URGENT – Medical Device Correction

GEMINI TF 16, GEMINI TF 64, GEMINI TF Big Bore, TruFlight Select, GEMINI TF Ready and GEMINI LXL PET/CT Systems

Lock up of the PET Reconstruction Server (PRS) Database may result in a patient CT rescan and/or PET reinjection resulting in undesired radiation exposure.

Dear Customer,

Philips Healthcare has become aware of a problem where the PET Reconstruction Server (PRS) database may lock up after a CT acquisition is completed and before a PET acquisition is started on GEMINI TF 16, GEMINI TF 64, GEMINI TF Big Bore, TruFlight Select, GEMINI TF Ready and GEMINI LXL PET/CT Systems

If the lock up was to occur, resulting in an incomplete study, there is a potential of a CT rescan and/or PET reinjection posing a risk for patients

This Field Safety Notice 88200465-471 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

To ensure a safe operating condition for users, Philips will correct the issue by installing a software update.

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 these issues, 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, option 5: Enter Site ID or follow the prompts).

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Scott Christiansen
Director of Q&R for CT/AMI

CNT-073105-03
Revision: 02
Status: Approved
Effective: 12 September 2013

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Lock up of the PET Reconstruction Server (PRS) Database may result in a patient low dose CT rescan and/or PET reinjection resulting in undesired radiation exposure.

AFFECTED PRODUCTS	• GEMINI TF PET/CT 16 and GEMINI TF PET/CT 64 Software Version 3.5.1 • GEMINI TF PET/CT 16 and GEMINI TF PET/CT 64 Software Version 3.5.1.1 • GEMINI TF PET/CT 16, GEMINI TF PET/CT 64, GEMINI TF Ready and GEMINI LXL Software Version 3.5.2 • GEMINI TF PET/CT 16 and GEMINI TF PET/CT 64 Software Version 3.5.2.1 • GEMINI TF Big Bore Software Version 3.6; • GEMINI TF Big Bore Software Versions 3.6.1 and 3.6.2 • TruFlight Select systems Software Version V3.5.3
PROBLEM DESCRIPTION	The PET Reconstruction Server (PRS) database may randomly lock up after the low dose CT acquisition is complete and will not allow the PET acquisition to begin, resulting in an unexpected incomplete study.
HAZARD INVOLVED	During a patient study if the PRS database experiences the lock up, it will not allow the PET acquisition to begin, interrupting the current patient study and will require Philips interaction before the system is operational. If the patient's study is delayed it will: • Result in a patient low dose CT rescan; and, • May require a reinjection, if a short half-life isotope/ radiopharmaceutical was used, resulting in undesired radiation exposure to the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	To identify the software version of the product: • Click the "Help" button, • Click the "Product Info" tab, and the software version is then displayed Refer to the "AFFECTED PRODUCTS" section of this Field Safety Notice for the list of systems affected by this correction.
ACTION TO BE TAKEN BY CUSTOMER / USER	Please be aware that if this condition occurs, users cannot remedy this issue and will require service interaction prior to the system being operational.

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is initiating a corrective action consisting of: • Distribution of this Field Safety Notice 88200465-471 to notify all affected customers of this issue. • Scheduling service to the affected systems to install a software update that will correct the problem described in this Field Safety Notice. Your Field Service Engineer will contact you for implementation of the software update on your affected system(s).
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. For North America and Canada contact the Customer Care Solutions Center (1- 800-722-9377, option 5: Enter Site ID or follow the prompts).