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URGENT Field Safety Notice

Spectral CT with software version V5.0 or V5.2
Uncommanded motion may result in collision and additional software issues

May 21, 2025

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 two (2) unintended motion issues that may lead to contact between the Gantry or table with the operator or patient, as well as additional software issues that could affect the performance of your CT system(s). This URGENT Medical Device Correction letter is intended to inform you about:

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

   Interventional Control Touch Panel Motion Button not Released:
   When releasing the motion button in touch panel of Interventional control (IVC) by sliding or dragging off the touch panel area, the motion button of vertical table motion and/or rocker tilt angle may not be released. This issue could result in additional table up/down motion and can be found in both software versions V5.0 and 5.2.

   Free Float Mechanism Allows Couch and Gantry Contact:
   When one user pushes the couch pallet in towards the gantry by using the free float mechanism as a second user presses and holds the couch down to the vertical position, contact between the couch and gantry can happen. This issue could result in the table moving to a location the operator does not expect and can be found in both software versions V5.0 and 5.2.

   Philips has identified other software issues affecting Philips Spectral CT system that are not likely to cause harm but may impact clinical workflow. Detailed descriptions and advice to customers pertaining to these issues are provided in Appendix A. Resolution details pertaining to these issues are provided in Appendix B.

   Philips has not received any reports of an adverse event associated with these issues as of April 2025.

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2. **Hazard/harm associated with the issue**

Interventional Control Touch Panel Motion Button not Released:
The additional Gantry or table motion could cause pain, abrasions, or lacerations, if not noticed and stopped by the operator,

- It may cause contact between the Gantry and the operator.
- In case of accidental contact of the Gantry or table with the operator who is holding a needle, or contacting the needle directly during interventional procedures, it may also impact the placement of a needle.

Free Float Mechanism Allows Couch and Gantry Contact:
If the table moves to a position that is not expected by the operator there is a risk that:

- It may cause contact, impact or trapping zone between objects and/or object and person during normal clinical use.

Additional issues listed in Appendix A may result in patient rescan and additional radiation exposure.

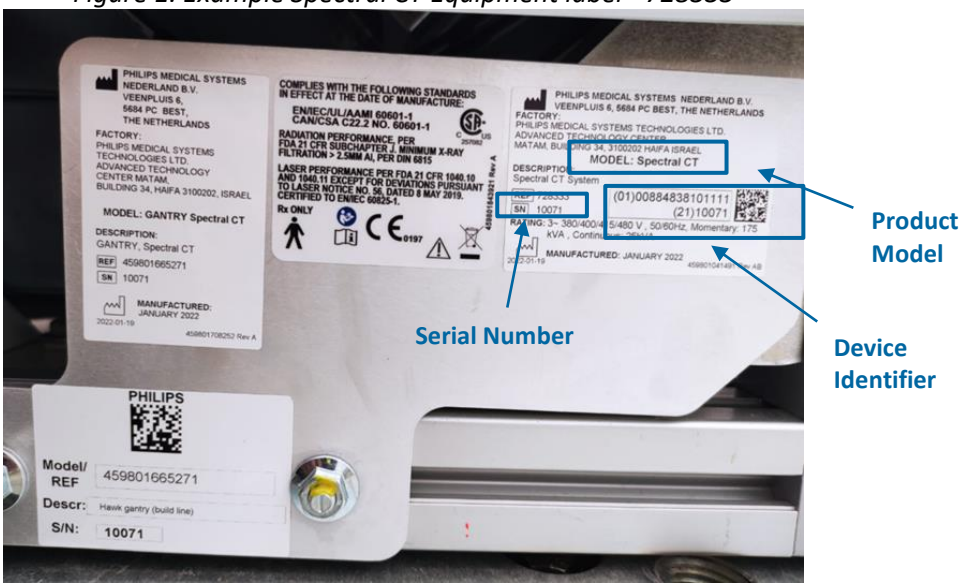
3. **Affected products and how to identify them**

The products listed below are affected:

Product Code (REF)	Product Model	Software	Device Identifier
728333	Spectral CT	V5.0.0.78188 V5.0.0.78231 V5.2.0.80101 V5.2.0.80106	(01)00884838101111
728340	Spectral CT China	V5.0.0.78188 V5.0.0.78231	(01)00884838111103
728344	Spectral CT Plus China	V5.0.0.78188 V5.0.0.78231	(01)00884838117822
728343	Spectral CT RT	V5.0.0.78188 V5.0.0.78231	No Device Identifier

To identify if your system is affected:
Locate the Device Identifier, product model name (Spectral CT) and serial number on the back of the gantry in the bottom right corner as shown in Figures 1, as an example.

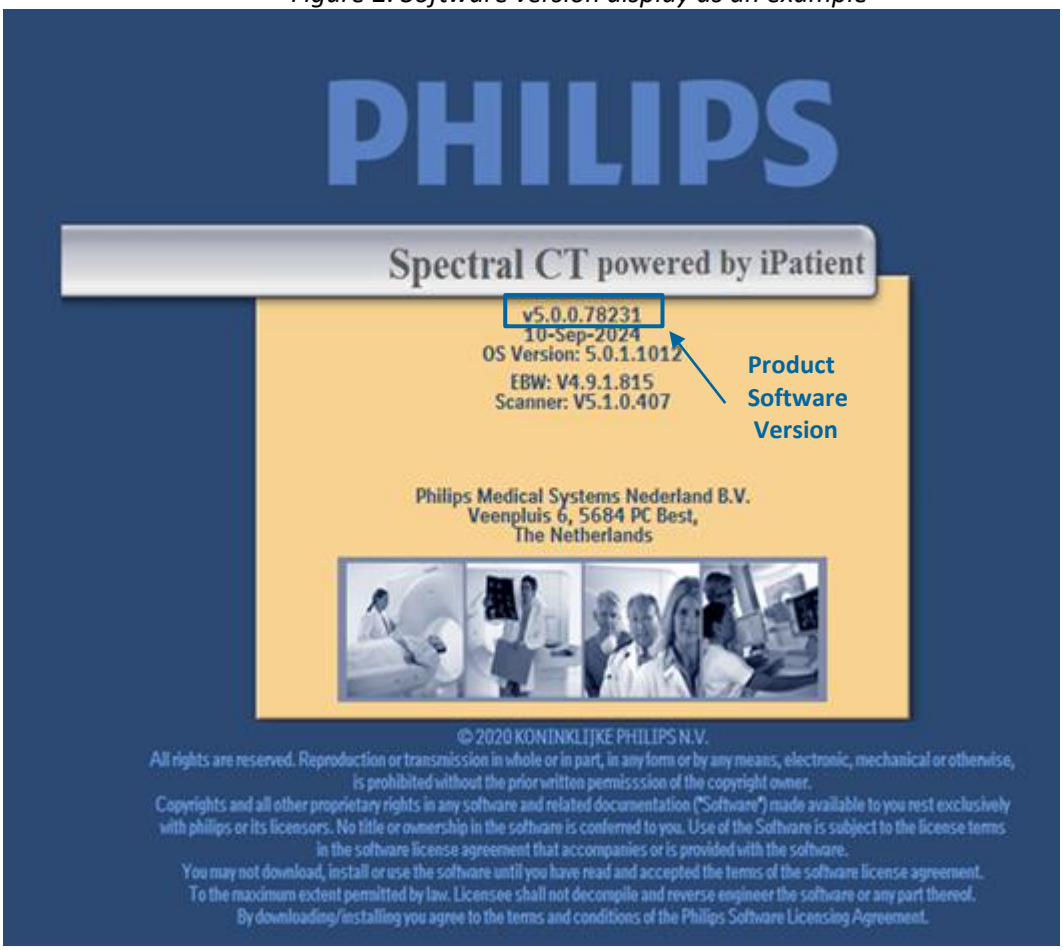
Figure 1. Example Spectral CT Equipment label - 728333



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. 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.

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 avoid an unreleased Interventional Control Touch Panel Motion Button, the operator should directly remove their finger from the touch panel motion buttons to release them, rather than dragging or sliding their finger across the panel area. Press any of the Emergency STOP buttons to stop unintended patient table or Gantry motion.
  - To avoid contact or entrapment while using the free float mechanism, the operator is expected to watch the patient during all movements. Press any of the Emergency STOP buttons to immediately halt all motion of the system when necessary.
- 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 30 days from receipt. Completing this form confirms receipt of the Urgent Medical Device Correction Letter, understanding of the issues, and required actions to be taken.
- Circulate this Urgent Medical Device Correction Letter to all users of this device so that they are aware of the issues. 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 solution to resolve the issue (reference FCO72800828 or FCO72800829).

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.

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 additional issues identified, the potential impact to the customer/patient, and the advice for the customer, If applicable.

Issue #	Affected Software Version	Issue Description	Clinical Impact	Manufacturer Recommendations
1	***V5.0 and V5.2***	***Striped Artifacts Appear on Images*** Simultaneous failure in detector groups Periph 1 and Periph 8 due to slice misplacement at module 1-3 and 28-30, resulting in error code Periph_Conc_Slice-num_mismatch appearing in the log files.	Image may appear with artifact (stripes) and a rescan may need to occur.	No action required.
2	***V5.0 and V5.2***	***Step or Staircase Artifacts*** Step artifacts or staircase artifacts appear in reconstructed images when using Step&Shoot exam cards. The artifact appears in both axial and sagittal images.	Step artifact may make the area between shots difficult to evaluate and rescan may be required.	No action required.
3	***V5.0 and V5.2***	***Ripple or Low Density Artifacts*** Ripple or low density artifact present on clinical images in places where there are sharp anatomical differences.	Image may appear with artifact (ripple/low density) and the operator may need to rescan a patient.	No action required.
4	***V5.2 Only***	***Unable to Perform Offline Recon with EFOV*** Offline reconstruction cannot be performed for FOV >500 (EFOV) if the Conventional results are scanned with "Save SBI" enabled.	User cannot do offline EFOV reconstruction when "Save SBI" is checked true and may decide to perform a new scan.	Create EFOV result in active exam: With online planning (before the scan), user can set FOV larger than 500 for the same result with "Save SBI"
5	***V5.0 and V5.2***	***Uric Acid Images False Positives*** Spectral Uric acid images have a high rate of false positives.	There is potential for the risk of Misdiagnosis due to incorrect measurement. User may decide to rescan patient in another system.	No action required.
6	***V5.0 and V5.2***	***Extra Tracker Shot*** When the Bolus Tracking Algorithm reaches the threshold it sometimes does not immediately trigger the clinical scan.	There is potential that an extra tracker scan is triggered due to system processing delay OR The operator may decide to cancel the scan and rescan the patient.	No action required.
7	***V5.0 Only***	***Clinical Scan did not Start*** The Clinical scan did not start when the CT threshold was reached. The Cardiac CTA examination did not automatically scan after the CT value was reached.	There is potential that an extra tracker scan is triggered due to system processing delay OR The operator may decide to cancel the scan and rescan the patient.	No action required.
8	***V5.0 and V5.2***	***"Not All Images" Error*** A *Not All Images* error message can appear on the Console GUI (Graphical User Interface) for an offline reconstruction.	The operator may decide to rescan the patient.	No action required.

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Issue #	Affected Software Version	Issue Description	Clinical Impact	Manufacturer Recommendations
9	***V5.0 and V5.2***	***GPC OS Crash*** The GPC OS (Gantry Personal Computer Operating System) crashed right after disconnecting PIM (Patient Input and Monitoring) from the couch.	The operator may decide to rescan the patient.	No action required.
10	***V5.0 and V5.2***	***System Error Message and Application Crash*** When copying the surview scan step and pasting it between the bolus tracker scans, this can result in a system error message appearing and the application can crash.	The operator may decide to rescan the patient.	No action required.
11	***V5.0 and V5.2***	***System Error Message During Performance Testing*** While performing continuous performance testing the system displayed an error message between the 37th and 38th scans. The system error that appeared was *There seems to be a problem in the application. Would you like to create a bug report*, when the user clicked on NO, the exam was terminated, and a system error message appeared.	The operator may decide to rescan the patient.	No action required.
12	***V5.0 and V5.2***	***System Crash During Re-plan of the Surview*** During a re-plan of the surview after the surview and helical scans are completed but before the images are reconstructed, the system can crash.	The operator may decide to rescan the patient.	No action required.
13	***V5.0 and V5.2***	***Free Hand Performance test resulting in Error Messages*** While running a free hand performance 4 error messages were identified that can appear, while executing the 18 studies. 1. During the 4th study: *There seems to be a problem, would you like to collect bugrep* message can appear and remove the user from the workflow. 2. During the 6th study: *There seems to be a problem, would you like to collect bugrep* message can appear and remove the user from the workflow. 3. During the 17th study: Yellow screen and *SYSTEM ERROR* message can appear and remove the user from the workflow. 4. During the 18th study: System error *Please restart the system, There seems to be a problem…. ExamApp has stopped working* messages can appear.	The operator may decide to rescan the patient.	No action required.
14	***V5.0 and V5.2***	***VTV Errors*** When the reliabilityVT /VTabdomen protocol is ran, the system may display 10 virtual tilt viewer error messages and the application may crash.	Clinical User may decide to rescan a patient.	No action required.
15	***V5.0 and V5.2***	***Security*** Avenues for an attacker to bypass the kiosk mode have been identified, potentially allowing the attacker to cause data corruption and scan acquisition failure caused by security breach of the system.	Clinical User may decide to rescan a patient.	No action required.
16	***V5.0 and V5.2***	***Host PC vulnerabilities*** Vulnerabilities on the HOST PC have been identified. The system is vulnerable to security threats which can cause data corruption on scan acquisition.	Clinical User may decide to rescan a patient.	No action required.

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Issue #	Affected Software Version	Issue Description	Clinical Impact	Manufacturer Recommendations
17	***V5.0 and V5.2***	***Host PC vulnerabilities*** Vulnerabilities on the HOST PC have been identified. The system is vulnerable to security threats which can cause data corruption on scan acquisition.	Clinical User may decide to rescan a patient.	No action required.
18	***V5.0 and V5.2***	***Clinical Scan Aborted*** The clinical scan can abort with the message *Gantry acquisition system cannot comply, Please retry".Errorcode"S_MASTER_SEQUENCER_ACQ_NOT_OK* after bolus scans and injection.	Clinical User may decide to rescan a patient.	No action required.
19	***V5.0 and V5.2***	***Admin Tool Access*** It has been identified that it is possible to run admin PowerShell to update system settings (e.g. Windows Registry Values) from a clinical account. After 1-click installation the user could launch admin tools using a keyboard shortcut Windows + X and could execute any management applications.	User may move the patient to a new scanner or rescan on the current system.	No action required.
20	***V5.0 and V5.2***	***Gantry Acquisition Error*** Intermittently, the clinical scan fails with a *Gantry acquisition system cannot comply, please retry* error message.	The operator may decide to rescan the patient.	No action required.
21	***V5.0 and V5.2***	***Merged Helical scans*** An issue can occur when the Helical scan is executed and then the scan is extended. The DICOM tags become missing from the extended series when the series is merged with the original, and certain diagnostic tools, such as the Eclipse TPS system., cannot be used.	The operator may decide to rescan the patient.	No action required.
22	***V5.0 and V5.2***	***Breath Light Error in Brazilian Portuguese Language*** The main Bolus tracker scan can stop due to breath light error in Brazilian Portuguese language. The system displays a popup message saying: *A problem has occurred, please retry ...* and the scan may not start.	The operator may decide to rescan the patient.	No action required.
23	***V5.0 and V5.2***	***Microsoft .NET Framework missing security update*** It has been identified that The Microsoft .NET Framework installation on the remote host is missing a security update. A remote code execution vulnerability was found, if the users' applications is running on IIS using their parent Application Pool, this can lead to privilege escalation and other security bypasses. A spoofing vulnerability where an unauthenticated remote attacker can sign ClickOnce deployments without a valid code signing certificate. (CVE-2023-36873).	Clinical User may decide to rescan a patient.	No action required.

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Issue #	Affected Software Version	Issue Description	Clinical Impact	Manufacturer Recommendations
24	***V5.0 and V5.2***	***Adobe Reader not up to Date*** It has been identified that vulnerabilities related to Adobe Acrobat Reader application can potentially lead to Arbitrary code execution.	Clinical User may decide to rescan a patient.	No action required.
25	***V5.0 and V5.2***	***Calcium Score Scan did not Start*** During a cardiac exam the calcium score scan may not start, presenting the system failed error message: *S_MASTER_SEQUENCER_STATE_TIMEOUT_ERR*.	The operator may decide to rescan the patient.	No action required.
26	***V5.0 and V5.2***	***Insecure Windows Permissions*** It has been identified that Privilege escalation attack can happen since some of the newly introduced windows services have modify/write access for below users/groups.	User may move the patient to a new scanner or rescan on the current system.	No action required.
27	***V5.0 Only***	***Gantry Delayed Error Message*** A gantry error message can appear due to delayed command on Gantry side. In the specific defect case, the gantry initialization took too long and was cancelled by the user.	Clinical User may decide to rescan a patient.	No action required.
28	***V5.0 Only***	***Helical Dose Saving (HDS)*** When using Noah couch with low speed (<20mm/sec.) a delay from the couch side can cause premature expiration of the HDS safety time which then will stop the acquisition.	Clinical User may decide to rescan a patient.	No action required.
29	***V5.0 Only***	***CCT Scan Mode Error Message*** A message *Please wait, acquisition ongoing* while using VTV (Virtual Tilt Viewer) can appear and can affect the operator from continuing to the next step of the scan.	Clinical User may decide to abort the CCT sequence and rescan a patient.	No action required.
30	***V5.0 and V5.2***	***No Hazard Issues*** In addition to the issues described above, there are 46 field issues that are non-safety related and are planned to be fixed through this software release. The 46 issues have no hazards associated with them.		

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URGENT Medical Device Correction Response Form

Reference: Motion issues on Spectral CT, 2025-PD-CTAMI-004 (FCO72800828 or FCO72800829)

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 Medical Device Correction letter, 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 Urgent Medical Device Correction letter.

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Correction letter and confirm that the information from this Letter has been properly distributed to all users that handle the affected 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 at: Philips.Recall@philips.com