

URGENT – Medical Device Correction
Brilliance CT Big Bore with Software Versions 2.4.7 or 2.4.8

System may open e-stop when sitting idle.

Dear Customer,

A problem has been detected in the Philips Brilliance CT Big Bore 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.

See attached for more specific information about the issue.

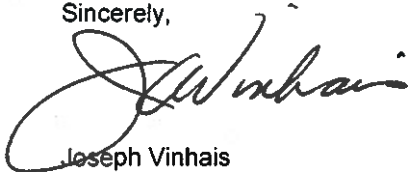
If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office:

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,



Joseph Vinhais
Senior Director Quality and Regulatory
Philips Healthcare



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AFFECTED PRODUCTS	Brilliance CT Big Bore with software versions 2.4.7 or 2.4.8 is affected.
PROBLEM DESCRIPTION	Philips Healthcare received a complaint stating the system opens e-stop while sitting idle causing all movements and scan to stop. The problem has only occurred one time when the scan was out of "Ready for Scan" or scanning mode.
HAZARD INVOLVED	There is a risk of undesired radiation due to the potential for a rescan if this issue happened during scanning mode.
HOW TO IDENTIFY AFFECTED PRODUCTS	If you have received this notification, your system could be affected. To identify the software version: <ul style="list-style-type: none"> • Click the "Help" button, • Select "About", and the software version is indicated. If you have software version: 2.4.7 or 2.4.8, you are affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	The user is advised to close e-stop, turn the key switch and continue operating the system normally.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying all affected customers of this issue via this Field Safety Notice, and will be installing a software update version 2.4.9, addressing the above identified issue. A Philips Service Engineer will contact the customer for implementation of the software update on the affected system.
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).

