

**URGENT Field Safety Notice**

Allura Xper and Azurion systems

Wireless foot switch connection issues causing interruption of Fluoroscopy and exposure.

22-Oct-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 Philips Allura Xper and Azurion 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 used to control fluoroscopy and exposure with the Philips Allura Xper and Azurion systems.

Philips has discovered that the wireless foot switch can suddenly stop responding due to a firmware bug 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, fluoroscopy imaging and exposure will not be available until a cold restart of the system [power down, power up] is performed.

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

If this problem occurs with the wireless foot switch, there will be a delay in procedure and potentially an interruption of procedure.

To date, Philips has received one report of patient harm due to interruption of the procedure. The patient suffered a larger myocardial infarction than would have been predicted.

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

The following wireless foot switches are affected by this issue:

Description	Model number
WFS Ad7(X) Option 3P	459801319471
WFS Ad7(X) Option 4P+2	459801319521
WFS Ad7(X) Option 3P	459801319361
WFS Ad7(X) Option 4P+2	459801319421
WFS Field Extension Set 3P (ORT)	459801319481
WFS Field Extension Set 4P+2 (ORT)	459801319531
WFS Field Extension Set 3P	459801319511
WFS Field Extension Set 4P+2	459801319541
WFS Field Extension Set Mono	459801319371
WFS Field Extension Set Biplane	459801319431
WFS Field Extension Set Mono (ORT)	459801319391
WFS Field Extension Set Biplane (ORT)	459801319441
Wireless Footswitch Set 3P	459801238241
Wireless Footswitch 3P	459801238231
Wireless Footswitch Set 4P+2	459801238261
Wireless Footswitch 4P+2	459801238251
Wireless Footswitch Set 3P	459801238201
Wireless Footswitch 3P	459801238191
Wireless Footswitch Set 4P+2	459801238221
Wireless Footswitch 4P+2	459801238211
Wireless Footswitch 3P Kit	459801733051
Wireless Footswitch 3P Kit	459801733061
Wireless Footswitch 4P+2 Kit	459801733071
Wireless Footswitch 4P+2 Kit	459801733081
WFS Base Station	459801257861
WFS Base Station Kit	459801733091

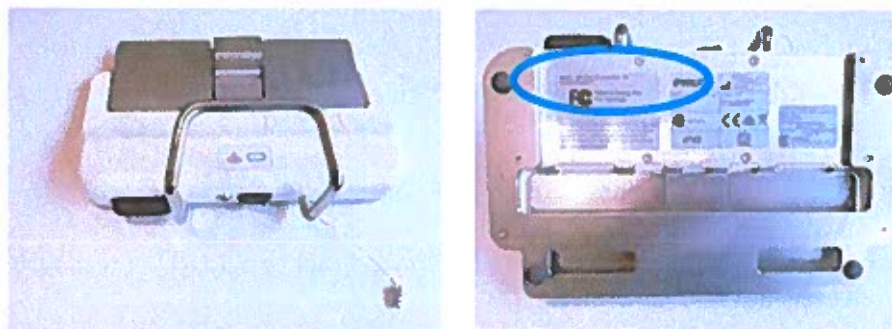


Figure 1: Label location on the bottom of the foot switch

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

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

- Ensure that the wired foot switch is always connected to the system. The wired foot switch is always provided with the Allura Xper and the Azurion systems.
- Immediately start using the wired foot switch in case the wireless foot switch loses connection.
- 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 Allura Xper or Azurion system.
- Return the attached reply form to Philips to confirm that:
  - the Allura Xper and Azuarion system 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 Systems to correct the problem

You will be contacted by your local Philips representative as soon as this 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.

Sincerely,



Rajesh Kathuria  
Head of Quality – IGT Systems



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**URGENT Field Safety Notice RESPONSE FORM**

**Reference: 2021-IGT-BST-020: Wireless foot switch connection issues causing interruption of Fluoroscopy and 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 Allura Xper and the Azurion systems.
- Immediately start using the wired foot switch in case the wireless foot switch loses connection.
- 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 Allura Xper or Azurion system.
- Return the attached reply form to Philips to confirm that:
  - a wired foot switch is connected to the system
  - the users of the system have reviewed and understood this Field Safety Notice.

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 Allura Xper or Azurion 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">