Field Safety Notice

Computed Tomography   FSN CLE16-045 72800666   2016 AUG 26

<h1 style="color:red; text-align:center">URGENT - Field Safety Notice
Medical Device Correction</h1>

Philips Brilliance 64 and Ingenuity CT/Core/Core[128]

Issue with High Resolution Brain Scans:

Dear Customer,

A performance issue has been detected in the Philips Brilliance 64 and Ingenuity CT products with software version 4.1.6.XX030. Not all customers receiving this letter have this version of the product. Please see the enclosed information to determine the version of your system. 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.

To correct this issue, a Philips field service representative will install a software update on the affected systems. Reference field change order (FCO) 72800666.

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, follow the prompts).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wright Lee
Manager, Quality & Regulatory

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Philips Brilliance 64 and Ingenuity CT/Core/Core^{128}

Issue with High Resolution Brain Scans:

AFFECTED PRODUCTS	The following CT systems are potentially affected only if they are running software version 4.1.6.XX030: Brilliance 64, Ingenuity Core, Ingenuity Core^{128} , Ingenuity CT

PROBLEM DESCRIPTION	While performing High Resolution head scans, the reconstructed images may exhibit degraded image quality manifested as:
	    - Non uniformity of the image,
	    - CT number shift, greater than 5 Hounsfield units,
	    - Reduction in gray/white matter differentiation.
	
	The issue is most severe in the high resolution mode. Philips provides factory reference pediatric scan protocols which are set to high resolution by default. Adult head scans have a factory reference protocol that defaults to standard resolution which does not experience the issue.

HAZARD INVOLVED	If Radiologist or physician does not recognize the CT number shift and the image artifacts align with patient history, in the most severe cases, this issue could lead to misdiagnosis.

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 the following software version 4.1.6.XX030

ACTION TO BE TAKEN BY CUSTOMER / USER	To avoid this image quality issue as stated above, Philips recommends performing head scans with standard resolution across all patient populations on systems running software version 4.1.6.XX030.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users of these issues via this Field Safety Notice. Field Change Orders (FCO) involving installation of a software update will be released to correct the issue at no charge to you. A Philips Field Service Engineer 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, follow the prompts).