Computed Tomography FSN72800642 Rev 01 2015 Aug 07

URGENT - Field Safety Notice

Brilliance 64 and Ingenuity CT Scanners

Scan Length Longer than Planned

Dear Customer,

A problem has been detected in the Philips Brilliance 64 and Ingenuity CT Scanners 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.

Some scans unexpectedly set the Axial (Z axis) scan length to a greater length than the user set in the plan. The issue occurs only when the following 3 conditions are met:

- The plan employs Dual-SurView
- The plan requests either a Sagittal or a Coronal reconstruction.
- The gantry is tilted

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Yuchol Kim
Sr. Manager, Quality and Regulatory

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AFFECTED PRODUCTS	The following CT systems are affected: • Brilliance 64 • Ingenuity CT • Ingenuity Core • Ingenuity Core^{128} And only for systems with the following versions: • 4.0.x.xxxx – Any version of 4.0 • 4.1.y.xxxx – Only version up to and including 4.1.4.
PROBLEM DESCRIPTION	Some scans unexpectedly set the Axial (Z axis) scan length to a greater length than the user set in the plan. The issue occurs only when the following 3 conditions are met: • The plan employs Dual-SurView • The plan requests either a Sagittal or a Coronal reconstruction. • The gantry is tilted
HAZARD INVOLVED	There is a potential for undesired radiation to areas not intended to be scanned.
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 The products affected will display one of the following the software versions • 4.0.x.xxxx – Any version of 4.0 • 4.1.x.xxxx – Only version up to and including 4.1.4.
ACTION TO BE TAKEN BY CUSTOMER / USER	Philips Healthcare is not recommending to stop using the equipment. To eliminate the possibility of the defect from occurring, the user can eliminate any one of the three conditions needed to trigger the behavior: • The plan employs Dual-SurView • The plan requests either a Sagittal or a Coronal reconstruction. • The gantry is tilted Note that if the user chooses to eliminate the reconstruction from the plan, then that reconstruction can be created after the scan is complete.

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is directly notifying affected users of this issue via this letter. Philips Healthcare is developing a new version of software that will eliminate the defect. Deployment of this new software will begin before the end of April, 2016. All customers will be updated by the end of October, 2016. A Philips Field Service Engineer (FSE) will service your system to resolve the issue via a Field Change Order. A Philips FSE will contact you to schedule the software upgrade.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.