



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 250 dated 28/11/2023 Regarding NCMDR Field Safety Notice of Ingenuity CT & Brilliance CT 64 from (mfr: Philips Medical Systems).

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





لنقدم بثقة
Moving Forward
with Confidence



Circular No. 250 2023

14 -05-1445 H
28 -11-2023

Field Safety Notice of Ingenuity CT & Brilliance CT 64 from Philips Medical Systems.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19792
Product	Ingenuity CT & Brilliance CT 64.
Description	Computed Tomography Systems.
Manufacturer	Philips Medical Systems.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Systems below with software version 4.1.7: Product Code (REF): 728321, 728323, 728326, 728327, 728324, 728325, 728231, 728232 Please refer to the product models in the attachment.
Reason	Two software issues have been identified affecting the performance of the above systems: Issue 1: Ingenuity CT 4.1.7 systems cannot be registered to the Remote Service Network. Issue 2: Customer service intellectual property tool cyber security vulnerability.
Action	1. Customers will be contacted by Philips to schedule a time for a Philips Field Service Engineer (FSE) to visit site and install the solution (refer to FCO72800759) to improve system performance. 2. 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 Handan Al Rubaie
Director General



IMPORTANT PRODUCT NOTICE

06-Nov-2023

RE: Serviceability and cybersecurity issues on Ingenuity CT & Brilliance CT 64 with software version 4.1.7

Dear Customer,

Philips has identified two (2) issues with Ingenuity CT and Brilliance CT 64 software version 4.1.7 that could affect the performance of the equipment. This Important Product Notice is intended to inform you about the issues and Philips' plan to correct them.

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

Philips has identified two software issues affecting the performance of Ingenuity CT and Brilliance CT 64 systems with software version 4.1.7:

Issue 1: Ingenuity CT 4.1.7 systems cannot be registered to the Remote Service Network

These systems cannot be connected to the Philips Remote Service Network (RSN), resulting in no access to the remote services such as software distribution or remote desktop connection abilities.

Issue 2: Customer service intellectual property tool cyber security vulnerability

This issue impacts both Ingenuity CT and Brilliance CT 64 systems with version 4.1.7. If an unauthorized user utilizes counterfeit service tool security certificates; they may gain access to patient data, the service manual, and restricted service functions of CT devices.

Philips has not received any reports of adverse events associated with these issues as of October 2023.

2. Affected products and how to identify them

The issue affects these systems below with software version 4.1.7:

Product Code (REF)	Product Model
728321	Ingenuity CT 728326
728323	Ingenuity Core 128
728326	Ingenuity CT
728327	Ingenuity CT Upgrade
728324	Ingenuity Core 128 (China L4L)
728325	Ingenuity CT Brazil SKD
728231	Brilliance CT 64
728232	Brilliance CT 64 Upgrade

To identify your affected system:

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.

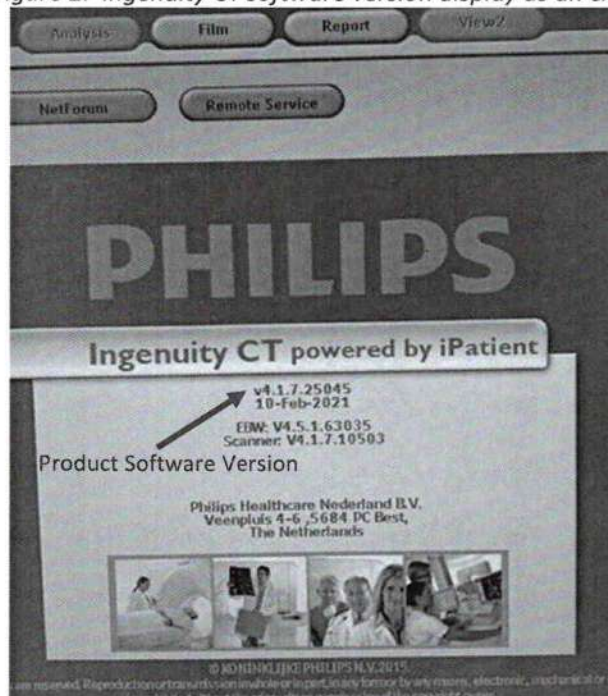
Figure 1. Example system label



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. Ingenuity CT 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.

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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.
- Circulate this notice to all users of this device so that they are aware of these 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 solution (refer to FCO72800759) to improve system performance.

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,