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URGENT Field Safety Notice

Spectral CT with software version 5.0.X
Plan Box not Updated during Interventional procedure and Incorrect Patient ID issues

November 8, 2024

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 become aware of a plan box not updated issue during Interventional procedure with Spectral CT that may lead to a collision with the operator or with the needle placed inside the patient, and an incorrect patient ID software issue that may lead to misdiagnosis. This URGENT Field Safety Notice is intended to inform you about:

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

Plan Box not Updated during Interventional Procedure:
The *Plan Box* may not move to the desired *Needle Position* or *Work Position* under the following circumstances:

- Operator manually edits the *Needle Position* or *Work Position* value, and
- Operator moves *Plan Box* by dragging it or by changing its center value and plan box position, and then
- Operator uses Interventional Controls *Move to Selected <Scan>/<Work> Position* buttons.

This issue could result in the table moving to a location the operator does not expect. If this occurs, it presents a risk that the scan could occur at an incorrect location, or that the unintended motion of the table could cause a collision with the user or needle.

Incorrect Patient ID:
Philips has identified that there is a software issue that can incorrectly set the patient ID for anonymous study. If *Anonymous* is selected in the *Patient* tab, the system may not automatically set the patient ID with an increment of 1. The issue does not occur if the operator immediately renames the *Anonymous* record with the patient's name at the time of the scan. The other patient fields are not impacted. This situation may occur after receiving an error message that cannot be cleared unless the system is restarted.

Philips has identified other software issues affecting Philips Spectral CT systems that do not present a risk to health. Detailed descriptions and advice to customers pertaining to these issues are provided in Appendix A.

Philips has not received any reports of an adverse event associated with these issues as of October 2024.

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2. Hazard/harm associated with the issue

Plan Box not Updated during Interventional Procedure:
If the patient table moves to a position that is not expected by the operator there is a risk that:

- A scan may occur at an unintended location. Scanning an unintended location could cause additional re-scans to be required. Re-scans will cause additional radiation exposure.
- A collision with the operator or with the needle placed inside the patient may occur. A collision with the table could cause pain, abrasions, or lacerations.

Incorrect Patient ID:
If the incorrect patient ID issue occurs, there is a risk that:

- The operator may not identify the patient correctly while reviewing the results, and a misdiagnosis may occur due to incorrect images.

These other software issues in Appendix A may cause CT rescan.

3. Affected products and how to identify them

To identify if your system is affected:
These issues affect all Spectral CT systems with model number listed in Table 1.

Table 1. Affected Systems

Product Code	Product Model	Software Version	Device Identifier
728333	Spectral CT	5.0	(01)00884838101111
728340	Spectral CT	5.0	N/A
728344	Spectral CT Plus	5.0	N/A

To locate the product model name and product model number, locate the equipment label on the back of the gantry near the bottom as shown in Figure 1 and 2. Figure 1 is showing a sample label for Spectral CT product model 728333 as an example. Figure 2 is showing a sample label for Spectral CT product model 728340 as an example.

Figure 1. Example system label of model 728333

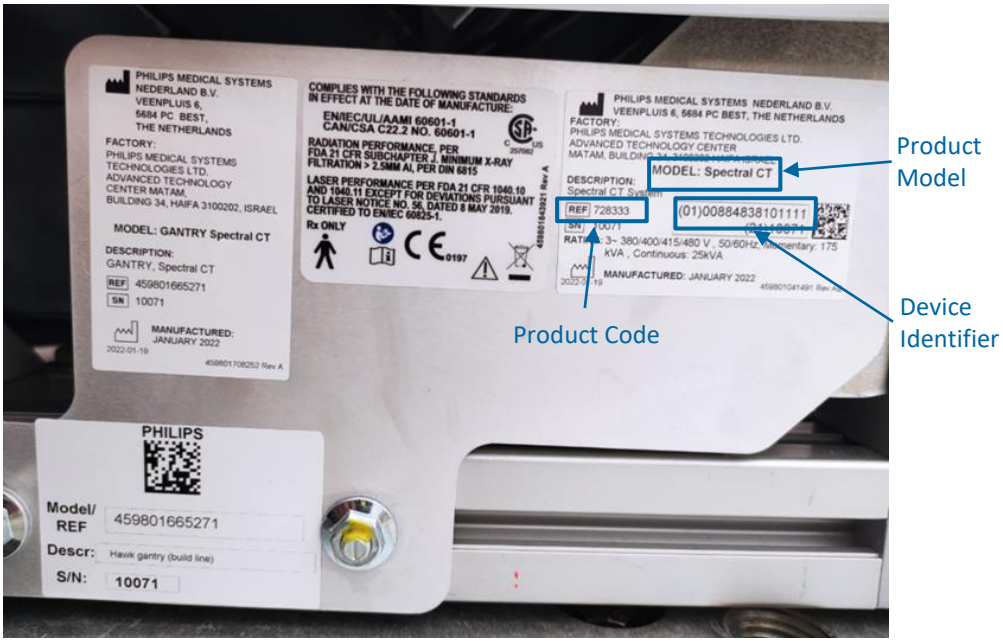
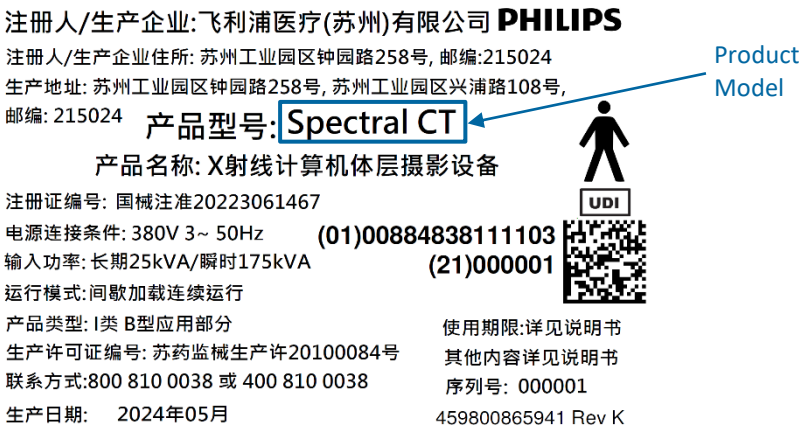


Figure 2. Example system label of model 728340



To identify the software version of your product:

1. Navigate to the Home screen and click the ***Help*** button.
2. Select ***About*** and the software version is then displayed as shown in Figure 3. The software version begins with **v**.

Figure 3. Spectral CT Software version shown 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.

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

- You may continue to use your system(s) in accordance with the intended use and by following the recommendation listed below.
- To protect you and the patient from the issue of Plan Box not Updated, remain vigilant and confirm table position during procedures. Press any of the Emergency STOP buttons to stop unintended patient table motion, and follow safety instructions in Section 6 of the IFU: Working with Specialized Exams.

- To avoid the issue of Wrong Patient ID with *Anonymous* patient, the operator should verify the patient information loaded into the patient data field is correct before scanning and rename the *Anonymous* record with the patient's name at the time of the scan.
- Refer to Appendix A for specific details regarding other issues and recommended actions.
- Please complete and return the attached response form to Philips promptly and no later than 3 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.
- 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.

5. 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 issue (reference FCO72800823 for Spectral CT system with Serial Number 10027, FCO72800829 for Spectral CT systems in China and Thailand, and FCO72800808 for all other Spectral CT systems).

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 these issues, please contact your local Philips representative:

Telephone 80 30 30 35
Email philips.service@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Idan Lazar
Head of Quality, CT/AMI

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Appendix A

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

Issue #	Issue Description	Clinical Impact	Manufacturer Recommendations
1	***Liver not detected in Surview:*** After performing a Surview of a Chest or Abdomen, the Liver Dose Right Index (DRI) does not detect the superior and inferior borders of the liver.	Dose Right Index (DRI) may not set correctly for liver area, resulting in suboptimal image quality.	In case the Liver Dose Right Index (DRI) does not detect the superior and inferior borders of the liver, do not continue with the scan. To recover: • End the exam. • Select the current patient and proper exam card. • Use previous Surview. The liver will be detected and indicated on the Surview.
2	***CTA scan with 20% dose in case R-tag not detected:*** During a contrast injected cardiac exam utilizing Cardiac DoseRight, if the ECG lead disconnects or the patient has heart rate less than 30 bpm, or an arrythmia occurs, the system may not detect a heartbeat, the scan will provide 20% of the dose required instead of 100% dose.	Suboptimal cardiac image quality.	Ensure the patient's heart rate is between 30-180 bpm to perform a cardiac scan. Do not start the scan with the heart rate below 30 bpm.
3	***System stops scan with error code ACQ NOT OK:*** The helical scan may be interrupted due to "ACQ_NOT_OK" error at around 200mm/sec couch speed.	Scan interruption.	N/A.
4	***System Cannot use previous Surview:*** In case the user adds/replaces Exam Card (EC) after completing surview scan there is a pop up message asking to use previous surview, after the user selects YES, an error message may appear, and the system will return to the patient details screen.	Not able to use previous Surview.	Complete a new Surview and continue with examination.
5	***Scan with closed collimator:*** Failure of collimator to open, due to a faulty cable or signal connection, should stop the acquisition, but it does not.	Suboptimal image quality.	N/A.
6	***Incorrect Water Equivalent Diameter calculation:*** When performing a frontal surview (180 degrees) the Water Equivalent Diameter (WED) estimate of the patients' size is underestimated when using Z or 3D dose modulation, so the applied dose is lower than expected. For Adult body sizes, this can be as much as 15% lower.	Suboptimal image quality.	As stated in IFU, even if Dose Right is used, the operator shall review and select scan parameters before scanning including Dose Right parameters, to carefully balance patient radiation dose and image performance.
7	***"Start final recon" button grayed out:*** When Host CPU is under heavy load, following a scan completion, the "*Start final recon*" button is grayed out and the user cannot select it to complete the final reconstruction.	The user cannot initiate "*Start final recon*".	Perform offline reconstruction on the scan raw data.
8	***Tracker scan crashed:*** During Bolus tracking scan, the application crashes due to the user changing the bolus tracking value below the threshold during the tracker acquisition.	Scan interruption.	Set bolus tracking value before selecting *Go* and completing the tracker scan.

Issue #	Issue Description	Clinical Impact	Manufacturer Recommendations
9	***Injection parameters mismatch:*** If the injection parameters do not match between the Console and Injector, the system fails to execute the tracker scan, instead of notifying the user of the discrepancy.	Scan interruption.	Ensure your injection parameters are consistent across the injector and console prior to the acquisition.
10	***Dual Surview image not reconstructed:*** During Dual surview scan, following the completion of the Frontal surview image (first shot), the lateral surview may not be reconstructed in a specific scenario where the error message *Geometry of acquisition #X was changed automatically on the surview* is displayed on the user interface.	Lateral Surview image not reconstructed.	If this scenario does happen, the operator can plan the result on the current Frontal Surview, or they may repeat the Dual Surview if necessary.
11	***4DCT degraded recon with partial waveform:*** If a partial breathing wave is imported to the scanner (meaning not recorded completely prior to the scan and stopped after the scan), system will perform gated reconstruction with wrong phase calculation which can lead to poor image quality.	Suboptimal image quality.	• Start to record the pulmonary wave before the scan starts and stop recording following the completion of the scan. • If a partial breathing wave is imported to the scanner, perform ungated recon on the raw data.
12	***4DCT white streak artifact with low pitch scan:*** Gated pulmonary reconstructions resulting from scans using low pitch parameters (pitch value lower than 0.02), may result in images with white streak artifacts.	Suboptimal image quality.	N/A.
13	***4DCT User interface frozen with network interruption:*** In case network connection is interrupted during the pulmonary waveform import, the system will present a popup: “Pulmonary wave will not be imported”. Once the user closes the popup, untagged reconstruction should take place. However, the issue is, the popup cannot be closed, and user interface is frozen. The system has only one opportunity for wave import in case of network interruption.	System unresponsive and suboptimal image quality.	Perform offline reconstruction for Untagged results.
14	***Cardiac dark image artifact or broken pixel artifact*** Dark images and/or Broken Pixel may appear in Cardiac Motion Compensation reconstructed (MCR) images.	The hypodense (dark) artifact and pixelated artifacts are recognizable.	N/A
15	***Decubitus dose modulation*** Three dimensional dose modulation (3D DOM) is sub-optimal when the patient is in the decubitus orientation and angular modulations are selected.	Streak artifacts and excess noise through a patient’s pelvis or shoulders.	N/A
16	***Bolus tracking scan trigger delayed*** There may be delay to trigger the clinical scan due to bolus tracking algorithm performance limitation during bolus tracking scan after the contrast threshold is exceeded.	It may lead to additional tracker scans or suboptimal image quality.	The operator should monitor the bolus values on the image, and manually trigger the clinical scan after the contrast threshold is exceeded.

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URGENT Field Safety Notice Response Form

Reference: Plan Box not Updated during Interventional procedure and Incorrect Patient ID issues on Spectral CT, 2024-PD-CTAMI-014 (FCO72800823, FCO72800808, and FCO72800829)

Instructions: Please complete and return this form to Philips promptly and no later than 3 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Refer to the instructions provided in Section 4 of the Field Safety Notice Letter.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected Spectral CT systems.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to FCO.Nordic@philips.com