

**URGENT Field Safety Notice**

**Incisive CT System**

Potential for System Shutdown and Expelled Parts

25-Apr-2023

**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 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 exchanger box) located within the Incisive CT system. This component may become detached and make contact with other components located within the Incisive CT 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).

As of Mar-2023, Philips has received one (1) complaint which was reported as an adverse event associated with this issue. In this reported case, there was no harm to the patient, operator, or bystander.

**2. Hazard/harm associated with the issue**

If the Incisive CT system shuts down during clinical scanning, the operator may decide to rescan the patient on another CT system or utilize a different type of imaging, which may result in a delay in diagnosis.

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 Incisive CT Systems:**

This issue affects certain Incisive 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    |
| 728146 | 00884838104481    |
| 728148 | 00884838103467    |
| 728149 | 00884838103474    |

Figure 1. System Label Example



**Intended Use:**

Philips Incisive CT 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.

**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**

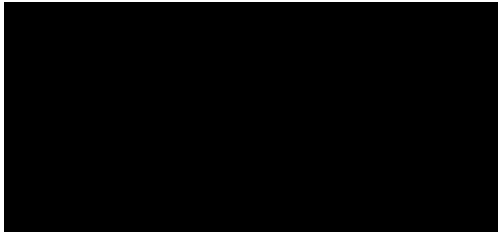
Philips will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site and install a solution to address the issue (reference FCO72800798).



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,



**Appendix A – Affected Serial Numbers**

| Serial Numbers for Incisive CT (REF: 728143)                          |        |        |        |        |        |        |        |        |
|---|--------|--------|--------|--------|--------|--------|--------|--------|
| Unique Device Identifier Rule: (01)00884838085015(21) + Serial number |        |        |        |        |        |        |        |        |
| 530522  | 530504 | 530503 | 530499 | 530498 | 530497 | 530496 | 530495 | 530493 |
| 530491  | 530490 | 530488 | 530487 | 530484 | 530479 | 530478 | 530477 | 530473 |
| 530472  | 530471 | 530469 | 530468 | 530467 | 530465 | 530463 | 530459 | 530457 |
| 530455  | 530454 | 530453 | 530451 | 530450 | 530448 | 530447 | 530446 | 530444 |
| 530443  | 530442 | 530441 | 530440 | 530439 | 530438 | 530434 | 530433 | 530429 |
| 530428  | 530427 | 530426 | 530425 | 530424 | 530423 | 530422 | 530418 | 530417 |
| 530416  | 530415 | 530414 | 530413 | 530412 | 530411 | 530410 | 530407 | 530406 |
| 530405  | 530403 | 530402 | 530401 | 530400 | 530399 | 530398 | 530397 | 530396 |
| 530395  | 530394 | 530393 | 530392 | 530391 | 530390 | 530387 | 530386 | 530385 |
| 530383  | 530382 | 530381 | 530380 | 530379 | 530377 | 530376 | 530375 | 530371 |
| 530367  | 530366 | 530365 | 530364 | 530362 | 530361 | 530359 | 530356 | 530355 |
| 530354  | 530353 | 530352 | 530351 | 530348 | 530347 | 530346 | 530344 | 530343 |
| 530341  | 530340 | 530339 | 530337 | 530336 | 530334 | 530333 | 530330 | 530328 |
| 530327  | 530326 | 530325 | 530324 | 530323 | 530322 | 530321 | 530319 | 530318 |
| 530317  | 530316 | 530315 | 530314 | 530313 | 530312 | 530311 | 530310 | 530309 |
| 530308  | 530306 | 530305 | 530304 | 530303 | 530302 | 530300 | 530299 | 530298 |
| 530297  | 530296 | 530295 | 530293 | 530292 | 530291 | 530290 | 530289 | 530288 |
| 530287  | 530286 | 530285 | 530284 | 530283 | 530282 | 530281 | 530280 | 530279 |
| 530278  | 530277 | 530276 | 530275 | 530274 | 530273 | 530272 | 530271 | 530270 |
| 530269  | 530268 | 530267 | 530266 | 530265 | 530264 | 530263 | 530262 | 530261 |
| 530260  | 530259 | 530258 | 530257 | 530256 | 530255 | 530254 | 530253 | 530252 |
| 530251  | 530250 | 530249 | 530248 | 530247 | 530246 | 530245 | 530244 | 530243 |
| 530242  | 530241 | 530240 | 530239 | 530238 | 530237 | 530235 | 530234 | 530233 |
| 530232  | 530231 | 530230 | 530229 | 530228 | 530227 | 530226 | 530225 | 530224 |
| 530223  | 530222 | 530221 | 530220 | 530219 | 530218 | 530217 | 530216 | 530215 |
| 530214  | 530213 | 530212 | 530211 | 530210 | 530209 | 530208 | 530207 | 530206 |
| 530205  | 530204 | 530203 | 530202 | 530201 | 530200 | 530199 | 530198 | 530197 |
| 530196  | 530195 | 530194 | 530193 | 530192 | 530191 | 530190 | 530189 | 530188 |
| 530187  | 530186 | 530185 | 530184 | 530183 | 530182 | 530181 | 530180 | 530179 |
| 530178  | 530177 | 530176 | 530175 | 530174 | 530173 | 530172 | 530171 | 530170 |
| 530169  | 530168 | 530167 | 530166 | 530165 | 530164 | 530163 | 530162 | 530161 |
| 530160  | 530159 | 530158 | 530157 | 530156 | 530155 | 530154 | 530153 | 530152 |
| 530151  | 530150 | 530149 | 530148 | 530147 | 530146 | 530145 | 530144 | 530143 |
| 530142  | 530141 | 530140 | 530139 | 530138 | 530137 | 530135 | 530134 | 510041 |
| 510038  | 510037 | 510036 | 510035 | 510034 | 510033 | 510032 | 510031 | 510030 |
| 510029  | 510028 | 510027 | 510026 | 510025 | 510024 | 510023 | 510022 | 510021 |
| 510020  | 510019 | 510018 | 510017 | 510016 | 510015 | 510014 | 510013 | 510012 |
| 510011  | 510010 | 510009 | 510008 | 510007 | 510006 | 510005 | 510004 | 510003 |
| 510002  | 510001 | 510000 | 500498 | 500497 | 500495 | 500494 | 500493 | 500492 |
| 500491  | 500490 | 500489 | 500488 | 500487 | 500486 | 500485 | 500484 | 500483 |
| 500482  | 500481 | 500480 | 500479 | 500478 | 500477 | 500476 | 500475 | 500474 |
| 500473  | 500472 | 500471 | 500470 | 500469 | 500468 | 500467 | 500466 | 500465 |
| 500464  | 500463 | 500462 | 500461 | 500460 | 500459 | 500458 | 500457 | 500456 |

| Serial Numbers for Incisive CT (REF: 728143)                          |        |        |        |        |        |        |        |        |
|---|--------|--------|--------|--------|--------|--------|--------|--------|
| Unique Device Identifier Rule: (01)00884838085015(21) + Serial number |        |        |        |        |        |        |        |        |
| 500455  | 500451 | 500450 | 500449 | 500448 | 500447 | 500446 | 500445 | 500444 |
| 500443  | 500442 | 500441 | 500440 | 500439 | 500438 | 500437 | 500436 | 500435 |
| 500434  | 500433 | 500432 | 500431 | 500430 | 500429 | 500428 | 500427 | 500426 |
| 500425  | 500424 | 500423 | 500422 | 500421 | 500420 | 500419 | 500418 | 500417 |
| 500416  | 500415 | 500414 | 500413 | 500412 | 500411 | 500410 | 500409 | 500408 |
| 500407  | 500406 | 500405 | 500404 | 500403 | 500402 | 500401 | 500400 | 500399 |
| 500398  | 500397 | 500396 | 500395 | 500394 | 500393 | 500392 | 500391 | 500390 |
| 500389  | 500388 | 500387 | 500386 | 500385 | 500384 | 500383 | 500382 | 500381 |
| 500380  | 500379 | 500378 | 500377 | 500376 | 500375 | 500374 | 500373 | 500372 |
| 500371  | 500370 | 500369 | 500368 | 500367 | 500366 | 500365 | 500364 | 500363 |
| 500362  | 500361 | 500360 | 500359 | 500358 | 500357 | 500356 | 500355 | 500354 |
| 500353  | 500352 | 500351 | 500350 | 500349 | 500348 | 500347 | 500346 | 500345 |
| 500344  | 500343 | 500342 | 500341 | 500340 | 500339 | 500338 | 500337 | 500336 |
| 500335  | 500334 | 500333 | 500332 | 500331 | 500330 | 500329 | 500328 | 500327 |
| 500326  | 500325 | 500324 | 500323 | 500322 | 500321 | 500320 | 500319 | 500318 |
| 500317  | 500316 | 500315 | 500314 | 500313 | 500312 | 500311 | 500310 | 500309 |
| 500308  | 500307 | 500306 | 500305 | 500304 | 500303 | 500302 | 500300 | 500299 |
| 500298  | 500296 | 500293 | 500288 | 500287 | 500286 | 500285 | 500284 | 500283 |
| 500279  | 500278 | 500277 | 500276 | 500275 | 500274 | 500273 | 500272 | 500271 |
| 500270  | 500269 | 500268 | 500267 | 500266 | 500265 | 500263 | 500262 | 500261 |
| 500260  | 500257 | 33018  | 33021  | 33022  | 33023  | 33026  | 33027  | 33029  |
| 33030   | 33032  | 33036  | 33040  | 33043  | 33044  | 530125 | 500244 | 500245 |
| 500246  | 530129 | 530128 | 530130 | 530132 | 500256 | 500254 | 500253 | 500259 |
| 500258  | 530136 | 530133 | 500264 | 530118 | 530117 | 530119 | 530120 | 530121 |
| 530124  | 500241 | 500248 | 530126 | 530127 | 500247 | -      | -      | -      |

| Serial Numbers for Incisive CT (REF: 728146)                          |        |        |        |        |        |        |        |
|---|--------|--------|--------|--------|--------|--------|--------|
| Unique Device Identifier Rule: (01)00884838104481(21) + Serial number |        |        |        |        |        |        |        |
| 540000  | 540001 | 540002 | 540003 | 540004 | 540005 | 540006 | 540007 |
| 540008  | 540009 | 540010 | 540011 | 540012 | 540013 | 540014 | 540015 |
| 540016  | 540017 | 540018 | -      | -      | -      | -      | -      |

| Serial Numbers for Incisive CT (REF: 728148)                           |        |        |        |        |        |        |        |        |
|--|--------|--------|--------|--------|--------|--------|--------|--------|
| Unique Device Identifier Rule: (01)00884838103467 (21) + Serial number |        |        |        |        |        |        |        |        |
| 530502   | 530501 | 530500 | 530494 | 530492 | 530489 | 530482 | 530481 | 530480 |
| 530476   | 530475 | 530470 | 530466 | 530464 | 530462 | 530461 | 530460 | 530458 |
| 530456   | 530452 | 530436 | 530435 | 530432 | 530431 | 530421 | 530420 | 530419 |
| 530409   | 530404 | 530389 | 530388 | 530384 | 530378 | 530374 | 530373 | 530372 |
| 530370   | 530369 | 530368 | 530363 | 530360 | 530358 | 530357 | 530350 | 530349 |
| 530345   | 530342 | 530338 | 530335 | 530329 | 530307 | 530301 | 530294 | -      |

| Serial Numbers for Incisive CT (REF: 728149)                          |        |        |        |        |        |
|---|--------|--------|--------|--------|--------|
| Unique Device Identifier Rule: (01)00884838103474(21) + Serial number |        |        |        |        |        |
| 530474  | 530437 | 530430 | 530408 | 530332 | 530320 |

**URGENT Field Safety Notice Response Form**

**Reference:** Potential for System Shutdown and Expelled Parts on Incisive CT Systems (Reference FCO72800798)

**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>](#)