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URGENT Field Safety Notice

Incisive CT & CT 3500 System

Potential for Incorrect Image Orientation

10-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 and CT 3500 systems, that could pose a risk for patients. This URGENT Field Safety Notice is intended to inform you about:

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

An issue with the Precise Position option installed with Incisive CT & CT 3500 systems may result in incorrect image orientation (i.e. flipped or reversed images).

The Precise Position option uses automatic camera detection for patient orientation. This automatic detection function will overwrite the preset patient orientation defined in the scan protocol. If the auto-detected patient orientation is incorrect and is unnoticed by the operator prior to scanning, the resulting images may be flipped or reversed.

The following conditions may affect the Precise Position automatic detection feature and result in incorrect patient orientation:

- When the patient is covered by a sheet, blanket etc.
- When the patient is not completely covered by the ceiling camera view (e.g. blocked by the gantry or out of the camera's FOV etc.)
- When the patient is wearing clothing that reflects light (e.g. plastic-like clothes).
- When the patient is wearing black clothing.
- When the patient is wearing thick clothing.
- When there are other people around the patient.

As of Mar-2023, Philips has received one (1) reported adverse event associated with this issue. In this reported case, there was no harm to the patient, however the patient was initially misdiagnosed due to incorrect image orientation.

2. Hazard/harm associated with the issue

Incorrect image orientation may result in misdiagnosis, incorrect treatment of a condition, or additional radiation exposure if a rescan is required.

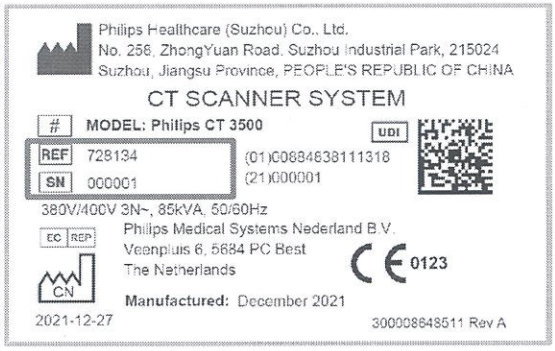
3. Affected products and how to identify them

Identification of Impacted Incisive CT & CT 3500 Systems:
A listing of impacted systems is provided in Appendix A. Impacted systems can be identified by the model number (REF) and system serial number (SN).

To determine if your product is impacted, refer to the system label (Figure 1 & 2) located on the back left corner of the gantry.

Figure 1. Incisive CT System Label Example

Figure 2. CT 3500 System Label Example



Intended Use:
Philips Incisive CT and 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.

Precise Position on Incisive CT and CT 3500 system is a camera-based workflow designed to assist with positioning the patient automatically from console or OnPlan, it can:

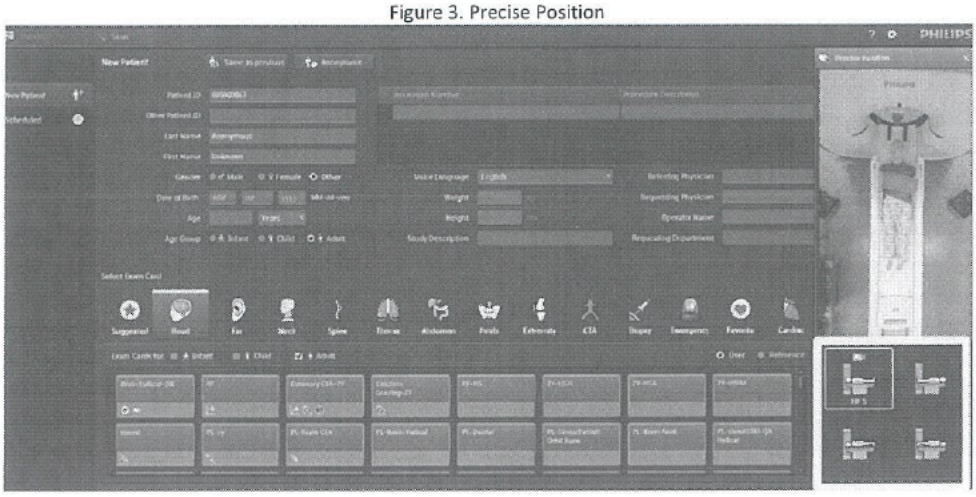
- automatically select patient orientation.
- automatically set vertical centering & positioning of the patient to the Surview start and end positions.
- support editing Surview start & end range and scan direction.

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

- Refer to the IFU of your Incisive CT / CT 3500 system to ensure proper use of the Precise Position function (IFU Section 4.9).

- If the patient orientation automatically selected by Precise Position (see Figure 3) is inconsistent with the preset protocol, please correct the settings as described below:
  - Manually select the correct orientation in the **Select Patient Orientation** area in the **New Patient** interface, or
  - Open the **Select Patient Orientation** list by clicking the patient orientation icon in the left upper corner of the series list and select the correct orientation.

Figure 3. Precise Position



- Circulate this URGENT Field Safety Notice to all users of this device so that they are aware of the issue.
- Place this URGENT Field Safety Notice 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 software upgrade to address the issue (reference FCO72800793 for Incisive CT system and FCO72800797 for CT 3500 system).

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,

[redacted]

Quality Leader
Philips Precision Diagnostics (PD) China

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Appendix A – Affected Serial Numbers

Serial Numbers for: Incisive CT (Model Number: 728143) Unique Device Identifier Rule: (01)00884838085015(21) + Serial number				
33018	500001	500119	500146	500223
500439	500462	530003	530008	530012
530109	530115	530118	530274	530315
530383	530440	530465	530491	530497
530541	530579			

Serial Numbers for: Incisive CT (Model Number: 728144) Unique Device Identifier Rule: (01)00884838105508(21) + Serial number						
34010	34020	34061	34070	34107	34108	34127
34142	34147	34157	34158	34161	34166	34176
34177	34178	34180	34194	34202	500453	500499
500501	500504	500506	500508	500511	500518	500529
550004	550023	550025	550034	550041	550052	550065
550069	550077	550079	550084	550086	550093	550103
550107	550114	550115	550119	550121	550128	550130
550140	550150	550162	550164	550169	550174	550176
550181	550187	550188	550191	550194	550195	550203
550212	550234	550241	550248	550249	550251	550256
550266	550270	552038	552040	554023	550141	

Serial Numbers for: Incisive CT (Model Number: 728148) Unique Device Identifier Rule: (01)00884838103467 (21) + Serial number
554056

Serial Numbers for: Incisive CT (Model Number: 728149) Unique Device Identifier Rule: (01)00884838103474(21) + Serial number				
530537	554032	554060	554065	554078

Serial Numbers for: CT 3500 (Model Number: 728134) Unique Device Identifier Rule: (01)00884838111318(21) + Serial number	
610001	610003

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URGENT Field Safety Notice Response Form

Reference: Potential for Incorrect Image Orientation on Incisive CT and CT 3500 Systems (Reference FCO72800793 for Incisive CT system and FCO72800797 for CT 3500 system)

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 provide in Section 4 of this *URGENT Field Safety Notice*.
- Circulate this *URGENT Field Safety Notice* to all users of this device so that they are aware of the issue.
- Place this *URGENT Field Safety Notice* 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>