PHILIPS

URGENT Field Safety Notice

Big Bore RT, Upgrade Brilliance CT Big Bore (Product Codes 728242, 728243, 728244)

Patient Position Image Shift may result in Incorrect Treatment

09-OCT-2023

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 this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with the Philips Big Bore RT and Upgrade Brilliance CT Big Bore where it may be difficult for the user to accurately identify the image position under specific clinical scenarios. This Urgent Field Safety Notice is intended to inform you about:

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

   After performing an off-center reconstruction and sending the image data to other Therapy Planning Solution (TPS) workstations or exporting to a post processing software, a two-dimensional image shift (X and Y coordinates) may occur.

   In oncology scenarios this could cause the contours to be misplaced or the ISO center of the tumor to be incorrect.

   In radiology scenarios this could cause the Relate function to show different positions on the IntelliSpace Portal or other post-processing workstations, when comparing images.

   Philips has received a complaint associated with this issue; however, there are no reports of injury or serious harm.

2. **Hazard/harm associated with the issue**

   For oncology users
   If the user performed off-set reconstruction on CT devices:
   - A shift could be observed on the contouring area of the primary and secondary image sets in the same CT study, when using image fusion (on TPS).
   - Incorrect coordinates may be sent to TPS system for further treatment when using absolute patient marking.

   This misplacement on the contour area or the incorrect marking before treatment may lead to incorrect radiation therapy planning. The incorrect result could interfere with the user's ability to identify the patient image information and the planning of subsequential treatment. The immediate health consequences include incorrect treatment regimen. The long-term health consequences include the growth or spread of cancer due to incorrect early treatment regimen.

PHILIPS

For radiology users
If the user performed off-set reconstruction on CT devices, after multiple acquisitions in a CT study, the Relate Position could be inaccurate for the same position on different images.

The incorrect result could interfere with the user's ability to identify the patient image information and subsequential diagnosis/treatment. The immediate health consequences include the incorrect diagnosis/treatment. There are no long-term health consequences.

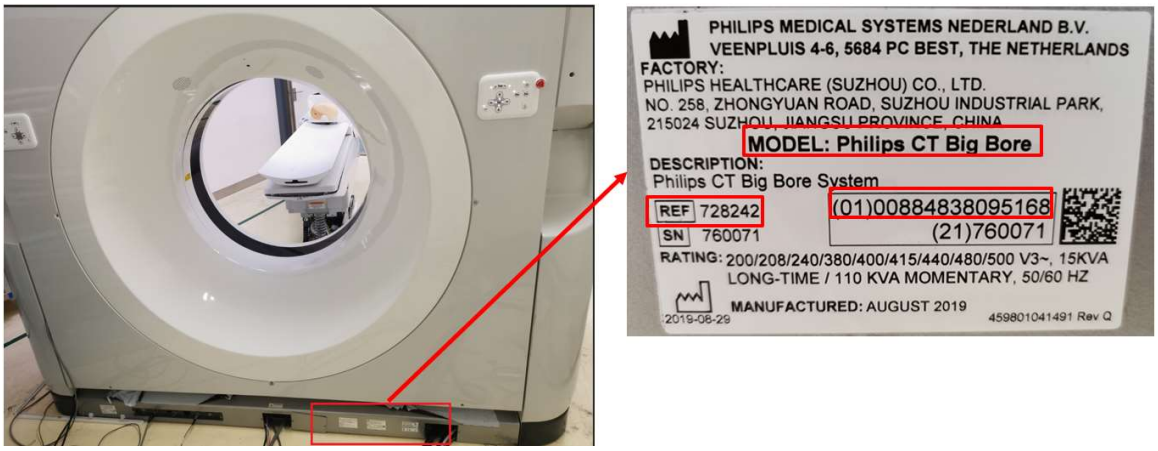
3. Affected products and how to identify them

The products listed below are affected:

Product Code (REF)	Product Model	Software	Device Identifier
728242	Big Bore RT	V4.8.0.10421	(01)00884838095168
728244	Brilliance CT Big Bore	V4.8.0.10421	(01)00884838059450
728243	Brilliance CT Big Bore Oncology	V4.8.0.10421	(01)00884838059450

To identify if your system is affected:
Identify the product model name and product code on the back of the gantry in the bottom right corner as shown in Figure 1.

Figure 1. Example system label



To identify the software version of your product:

1. From the Directory, select the ***Help*** button.
2. Select ***About*** and the software version is then displayed. The software version begins with **v**.

Figure 2. Big Bore software version display as an example

Intended Use:
The Philips CT Big Bore is a Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components and accessories.

4. **Actions that should be taken by the customer / user in order to prevent risks for patients or users**
Below are short-term precautions to take until the permanent solution is installed.

- Enable the Force X/Y to 0/0 option on your device (Refer to the Instructions For Use, Section 3 Preparing for an Exam under Preferences, as well as Section 5 Summary of Scanning Workflows under Scan Workflow). Enabling this option will avoid the issue.
- After enabling the above referenced option, you may continue to use your system(s) in accordance with the intended use.
- Please complete and return the attached response 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.
- Circulate this Urgent Field Safety Notice to all users of this device so that they are aware of the issue. Please retain this letter with your system(s) until a solution is installed on your system; ensure the letter is in a place likely to be seen/viewed.

5. **Actions planned by Philips to correct the problem**

Philips will contact you to schedule a time for a Philips Field Service Engineer (FSE) to visit your site and install the software update (FCO 72800806) to resolve the issue.

PHILIPS

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.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Cassandra Kocsis

Cassandra Kocsis
Sr. Manager, Corrections and Removals

PHILIPS

URGENT Field Safety Notice Response Form

Reference: Big Bore RT and Upgrade Brilliance CT Big Bore Patient Position Image Shift may result in Incorrect Treatment, 2023-PD-CTAMI-015 (FCO72800806)

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 retain this letter with your system(s) until a software solution is installed on your system; ensure the notice is in a place likely to be seen/viewed.
- Circulate this notice to all users of this device so that they are aware of the issues.
- Until Philips has completed the system updates, follow the instructions provided in section 4 of the Urgent Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the Big Bore RT and Upgrade Brilliance CT Big Bore.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to Philips at: CTNM.QARA@philips.com