PHILIPS

URGENT Field Safety Notification

Spectral CT 7500, Spectral CT 7500 China, and Spectral CT on Rails

Images Incorrectly Labeled as "Last Shot" May Lead to Misdiagnosis and Subsequent Incorrect Treatment

December 13, 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,

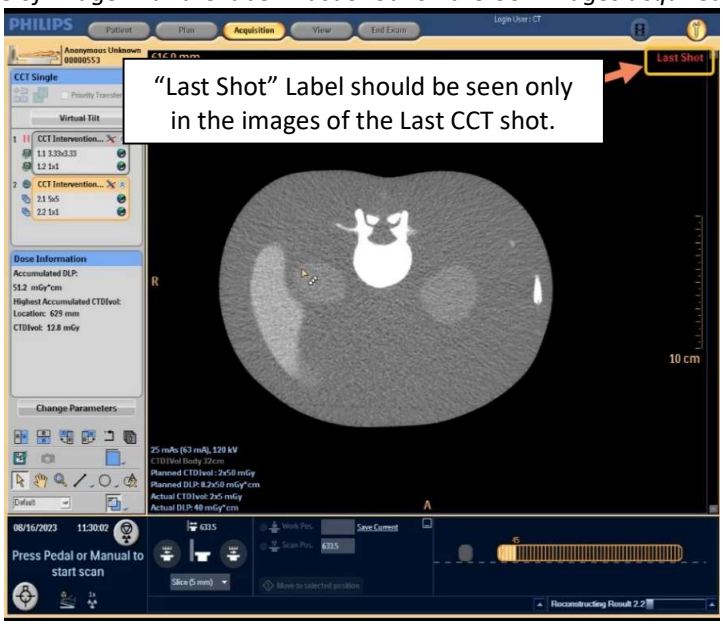
Philips has become aware of a potential safety issue when using the Spectral CT 7500, Spectral CT 7500 China, and the Spectral CT on Rails systems that may lead to misdiagnosis and subsequent incorrect treatment. This issue is found in software version 5.0 for Spectral CT 7500 and Spectral CT 7500 China, and software version 5.1.0.X for Spectral CT on Rails. 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 that there is a software issue that can incorrectly label all captured images as the "Last Shot". This situation can occur under the following circumstances:

- Volume Display Mode is selected and
- More than one Continuous CT (CCT) single shot or continuous shots are performed.

Figure 1. Picture of Image with the label "Last Shot" on the CCT images acquired in Volume Mode.



Philips has not received any reports of an adverse event associated with this issue as of December 2023.

2. Hazard/harm associated with the issue

If this issue occurs, it could potentially cause misdiagnosis and subsequent incorrect treatment. This can be due to needle position uncertainty based on the use of an image taken prior to the last shot.

3. Affected products and how to identify them

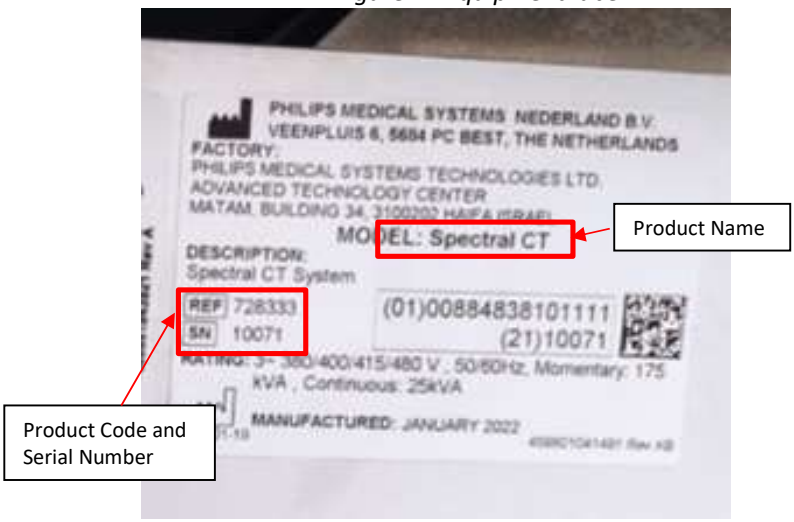
To identify if your system is affected:
This issue affects all Spectral CT 7500, Spectral CT 7500 China, and Spectral CT on Rails systems with model number listed in Table 1.

Table 1. Affected Systems

Product Code	Product Model	Software Version	Device Identifier
728333	Spectral CT 7500	5.0	(01)00884838101111(21)
728334	Spectral CT on Rails	5.1.0.X	(01)00884838103627(21)
728340	Spectral CT 7500 China	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 2. Figure 2 is showing a sample label for Spectral CT 7500 product model 728333 as an example.

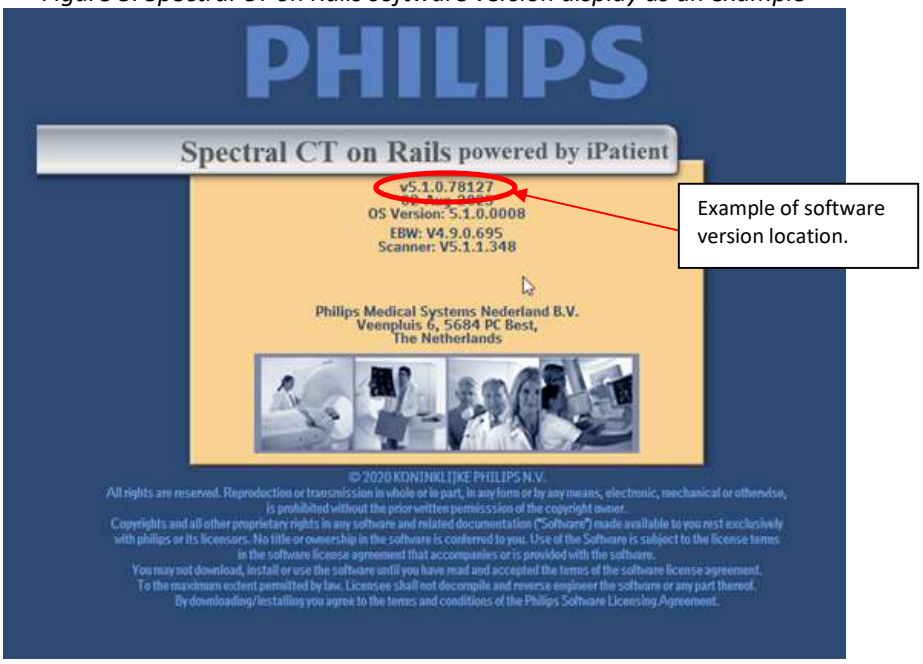
Figure 2. Equipment label



To identify the software version of your product:

1. Click the ***Help*** button.
2. Select ***About*** and the software version is then displayed. The software version begins with **v**.

Figure 3. Spectral CT on Rails software version display as an example



Intended Use:

Spectral CT 7500 and Spectral CT 7500 China Intended Use:

The Philips CT system is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment support, component parts, and accessories.

Spectral CT on Rails Intended Use:

The Spectral CT system acquires one CT dataset – composed of data from a higher-energy detected x-ray spectrum and a lower- energy detected x-ray spectrum. The two spectra may be used to analyze the differences in the energy dependence of the attenuation coefficient of different materials. This allows for the generation of images at energies selected from the available spectrum and to provide information about the chemical composition of the body materials and/or contrast agents. Additionally, materials analysis provides for the quantification and graphical display of attenuation, material density, and effective atomic number.

PHILIPS

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

- To avoid the issue, the Operator can update the default exam card to have 1mm slice thickness and not thicker slices. **In these cases, the issue will not be seen.**
    - As outlined in the *Interventional (CCT) Workflow* section in the Instructions for Use: Basic parameters can be changed without pausing the procedure. To change the slice thickness, select "Change Parameters" while the images are still displayed.
- You may continue to use your system(s) in accordance with the intended use and by following the recommendation listed above.
- 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 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 FCO72800807 for Spectral CT on Rails for and FCO72800808 for Spectral CT 7500 and Spectral CT 7500 China).

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,

Cassandra Kocsis

Cassandra Kocsis
Sr. Manager, Corrections & Removals

PHILIPS

URGENT Field Safety Notice Response Form

Reference: 2023-PD-CTAMI-017 Spectral CT 7500, Spectral CT 7500 China, and Spectral CT on Rails (FCO72800807 for Spectral CT on Rails for and FCO72800808 for Spectral CT 7500 and Spectral CT 7500 China).

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:

- 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 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 your local Philips representative.