

URGENT Field Safety Notification

Spectral CT

Reflective Laser Line May Lead to Misdiagnosis and Subsequent Incorrect Treatment

March 27, 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 potential safety issue when using the Spectral CT, that may lead to misdiagnosis and subsequent incorrect treatment. This issue affects Spectral CT systems that have the CSTE447 Oncology Essentials Package, with an installed 3rd party laser used for Radiation Treatment. 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 potential hardware issue with Spectral CT systems that have the NCTE447 Oncology Essentials Package, which allows for a 3rd party oncology marking laser to be installed and used. Systems with an installed laser have the potential for the laser line to be reflected off the gantry cover surface. This reflection can modify the laser line projection to have irregularities in the line, causing the laser line to appear thicker or duplicated (Figure 1).

Representation of the reflected laser line duplicated onto the patient surface. The green arrow points to the laser line, and the red arrow is a demonstration of the laser line that is reflected off the gantry cover, causing the appearance of duplication or thickness of the laser line.



Figure 1. Image showing the double laser line.

Figure 2 below shows the normal state single laser line, without duplication.

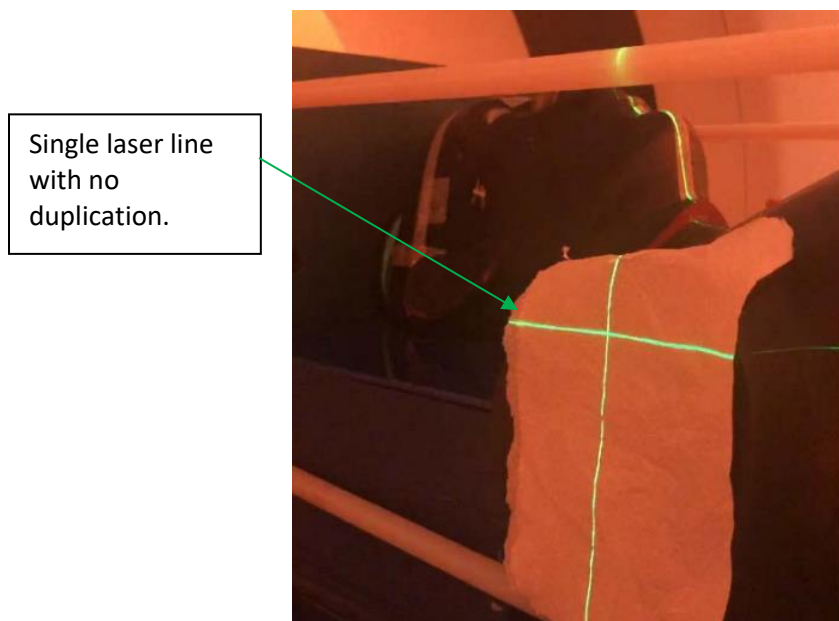


Figure 2. Image showing the single laser line.

Philips has not received any reports of an adverse event associated with this issue as of March 2024.

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 marking position uncertainty based on the thickness or duplication of the laser line.

3. Affected products and how to identify them

To identify if your system is affected:

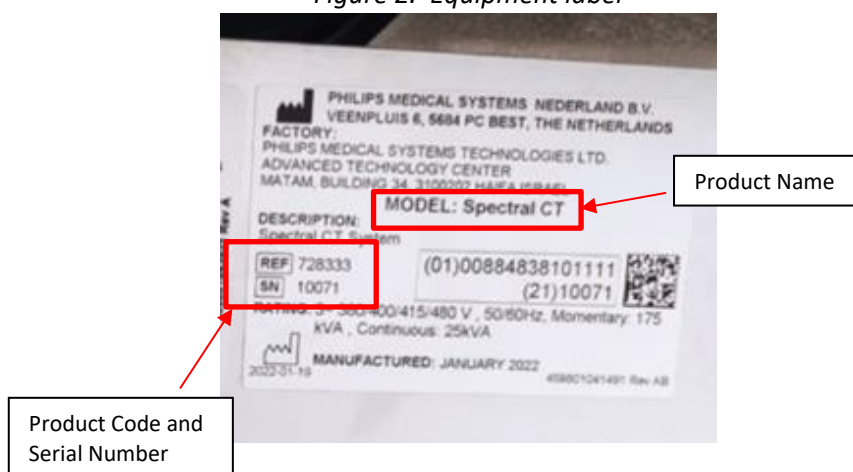
This issue affects Spectral CT systems with model number listed in Table 1, which have an installed 3rd party laser used for Radiation Treatment.

Table 1. Affected Systems

Product Code	Product Model	Hardware	Device Identifier
728333	Spectral CT	3 rd party laser	(01)0088483810111(21)

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 3. Figure 3 shows a sample label for Spectral CT product model 728333 for reference.

Figure 2. Equipment label



Intended Use:

Spectral CT:

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.

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

- Identify if you installed a 3rd party laser onto your system.
- If a 3rd party laser is installed:
 - Identify if the system is displaying a reflected, duplicated or thickened laser line. Not all systems are affected by this issue, as it depends on the installation of the 3rd party laser.
 - If the system displays the issue:
 - Before treatment of a patient, reposition or re-image as necessary to verify proper placement of the localization laser marks on the patient's skin.
- 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 hardware update to resolve the issue (reference FCO72800818).

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

URGENT Field Safety Notice Response Form

Reference: 2023-PD-CTAMI-027 Spectral CT (FCO72800818).

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.