Field Safety Notice

PHILIPS

Philips Healthcare

URGENT – Medical Device Correction

Brilliance CT Big Bore Oncology, Brilliance CT Big Bore Radiology and Brilliance CT 16 (Air) Software Version 3.6.0

Artifacts on Bolus Tracker Images Using Rotation Time of 0.4 seconds

Dear Customer,

A problem has been detected in the Philips Brilliance CT Big Bore Oncology, Brilliance CT Big Bore Radiology and Brilliance CT 16 (Air) software version 3.6.0 that if it were to re-occur could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem

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.

If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office.

For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377, Option 5: Enter Site ID or follow the prompts).

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Sr. Director, Quality and Regulatory

URGENT – Medical Device Correction

Brilliance CT Big Bore Oncology, Brilliance CT Big Bore Radiology and Brilliance CT 16 (Air) Software Version 3.6.0

Artifacts on Bolus Tracker Images Using Rotation Time of 0.4 seconds

AFFECTED PRODUCTS	All Philips Brilliance CT Big Bore Oncology, Brilliance CT Big Bore Radiology and Brilliance CT 16 (Air) systems using software version 3.6.0 are affected.
PROBLEM DESCRIPTION	The issue is restricted to a threshold-triggered bolus scan with a subsequent clinical step that has a rotation time of 0.4 seconds. There are artifacts appearing on the tracker images during threshold-triggered bolus scans with protocols using a Rotation Time of 0.4 seconds. In those cases only, the scan might be triggered either too soon or too late, which may lead to inappropriate contrast opacification during the clinical scan. If the acquired images are not diagnostically acceptable, a rescan of the patient may be performed.
HAZARD INVOLVED	If a rescan of the patient is performed, there will be unnecessary radiation.
HOW TO IDENTIFY AFFECTED PRODUCTS	To identify the software version of the product: • Click the "Help" button, • Select "About" and the software version is then displayed If you have a Brilliance CT Big Bore Oncology, Brilliance CT Big Bore Radiology, or Brilliance CT 16 (Air) system and software version 3.6.0, you are affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	Clinical judgment should be used by the customer/user to determine if the images acquired in the dataset contain enough information to make a diagnosis.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is implementing software update version 3.6.2 to correct the above-described issues. A Philips Field Service Engineer will contact you to schedule the software installation at your site.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. In the United States and Canada, please contact the Philips Healthcare Customer Solutions Center at 1-800-722-9377 and follow the recorded menu options to reach a Customer Solutions Engineer; in all other countries, please dial your local Philips Healthcare office.