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URGENT Field Safety Notice

Spectral CT 7500 with software version 5.0.0.X
Software issues with a potential to cause misdiagnosis, CT rescan, or burning smell and smoke

November 30, 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 become aware of software issues with Spectral CT 7500 that could pose risks to patients and users. This URGENT Field Safety Notice is intended to inform you about:

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

   Philips has identified multiple software issues affecting Spectral CT 7500 systems. The detailed descriptions of these issues are provided in Table 1.

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

   Of the eight (8) issues, the first five (5) shown in Table 1 could pose risk to patients. One (1) of these five (5) issues could also impact system users. The risks include a potential for misdiagnosis, or a CT rescan, or may result in burning smell and smoke. Refer to Table 1 for details of potential hazard/harm.

Table 1

Issue #	Issue Description	Potential Hazard/Harm
1	**Cone Beam Artifact-Correction Artifacts in the Brain:** A defect in Cone Beam Artifact-Correction (CBAC) algorithm when using 64 slice collimation can result in motion related artifacts.	Hyperdense/hypodense and/or split artifacts occur in the axial, sagittal and coronal reconstructions near the bone-brain interface and/or streak artifacts occur in MPR (Multi Planar Reformation). If this issue occurs, there is a potential for misdiagnosis, or a CT rescan.
2	**Cone Beam Artifact-Correction Artifacts in the Body:** A defect in Cone Beam Artifact-Correction algorithm when using 128 slice collimation can result in motion related artifacts.	Hyperdense/hypodense and/or split artifacts occur in the axial, sagittal and coronal reconstructions and/or streak artifacts occur in MPR. If this issue occurs, there is a potential for misdiagnosis, or a CT rescan.

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Issue #	Issue Description	Potential Hazard/Harm
3	**Virtual Non-Contrast Images Issue:** Virtual non-contrast (VNC) image reconstruction on head scan can result in artifacts.	A banding artifact appears on the virtual non-contrast images of the brain. If this issue occurs, there is a potential for CT rescan.
4	**Philips Medical Systems Remoting Component Issue**: While performing reconstructions and while accessing Exam Card Manager, an error message appears: "System Error, please restart the system".	The scan is paused. If this issue occurs, there is a potential for CT rescan.
5	**Couch Vertical Servo Failure:** Vertical motion of the couch is interrupted.	Burning smell and a small amount of smoke may occur. If this issue occurs, there is a potential for breathing problems and a first-degree burn.
6	**Recon box (CIRS) cannot initialize Error:** While trying to reconstruct images during clinical use, an error message appears: "Recon box (CIRS) cannot initialize. Please change scan parameters or restart the Recon box. If problem persists, please contact service."	The image reconstruction is paused. This issue has no impact to patients/users.
7	**Constancy test failure:** During software upgrade of a system and performing Acceptance & Constancy tests, the Constancy test fails with an error message: "The Loaded Baseline do not match, image number 1 is missed in Baseline, please recreate one" being displayed.	None. This issue has no impact to patients/users as it occurs during software upgrade and not during clinical use.
8	**Firmware (FW) error:** Philips identified a firmware error in the DMS Peripheral reset code block.	None. This issue has no impact to patients/users.

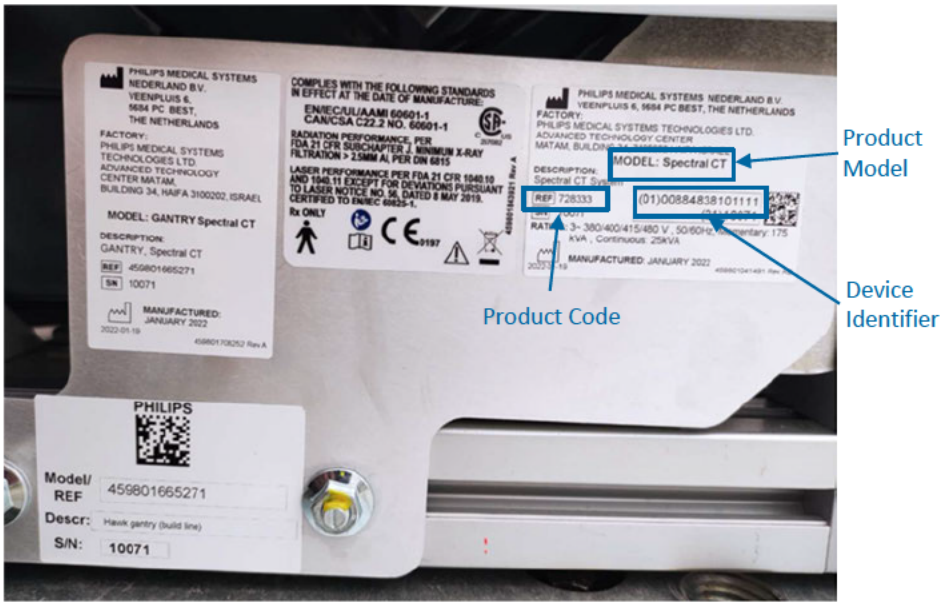
Philips has received complaints associated with these issues; however, there are no reports of injury or serious harm.

3. Affected products and how to identify them

These issues affect Spectral CT 7500 (product code 728333 and 728340) with software version 5.0.0.X (X is a 5-digit number starting with 78).

To identify if your system is affected:
These issues affect Spectral CT 7500 systems, which have Device Identifier 00884838101111 and 00884838111103. Locate the Device Identifier, product code (728333 or 728340) and the product model name (Spectral CT) 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. Navigate to the Home screen and click the ***Help*** button.
2. Select ***About*** and the software version is then displayed as shown in Figure 2. The software version begins with **v**.

Figure 2. Spectral CT 7500 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 the Philips CT systems in accordance with their intended use.
- Refer to Table 2 for specific details of short-term precautions to take until the permanent solution is installed.

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Table 2

Issue #	Issue Description	Advice to user
1	**Cone Beam Artifact-Correction Artifacts in the Brain:** A defect in Cone Beam Artifact-Correction (CBAC) algorithm when using 64 slice collimation can result in motion related artifacts.	1) Change the collimation to 32 which will turn CBAC off. Refer to Appendix A for the instructions. 2) Ensure anatomy is in iso-center. 3) Since patient movement can result in this artifact, instruct the patient not to move or swallow during acquisition.
2	**Cone Beam Artifact-Correction Artifacts in the Body:** A defect in Cone Beam Artifact-Correction algorithm when using 128 slice collimation can result in motion related artifacts.	1) Change the collimation to 112 (or any value below 128) which will turn CBAC off. Refer to Appendix A for the instructions. 2) Ensure anatomy is in iso-center. 3) Since patient movement can result in this artifact, instruct the patient not to move or breathe during acquisition.
3	**Virtual Non-Contrast Images Issue:** Virtual non-contrast (VNC) image reconstruction on head scan can result in artifacts.	As stated in the Spectral CT Instructions for Use (refer to "Spectral Results" in section 3), VNC images are recommended to be used on body scans only.
4	**Philips Medical Systems Remoting Component Issue**: While performing reconstructions and while accessing Exam Card Manager, an error message appears: "System Error, please restart the system".	• Do not open the Exam Card Manager when image reconstruction is in process. • If error message is received, user needs to restart the workflow and perform offline reconstruction if raw data is available. Refer to "Offline Reconstruction" in section 7 in the Spectral CT Instructions for Use, for steps to restore the patient scan data. • If no raw data is available, a rescan may be needed.
5	**Couch Vertical Servo Failure:** Vertical motion of the couch is interrupted.	To reduce the occurrence of this issue, limit keeping the couch at its lowest position when the system is powered up and not in use. If this issue occurs, 1) Remove patients and operators from the vicinity to limit exposure. 2) Contact your local Philips representative for further support.
6	**Recon box (CIRS) cannot initialize Error:** While trying to reconstruct images during clinical use, an error message appears: "Recon box (CIRS) cannot initialize. Please change scan parameters or restart the Recon box. If problem persists, please contact service."	Perform offline reconstruction. Refer to "Offline Reconstruction" in section 7 in the Spectral CT Instructions for Use, for steps to restore the patient scan data.

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Issue #	Issue Description	Advice to user
7	**Constancy test failure:** During software upgrade of a system and performing Acceptance & Constancy tests, the Constancy test fails with an error message: "The Loaded Baseline do not match, image number 1 is missed in Baseline, please recreate one" being displayed.	None.
8	**Firmware (FW) error:** Philips identified a firmware error in the DMS Peripheral reset code block.	None.

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.

Circulate this URGENT Field Safety Notice 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 solution to resolve these issues (reference FCO72800809 and FCO72800810).

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.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]

Cassandra Kocsis
Sr. Manager, Corrections and Removals

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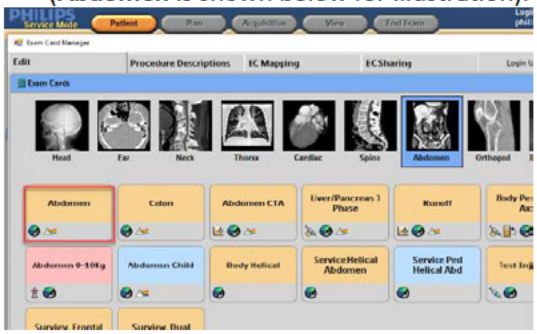
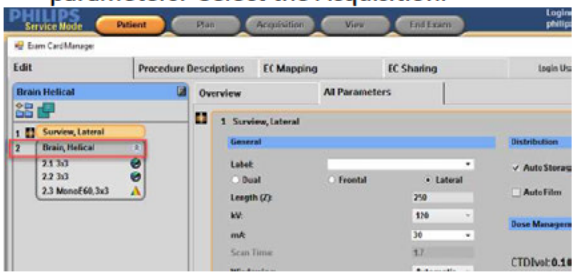
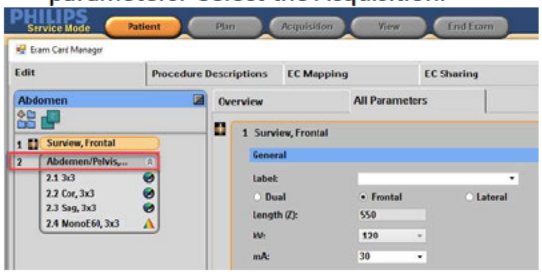
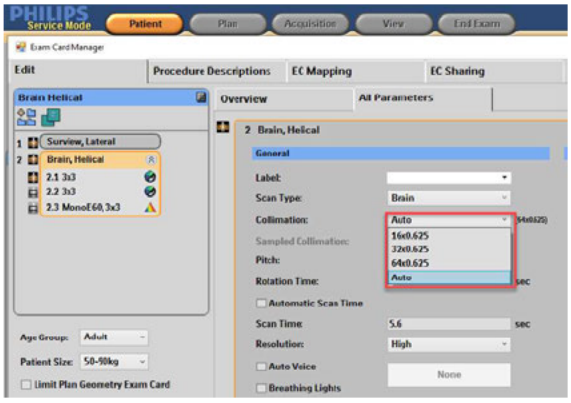
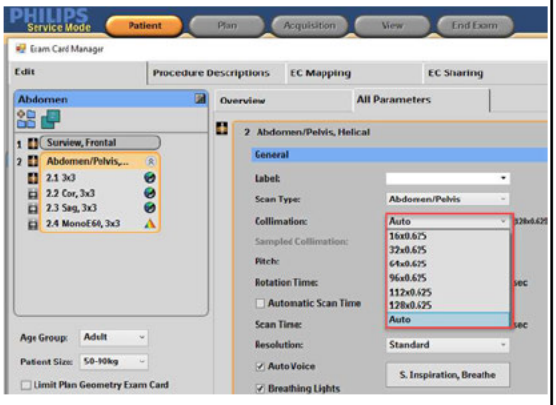
Appendix A

To change the collimation, follow the steps below: 1) for the Brain scan and 2) for the Body scan.

Steps to change the collimation to 32 which will turn CBAC off (Brain scan)	Steps to change the collimation to 112 (or any value below 128) which will turn CBAC off (Body scan)
1) Click the **Tool icon** on the top right corner to open the system utilities.	1) Click the **Tool icon** on the top right corner to open the system utilities.
2) Click **Exam Card Manager** on the top left side menu. 	2) Click **Exam Card Manager** on the top left side menu. 
3) Select the **Head** Exam Card Group.	3) Select the appropriate Exam Card Group. For this illustration, **Abdomen** is selected.
4) Select the Exam Card that you want to edit (**Brain Helical** is shown below for illustration). 	4) Select the Exam Card that you want to edit (**Abdomen** is shown below for illustration). 
5) The Exam Card opens to the surview parameters. Select the Acquisition. 	5) The Exam Card opens to the surview parameters. Select the Acquisition. 
6) The acquisition parameters are displayed. Select the drop-down menu for **Collimation** choices. 	6) The acquisition parameters are displayed. Select the drop-down menu for **Collimation** choices. 

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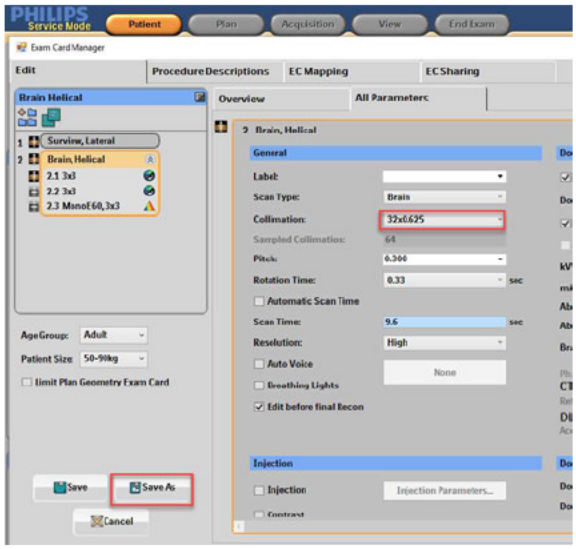
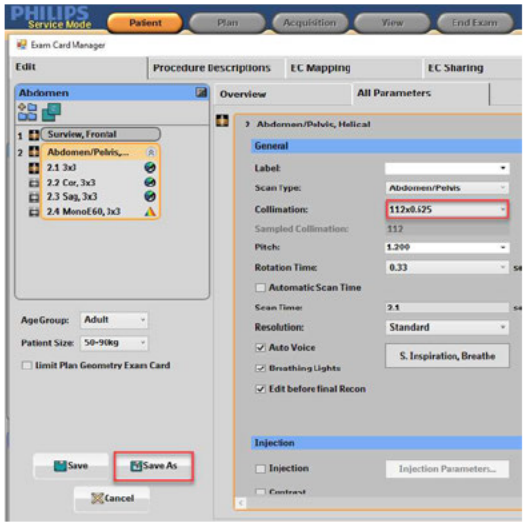
7) Select **Collimation: 32x0.625** and then click **Save As** on the bottom left side of screen.

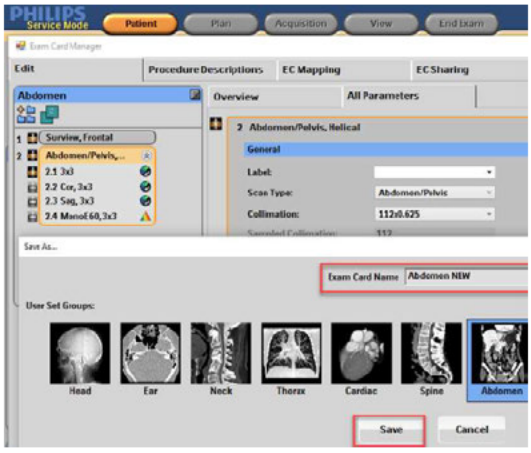


7) Select any Collimation below 128x0.625. For this illustration, **Collimation: 112x0.625** is selected. Then click **Save As** on the bottom left side of screen.



8) Update the name of the Exam Card in **Exam Card Name** section and click **Save**.

8) Update the name of the Exam Card in **Exam Card Name** section and click **Save**.



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URGENT Field Safety Notice Response Form

Reference: Software issues on Spectral CT 7500, 2023-PD-CTAMI-010 (FCO72800809 and FCO72800810)

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 issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Please retain this letter with your system(s) until a solution is installed on your system; ensure the notice is in a place likely to be seen/viewed.
- Circulate this notice to all users of this device so that they are aware of the issues.
- Until Philips has completed the system updates, follow the instructions provided in section 4 of the URGENT Field Safety Notice.

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 7500 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 your local Philips representative.