

URGENT Field Safety Notice

Spectral CT 7500

Multi-Function Foot Switch Unload Pedal Foot Entrapment

March 17, 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 *Unload Pedal* of the foot switch on the Spectral CT 7500 system. Pressing the Unload Pedal of the foot switch to perform the unload function may cause entrapment of the operator’s foot. 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 pressing the Unload Pedal of the foot switch to perform the unload function may cause entrapment of the operator’s foot.

Three foot pedals are located on the Multi-Function Foot Switch which can be operated from either side of the patient table. They are located on the floor between the base of the patient table and the gantry. Starting at the base of the table, they include the unload pedal, the load pedal, and the free-float pedal, as shown in Figure 1 and Figure 2.

Figure 1. Multi-Function Foot Switch Pedal layout

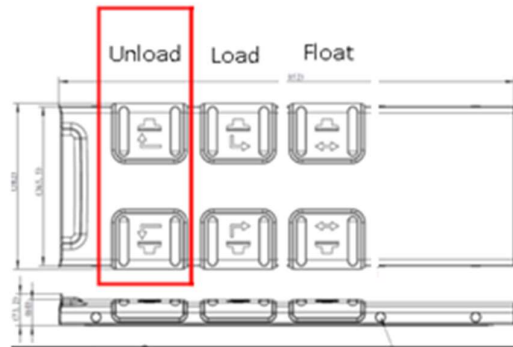
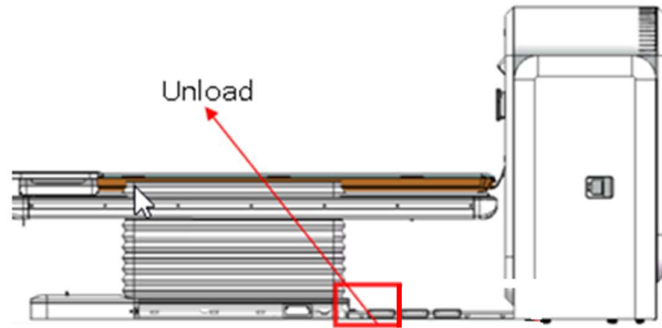


Figure 2. Patient Table, Multi-Function Foot Switch, and Gantry layout side view



Pressing the *Unload Pedal* will move the patient table out of the Gantry and down to the unload position. The patient table stops moving when the operator releases the *Unload Pedal*, or the unload position is reached.

Philips has received one (1) report of an adverse event associated with this issue, which resulted in bruising to the operator's foot and lower leg. In this reported event, the operator positioned a patient stretcher near the patient table while pressing the *Unload Pedal*. If the operator is positioned in a tight space between the patient table and the ancillary equipment so the operator's range of mobility in removing his/her foot from under the table is limited, then the table downward motion may entrap the operator's foot and lower leg between the bottom of the table, the Multi-Function Foot Switch, and the ancillary equipment. However, please note, the potential for entrapment is not limited to the cited scenario.

2. Hazard/harm associated with the issue

If foot or leg entrapment occurs while pressing *Unload Pedal*, the risk to operators may include: pain, muscle or ligament sprain, abrasion, laceration, contusion, fracture, loss of function, and joint dislocation.

3. Affected products and how to identify them

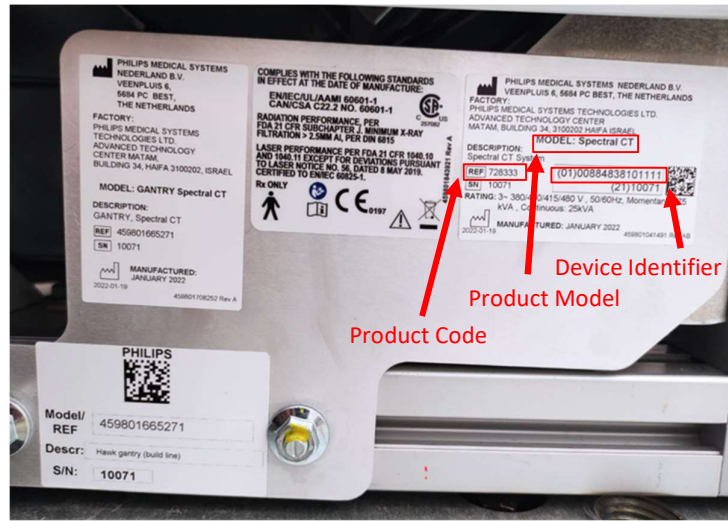
Intended Use:

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.

To identify if your system is affected: This issue affects all Spectral CT 7500 (728333) systems, which have Device Identifier 00884838101111.

Locate the Device Identifier, product model name (Spectral CT) and product code (REF: 728333) on the back of the gantry in the bottom right corner as shown in Figure 3.

Figure 3. Equipment label



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

- **Immediately stop using the *Unload Pedal*** of the Foot Switch until Philips installs a solution on your system.
 - Instead of using the *Unload Pedal*, please use the *Unload Patient* function on the Gantry Control Panels, or use other *Table In/Out, Up/Down* functions on the Gantry Control Panels, CT Scan Control Box, or Hardware Interventional Controls to fulfill the normal patient unloading function, as instructed in the IFU.
- You may continue to use *Load Pedal*, and *Free-Float Pedal* of Foot Switch, as they are not affected by this Urgent Field Safety Notice Letter.
- 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 solution to resolve this issue (refer to FCO72800795).

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 and Removals

URGENT Field Safety Notice Response Form

Reference: Multi-Function Foot Switch Unload Pedal Entrapment on Spectral CT 7500 (FCO 72800795)

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:

- **Immediately stop using the *Unload Pedal*** of the Foot Switch until Philips installs a solution on your system.
- Instead of using the *Unload Pedal*, please use the *Unload Patient* function on the Gantry Control Panels, or use other *Table In/Out, Up/Down* functions on the Gantry Control Panels, CT Scan Control Box, or Hardware Interventional Controls to fulfill the normal patient unloading function, as instructed in the IFU.
- You may continue to use *Load Pedal*, and *Free-Float Pedal* of Foot Switch, as they are not affected by this Urgent Field Safety Notice Letter.
- 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.

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 Philips representative.