Advanced Molecular Imaging FSN 88200485_486 2014 November 04

URGENT - Field Safety Notice
BrightView XCT

Interruption of the CT acquisition portion of the scan may cause a rescan resulting in unintended radiation

Dear Customer,

A problem has been detected in the Philips BrightView XCT system that a tube arc may occur, interrupting the CT acquisition portion of the scan. This interruption may require a patient CT rescan of the interrupted segment, resulting in unintended radiation.

This Field Safety Notice (FSN) 88200485_486 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
- 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 UK Philips Customer Care Service Centre on 0870 532 7941.

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Daniel R. Brown
Director, AMI/CT Quality and Regulatory

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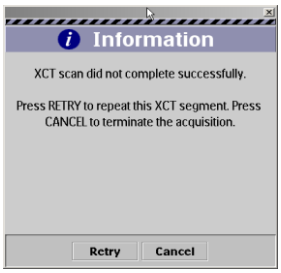
AFFECTED PRODUCTS	• BrightView XCT, Model Numbers: 882482 and 882454
PROBLEM DESCRIPTION	Philips received a report from the field that while performing a clinical SPECT/CT study on a BrightView XCT SPECT/CT systems, the CT portion of the scan was interrupted (stopping the CT exposure at the time of interruption) and did not complete successfully. From the gantry PC, an INFORMATION message appears indicating to the operator that the scan did not complete successfully. See INFORMATION message below.  An incomplete study results in the operator having to retry the interrupted segment acquisition to complete the patient exam. There was no report of harm to a patient from the received report.
HAZARD INVOLVED	Interruption of the CT acquisition portion of the scan may necessitate a rescan of the interrupted segment, resulting in overall radiation to the patient being higher than planned. The additional radiation would be less than the amount delivered from a successful scan of that segment.

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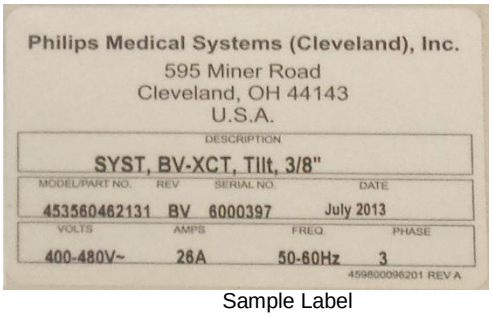
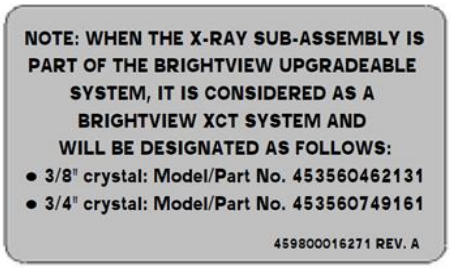
HOW TO IDENTIFY AFFECTED PRODUCTS	Refer to the System Label affixed to the bottom right rear of the gantry cover. The "Description" box will identify the system description: Refer to the Sample Label below:  Sample Label ← "Description" box • <u>BrightView X system upgraded to a BrightView XCT system:</u> At the time of a BrightView X system upgrade to a BrightView XCT system, an additional label is added to the bottom right rear of the gantry cover, which considers the system has received the upgrade kit: "BrightView X to BrightView XCT". Refer to the additional system label affixed at the time of the upgrade.  BrightView X system upgrade to a BrightView XCT System Label Example
ACTION TO BE TAKEN BY CUSTOMER / USER	Please be aware that if this condition occurs, users will not be able to detect the situation prior to the interruption of the CT acquisition. However, if the INFORMATION message appears during a clinical study indicating to the operator that the scan did not complete successfully, Philips advises users to understand the following available options, and use their clinical judgment to determine which option best suits their clinical needs: • The operator chooses ***not*** to rescan the patient: Continue with the SPECT portion of the of the scan and use only the portion of the segments that were acquired prior to the interruption for interpretation; or • The operator chooses to rescan the patient: Retry the interrupted segment acquisition.

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is initiating a corrective action consisting of : • Distribution of this Field Safety Notice 88200485_486, • Conducting the appropriate field safety correction will address the above issue that has been identified.
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 7941.