PHILIPS

URGENT Field Safety Notice

Philips Intuis Systems
Intermittent loss of X-ray

22-Sept-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's Instruction for Use.

Dear Customer,

A problem has been identified in the Philips Intuis system 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

Philips has identified a software defect that randomly causes a situation where the X-ray is not activated when pressing the footswitch. This can occur in any X-ray mode.

When the system is used in Cine or DSA modes, in some instances the Error 152 (tube thermal overload) will be displayed on the X-ray Generator Console as well as on the Live Image Viewing Monitor. Although the error can be cleared (by releasing the footswitch and pressing OK on the Generator Console), X-ray will not be activated when the footswitch is pressed.

To date, Philips has not received any reports of harm or injury on account of this problem.

2. Hazard/potential harm associated with the issue

If the problem occurs, there will be a delay in the procedure since X-ray is not available. In the event the complete system is restarted (Mobile Viewing Station, C-Arm Stand, and X-ray generator), there will be a delay of 4 minutes.

3. Affected products and how to identify them

Product Name	Model Numbers
Intuis	723005

Affected systems can be identified through the model number on the System identification label placed on the C-arm stand cover.

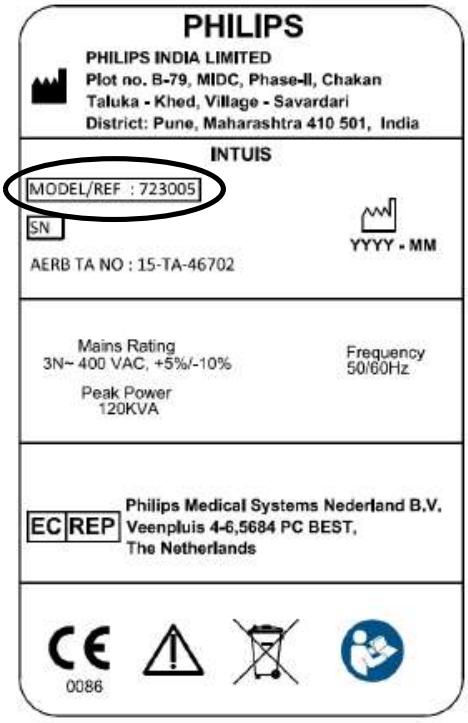

Figure – 1: Philips Intuis label placed on the C-arm stand cover.

4. **Actions that should be taken by the customer / user to prevent risks for patients or users**
   - If the problem occurs, users should perform the following actions:
     a) When "Error 152" appears on the Generator Console and the Live Image Viewing Monitor:
        1. Release the Foot Switch.
        2. Acknowledge the error on the Generator Console by pressing "OK".
        3. Switch the generator power OFF from the generator console.
        4. Switch the generator power back ON from the generator console and wait for 35-40 seconds until the console powers up.
        5. Switch back to the Patient User Interface and return to the Acquisition User Interface.
        6. System is now fully operational and will generate X-ray when the footswitch is pressed.

        After these actions are taken, X-ray should be available when the footswitch is pressed. Note that Steps 3 to 6 may take up to 1 (one) minute.

     b) When the problem occurs randomly without any "Error 152" presented on the Generator console and Live Image Viewing Monitor:

        1. Switch the generator power OFF from the generator console.
        2. Switch the generator power ON from the generator console and wait for 35-40 seconds until the console powers up.
        3. Switch back to Patient User Interface and return to Acquisition User Interface.
        4. System is fully operational and will generate X-ray when footswitch is pressed.

        After these actions, X-ray should be available when the footswitch is pressed. This may take up to 1 (one) minute.

   - Review this Urgent Field Safety Notice with all users of the system and place a copy of it with the instructions for use provided with the system.

- Transfer this notice within your organization or to any organization if the affected system has been transferred.
- Complete the enclosed Customer Reply Form and send it back to confirm that users have received and understood this Urgent Field Safety Notice.

5. Actions planned by Philips IGT Systems to correct the problem

The problem will be resolved by a software update. You will be notified by your local Philips representative when the software update is available for installation.

This notice has been reported to the appropriate Regulatory Agencies.

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,

S. S. Srinivas N.
Quality & Regulatory

PHILIPS

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: **Intermittent loss of X-ray, C&R 2021-IGT-PUN-010**

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, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

- Please review this Field Safety Notice with all user of the system.
- Place a copy of it with Instructions for Use of systems.
- Customer can continue using of the system following action provided in this Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly reviewed with all users who handle the impacted product.

Name of person completing this response form:_____

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

<Philips Market organizations 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>