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URGENT Field Safety Notice

Spectral CT with software version V5.0, V5.2, or V5.4
Image artifacts, wrong slice thickness, unintended motion

18-AUG-2026

Dear Customer,

Philips has become aware of software issues that may affect the safety and performance of your CT system(s). This URGENT Field Safety Notice is intended to inform you of these issues and provide recommendations to help minimize potential impact until a software correction is implemented. Philips has not received any reports of harm or injuries associated with these issues as of Jul 2026.

Issue Descriptions

Table 1 summarizes the identified safety issues and corresponding recommendations.

Table 1. Potential safety issues

Issue #	Software Version	Issue Description	Hazardous Situations	Manufacturer Recommendations
1	V5.0, V5.2, V5.4	***Image artifacts @ 80kVp:*** Hyperdense or hypodense image artifacts or Image quality degradation may occur when using 80kVp scans.	If the issue is recognizable, it may prompt a CT rescan. If the issue is not recognizable, the artifacts may be misinterpreted as pathological findings, leading to misdiagnosis.	No action required.
2	V5.0, V5.2, V5.4	***Image quality issues with brain scans:*** Brain scans with the head positioned off-center exhibit degraded image quality of hyperdense and hypodense artifacts. Dark/ white artifacts may appear in the bone-brain area (BBA) in Brain images in conventional and Spectral MonoE images.	If the issue is recognizable, it may prompt a CT rescan. If the issue is not recognizable, the artifacts may be misinterpreted as pathological findings, leading to misdiagnosis.	Center the head position before scanning.
3	V5.2, V5.4	***Wrong slice thickness with extended field of view (EFOV):*** When slice thicknesses larger than 2.5 mm are requested with a Field of View (FOV) larger than 500 mm (EFOV)), the scanner reconstructs the EFOV images with an actual slice thickness of approximately 2.5 mm instead of the requested slice thickness while image annotations show the requested slice thickness.	Wrong slice thickness in the reconstructed images compared to the actual slice thickness may affect image interpretation and could lead to misdiagnosis.	Follow Instructions for Use (IFU) to review both EFOV reconstruction and corresponding non-EFOV reconstruction when EFOV is utilized.
4	V5.0, V5.2	***Couch incorrect motion during interventional procedure:*** During a continuous CT (CCT) scan, the couch should remain at the current scan position after pressing Go. However, under certain circumstances the couch moves to a previous CCT acquisition position.	If the couch moves to the unexpected previous CCT acquisition position, there is a risk of a collision with the operator or with the needle while placed inside the patient. In addition, the patient may receive one additional CCT shot.	To avoid collision, check the image position and the table position on the gantry touch panel or the interventional control, and keep the patient under continuous observation.

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Issue #	Software Version	Issue Description	Hazardous Situations	Manufacturer Recommendations
5	V5.0, V5.2, V5.4	***Unexpected rotor rotation during service:*** When the system fails the tube alignment calibration, a message appears prompting the user to disconnect the air supply. If the gantry air supply is not disconnected for approximately 20 minutes, the system may rotate the rotor to zero position.	No impact to patients or clinical users. However, unexpected gantry movement may cause injury to service personnel if a hand or other body part is within the gantry.	Follow the service manual safety instructions. Before servicing, disable the rotor air-bearing air supply and prevent rotor rotation.

User Instructions

Philips recommends the following actions be taken for continued safe use of the device:

- Continue to use your system(s) in accordance with the intended use;
- Circulate this notice to all users of the device so that they are aware of the product issues, associated potential hazards, and manufacturer recommendations (refer to Table 1 for specific details regarding recommended actions);
- Post this notice near the affected unit(s) for ease of reference until a solution is installed on your system.
- Please complete and return the attached response form within 30 days to confirm receipt and understanding of this notice.

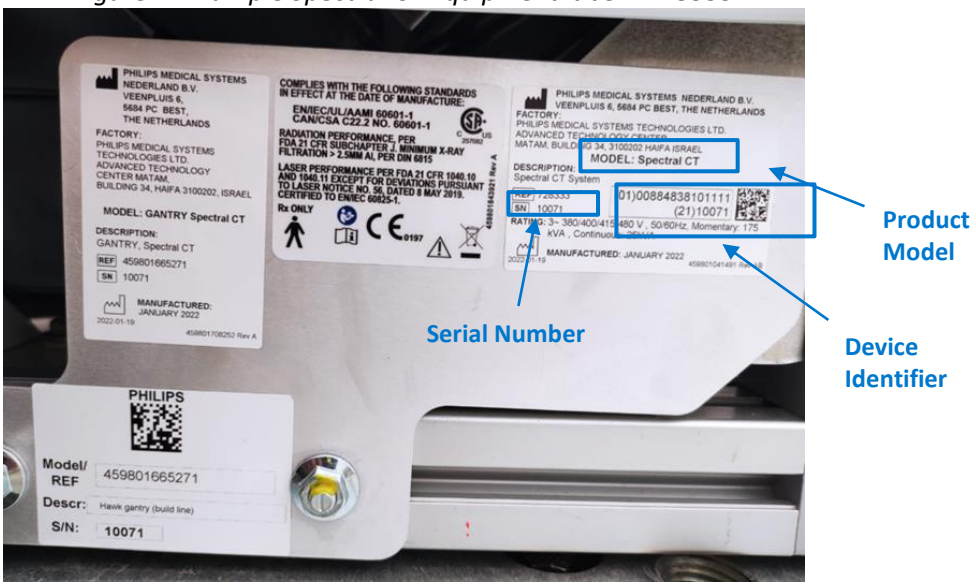
Identification of Affected Product

The products listed below are affected:

Product Code (REF)	Product Model	Software	Device Identifier
728333	Spectral CT	V5.0.x, V5.2.x, V5.4.x	(01)00884838101111
728340	Spectral CT China	V5.0.x	(01)00884838111103
728342	Spectral CT 7600	V5.2.x	(01)00884838117938
728344	Spectral CT Plus China	V5.0.x	(01)00884838117822
728345	Spectral CT Verida	V5.4.x	(01)00884838123748
728346	Spectral CT Verida L4L	V5.4.x	N/A

To identify if your system is affected:
Locate the Device Identifier, model name (Spectral CT), and serial number on the lower right rear of the gantry, as shown in Figure 1.

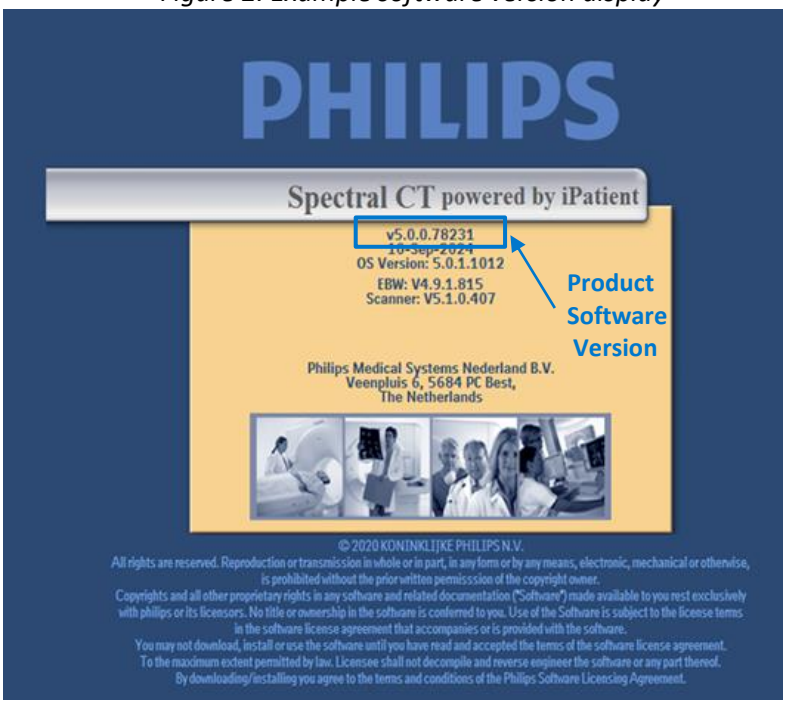
Figure 1. Example Spectral CT Equipment label - 728333



To identify the software version of your product:

1. From the Directory, select the ***Help*** button.
2. Select ***About*** and the software version is then displayed. The software version begins with **v**.

Figure 2. Example software version display



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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Manufacturer Actions SRN: NL-MF-000001489

Philips has identified the affected installed base and will proactively contact you to provide a software update to resolve these issues (reference FCO72800852, FCO72800860, FCO72800861). You may continue to use your system(s) in accordance with the guidance provided in this notice.

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 with any additional questions.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Idan Lazar
Head of Quality, CT/AMI

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URGENT Field Safety Notice Response Form

Reference: Spectral CT with software version V5.0, V5.2, or V5.4. Image artifacts, wrong slice thickness, unintended motion. C&R 2026-PD-CTAMI-003, FCO72800852/860/861

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, understanding of the issues, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

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 Spectral CT system(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to Philips.