PHILIPS

Field Safety Notice

Philips StentBoost Live R2.0 application
Acquisition does not stop automatically
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,

Two problems have been identified in the Philips StentBoost Live R2.0 application, when used with the Philips Azurion with software release R2.x, that could pose a risk for patients. This letter is intended to inform you about:

1. **What are the problems and under what circumstances they can occur**
   A – Acquisition does not stop automatically:
   Due to an incorrect configuration setting in the EPX database of StentBoost Live, acquisition does not stop automatically as it should. When the user selects the StentBoost Live protocol on the Philips Azurion system, the following on-screen message is displayed to the user in the Philips StentBoost Live application: "*Press the cine pedal until the acquisition stops*". However, due to the incorrect configuration of the EPX database, the acquisition does not stop after 40 images, but continues as long as the pedal is pressed.

   This problem has been identified through the investigation of a customer complaint.

   B – X-ray images might not be processed:
   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 these issues**

A – Acquisition does not stop automatically:
If the problem occurs, the radiation exposure will not stop until the user releases the cine pedal, which will lead to higher radiation dose than clinically necessary. The additional X-ray dose is not expected to cause harm.

B – X-ray images might not be processed:
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, causing a delay in the procedure.

To date, Philips has not received any reports of harm associated with these problems.

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

Philips StentBoost Live R2.0 application, when used with Philips Azurion with software release R2.x, is affected by these issues. The users can identify the software version of the Philips StentBoost Live application in the "About" box displayed on the screen when the application is opened (see Fig. 1 and 2 below).

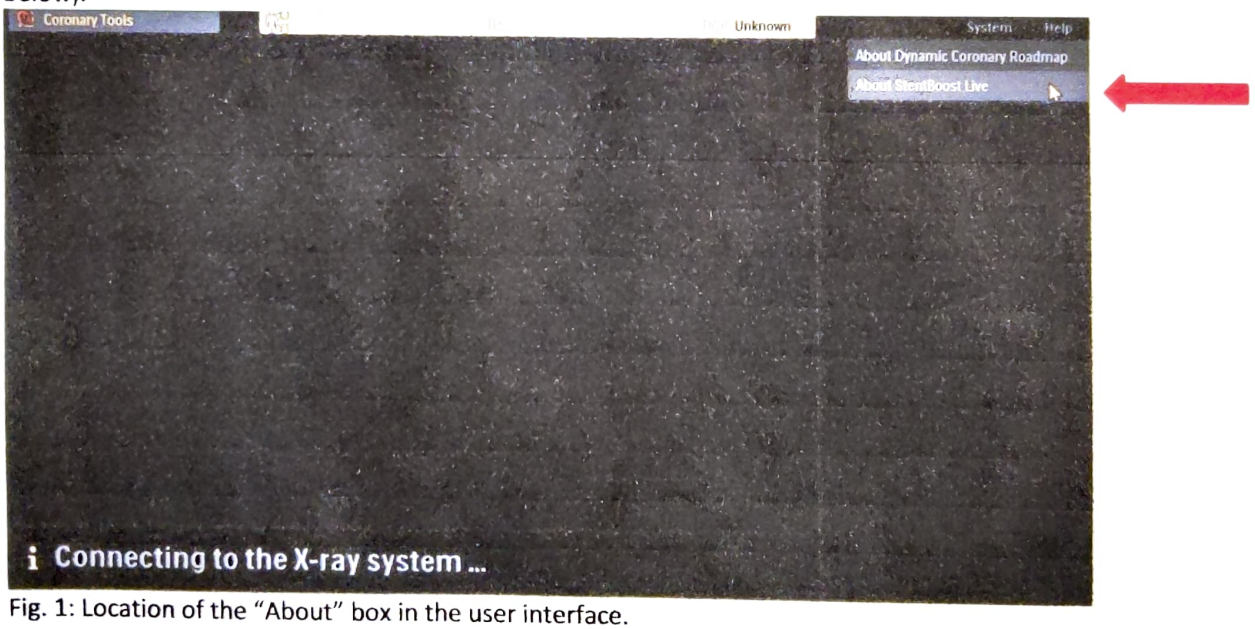

Fig. 1: Location of the "About" box in the user interface.

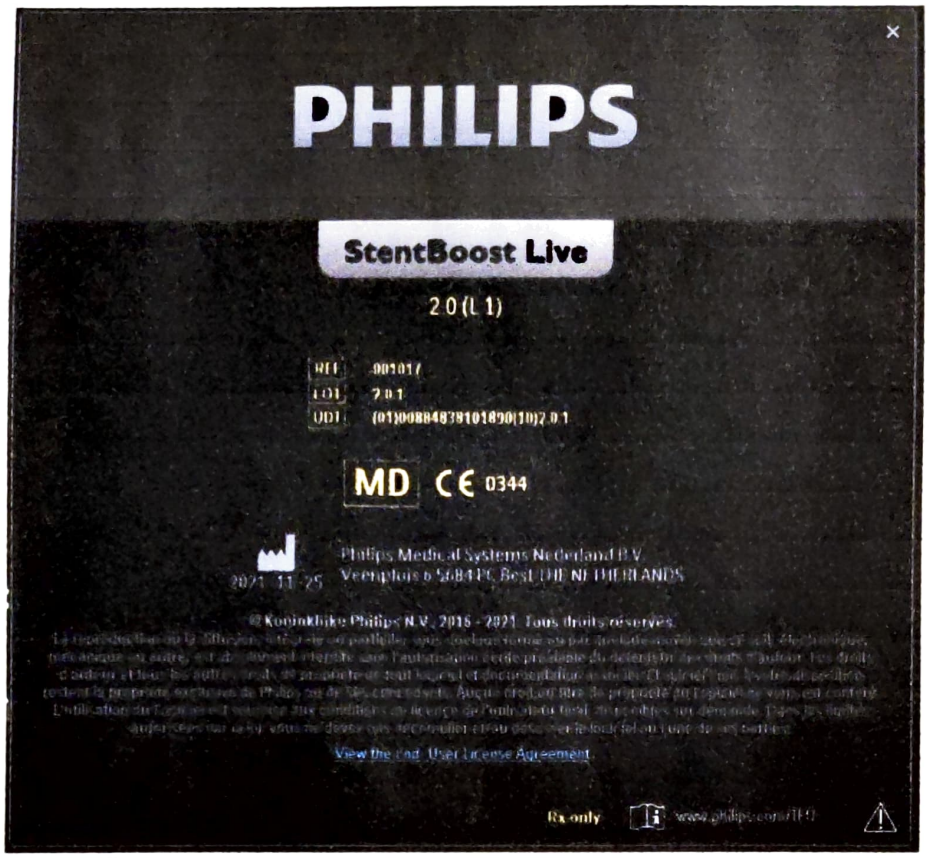

Fig. 2: Software version of StentBoost Live.

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 problem A (*Acquisition does not stop automatically*) occurs, the user shall release the cine pedal after 2 seconds of exposure. The 40 images will be acquired after 1,6 seconds of cine run.
- If problem B (*X-ray images might not be processed*) 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.
- Return the attached reply form to Philips to confirm that the users of the system have reviewed and understood this Field Safety Notice.

5. What are the actions planned by Philips IGT Systems to correct these problems

These problems 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 to FCO72200503).

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Sincerely,

Rajesh Kathuria
Head of Quality – IGT-Systems

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Field Safety Notice RESPONSE FORM

Reference: 2021-IGT-BST-033

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 problem A (*Acquisition does not stop automatically*) occurs, the user shall release the cine pedal after 2 seconds of exposure. The 40 images will be acquired after 1,6 seconds of cine run.
- If problem B (*X-ray images might not be processed*) 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):_____