URGENT – Medical Device Correction

Brilliance iCT and iCT SP up to and including Software Version 3.2.5

Artifact with 80kVp Contrasted Head/Neck Scan with U-Filters

Dear Customer,

A problem has been detected in the Philips Brilliance iCT and iCT SP 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 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).
This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Sr. Director, Quality and Regulatory

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AFFECTED PRODUCTS	All Philips Brilliance iCT and iCT SP up to and including software version 3.2.5 are affected.
PROBLEM DESCRIPTION	When using 80 kVp with intravenous contrast in head and neck studies with U-filters (UA, UB, UC), a vascular artifact that resembles thrombus may appear on the image.
HAZARD INVOLVED	There is a risk of misdiagnosis which can lead to unnecessary treatment of a patient. For certain patient populations, this could contribute to serious injury.
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 iCT and iCT SP and software versions up to and including 3.2.5, you are affected. To ensure the continued safe use of your system, please follow the steps in the "**ACTION TO BE TAKEN BY CUSTOMER / USER**" which follows.

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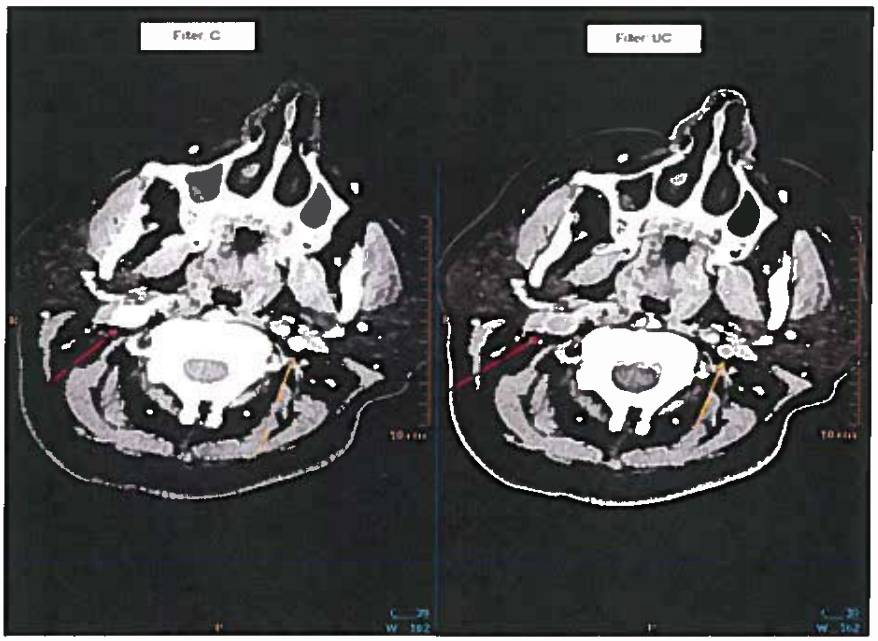
ACTION TO BE TAKEN BY CUSTOMER / USER	- When using 80 kVp with intravenous contrast in head and neck studies with U-filters (UA, UB, UC), an artifact that resembles thrombus may appear on the image.  Arrows show Normal Vessel enhancement Arrows show Thrombus Artifact - When the settings (80 kVp with intravenous contrast in head and neck studies with U-filters (UA, UB, UC)) are used, Philips recommends performing additional reconstruction with a non-U filter and comparing the result images to verify no such artifact is evident. **<u>Brain Perfusion Application</u>** You can continue to use 80 kVp with U-filters for brain perfusion scans. Refer to the Instruction For Use for the selection of an arterial input unaffected by discontinuity should occur.
ACTIONS PLANNED BY PHILIPS	Philips is providing additional instructions as part of this Field Safety Notice to be retained with the equipment Instruction for Use.

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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).