

Computed Tomography

FSN 16-034-72800665-72800670

2016 Oct 26

**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<sup>128</sup>**

**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 the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,



**Holly Wright Lee**  
Sr. Manager Quality and Regulatory

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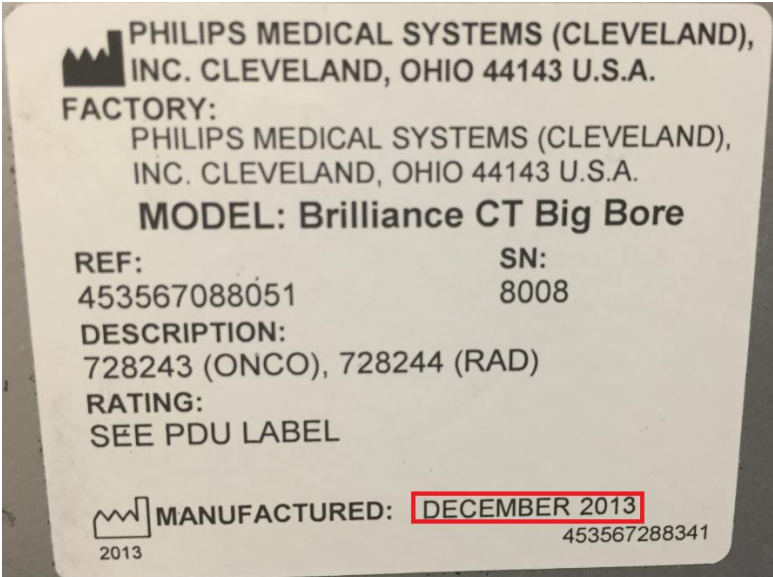
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<p><b>AFFECTED PRODUCTS</b></p>	<p>The CT products below manufactured from January 1, 2006 to June 30, 2014 are potentially affected: Brilliance iCT SP / Brilliance iCT / Brilliance 64 / Brilliance 40 / Brilliance16 Brilliance 16P / Brilliance 10 / Brilliance 6 / Brilliance Big Bore Oncology Brilliance Big Bore Radiology / Ingenuity Core / Ingenuity Core<sup>128</sup> / Ingenuity CT</p>
<p><b>PROBLEM DESCRIPTION</b></p>	<p>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.</p>
<p><b>HAZARD INVOLVED</b></p>	<p>Undesired radiation due to multiple exposures of the same anatomical region caused by failed couch motion during CT scanning.</p>
<p><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p>	<p>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. <b>Affected systems were manufactured from January, 2006 to June, 2014.</b> Refer to the red box on the product label example below to find the system manufacture date.</p>  <p>The image shows a white product label with black text. At the top, it reads 'PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. CLEVELAND, OHIO 44143 U.S.A.' followed by 'FACTORY: PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. CLEVELAND, OHIO 44143 U.S.A.' and 'MODEL: Brilliance CT Big Bore'. Below this, it lists 'REF: 453567088051' and 'SN: 8008'. The 'DESCRIPTION:' is '728243 (ONCO), 728244 (RAD)'. The 'RATING:' is 'SEE PDU LABEL'. At the bottom, it says 'MANUFACTURED: DECEMBER 2013' with 'DECEMBER 2013' enclosed in a red rectangular box. There is also a small Philips logo and the number '2013' at the bottom left, and the number '453567288341' at the bottom right.</p>

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<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>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."</p> <p>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.</p>
<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<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 FCO updates at your site. Reference Field Change Order (FCO) 72800665 (as necessary) and 72800670.</p>
<p><b>FURTHER INFORMATION AND SUPPORT</b></p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>