

**URGENT Field Safety Notice**

**Incisive CT**

**Multi-Function Foot Switch Unload Pedal Foot Entrapment**

March 20, 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 Incisive CT 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*

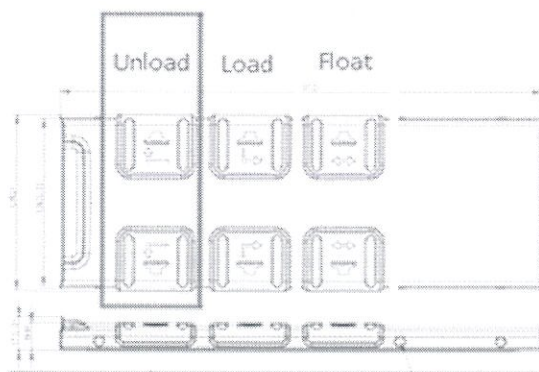
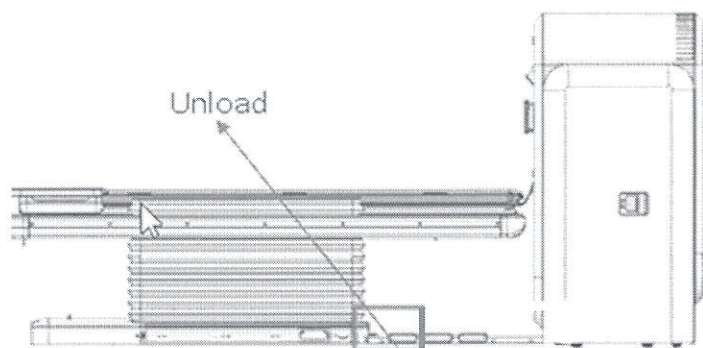


Figure 2. Patient Table, Multi-Function Foot Switch, and Gantry layout side view



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.

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.

As of February 2023, Philips has not received any reports of adverse events associated with this issue on the Incisive CT system.

## 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.

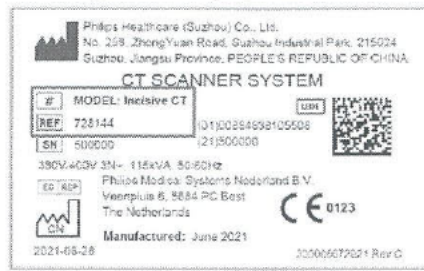
### To identify if your system is affected:

This issue affects the Incisive CT (728143,728144).

Locate the product model name (Incisive CT) and product code (REF: 728143,728144) on the back of the gantry in the bottom right corner as shown in Figure 3.

Please see Appendix A for the list of affected models and serial numbers.

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 FCO72800794).

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: <When a Philips representative is required, contact details to be provided by the Market>

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,



Philips Precision Diagnostics (PD) China

## Appendix A – Affected Serial Numbers

Serial Numbers for: Incisive CT (Model Number: 728144)				
Unique Device Identifier Rule: (01)00884838105508(21) + Serial number				
550263	550249	550239	550215	550211
550091	550188	550187	550186	550174
550172	552041	550164	34107	550140
34062	550099	550082	550071	550068
550059	34020	550038	550040	550021
550036	550018	550014	550011	550010
550009	550008	550007	550240	550241
550126				

Serial Numbers for: Incisive CT (Model Number: 728143)	
Unique Device Identifier Rule: (01)00884838085015(21) + Serial number	
33040	500408

## URGENT Field Safety Notice Response Form

**Reference:** Multi-Function Foot Switch Unload Pedal Entrapment on Incisive CT (FCO 72800794)

**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 Philips at: <local market email address>