Computed Tomography FSN 16-034-72800665-72800670 2016 Oct 13

URGENT - Field Safety Notice
Medical Device Correction

Brilliance iCT / Brilliance iCT SP / Brilliance Big Bore / Brilliance 64 Brilliance 40 / Brilliance 16 / Brilliance 6 / Brilliance 10 / Brilliance 16P Ingenuity CT / Ingenuity Core / Ingenuity Core[128]

Failed Couch Tabletop Motion

Dear Customer,

Philips Healthcare has become aware of an issue with the couch tabletop not moving during CT scan, 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) 72800665 and 72800670 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,

[redacted]

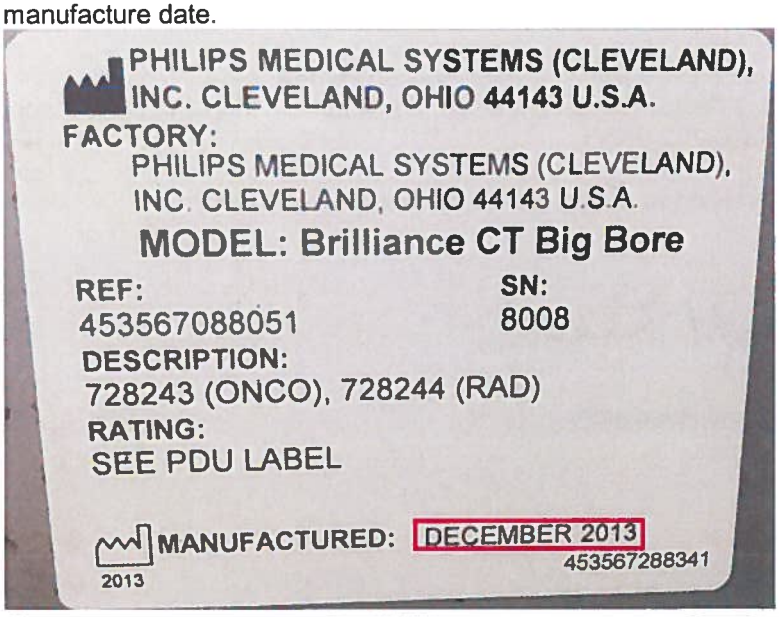
Holly Wright Lee
Sr. Manager Quality and Regulatory

Computed Tomography FSN 16-034-72800665-72800670 2016 Oct 13

URGENT - Field Safety Notice
Medical Device Correction

Brilliance iCT / Brilliance iCT SP / Brilliance Big Bore / Brilliance 64 Brilliance 40 / Brilliance 16 / Brilliance 6 / Brilliance 10 / Brilliance 16P Ingenuity CT / Ingenuity Core / Ingenuity Core^{128}

Failed Couch Tabletop Motion

AFFECTED PRODUCTS	The CT products below manufactured from January 1, 2006 to June 30, 2014 are potentially affected: Brilliance iCT SP / Brilliance iCT / Brilliance 64 / Brilliance 40 / Brilliance16 Brilliance 16P / Brilliance 10 / Brilliance 6 / Brilliance Big Bore Oncology Brilliance Big Bore Radiology / Ingenuity Core / Ingenuity Core^{128} / Ingenuity CT
PROBLEM DESCRIPTION	The patient support table top may fail to move in the horizontal direction when it is commanded to do so during CT scans, due to a potential mechanical linkage failure. The system cannot automatically detect this failure to abort the scan or to alert the user. Of the 5000 CT systems potentially affected, there have been 2 occurrences of this failure mode in the past 10 years.
HAZARD INVOLVED	Undesired radiation due to multiple exposures of the same anatomical region caused by failed couch motion during CT scanning.
HOW TO IDENTIFY AFFECTED PRODUCTS	If you have a potentially affected product (see above for models), identify the manufacture date of the system using the label located at the bottom of the rear Gantry base. **Affected systems were manufactured from January, 2006 to June, 2014.** Refer to the red box on the product label example below to find the system manufacture date. 

Computed Tomography FSN 16-034-72800665-72800670 2016 Oct 13

URGENT - Field Safety Notice
Medical Device Correction

Brilliance iCT / Brilliance iCT SP / Brilliance Big Bore / Brilliance 64 Brilliance 40 / Brilliance 16 / Brilliance 6 / Brilliance 10 / Brilliance 16P Ingenuity CT / Ingenuity Core / Ingenuity Core^{128}

Failed Couch Tabletop Motion

ACTION TO BE TAKEN BY CUSTOMER / USER	Customer is advised to follow the warning in the Instruction for Use: "During all movements of the gantry and the patient table (automatic and manual), keep the patient under continuous observation." If the patient table is not moving when it is commanded to move during CT scan, abort the scan by pressing the Pause button or Emergency stop actuator. Call your local Philips representative.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users of this issue via this Field Safety Notice. Field Change Orders (FCO) will be released to correct this issue. A Philips Field Service Engineer will contact you to schedule the FCO updates at your site. Reference Field Change Order (FCO) 72800665 (as necessary) and 72800670.
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).