



Field Safety Notice

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Computed Tomography

FSN 72800693_72800698 Revision: 01

2017-NOV-01

URGENT - Field Safety Notice Medical Device Correction

Brilliance iCT, Brilliance 64, Ingenuity Core, Ingenuity Core 128

Fastener Replacement

Dear Customer,

cc: Chairman Medical Board and relevant Head of Departments

A potential problem has been detected in a limited number of Philips Brilliance iCT, Brilliance 64, Ingenuity Core, and Ingenuity Core 128 systems that may pose a risk for patients, users, or service personnel. 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

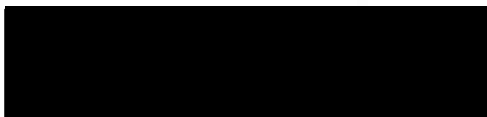
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

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 or the Customer Care Solutions Center (1-800-722-9377, follow the prompts). Healthcare Representative /Modality Engineer: 1800-744-5477 or (Overseas Number).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,



Holly Wright Lee
Sr. Manager, Post Market Surveillance
Quality & Regulatory





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Fastener Replacement

AFFECTED PRODUCTS	A limited number of Philips Brilliance iCT, Brilliance 64, Ingenuity Core, and Ingenuity Core 128 are affected by this issue.
PROBLEM DESCRIPTION	Philips has identified that certain fasteners cannot be confirmed to have been torqued according to specification.
HAZARD INVOLVED	<p>If the fasteners were not torqued as specified and a failure occurs while the system is in use, the parts secured by the fasteners may become loose, which may have a potential for harm.</p> <p>There are multiple fasteners and all of the fasteners securing a part would have to fail in order for a potential hazard to occur. The potential hazards are the following:</p> <ol style="list-style-type: none">1) Loose parts may be expelled from the system. Expelled parts may break through the gantry covers. Any patient, operator, service personnel, or bystander in the path of the expelled part could sustain injury.2) Loose parts may cause the patient support subframe to move unexpectedly, resulting in potential injury.3) Loose parts may cause the system to shut down, or be shut down by the operator due to unusual noise, resulting in a potential need for a patient rescan.4) Front cover, when open, may fall or dislodge unexpectedly. Any service personnel or bystander in the path of the cover could sustain injury. <p>However, based on engineering analysis, there is a high statistical confidence that the fasteners were torqued to meet their intended design requirements and therefore do not pose any immediate safety risk.</p>



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HOW TO IDENTIFY AFFECTED PRODUCTS	The following system models and system serial numbers are affected.			
	System Description	System Serial No	FCO 72800693	FCO72800698
	Brilliance 64		x	
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Brilliance iCT		x	x
	Ingenuity Core		x	
	Ingenuity Core 128		x	
	Ingenuity Core 128		x	
	Ingenuity Core 128		x	



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	<p>Serial Number labels are located on the back of the gantry in the bottom right corner:</p> 
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>If any unusual noises are heard within the gantry, or if the patient support tabletop is in free float, halt use of the system immediately and contact your Philips Field Service Engineer.</p> <p>Service personnel should not operate the system (for any tests or service activities) with the covers open until the Field Change Order is implemented.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips Field Service Engineers will correct your system by replacing the affected fasteners. Field Change Orders (FCO) 72800693 and 72800698 will be issued to correct this issue.</p> <p>FCO 72800693 will correct items 1) and 2) in section HAZARD INVOLVED.</p> <p>FCO 72800698 will correct items 3) and 4) in section HAZARD INVOLVED.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative /Modality Engineer: 1800-744-5477 or (Overseas Number).</p>

