

URGENT - Field Safety Notice

Medical Device Correction

Ingenuity Flex, Ingenuity CT, Ingenuity Core, Ingenuity Core¹²⁸, 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 Core¹²⁸, 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:

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wright Lee
Sr. Manager, Quality & Regulatory



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<p>AFFECTED PRODUCTS</p>	<p>Ingenuity Flex - 728317 Ingenuity CT - 728326, 728325 Ingenuity Core - 728321 Ingenuity Core¹²⁸ - 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>
<p>PROBLEM DESCRIPTION</p>	<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>
<p>HAZARD INVOLVED</p>	<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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HOW TO IDENTIFY AFFECTED PRODUCTS	<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>Figure1 (Example: six digit serial number):</p> 



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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	30196	30197
30199	30200	30202
30204	30205	30209
30210	30214 thru 30216	30218 thru 30226
30228 thru 30231	30234	30235
30237	30238	30240 thru 30257
30263	30271	30277
40083 thru 40086	40088 thru 40101	40103
40104	40106	40108 thru 40112
40117	40118	40124
40127 thru 40143	40146 thru 40152	40155
40157	40159 thru 40165	40167
40169 thru 40186	40188	40189
40191	40192	40195
40212 thru 40215	40217	
50535 thru 50543	50545	50546
50548 thru 50556	50558 thru 50568	50570 thru 50574
50577	50579	50582
50585	50597 thru 50599	50601 thru 50622
50625	50626	50628
50632 thru 50635	50637 thru 50640	50642 thru 50646
50648 thru 50651	50653 thru 50655	50657
50658	50661 thru 50663	50665 thru 50684
50689	50691	50693
50697	50705	50707
60148 thru 60155	60157 thru 60163	60165
60169	60171 thru 60187	
83200 thru 83208	83210 thru 83214	83216 thru 83220
83223 thru 83238	83241 thru 83244	83247
83249 thru 83251	83253	83281
83282	83284 thru 83310	83312 thru 83314
83317	83319	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
ACTION TO BE TAKEN BY CUSTOMER / USER	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.		
ACTIONS PLANNED BY PHILIPS	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.		
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: 0800 80 3000		

