

Computed Tomography

FSN 72800625, Rev B

2014 DEC 04

**URGENT - Field Safety Notice
Medical Device Correction**

**Brilliance CT 16 Air, 64, Big Bore, iCT, iCT SP,
Ingenuity CT, Ingenuity Core, Ingenuity Core¹²⁸, and Ingenuity Flex**

Uncommanded Vertical Patient Support / Couch Motion

Dear Customer,

According to our records, you currently have one of the systems noted above. This Field Safety Notice (FSN) is intended to inform you that Philips became aware there is a potential for uncommanded vertical patient support / couch motion.

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

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Daniel R. Brown
Director, Quality and Regulatory

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<p>AFFECTED PRODUCTS</p>	<p>The following CT systems with a specific patient support / couch manufacturing lot are affected:</p> <ul style="list-style-type: none"> • Brilliance CT 16 Air • Brilliance CT 64 • Brilliance CT Big Bore Oncology & Radiology • iCT • iCT SP • Ingenuity CT • Ingenuity Core • Ingenuity Core¹²⁸ • Ingenuity Flex
<p>PROBLEM DESCRIPTION</p>	<p>A potential problem with the vertical motor / brake assembly on the patient support / couch was discovered with a specific patient support / couch manufacturing lot, which may result in uncommanded vertical patient support / couch motion.</p> <p>To date, there have been no reported occurrences of harm.</p>
<p>HAZARD INVOLVED</p>	<p>There is a possibility that the vertical brake may fail while the patient is on the table. Although no injuries due to this failure mode have been reported, if the vertical brake malfunctions, a technologist, patient, or other users who are in close proximity of the table could experience an injury due to the uncommanded vertical motion of the table.</p>

Effective: 18 July 2014. See approved document for rationale and signatures.

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<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>Philips Healthcare is directly notifying affected users of this issue via this Field Safety Notice (FSN).</p> <p>To determine if you have a potentially affected product in the “Affected Products” list above, check your system identification.</p> <p>Your system identification is located at the rear, bottom right corner of the gantry cover as referenced in the <i>example</i> picture below:</p> <div data-bbox="672 1058 1175 1388" data-label="Image"> </div>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>If you experience uncommanded vertical patient support / couch motion, please discontinue use of the device and contact your local service provider. Philips Healthcare is not making a recommendation to remove the couch from service. The personnel who prepare and operate the system with a patient are advised to be extra vigilant while the patient is on or near the Patient Support especially with intubated patients or similar patient situations until the system is corrected.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips Healthcare is directly notifying affected users of this issue via this Field Safety Notice (FSN).</p> <p>In addition, a Philips Field Service Engineer (FSE) will service your system to resolve the issue via a Field Change Order (FCO). A Philips FSE will contact you to schedule this appointment.</p>

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PRINTED COPIES ARE UNCONTROLLED. VERIFY DOCUMENT VERSION PRIOR TO USE.

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FURTHER INFORMATION AND SUPPORT	<p>This problem was found during internal inspection of the product. After analyzing customer complaints, no incidence of harm due to this cause has been found. Analysis of the probability of occurrence indicates that the failure is not expected to occur.</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>
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