

## URGENT - Field Safety Notice

### Medical Device Correction

Ingenuity Flex, Ingenuity CT, Ingenuity Core, Ingenuity Core<sup>128</sup>, Brilliance iCT, Brilliance iCT SP, Brilliance Big Bore Oncology, Brilliance Big Bore Radiology, Brilliance 16, Brilliance 40, Brilliance 64, IQon, Brilliance 6, Brilliance 10

#### Couch Horizontal Motion Controller

Dear Customer,

A problem has been detected in certain Philips CT couches used on Ingenuity Flex, Ingenuity CT, Ingenuity Core, Ingenuity Core<sup>128</sup>, Brilliance iCT, Brilliance iCT SP, Brilliance Big Bore Oncology, Brilliance Big Bore Radiology, Brilliance 16, Brilliance 40, Brilliance 64, IQon, Brilliance 6, Brilliance 10 systems, that, if it were to re-occur, could pose a risk to 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. 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 & Regulatory



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<b>AFFECTED PRODUCTS</b>	<p>Ingenuity Flex - 728317  Ingenuity CT - 728326, 728325  Ingenuity Core - 728321  Ingenuity Core<sup>128</sup> - 728323, 728324  Brilliance iCT - 728306  Brilliance iCT SP - 728311  Brilliance Big Bore (Oncology) - 728243  Brilliance Big Bore (Radiology) - 728244  Brilliance 16 Slice (Air) - 728246  Brilliance 16 Slice (Power) - 728240  Brilliance 40 - 728235  Brilliance 64 - 728231  IQon Spectral CT - 728332  Brilliance 6 Slice (Air) - 728256  Brilliance 10 Slice (Air) - 728251  Brilliance CT Private Practice CV config. - 728241</p>
<b>PROBLEM DESCRIPTION</b>	<p>Upon closing the Emergency Stop (E-STOP) the system performs an internal check. As a result of the motion controller in the couch, there is a delay in the response to the internal check. This delay may cause the couch carbon top to enter a free float state, which may allow it to move during patient load or unload activities. This free float motion results in the ESTOP being opened due to the unexpected couch motion.</p> <p>This issue occurs frequently after closing E-STOP. The motion controller in the couch detects a power problem and disables the horizontal motor, which allows the couch top to free-float*.</p> <p><i>*The term free float refers to the couch top being in a state that is not locked in position by the brake or being moved in a controlled fashion (manual or automatic motion).</i></p>
<b>HAZARD INVOLVED</b>	<p>The couch horizontal motion controller does not respond as expected, allowing the couch to free float without notification to the user once E-STOP is closed during normal use. If the couch is in free float state and the operator attempts to load a patient, serious injury to a patient and/or operator may occur due to unintended horizontal couch motion.</p>




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<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>There are two sets of serial number ranges that may be impacted. Serial numbers can be either five digit or six digit numbers. The patient support (couch) serial number can be found on a label located on the front closest to the gantry of the patient support (couch) cover. Refer to Figure 1 and Figure 2 for examples of serial numbers. Refer to Table 1 and Table 2 for list of affected patient support (couch).</p> <p><b>Figure1 (Example: six digit serial number):</b></p> 



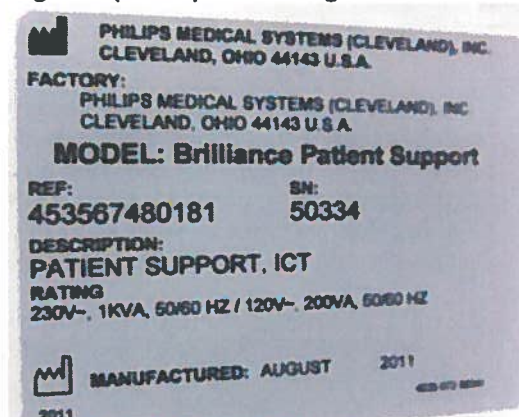
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### Couch Horizontal Motion Controller

Figure2 (Example: five digit serial number):



The following CT couch six digit serial number ranges are affected:

Table 1:

Ranges of affected six digit Serial Numbers
901001 - 901992
911001 - 911221
921001 - 921369
931001 - 931044
941001 - 941137
951001 - 951130
957001 - 957050



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The following CT couch **five** digit serial number ranges are affected:

**Table 2:**

Ranges of affected five digit Serial Numbers		
30191 thru 30194 30199 30204 30210 30228 thru 30231 30237 30263	30196 30200 30205 30214 thru 30216 30234 30238 30271	30197 30202 30209 30218 thru 30226 30235 30240 thru 30257 30277
40083 thru 40086 40104 40117 40127 thru 40143 40157 40169 thru 40186 40191 40212 thru 40215	40088 thru 40101 40106 40118 40146 thru 40152 40159 thru 40165 40188 40192 40217	40103 40108 thru 40112 40124 40155 40167 40189 40195
50535 thru 50543 50548 thru 50556 50577 50585 50625 50632 thru 50635 50648 thru 50651 50658 50689 50697	50545 50558 thru 50568 50579 50597 thru 50599 50626 50637 thru 50640 50653 thru 50655 50661 thru 50663 50691 50705	50546 50570 thru 50574 50582 50601 thru 50622 50628 50642 thru 50646 50657 50665 thru 50684 50693 50707
60148 thru 60155 60169	60157 thru 60163 60171 thru 60187	60165
83200 thru 83208 83223 thru 83238 83249 thru 83251 83282 83317	83210 thru 83214 83241 thru 83244 83253 83284 thru 83310 83319	83216 thru 83220 83247 83281 83312 thru 83314 83321 thru 83339



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	83342 83358 83384 83476 thru 83487 83505 thru 83513 83551 83567 thru 83570 83584 83589 83596 thru 83599	83345 thru 83351 83360 thru 83362 83386 thru 83359 83489 thru 83494 83515 thru 83523 83552 83574 thru 83577 83586 83593	83353 thru 83356 83365 thru 83381 83461 thru 83473 83496 thru 83503 83525 thru 83549 83561 thru 83564 83579 thru 83581 83587 83594
	91092 thru 91096 91101 91114 thru 91117 91141 thru 91146 91161 thru 91164 91183 thru 91188 91207 thru 91219	91098 91105 thru 91110 91133 91148 91166 thru 91176 91190 91237	91099 91112 91135 thru 91139 91151 thru 91159 91178 thru 91181 91192 thru 91205 91253
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	Once the E-stop has been closed the operator/technologist must initiate a brief horizontal motion (in or out) using any of the operator control panels, CT-Box or tape/foot switches. This action will ensure the couch carbon top (upper pallet) is in a controlled state.		
<b>ACTIONS PLANNED BY PHILIPS</b>	Philips Healthcare is notifying the affected users of the issue via this Field Safety Notice. Field Change Order (FCO) 72800696 will be deployed to correct the issue. A Philips Field Service Engineer will contact you to schedule the updates at your site.		
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact your local Philips representative. For SUPPORT North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377, follow the prompts).		



<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the <product name> due to FCO XXXXXXXXX . Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: XXXXXX, XXXXXX, XXXXXXXX, XXXXXX

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date: