500146	500147	500148	500149	500150	500151
500152	500153	500154	500155	500156	500157	500158	500159	500160
500161	500162	500163	500164	500165	500166	500167	500169	500170
500171	500172	500173	500174	500175	500176	500177	500179	500180
500181	500182	500183	500184	500185	500186	500187	500188	500189
500190	500191	500192	500193	500194	500195	500196	500197	500198
500199	500200	500201	500202	500203	500204	500205	500206	500207
500208	500209	500210	500212	500213	500214	500215	500218	500219
500220	500221	500223	500224	500226	500227	500228	500229	500231
500232	500233	500234	500235	500236	500237	500238	500239	500243
500249	500250	500251	530002	530003	530004	530005	530006	530007
530008	530009	530010	530011	530012	530013	530014	530015	530016
530017	530018	530019	530020	530021	530022	530023	530024	530025
530026	530027	530028	530029	530030	530031	530032	530033	530034
530035	530036	530037	530038	530039	530040	530041	530042	530043
530044	530045	530046	530047	530048	530049	530050	530051	530052
530053	530054	530055	530056	530057	530058	530059	530060	530061
530062	530063	530064	530065	530066	530067	530068	530069	530070
530071	530072	530073	530074	530075	530076	530077	530078	530079
530080	530081	530082	530083	530084	530085	530086	530087	530088
530089	530090	530091	530092	530093	530094	530095	530096	530097
530098	530099	530100	530101	530102	530103	530104	530105	530106
530107	530108	530109	530110	530111	530112	530113	530114	530115
530116	530122	530123	530131	530445	-	-	-	-

Serial Numbers for Incisive CT (REF: 728143) Unique Device Identifier Rule: (01)00884838085015(21) + Serial number Applied to FCO72800820								
500522	500523	510042	510049	510050	500527	500543	510052	500549
500550	500532	500541	500551	500533	510053	500552	500539	500553
510056	500546	500547	500556	510058	510051	500526	500528	500548
530485	500558	510057	500560	510059	500562	500564	500563	500524
500568	500565	530505	500570	500567	530512	510061	510062	500566
500571	530511	530513	530520	530518	500573	500569	530525	530519
500576	510064	500575	530536	530532	530538	530544	530539	530542
500574	510065	510066	530556	530555	530551	530557	530558	510067
530560	500582	510068	500580	510069	500581	530571	530570	500583
510070	510071	500584	530573	510072	500585	530579	530582	530580
500589	500587	500588	510073	500590	530586	500591	510075	530593
500592	500593	530590	530594	500594	530595	500595	500596	500597
500598	510076	500600	500599	500601	500602	500603	510077	500604
500605	510078	510080	510079	500607	500608	500612	500613	510083
500614	510084	510085	510086	510087	500609	510082	510088	510089
500617	510094	500616	510090	510091	510092	510093	500496	500513
500521	510044	500540	500535	500544	510048	510054	510055	500554
500545	500542	500557	500525	500555	500559	500561	510060	510063
500572	530517	530516	500577	530526	500578	530528	500579	530531
530540	530541	530546	530548	530553	530565	530568	530566	530572
500586	530574	510074	530583	530587	500606	500610	500611	510081
500618	510095	500620	500619	500621	500622	500623	500624	500625
33043	-	-	-	-	-	-	-	-

Serial Numbers for Incisive CT (REF: 728144) Unique Device Identifier Rule: (01) 00884838105508(21) + Serial number Applied to FCO72800820								
34171	500454	500452	500453	500507	500515	500505	500504	500506
510039	500516	500511	500519	500514	500517	510040	510043	500536
510046	550000	510045	510047	550001	550003	550005	552001	550010
500537	550004	550012	550011	550009	550014	550008	550002	550007
550013	550016	550020	550017	550022	550025	550024	550026	550032
550028	550027	550030	550018	550036	550035	550029	550037	550021
550034	550033	34004	550019	550038	34013	34011	34014	550039
34008	34015	34016	34020	550043	550045	550052	552007	550051
550058	550031	550047	550044	550048	550053	550057	552009	550056
552005	550060	550049	550063	550059	552010	552011	550065	552014
34022	34027	34009	550070	550069	550068	550071	550061	550072
34028	552015	34029	34030	34034	34037	34039	552016	550075
550076	34044	34046	550079	550073	550081	552018	552017	550080
552022	550086	34043	550094	550074	550089	550088	550085	550100
552020	550090	550097	550087	34065	550101	550099	550102	550096
550098	550104	550095	550105	34061	550108	552025	552028	550107

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Serial Numbers for Incisive CT (REF: 728144) Unique Device Identifier Rule: (01) 00884838105508(21) + Serial number Applied to FCO72800820								
552026	552027	552029	550092	550111	550112	550123	550113	550124
550117	550125	550118	550129	550119	550122	550127	550126	550120
550130	550132	34076	34070	550133	550134	552032	550135	34084
554004	554000	554003	34087	556000	550141	550121	550140	554006
554007	550143	550128	550136	550147	554008	554009	550138	550137
550139	34094	554015	554010	554012	554013	554014	554011	34104
554016	34107	554019	554018	554021	554022	554020	34109	34113
34114	34115	554023	34120	34110	34108	34121	550152	550153
550161	552034	550145	550170	552042	550173	552038	552040	552039
552041	550175	554024	554025	556001	550156	552037	554026	552044
552045	550182	550184	34123	550162	550169	550186	34127	550190
550174	550163	552048	550199	34140	34138	34141	34145	550194
552036	550160	550166	550158	550178	552047	550167	550168	550165
550216	554027	34151	34124	34125	34142	34139	34144	550204
550179	550176	550177	550181	550187	550200	34129	550210	554035
552050	34147	550213	550206	550207	552043	550211	550183	550185
552046	550205	554033	550212	34154	554034	550195	34155	550203
550198	550201	550193	550202	550209	550191	550215	550188	550189
550196	550197	550218	34158	556002	554043	554047	34161	554044
550225	554048	550223	550219	550227	550236	550252	34157	550230
554050	550228	554049	554052	556003	550244	550224	550235	550214
34167	550240	550241	550238	34166	550245	34170	550253	552052
552051	550220	550221	550222	550251	554061	554063	550250	34173
34172	550208	552049	550247	34176	34180	34177	550254	550259
552060	552061	550260	34183	550257	34182	550258	34178	550261
550262	34184	550264	552059	552062	552063	34186	550265	550192
550237	552058	552056	550232	552057	550255	550234	550217	550233
550231	550248	552055	550229	550249	550242	34188	34189	34192
550239	550267	550246	552054	550226	550270	550268	34199	34202
34185	34204	550266	34194	34197	34207	34156	34209	34196
34211	34212	34215	34216	34213	34217	550269	34210	34222
34228	34214	34232	34148	550489	55400406110738		55400406111210	
55400406110740		34309	34307	34357	34306		34364	
500500	500508	500509	500501	500499	500503	500512	500502	500518
500531	500520	552000	500530	500529	552002	550006	550015	500538
552003	550023	34010	552004	34005	550041	550042	552008	550040
552006	550050	550054	550055	550064	550046	550062	550066	552013
552012	550067	34021	34035	34024	34045	550077	550083	550078
550084	550082	550091	34048	552019	34036	550093	34062	550103
552021	552023	552024	550106	550114	550109	34063	550115	34069
550116	550110	550131	554001	554002	554005	550142	554017	550149
552033	550150	550146	550151	550148	34118	550154	550155	550144
550172	552035	550164	34136	550159	550157	554028	550171	550180
34001	554068	554067	550256	550263	552065	554072	554071	554073
554070	550271	550272	554074	550274	550275	550273	550278	550279

Serial Numbers for Incisive CT (REF: 728144) Unique Device Identifier Rule: (01) 00884838105508(21) + Serial number Applied to FCO72800820								
552066	552064	550277	550280	550282	550283	552067	550285	550286
554077	550291	554082	554081	554085	550298	550297	554083	550296
550299	550306	550300	550301	550304	550303	554086	554088	550309
550310	550311	550320	554094	550314	552074	550312	550313	34220
550316	550319	554091	554114	34227	550321	550276	554092	550325
554093	550326	552075	552076	550323	550327	550328	550292	550281
552070	550330	552069	550294	550308	550329	34231	554097	552077
550331	550332	554099	34236	34239	34237	550333	34238	550336
552113	34230	550284	552068	550288	550289	550318	550295	550337
550334	554106	554095	554096	554102	550343	34234	34224	550339
550346	550307	550317	550322	550305	552072	550302	552082	550344
550345	552079	552080	550340	550287	550324	554109	554100	550352
550353	550354	550341	550342	550351	554103	34242	550290	34243
554115	552085	550355	550362	552086	554107	34245	34246	550361
550363	552087	552088	554119	34241	552091	550356	34225	554120
550366	554123	554121	554124	554122	34219	550374	550368	550369
550370	550371	552089	550364	550335	550338	34248	552090	552092
34249	554128	554111	550373	34250	552083	550365	552081	554129
550359	34252	34247	550383	556004	550384	550385	550387	34253
34254	550315	34256	552094	554131	34255	550380	550381	550378
550367	550379	552084	550382	550389	550375	554136	554135	554133
550392	34261	550372	550376	550377	550395	552096	550348	550350
550357	550358	550360	550394	552095	552093	554138	34262	34258
552098	554141	550349	550347	550386	552097	550398	554140	34273
34272	34274	34275	550399	55400406110607	34233	550400	550390	550391
550388	550403	554108	554104	55400406111115	554143	552101	550393	550405
552102	550406	554147	554144	55400406111064	550413	550408	554113	34268
554151	554150	554152	550396	550397	550410	552099	554127	550418
554148	554154	550402	552106	34266	34278	550415	552105	550419
34269	554149	550414	550416	55400406111136	34283	552107	34284	552078
554155	550425	34286	550407	55400406111211	550401	550409	550420	550404
552103	552100	552104	550422	55400406111183	550427	552108	554159	554156
554158	554160	554157	550426	55400406111002	554161	554166	554163	34287
550429	550411	552109	552110	55400406110840	550430	552111	554162	550431
34271	550433	550421	550412	55400406111082	550417	554165	34290	34288
34291	34292	34293	550434	55400406110942	550439	550428	550423	550424
552115	34305	34299	34303	55400406111085	34296	554170	554169	552112
550454	554172	550455	550435	550451	552118	34297	34300	550436
550440	34302	550437	550450	550432	550442	550441	552114	554173
550449	554175	554171	34298	55400406110846	550443	34313	34308	34314
554176	554177	34311	34312	55400406111117	34316	34317	554182	554179
554180	554178	550459	34319	55400406111026	550457	34320	34318	34310
550460	552116	554183	550446	55400406111033	550444	550448	550445	550447
34323	34322	34304	550464	55400406111118	550465	550452	552117	34321
550453	554185	554184	550466	55400406111437	550473	554187	554188	554192

Serial Numbers for Incisive CT (REF: 728144) Unique Device Identifier Rule: (01) 00884838105508(21) + Serial number Applied to FCO72800820								
550463	552119	550462	550461	55400406111438	550458	550471	550472	550474
550469	550470	554195	550467	55400406111276	554194	556005	554181	554196
554191	554197	554198	550468	55400406111422	550480	550478	550479	34328
554200	554199	552120	550481	55400406111352	550477	554208	552121	550486
550482	550484	550476	550483	55400406111457	550485	550487	34330	34331
554203	554207	550456	554202	55400406111099	34332	550438	34336	34333
554204	554205	554206	34329	55400406111229	34345	550490	550491	550492
554211	554209	554210	552122	55400406111198	34347	34339	34334	34342
34340	34343	550488	554212	55400406111458	550494	554214	550493	550495
554216	554213	554215	550496	55400406111633	34349	550497	550500	554218
554220	554217	34352	550499	550508	554221	552123	550501	554219
550498	550502	34353	552126	55400406111613	550506	550507	550509	554227
552125	552124	550504	554222	55400406111636	34371	34373	554228	554226
554224	554223	552127	34362	55400406111614	34372	554230	554232	34366
34360	34355	34354	34361	55400406111895	552132	550511	34363	34375
34369	34365	34346	34370	55400406111221	550510	552129	552130	550512
552128	34356	34359	552131	55400406111876	550506	550507	550509	554227
550505	550513	554235	554234	55400406111960	34377	34378	34380	34381
554236	550514	550515	554238	55400406111961	34382	34383	34387	34388
554229	554237	554233	34379	55400406111629	34389	550519	550520	550521
552133	550518	550516	34376	55400406111975	550522	550523	550524	552134
552135	554240	55400406111644		55400406111940		55400406112070		

Serial Numbers for Incisive CT (REF: 728146) Unique Device Identifier Rule: N/A Applied to FCO72800820								
541004	541002	541003	541005	541006	541007	541011	541010	541012
541014	541016	541018	541017	541015	540020	540021	541000	540019
540024	540023	541009	541008	541013	541019	541020	541021	541024
541023	541031	541026	541022	541025	541041	541032	541042	541033
541040	541039	541027	541028	541037	541034	541035	541036	540022
541029	541030	-	-	-	-	-	-	-

Serial Numbers for Incisive CT (REF: 728148) Unique Device Identifier Rule: (01)00884838103467 (21) + Serial number Applied to FCO72800820								
530486	530508	530506	530507	530509	530510	530514	530515	530524
530527	530529	530535	530530	530534	530543	530549	530547	530552
530554	530559	530563	530564	530567	530569	530576	530575	530577
530581	530578	530585	530589	530592	530591	530598	530599	530600
530601	530602	530603	530604	530605	530610	530607	530608	530609
530611	530612	554030	554029	554031	554038	554037	554036	554040
554039	554046	554045	554042	554051	554057	554053	554055	554056
554059	554058	554064	554066	554062	554041	554069	530523	530545

Serial Numbers for Incisive CT (REF: 728148) Unique Device Identifier Rule: (01)00884838103467 (21) + Serial number Applied to FCO72800820								
530561	530562	530584	530588	530596	530597	530606	530614	530613
554076	554075	554079	554080	554084	554087	554089	554101	554098
554105	554117	554110	554112	554126	554118	554130	554132	554134
554137	554125	554139	554142	554145	554146	554153	554164	554167
554168	554174	554190	554193	554189	554186	554201	554225	554231
554239	-	-	-	-	-	-	-	-

Serial Numbers for Incisive CT (REF: 728149) Unique Device Identifier Rule: (01)00884838103474(21) + Serial number Applied to FCO72800819
530449

Serial Numbers for Incisive CT (REF: 728149) Unique Device Identifier Rule: (01)00884838103474(21) + Serial number Applied to FCO72800820								
530521	530533	530550	554032	554054	554060	554065	530537	554078
554090	554116	-	-	-	-	-	-	-

Serial Numbers for Incisive CT (REF: 728151) Unique Device Identifier Rule: (01) 00884838103481(21) + Serial number Applied to FCO72800820								
520000	520005	520006	520007	520008	520009	520010	520011	520012
520001	520002	520003	520004	520013	-	-	-	-

Serial Numbers for Incisive CT (REF: 728134) Unique Device Identifier Rule: (01) 00884838111318 (21) + Serial number Applied to FCO72800820								
610001	610003	610004	610005	610006	610007	610008	610009	610010

Serial Numbers for Incisive CT (REF: 728138) Unique Device Identifier Rule: (01) 00884838105522 (21) + Serial number Applied to FCO72800820								
620001	620002	620004	620005	620006	620007	620008	620009	620010
620011	620012	620013	620014	620015	620016	620017	620018	620021
620022	620023	620024	620025	620026	620027	620028	620029	620030

Serial Numbers for Incisive CT (REF: 728139) Unique Device Identifier Rule: (01) 00884838105539 (21) + Serial number Applied to FCO72800820	
620019	620020

Serial Numbers for Incisive CT (REF: 728285) Unique Device Identifier Rule: (01)00884838113237 (21) + Serial number Applied to FCO72800820				
800001	800002	800003	800004	800005

PHILIPS

URGENT Field Safety Notice Response Form

Reference: Potential for System Shutdown and Expelled Parts on Incisive CT/CT 3500/CT 5300 Systems (Reference FCO72800819 and FCO72800820)

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

- You may continue to use your system(s) in accordance with the intended use.
- Follow the instructions provided in Section 4 of this *URGENT Field safety Notice Letter*.
- Circulate this *Urgent Field Safety Notice Letter* to all users of this device so that they are aware of the issue.
- Place this *URGENT Field Safety Notice Letter* with your system documentation.

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 that handle the affected Philips CT System(s).

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please return this completed form to Philips at: <local market email address>