Computed Tomography FSN 72800597 2016 APR 08

URGENT - Field Safety Notice
Medical Device Correction

Brilliance 64, Ingenuity Core, Ingenuity Core^{128} Software version 3.5.4

Software issues were identified which may cause artifacts resulting in a patient rescan.

Dear Customer,

A problem has been detected in the Philips Brilliance 64, Ingenuity Core, and Ingenuity Core^{128} software version 3.5.4 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.

If you need any further information or support concerning this issue, please contact your local Philips representative:
<Philips representative contact details to be completed by the FCO Executer>

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

[redacted]

Quality & Regulatory

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AFFECTED PRODUCTS	All Brilliance 64, Ingenuity Core, Ingenuity Core^{128} systems using software version 3.5.4.
PROBLEM DESCRIPTION	Philips Healthcare received reports from the field that certain Brilliance 64, Ingenuity Core, and Ingenuity Core^{128} systems running software version 3.5.4 exhibited intermittent swirl-like ring artifacts that may appear on reconstructed images, which may impair the diagnostic quality of affected images.
HAZARD INVOLVED	A patient rescan may be required due to impairment of the diagnostic quality of the reconstructed images.
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 If you have a Brilliance 64, Ingenuity Core, or Ingenuity Core^{128} system and software version 3.5.4, you are affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	There are no proactive actions for the user. Clinical judgment should be used by the clinician to determine if the images contained in the dataset without artifacts contain enough information to make a diagnosis. If these images are sufficient, no further action is required. If the images are not sufficient, a rescan of the patient may be required.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is implementing software update version 3.5.5 to correct the above-described issue. A Philips Field Service Engineer will contact you to schedule the software 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: *<Philips representative contact details to be completed by the FCO Executer>*