Computed Tomography FSN CLE15-063/72800652 **2016 APR 20**

URGENT - Field Safety Notice
Medical Device Correction

Philips Brilliance 64 and Ingenuity CT

Software v4.1.3 and v4.1.4 software issues:
Undesired Radiation

Important
Electronic Product Radiation Warning

Dear Customer,

Some issues have been detected in software version 4.1.3 and 4.1.4 in Philips Brilliance 64 and Ingenuity CT products that, if it were to re-occur, could pose a risk for patients or users.

This Field Safety Notice (FSN) CLE15-063/72800652 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.

To correct this issue, Philips will release Field Change Order (FCO) 72800652 to install a software update on the affected systems.

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

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.

Sincerely,

[redacted]

Holly Wright Lee
Manager, Post Market Surveillance

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AFFECTED PRODUCTS	**The following CT systems are potentially affected:** ▪ Brilliance 64, ▪ Ingenuity Core, ▪ Ingenuity Core^{128} , ▪ Ingenuity CT Running software versions: ➢ 4.1.3 or ➢ 4.1.4

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PROBLEM DESCRIPTION

No.	Identified Software Issue
1	**Sagittal Result Shortened for 2D Axial Head Scans** The sagittal result is shortened every time the user repeats a tilted axial scan, if they select tilt with any of the following: ▪ Multi-Planner Reconstruction (MPR) ▪ Axial exam card As a result, one or more slices may be lost. The operator then may decide to rescan the patient. This problem was discovered during repeat and extended scenarios.
2	**Tilt Results in One Rotation for Axial 2D Head Scan** The scan increment can change, if the: ▪ Operator selects any axial exam card with tilt and, ▪ Operator types the scan increment manually with the value equal to the collimation coverage After the scan, the system displays images from only one rotation in the viewer. Since the view contains only a partial image set, the operator may choose to rescan the patient.
3	**Scan Length Changes with a Change in Field Of View (FOV)** For axial 3D scans, the scan increment changes when there is a change in Field of View (FOV). This change causes the scan length to also change.
4	**Scan Length Changes when Tilt is Applied to Unplanned Results** If the first result is an MPR result and tilt is applied to it, when the remaining result gets planned (either while pressing Go or when selecting an unplanned axial result), there is a change in the scan length and number of cycles of scan.

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	5 **184.4mm & 135.0mm Surview Scan Length Fails** Wrong scan time estimation due to incorrect integration time causes the Surview scan (near 184mm and 135) to issue an error message at the end of scan. 6 **Reconstruction length does not equal Scan Length due to rounding discrepancy between host and Common Image Reconstruction System (CIRS)** When the scan length is set to a value that is very close to a whole number, the calculated reconstruction length may round the length to a value larger than the actual scan length.
HAZARD INVOLVED	Undesired radiation
HOW TO IDENTIFY AFFECTED PRODUCTS	Determine your software version. **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 ▪ 4.1.3 or ▪ 4.1.4

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ACTION TO BE TAKEN BY CUSTOMER / USER

The table below provides recommended actions that user can take when using the affected product(s).

No.	Identified Software Issue	Actions to avoid or minimize effect of issue
1	**Sagittal Result Shortened for 2D Axial Head Scans** For axial 2D scans, the scan increment changes when there is a change in Field of View (FOV) causing the scan length to change as well.	➢ To produce the full result, perform offline reconstruction of the original coronal or sagittal result.
2	**Tilt Results in One Rotation for Axial 2D Head Scan** After performing a CT axial 2D head acquisition, the resulting saved Multi-Planar Reconstruction (MPR) images displayed as a split series, when a large tilt is utilized.	➢ The operator should review the scan length before performing the scan and, manually adjust the scan length as necessary.
3	**Scan Length Changes with a Change in Field Of View (FOV)** For axial 3D scans, the scan increment changes when there is a change in Field of View (FOV) causing the scan length to change as well.	➢ The operator should review the scan length before performing the scan and manually adjust the length.

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4	**Scan Length Changes when Tilt is Applied to Unplanned Results** If the first result is a Multi-Planer Result (MPR) and tilt is applied to it, when the remaining result gets planned (either while pressing Go or when selecting an unplanned axial result), there is a change in the scan length and number of cycles of scan.	➢ The first result of a 2D Axial brain should always be an axial result and planned first. If MPRs are included they should follow the axial result.
5	**184.4mm & 135.0mm Surview Scan Length Fails** Wrong scan time estimation due to incorrect integration time causes the Surview scan to issue an error message at the end of scan.	➢ The operator should avoid setting the surview scan length to any number near 184.4mm and 135.0mm.
6	**Reconstruction length does not equal Scan Length due to rounding discrepancy between host and Common Image Reconstruction System (CIRS)** When the scan length is set to a value that is very close to a whole number, the calculated reconstruction length may round the length to a value larger than the actual scan length.	➢ None

- Please inform those who need to be aware within your organization or any organization where the potentially affected devices have been transferred. (If appropriate)
- Please transfer this notice to other organizations on which this action has an impact. (If appropriate)

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	• Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users about these issues via this Field Safety Notice (FSN). Field Change Order (FCO) **72800652**, involving installation of a software update will be released to correct the issue. A Philips Field Service Engineer (FSE) will contact you to schedule the software update 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 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).

The manufacturer will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health and Human Services, the details of which will be included in a subsequent communication to you.