Computed Tomography FSN CLE15-063/72800644 2016 APR 19

URGENT - Field Safety Notice
Medical Device Correction
Philips Brilliance iCT

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 the software version 4.1.3 and 4.1.4 in Philips Brilliance iCT products that, if it were to re-occur, could pose a risk for patients or users.

This Field Safety Notice (FSN) CLE15-063/72800644 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.

To correct this issue, Philips will release Field Change Order (FCO) 72800644 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, running software versions 4.1.3 and 4.1.4 are potentially affected: ➢ Brilliance iCT ➢ Brilliance iCT SP
PROBLEM DESCRIPTION	➢ **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. ➢ **Different CTDI values with DoseRight** DoseRight recommends scan settings that produce different CT Dose Index (CTDI) when Surview scan(s) are performed at different Kilo Volt (kV) settings. When changing the kVp setting for a Surview scan, the DoseRight values (and Water Equivalent Diameters) vary by more than 10%. ➢ **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. **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 resulting from initial scanning or rescanning of patient.

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HOW TO IDENTIFY AFFECTED PRODUCTS	**Determine your product software version:** ➢ **To identify the software version of your product:** ▪ Click the "Help" button ▪ Select "About" and the software version is then displayed ➢ The product(s) 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	**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.
2	**Different CTDI values with DoseRight** DoseRight recommends scan settings that produce different CTDI's when surviews are performed at different kV settings. When changing the kVp setting for a surview, the DoseRight values (and Water Equivalent Diameters) vary by more than 10%.	➢ The operator should select the scan parameters that gives them their preferred image quality.
3	**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.
4	**Reconstruction length does not equal Scan Length due to rounding discrepancy between host and Common**	➢ None

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	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. ▪ Please notify all 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) ▪ 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 issue(s) via this Field Safety Notice (FSN). Field Change Order (FCO) 72800644 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.