Computed Tomography FSN # 72800614, Revised 2014 NOV 10

URGENT – Field Safety Notice
Medical Device Correction

Brilliance CT series (6, 10, 16, 16 Power, 40, 64, Big Bore, iCT, iCT SP), Ingenuity CT, Ingenuity Core, Ingenuity Core^{128}, Ingenuity Flex, and MX8000 Dual v. EXP

REVISED

Unintended Horizontal Patient Support / Couch Motion Correction and Service Labeling Update Due to Unlocked Service Latch

Dear Customer,

Please review this revised FSN which supersedes FSN 72800614 dated 2014 MAR 26.

Philips has received a request to provide additional details in the “Actions to be Taken by Customer/User” section. Philips believes this information benefits all customers / users and has therefore revised the FSN and resent to all customers. The only section revised in this FSN is the “Actions to be Taken by Customer/User” section.

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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AFFECTED PRODUCTS	All of the following selected CT systems are affected:
	• Brilliance CT series:
	  ○ 6
	  ○ 10
	  ○ 16
	  ○ 16 Power
	  ○ 40
	  ○ 64
	  ○ Big Bore
	  ○ iCT
	  ○ iCT SP
	• Ingenuity CT
	• Ingenuity Core
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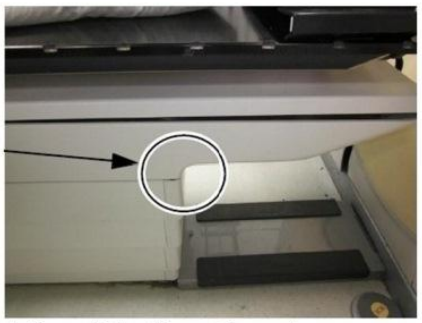
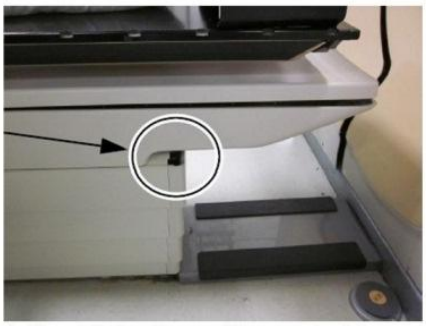
PROBLEM DESCRIPTION	We have found, if the service latch is not properly secured during servicing of the device, the table top's subframe becomes free floating causing unintended, horizontal motion. To date, there have been no reported injuries or deaths resulting from this issue. **Subframe Patient Support Cover Alignment: Engaged Versus Disengaged** Subframe  Subframe Patient Support Engaged, with Covers Aligned **Figure 1** Subframe  Subframe Patient Support Disengaged, with Covers Misaligned **Figure 2**
HAZARD INVOLVED	There is a risk of serious injury to the patient and Operator/Technician as a result of the patient support / couch subframe free floating. For the patient: • There is a potential for disconnection or movement of invasive medical devices such as I.V.'s, tracheostomies, and surgical drains For the Operator/Technician: • There is a potential pinch point on the subframe; and • A potential for entrapment between the table and the gantry if the Operator/Technician stands between them to shift the patient forward

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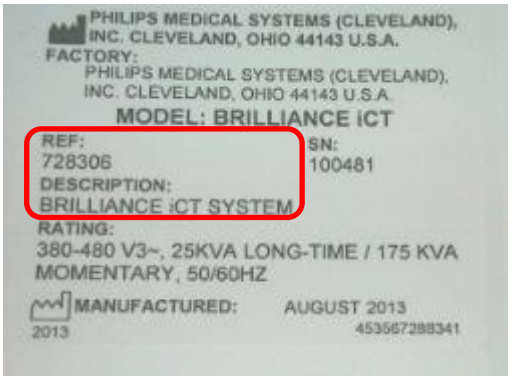
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips Healthcare is directly notifying affected users of this issue via this Field Safety Notice (FSN). To determine if you have one of the products on the "Affected Products" list above, check your system identification. All of the systems identified are affected by this issue. Your system identification is located at the rear, bottom right corner of the gantry cover as referenced in the example picture below: 
ACTION TO BE TAKEN BY CUSTOMER / USER	If you observe subframe motion (pictured below), when the system is powered on, in the nominal state, you can either complete the "Step-by-Step Instructions" or call your local service provider. Examples (but not limited to) when you may experience the subframe motion are as follows:

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	1. When loading / unloading a phantom for either: a. QA checks b. Quick IQ Tests 2. When loading / unloading a patient Step-by-Step Instructions: The below instructions and diagram will help you decide if a service provider should be called. 1. System must be powered on, in its nominal state (ready for clinical use), with no patient on the table. 2. Stand at the side of the patient support / couch towards the end farthest from the gantry. 3. Grasp at the “Rear of Patient Support (Carbon Top)” (see arrow in diagram below). 4. Without activating tape switch, attempt to move “Rear of Patient Support (Carbon Top)” away from the gantry (no motion is expected). a. If the subframe moves, it is not locked in place. Discontinue clinical use and contact your service provider immediately. b. If the subframe does not move, visually verify that there is no misalignment as shown in the photo in Figure 2 in the Problem Description and the lower diagram below. ○ If there is misalignment (identified by ‘Gap’ in the figure), discontinue clinical use and contact your service provider immediately. ○ If there is no misalignment, the system is clear for clinical use. Retain a copy of this Field Safety Notice with the equipment Instructions for Use (IFU).

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	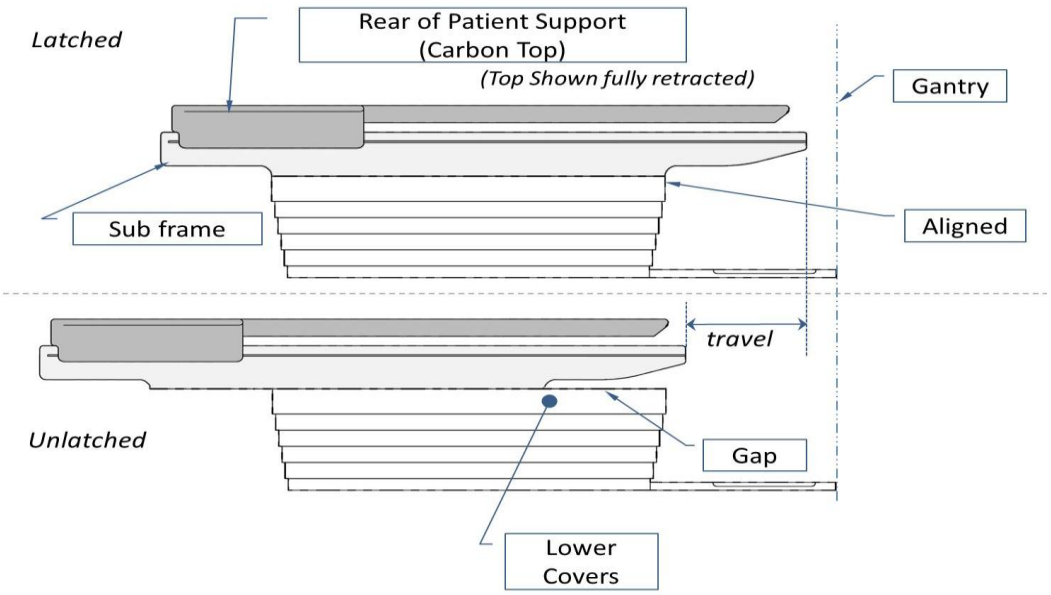
ACTIONS PLANNED BY PHILIPS	Philips is informing you to contact the Field Service Engineer immediately through this Field Safety Notice if you experience a free-floating horizontal subframe motion. Philips is amending service documentation to clarify the steps to confirm the locking mechanism is engaged.
FURTHER INFORMATION AND SUPPORT	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.