

Computed Tomography

FSN 72800635 Rev 01

2015 Sep 21

URGENT - Field Safety Notice

Brilliance 16-Slice (Air) / Brilliance 64 CT / Ingenuity Core / Ingenuity Core¹²⁸ / Brilliance CT Big Bore / Ingenuity Flex

Issue 1: Image Position Accuracy

Issue 2: Tracker Image Artifact

Issue 3: Ring-dot Image Artifact

Dear Customer,

Problems have been detected with software versions V3.6.1, V3.6.2, V3.6.4, and V3.6.5 in the Philips Brilliance 16-Slice (Air), Brilliance 64 CT, Ingenuity Core, Ingenuity Core¹²⁸, Brilliance CT Big Bore, Ingenuity Flex products that, if it were to re-occur, could affect the performance of the equipment. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- 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.

Philips Healthcare has become aware of three issues on

- Issue 1: The image angular position accuracy issue due to image rotation calibration software error
- Issue 2: Tracker image streaking artifact issue due to reconstruction software error
- Issue 3: Image artifact issue due to X-ray measurement firmware error

To correct those issues, Philips will release a field change order (FCO) 72800635 by installing a software update on the affected systems.

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).

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Yuchol Kim
Sr. Manager Quality and Regulatory

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AFFECTED PRODUCTS	<p>Those issues are software related. To determine whether your system is affected, you must have one of the following systems and an affected software version:</p> <p>Issue 1: Image Position Accuracy issue due to Image Rotation Calibration Software Error on</p> <ul style="list-style-type: none">• Brilliance 16-Slice (Air)• Brilliance CT Big Bore• Ingenuity Flex <p>Issue 2: Tracker Image Artifact issue due to Reconstruction Software Error on</p> <ul style="list-style-type: none">• Brilliance 16-Slice (Air)• Brilliance 64 CT• Ingenuity Core• Ingenuity Core¹²⁸• Brilliance CT Big Bore• Ingenuity Flex <p>Issue 3: Image Artifact issue due to X-ray Measurement Firmware Error on</p> <ul style="list-style-type: none">• Brilliance 64 CT• Ingenuity Core• Ingenuity Core¹²⁸ <p>All Issues: affected software versions:</p> <ul style="list-style-type: none">• 3.6.1• 3.6.2• 3.6.4• 3.6.5
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PROBLEM DESCRIPTION	<p>Issue 1: Image Position Accuracy - Image Rotation Calibration program performed by field service engineer can report pass but fail to produce the correct angular rotation offset value for the ultra-fast scan mode. The inaccurate angular rotation offset can impact the accuracy of radiation treatment planning.</p> <p>Issue 2: Tracker Image Artifact - Tracker scan image of CT Angiography (CTA) examination can exhibit a streaking artifact. Due to the streaking artifact, the automatic clinical scan may be triggered at the wrong time resulting in suboptimal CT diagnostic images that do not capture the bolus peak of the imaged body section.</p> <p>Issue 3: Ring/dot image Artifact due to X-ray Measurement - After a complete system power shutdown and power up, if a head scan is performed without air calibration and without quick IQ check scan after power up, intermittent ring/dot image artifacts in the reconstructed images may occur.</p>
HAZARD INVOLVED	<p>Issue 1: Image Position Accuracy - Although this defect is highly unlikely to occur, if this error is not detected, the incorrect image may be used to plan the radiation therapy treatment potentially leading to injury/mistreatment.</p> <p>Issue 2: Tracker Image Artifact - If the tracker scan image has streaking artifacts, erroneous scan trigger may occur for the CTA scan, causing insufficient contrast in the CT image for the CTA scan. The suboptimal CT image would necessitate a rescan and reinjection of contrast to the patient.</p> <p>Issue 3: Ring/dot image Artifact due to X-ray Measurement Firmware Error - There are two potential category of hazards associated with ring/dot image artifacts resulting from X-ray measurement system firmware error: Image misrepresentation due to artifacts may cause harm of unnecessary treatment/surgery/medication, and CT rescan may cause harm of radiation minor effects.</p>

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AFFECTED PRODUCTS**

Determine whether you have a potentially affected system, then determine your software version.

Issue 1: Image Position Accuracy issue due to Image Rotation Calibration Software Error on

- Brilliance 16-Slice (Air)
- Brilliance CT Big Bore
- Ingenuity Flex

Issue 2:

Tracker Image Artifact issue due to Reconstruction Software Error on

- Brilliance 16-Slice (Air)
- Brilliance 64 CT
- Ingenuity Core
- Ingenuity Core¹²⁸
- Brilliance CT Big Bore
- Ingenuity Flex

Issue 3:

Image Artifact issue due to X-ray Measurement Firmware Error on

- Brilliance 64 CT
- Ingenuity Core
- Ingenuity Core¹²⁸

To identify the software version of your product:

- Click the "Help" button
- Select "About" and the software version is then displayed

The products affected will display one of the following software versions

- 3.6.1
- 3.6.2
- 3.6.4
- 3.6.5

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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Issue 1: If you experience the image position accuracy issue described above, Philips suggests to contact your field service provider to perform the image rotation calibration.</p> <p>Issue 2: If you experience the tracker image streak artifact issue described above, there are three possible outcomes:</p> <ol style="list-style-type: none">1. The tracker image may not be affected by the streak artifact and the scan will trigger as expected.2. The streak artifact may cause the tracker to trigger prematurely resulting in suboptimal results or3. The track will not trigger when threshold is reached. In this scenario click 'Manually trigger the clinical scan?' in the console user interface to start the clinical scan. <p>Issue 3: If you experience a ring or dot artifact during a head scan, Philips recommends performing a full air calibration before the next clinical scan.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips Healthcare is notifying the affected users of those issues via this Field Safety Notice.</p> <p>A Field Change Order (FCO) will be released to correct those issues.</p> <p>A Philips Field Service Engineer will contact you to schedule the software update installation at your site.</p>
FURTHER INFORMATION AND SUPPORT	<p>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).</p>

DOCUMENT CHANGE SUMMARY

Revision	Date	Document Author	Description of Change
00	15-SEP-2015	Shufang Dong	Initial Release. This version was never distributed to customers.
01	21-SEP-2015	Shufang Dong	Update the hazard involved section on Issue 1.

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