
Computed Tomography

CIL72800648

2016-Apr-28

Customer Information

Ingenuity CT, Ingenuity Core, Ingenuity Core¹²⁸

Stainless steel fasteners used rather than specified alloy steel

Dear Customer,

A problem has been detected in Philips' Ingenuity CT, Ingenuity Core, and Ingenuity Core¹²⁸ 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 or the Philips Customer Care Solution Center: 1-800-722-9377.



Manager, Post-Market Surveillance

CONFIDENTIAL.

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

CNT-073105-04 Rev 04

Computed Tomography

CIL72800648

2016-Apr-28

Customer InformationIngenuity CT, Ingenuity Core, Ingenuity Core¹²⁸**Stainless steel fasteners used rather than specified alloy steel**

AFFECTED PRODUCTS	<p>Ingenuity CT systems with the following serial numbers are affected:</p> <p>300204, 300205, 300206, 300207, 300208, 300210, 310208, 310213, 310215, 310216, 310217, 310220, 310223, 310228, 320202, 320203, 320208, 320209, 320210, 320211, 320213, 320216, 320218, 320219, 320223, 320224, 320225, 320226, 320228, 320234, 320242, 320207, 320232, 320241, 320243, 310205, 310210, 320227, 320247, 300201, 320246, 310209, 320238, 320200, 320201, 320235, 310225, 310226, 320220, 320231, 310206, 310207, 320212, 320236, 320237, 320221, 320222, 300200, 300202</p>
PROBLEM DESCRIPTION	<p>During production two different length fasteners were found to be made of stainless steel rather than the specified alloy steel. The nonconforming fasteners may have been used to manufacture Ingenuity CT systems. The fasteners are used to secure sub-components 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 fasteners 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>

CONFIDENTIAL.

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

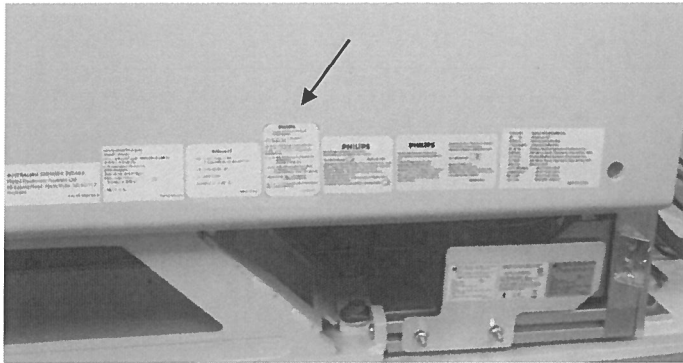
CNT-073105-04 Rev 04

Computed Tomography

CIL72800648

2016-Apr-28

Customer InformationIngenuity CT, Ingenuity Core, Ingenuity Core¹²⁸**Stainless steel fasteners used rather than specified alloy steel**

HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Ingenuity CT systems with a serial number listed above may contain nonconforming fasteners. 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 FCO72800648</i> for field service engineers to replace the nonconforming fasteners for affected units in the field <p>Note: <i>Action for Performance Proactive FCO72800648</i> will be implemented free of charge.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or the Philips Customer Care Solution Center: 1-800-722-9377</p>

CONFIDENTIAL.

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

CNT-073105-04 Rev 04