Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
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 61 **dated** 29/4/2024 **Regarding NCMDR Field Safety Notice of IQon, iCT, Ingenuity, and Brilliance CT 64 systems from (mfr: Philips Medical Systems).**

Copy to:

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

DSC
مركز سلامة الدواء
Drug Safety Center

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

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Ministry of Health
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سلطنة عُمان
وزارة الصحة
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Circular No. 61 **/ 2024**

20 -10-1445 H
29 -04-2024

Field Safety Notice of IQon, iCT, Ingenuity, and Brilliance CT 64 systems from Philips Medical Systems.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21003
Product	IQon, iCT, Ingenuity, and Brilliance CT 64 systems.
Description	Computed Tomography X-ray systems.
Manufacturer	Philips Medical Systems.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Please refer to the attachment for the affected products.
Reason	Potential of multiple software issues with the above systems that could affect the performance of the equipment.
Action	1. You may continue to use your system(s) in accordance with the intended use. 2. Refer to Appendix A in the attachment for specific details regarding the issue descriptions and advice on actions to be taken. 3. You will be contacted by Philips distributor to schedule a time for a Field Service Engineer (FSE) to visit your site and install the software update to resolve these issues. 4. 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

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

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

PHILIPS

IMPORTANT PRODUCT NOTICE

04-APR-2024

RE: Software Issues on IQon, iCT, Ingenuity CT, and Brilliance CT 64

Dear Customer,

Philips has identified software issues with the Philips IQon, iCT, Ingenuity, and Brilliance CT 64 systems that could affect the performance of the equipment. This Important Product Notice is intended to inform you about these issues and Philips' plan to correct them.

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

Philips has identified multiple software issues affecting Philips IQon, iCT, Ingenuity, and Brilliance CT 64 systems. Detailed descriptions and advice to customers pertaining to these issues are provided in Appendix A.

Philips has not received any reports of injury or serious harm associated with these issues.

2. Affected products and how to identify them

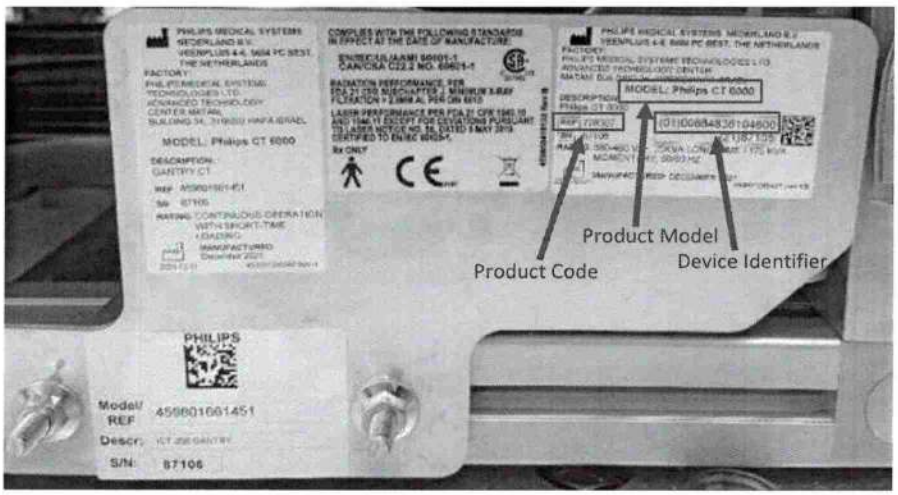
The products listed below are affected:

Product Code (REF)	Product Model	Software	Device Identifier
728306	Brilliance iCT	4.1.10.x	(01)00884838059474
728305	Brilliance iCT Upgrades	4.1.10.x	N/A
728307	CT6000	4.1.10.x	(01)00884838104600
728311	Brilliance iCT SP	4.1.10.x	N/A
728332	IQon Spectral CT	4.7.7.x	(01)00884838059542
728331	IQon Spectral CT Upgrades	4.7.7.x	N/A
728321	CT5000 Ingenuity Plus	4.1.10.x	(01)00884838059498
728323	CT5000 Ingenuity Pro	4.1.10.x	(01)00884838059504
728326	CT5000 Ingenuity Premium	4.1.10.x	(01)00884838059511
728327	Ingenuity CT Upgrades	4.1.10.x	(01)00884838098701
728324	Ingenuity CT China	4.1.10.x	(01)00884838059863
728325	Ingenuity Core 128 Elite Brazil	4.1.10.x	N/A
728231	Brilliance CT 64 Channel	4.1.10.x	(01)00884838083325
728232	Brilliance 64 Upgrades	4.1.10.x	N/A

To identify if your system is affected:

1. Identify the product model name and product code on the back of the gantry in the bottom right corner as shown in Figure 1.

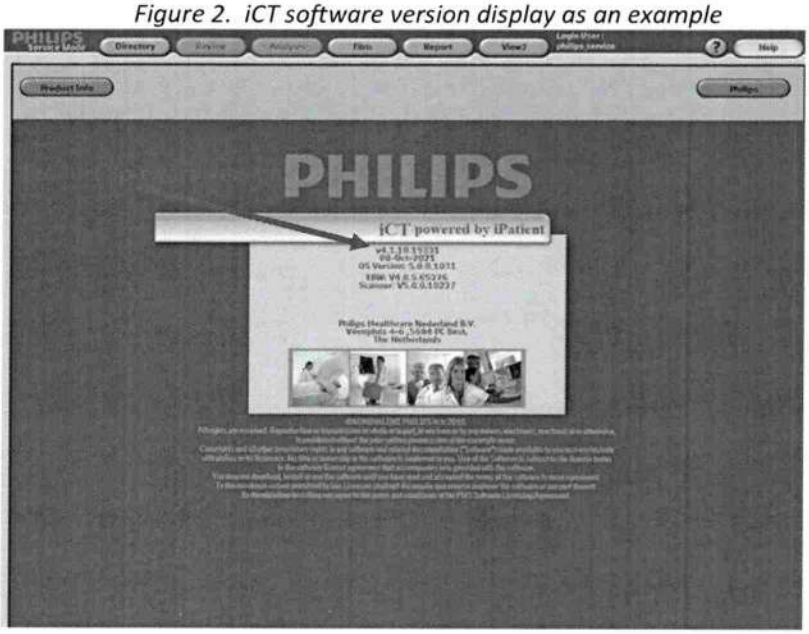
Figure 1. Example system label



To identify the software version of your product:

1. Click the ***Help*** button.
2. Select ***About*** and the software version is then displayed. The software version begins with **v.**

Figure 2. iCT software version display as an example



Intended Use:

Philips Computed Tomography X-ray systems produce 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.

3. The actions that you as a customer can take to minimize the effect of the problem

- You may continue to use your system(s) in accordance with the intended use.
- Refer to Appendix A for specific details regarding the issue descriptions and advice on actions to be taken.
- Circulate this notice to all users of this device so that they are aware of the issues.
- Please retain this letter with your system(s) until a software solution is installed; ensure the notice is in a place likely to be seen/viewed.

4. The 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 install the software update to resolve the issues listed in Appendix A.

Technical Solution Reference Number	Models Impacted
FCO72800812	728306, 728305, 728307, 728311, 728332, 728331
FCO72800814	728306, 728305, 728307, 728311, 728332, 728331
FCO72800815	728321, 728323, 728326, 728327, 728324, 728325, 728231, 728232
FCO72800816	728321, 728323, 728326, 728327, 728324, 728325, 728231, 728232

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

Sincerely,

Appendix A

The following table summarizes the issues identified, the impact to the customer/patient, and the advice to the customer.

Issue #	Issue Description	Clinical Impact	Manufacturer Recommendations
1	***Bolus Tracking Issue:*** The Bolus Tracking Algorithm exceeds the threshold point, but the clinical scan is not automatically started.	The clinical scan may not automatically trigger after the Bolus Tracking scan and may need to be triggered manually. Additional Bolus Tracking shots may occur.	To reduce the potential for this issue to occur follow the recommendations in your Instructions For Use, in the *Understanding Your Philips Scanner* section, to keep your system running efficiently.
2	***CIRS Initialization After Lateral Surview:*** The error message *CIRS is Initializing, This may take up to 10 minutes*, appears after the lateral Surview scan occurs. The image is not displayed.	The lateral Surview may not be displayed and the CIRS server crashes.	Reconstructions that are in progress will finish, however reconstructions that have not been started will not finish. The raw data is still available to perform offline reconstruction for all previously performed scans, however, there is not a means to reconstruct the surview. A rescan of the surview(s) may be required.
3	***System cannot perform scan with error code ACQ NOT OK:*** A red dot may appear asking to *Restart the CIRS.*	The scan cannot begin.	When starting or rebooting your system, start CIRS first and then start your console. Wait at least 5 minutes after restarting CIRS. This will prevent the issue.
4	***Recon Box (CIRS) error:*** When a workflow is launched *No Communication With CIRS* error message appears, and a Red Dot in the status area may appear.	The scan cannot begin.	Restart the CIRS system, console, and gantry.
5	***Edit Results on Slab Viewer is not enabled:*** Upon selecting the *End Exam and Continue working* button, the View2 will open in the right monitor but the option to *Edit Results* on the Slab Viewer function is not enabled for the first result (which is selected by default).	An additional step in normal workflow may be required to enable the *Edit Results* option.	Click on any other result and then click back on the first result. The *Edit Results* option will be enabled for the first result. You are also able to perform offline reconstruction.
6	***"Not all Images were created" error message:*** The Recon Server process could not handle the load and reconstruction failed.	An additional step in normal workflow may be required to perform offline reconstruction.	Perform offline reconstruction to get the missing images.
7	***IT account still locked after FSE reset password:*** System is locked out after several incorrect password attempts and the IT account is still inaccessible after the account is unlocked from the Philips Support Connect (PSC).	IT users may have to contact Philips Service Connect (PSC).	Ensure IT users are able to logon while PSC is still on the phone.

Issue #	Issue Description	Clinical Impact	Manufacturer Recommendations
8	***When extend scan functionality is used, the system failed to send DICOM info to Eclipse Treatment Planning system:*** Unable to import the dataset to Eclipse Treatment Planning system	Customers may not be able to import the dataset to their Eclipse Treatment Planning system.	Images are still created and are available for diagnostic purposes as intended on the CT scanner.
9	***"Start Final Recon" button is disabled after scanning is completed and "CIRS cannot initialize" message appears:***	Reconstructions that are in the queue may take a longer time to complete.	Click "OK" after the "CIRS cannot initialize" message appears. The reconstruction will complete. You may also perform offline reconstruction.
10	***During change patient details, Patient's Weight/height value remains if queried patient's weight/height value is empty:***	When searching results using the worklist in the "Change Patient Details" window multiple times, for different patients, and then clicking "Save", the patient's height/weight values may be recorded incorrectly.	Verify patients' height/weight values prior to saving.
11	***"Net Command has stopped working" message appears:***	No clinical impact. The error message may appear during a bug report.	Click *Yes* or *No* to continue or cancel bug report collection.
12	***"Start Final recon" button grayed out:***	The *Start Final Recon* button may be grayed out after performing several clinical scans.	The scan raw data is available on the system, and you can perform offline reconstruction as necessary.
13	***Bug report collection pop up and Patient Directory application crash:*** After completion of scans, a bug report collection message may appear.	Bug report collection may appear after finishing a scan.	Click *Yes* or *No* to continue or cancel bug report collection. Image raw data is still available for offline reconstruction as necessary.