PHILIPS

FIELD SAFETY NOTICE

Philips StentBoost Live R2.0 application
X-ray images might not be processed

2022-Feb-02

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 StentBoost Live R2.0 application when used with the Philips Allura and Azurion systems that could pose a risk for patients. This Field Safety Notice is intended to inform you about:

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

Due to a software defect, the Philips StentBoost Live R2.0 might not process X-ray images of the current run and instead show an image processed in a previous run. The image shown could be from the same patient or from a different patient.
When the problem occurs, the area of the boosted images remains black, and the small X-ray viewer in the upper right corner will show a single static image of the previous run. The correct patient information is shown on the Philips Allura / Azurion system. This defect is intermittent and is caused by a race condition when the software does not properly handle all the "process requests".

This problem has been identified through the investigation of 2 (two) customer complaints.

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

The incorrect image displayed to the user could lead to incorrect treatment. If the problem occurs, the StentBoost Live application will have to be restarted (see section 4), causing a delay in the procedure.

To date, Philips has not received any reports of harm associated with this problem.

3. Affected products and how to identify them

The Philips StentBoost Live R2.0 used with Philips Allura and Azurion systems is affected by this issue. The software version of the Philips StentBoost Live application can be seen by clicking on the "About" box displayed when the application is opened (see Fig. 1 and 2).

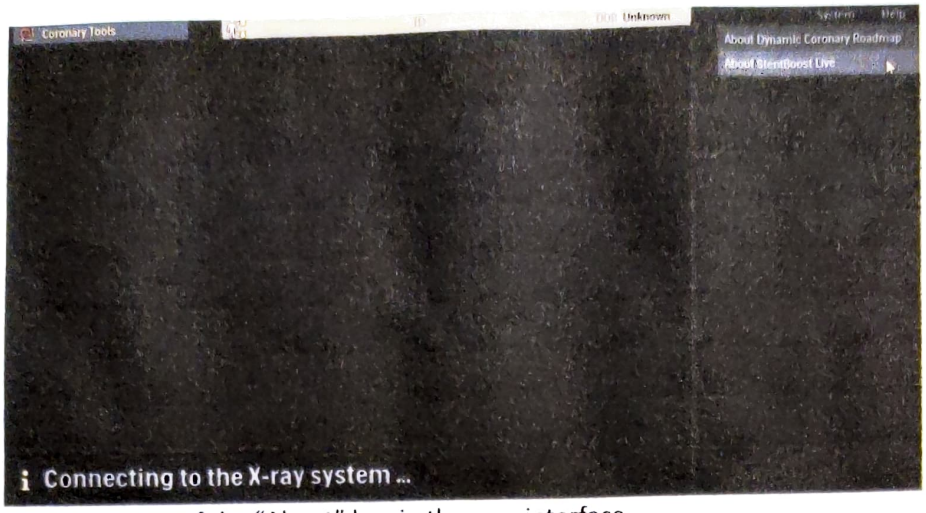

Fig. 1: Location of the "About" box in the user interface.

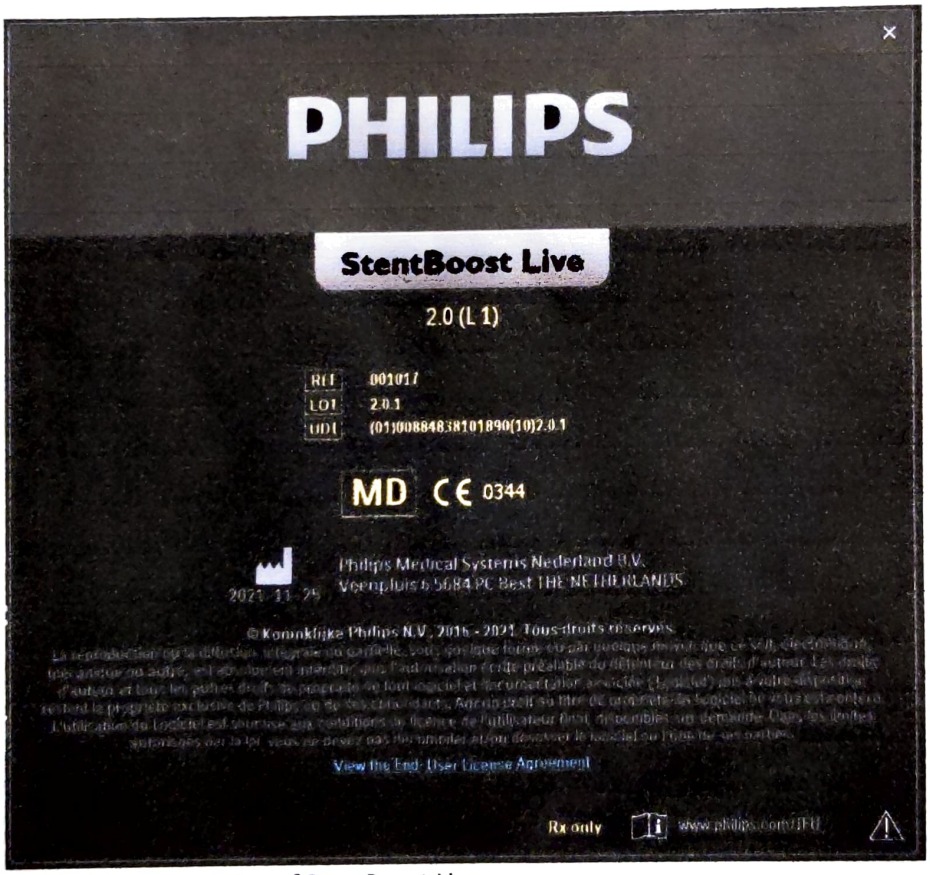

Fig. 2: Software version of StentBoost Live.

Philips is sending this notification directly to customers that have affected systems.

4. **What are the actions that should be taken by the customer / user in order to prevent risks for patients or users**
   - If the problem occurs, restart the Philips StentBoost Live application.
   - Place this Field Safety Notice with the documentation of the system until Philips has installed the software update in your system.

- Circulate this notice to all users so they are aware of the product issue.
- Return the attached reply form to Philips to confirm that users have reviewed and understood this Field Safety Notice.

5. What are the actions planned by Philips IGT Systems to correct this problem

This problem will be resolved by a software update, which is already available. You will be contacted by your local Philips representative to schedule the StentBoost Live software update.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information, please contact your local Philips representative (reference FCO72200503).

Sincerely,

[redacted]

PHILIPS

FIELD SAFETY NOTICE RESPONSE FORM

Reference: 2021-IGT-BST-027

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:

- If the problem occurs, restart the Philips StentBoost Live application.
- Place this Field Safety Notice with the documentation of the system until Philips has installed a software update in your system.
- Circulate this notice to all users so they are aware of the product issue.

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 StentBoost Live R2.0 application.

Name of person completing this response form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____