

Computed Tomography

CIL72800658

14-Jun-2016

Customer Information Big Bore Oncology, Big Bore Radiology

Stainless steel fasteners used rather than specified alloy steel

Dear Customer,

A problem has been detected in Philips' Big Bore Oncology and Big Bore Radiology systems that, if it were to re-occur, could affect the performance of the equipment. This Customer Information Letter is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions planned by Philips to correct the problem.

If you need any further information or support concerning this issue, please contact your local Philips representative:

Sincerely,



Holly Wright Lee
Sr. Manager, Post-Market Surveillance

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AFFECTED PRODUCTS	<p>Big Bore systems with the following serial numbers are affected:</p> <p>75002, 75003, 75004, 75005, 75006, 75007, 75008, 75009, 75010, 75011, 75012, 75014, 75015, 75016, 75017, 75018, 75019, 75020, 75021, 75022, 75023, 75024, 75025, 75026, 75030, 75032, 75033, 75035, 75036, 75037, 75040, 75042, 75044, 75047, 75048, 75049, 75051, 75053, 75060, 75064, 75100, 75102, 75104, 75105, 75110, 750111, 750114</p>
PROBLEM DESCRIPTION	<p>During production, a fastener made of stainless steel was found to be used rather than the specified alloy steel. The nonconforming fastener may have been used to manufacture Brilliance CT Big Bore systems. The fastener is used to secure a sub-component of the adjustment cradle within the system gantry.</p> <p>Analysis has concluded that the nonconforming fasteners continue to meet the tensile safety factor requirements for the application. However given the material characteristics of stainless steel, these fasteners may not be re-used (re-torqued). Since the adjustment cradle requires periodic adjustment, it is expected that the nonconforming fasteners would require re-torquing at some point during the system's lifetime.</p> <p>Repeated re-torquing of the stainless steel fasteners could introduce stresses that approach the ultimate yield strength of the fasteners. Therefore, while no fastener failures have been observed to date, Philips has decided to undertake the field correction described below to prevent future re-use of the nonconforming fasteners.</p>

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HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Brilliance Big Bore systems with a serial number listed above may contain a nonconforming fastener. The system serial number can be located on the serial tag label located on the rear/bottom of the gantry cover, as indicated below.</p> 
ADVICE ON ACTIONS BY CUSTOMER / USER	<p>No action is required of the customer for this issue. Systems that may have been manufactured with these stainless steel fasteners still meet the safety specifications required for the adjustment cradle and may continue to be used clinically.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips plans to undertake field action to correct this issue. The field action will consist of:</p> <ul style="list-style-type: none"> • Informing affected customers of the issue via this Customer Information Letter, and • Deploying <i>Action for Performance Proactive FC072800658</i> for field service engineers to replace the nonconforming fasteners for affected units in the field <p>Note: <i>Action for Performance Proactive FC072800648</i> will be implemented free of charge.</p>

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FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the FCO Executer>
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