Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 104 **dated** 24/5/23 **Regarding NCMDR Field Safety Notice of Incisive CT System from (mfr: Philips Healthcare).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
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سلطنة عُمان
وزارة الصحة
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مسقط

Circular No. 104/ 2023

04-11-1444 H

24 -05-2023

Field Safety Notice of Incisive CT System from Philips Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19522
Product	Incisive CT System.
Description	CT System.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Refer to "Appendix A – Affected Serial Numbers" in the attached FSN.
Reason	Potential for System Shutdown and Expelled Parts.
Action	1. 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. 2. Please retain the attached FSN with your system(s) until a solution is installed on your system; ensure the FSN is in a place likely to be seen/viewed. Place this FSN with your system documentation. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

NTP

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

PHILIPS

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).

PHILIPS

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: met.quality@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Li Xin
Quality Leader
Philips Precision Diagnostics (PD) China

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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

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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

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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: met.quality@philips.com