

URGENT - Field Safety Notice

Medical Device Correction

Brilliance Big Bore/ Ingenuity CT / Ingenuity Core / Ingenuity Core128 MRC880 Tube oil leakage

Dear Customer,

A problem has been detected in the Philips Brilliance Big Bore and Ingenuity CT family's MRC880 X-Ray Tube. The affected tubes have a production defect that allows oil leakage from the tube housing, if it were to re-occur, could pose a risk for patients or users. 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.

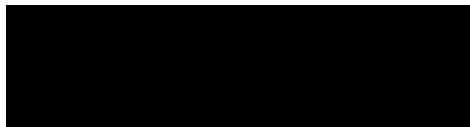
Please retain a copy with the equipment Instruction for Use.

Philips will release Field Change Order (FCO) 72800691 and 72800692 to correct the issue on the affected systems.

If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,



Holly Wright Lee

Sr. Manager Quality and Regulatory



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AFFECTED PRODUCTS	<p>The following CT systems which use the MRC 880 tube are potentially affected</p> <ul style="list-style-type: none">➤ Brilliance CT BigBore Oncology➤ Brilliance CT BigBore Radiology➤ Ingenuity Core➤ Ingenuity Core128➤ Ingenuity CT
PROBLEM DESCRIPTION	<p>Philips found a defect on the MRC880 X-ray tube. A small quantity of coolant oil may leak from the tube housing to the area of the tube window. The leaked oil would be confined within gantry covers.</p>
HAZARD INVOLVED	<p>Potential misrepresentation of images due to image artifacts resulting from leaked oil</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Identify the serial number of your system located on the label at the bottom of the rear Gantry base. Refer to the list of serial numbers of the affected systems below:</p>



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	System Code	System Code Description	System Serial Number
	728321	Ingenuity Core	333169
	728321	Ingenuity Core	310377
	728321	Ingenuity Core	310375
	728323	Ingenuity Core 128	320403
	728324	Ingenuity Core128/Elite China	336856
	728324	Ingenuity Core128/Elite China	336851
	728324	Ingenuity Core128/Elite China	336849
	728324	Ingenuity Core128/Elite China	336852
	728324	Ingenuity Core128/Elite China	336853
	728324	Ingenuity Core128/Elite China	336855
	728324	Ingenuity Core128/Elite China	336854
	728324	Ingenuity Core128/Elite China	336850
	728323	Ingenuity Core 128	320405
	728321	Ingenuity Core	333171
	728321	Ingenuity Core	333172
	728323	Ingenuity Core 128	320406
	728323	Ingenuity Core 128	336321
	728323	Ingenuity Core 128	320411
	728323	Ingenuity Core 128	336323
	728244	Brilliance CT Big Bore	76064
	728323	Ingenuity Core 128	320425
	728244	Brilliance CT Big Bore	76102
	728244	Brilliance CT Big Bore	76094
	728323	Ingenuity Core 128	320122
ACTION TO BE TAKEN BY CUSTOMER / USER		None	



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ACTIONS PLANNED BY PHILIPS	<p>Field Change Order (FCO 72800691 and 72800692) will be released to correct this issue.</p> <p>A Philips Field Service Engineer will contact you to schedule the FCO updates at your site.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377).</p>

