

**URGENT Field Safety Notice**  
Zenition 50, Zenition 70, Veradius Unity systems

Wireless footswitch connection issues causing  
interruption of live Fluoroscopy imaging or exposure

29-Nov-2021

**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 a copy with the equipment Instruction for Use.

Dear Customer,

A problem has been identified in the wireless foot switch of the Philips Zenition 50, Zenition 70 and Veradius Unity systems that could pose a risk for patients. This URGENT Field Safety Notice is intended to inform you about:

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

The wireless foot switch is an option for Philips Zenition 50, Zenition 70 and Veradius Unity systems to release live Fluoroscopy and exposure.

Philips has discovered that the wireless foot switch can suddenly stop responding due to a firmware issue when a number of ambient conditions coexist, such as EMC disturbance and the presence of other wireless devices in the room.

If the wireless foot switch fails it will no longer be possible to use it to release live fluoroscopy imaging or exposure unless a cold restart of the system [power down, power up] is performed.

Fluoroscopy imaging and exposure will be available using the hand switch which is permanently connected to the C-arm stand, or by using the wired foot switch.

**2. What the hazard/harm associated with the issue is**

If this problem occurs with the wireless foot switch, there could be a delay or potentially an interruption of procedure if the hand switch is not used or the if the wired foot switch is not connected to the system.

To date, Philips has not received any reports of patient harm due to this problem with the Philips Zenition 50, Zenition 70 and Veradius Unity.

**3. Affected products and how to identify them**

The following wireless footswitches are affected by this issue:

Model Name	Model Number
Wireless Foot switch 3P	459801238191
Wireless Foot switch 3P	459801238231

The model name and model number can be found on the label located on the bottom of the footswitch as shown in Figure 1.

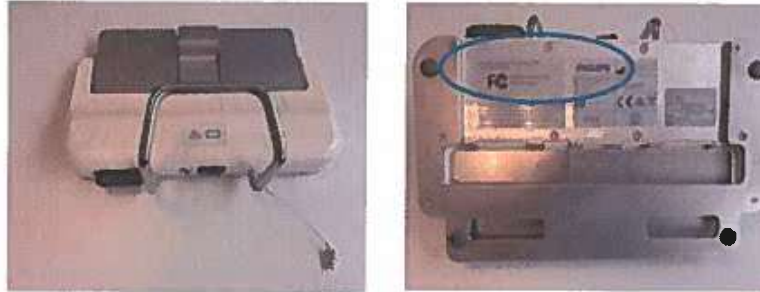


Figure 1: Label location on the bottom of the footswitch

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

- Ensure that the wired foot switch is always connected to the system.
- Immediately start using the wired foot switch or hand switch in the event the wireless foot switch loses connection.
- Perform a daily check for damage and correct functioning of the hand switch and wired foot switch as described by the “User Routine Checks” section in your Instruction for Use.
- Circulate this notice to all users of this device so that they are aware of the issue.
- Place this Field Safety Notice with the documentation of the Philips Zenition 50, Zenition 70 or Veradius Unity system.
- Return the attached reply form to Philips to confirm that:
  - the Zenition 50, Zenition 70 and Veradius Unity systems wired foot switch is connected to the system
  - the users of the system have reviewed and understood this Field Safety Notice.


#### 5. The actions planned by Philips IGT to correct the problem

Philips is working on a solution for this problem. You will be contacted by your local Philips representative once a solution is available.

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.

**PHILIPS**

Sincerely,



Rajesh Kathuria  
Head of Quality – IGT Systems



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## URGENT Field Safety Notice RESPONSE FORM

**Reference: 2021-IGT-PUN-011: Wireless footswitch connection issues causing interruption of live Fluoroscopy imaging or exposure**

**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 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:**

- Ensure that the wired foot switch is always connected to the system. The wired foot switch is always provided with the Zenition 50, Zenition 70 and Veradius Unity systems.
- Immediately start using the wired foot switch or hand switch in the event the wireless foot switch loses connection.
- Perform a daily check for damage and correct functioning of the hand switch and wired foot switch as described by the "User Routine Checks" section in your Instruction for Use.
- Circulate this notice to all users of this device so that they are aware of the issue.
- Place this Field Safety Notice with the documentation of the Philips Zenition 50, Zenition 70 or Veradius Unity system.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the Philips Zenition 50/ Zenition 70 / Veradius Unity system and the wired foot switch is connected to the system.

**Name of person completing this response form:**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Date  
(DD/MM/YYYY): \_\_\_\_\_

Please send this confirmation form to:  
<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx">