

URGENT - Field Safety Notice

Medical Device Correction

Brilliance iCT / Brilliance iCT SP Timed CT Scan without generated images

Dear Customer,

A problem has been detected in the Philips Brilliance iCT family, 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.

Philips will release field change orders (FCO) 72800675 to correct the issue on the affected systems.

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).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wright Lee

Sr. Manager Quality and Regulatory



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| AFFECTED PRODUCTS | <p>The following CT systems, running software version 4.1.6 are potentially affected</p> <ul style="list-style-type: none"> ➤ Brilliance iCT ➤ Brilliance iCT SP <p>Running software versions:</p> <ul style="list-style-type: none"> ➤ 4.1.6 |
| PROBLEM DESCRIPTION | <p>Upon completion of scan procedure during Bolus tracking on a Brilliance iCT with software version 4.1.6, no images were generated. This leads to unavailability of raw data for offline reconstruction.</p> |
| HAZARD INVOLVED | <p>This issue always leads to CT rescan</p> |
| HOW TO IDENTIFY AFFECTED PRODUCTS | <p>Determine your software version.</p> <p>To identify the software version of your product:</p> <ul style="list-style-type: none"> ▪ Click the “Help” button ▪ Select “About” and the software version is then displayed <p>The products affected will display the following software version:</p> <ul style="list-style-type: none"> ▪ 4.1.6 |
| ACTION TO BE TAKEN BY CUSTOMER / USER | <p>None</p> |



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| ACTIONS PLANNED BY PHILIPS | <p>Philips Healthcare is notifying the affected users of this issue via this Field Safety Notice.</p> <p>Field Change Orders (FCO) will be released to correct this issue.</p> <p>A Philips Field Service Engineer will contact you to schedule the updates to your system. Reference Field Change Order (FCO) 72800675</p> |
| FURTHER INFORMATION AND SUPPORT | <p>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).</p> |



