



URGENT FIELD SAFETY NOTICE

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 13715

To: Nuclear Medicine Department
Hospital Risk Manager
Hospital Administrator
Director of Radiology and Radiologists

RE: **PET Discovery 610 and Discovery 710 – List Mode Replay feature**

GE Healthcare has recently become aware of a potential safety issue due to scatter overcorrection associated with the **List Mode Replay** feature of your Discovery 610 and Discovery 710 system. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

A software issue exists when using **List Mode Replay**, such that subsequent reconstructions with that data could contribute to an image with scatter over-estimation and overcorrection. Reconstructed images with this issue will have many fewer counts than the acquired scan data and a high scatter fraction.

This issue may affect studies that use **List Mode Replay** and are reconstructed after subsequent acquisitions.

This issue may lead to image misinterpretation and/or inaccurate treatment decisions.

Safety Instructions

To avoid this potential issue, replay the list mode data prior to another acquisition.

In the event another acquisition is made before replaying the list data, or following reboot, do the following steps:

- Perform a PET only acquisition using the same tracer that is intended for the **List Mode Replay**.
- Then, proceed to perform the **List Mode Replay** and subsequent reconstructions.
- Make sure to perform a quality check on any images created after any replay of data.

Affected Product Details

PET Discovery 610 and PET Discovery 710, with software versions pet_coreload.44 and pet_mfk.44. The software version is visible on the homepage of the service desktop.

To determine the software version currently on your system, do the following:

1. On the right monitor upper left corner select the Service Icon.
2. Verify that the Service window is under Home.
3. Locate the SW Build Version listed in the center of the page.

All manufacturing dates of the above products are included. You are being contacted because you have been identified as an owner of one or more of these systems.

**Product
Correction**

GE Healthcare will provide a software update for all affected systems to address the issue. A GE Healthcare service representative will contact you to arrange for this correction. This activity will be performed at no cost to you.

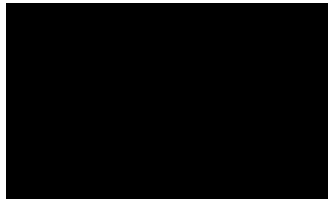
**Contact
Information**

If you have any questions or concerns regarding this notification, please contact your local GE Healthcare Service Representative.

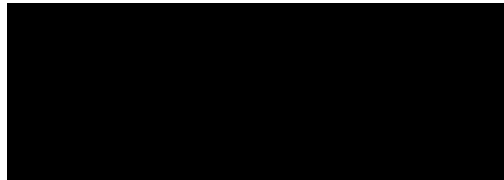
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 13716

To: Nuclear Medicine Department
Hospital Risk Manager
Hospital Administrator
Director of Radiology and Radiologists

RE: **PET Discovery 600 and Discovery 690 – List Mode Replay feature**

GE Healthcare has recently become aware of a potential safety issue due to scatter overcorrection associated with the **List Mode Replay** feature of your Discovery 600 and Discovery 690. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

A software issue exists when using **List Mode Replay**, such that subsequent reconstructions with that data could contribute to an image with scatter over-estimation and overcorrection. Reconstructed images with this issue will have many fewer counts than the acquired scan data and a high scatter fraction.

This issue may affect studies that use **List Mode Replay** and are reconstructed after subsequent acquisitions.

This issue may lead to image misinterpretation and/or inaccurate treatment decisions.

Safety Instructions

To avoid this potential issue, replay the list mode data prior to another acquisition.

In the event another acquisition is made before replaying the list data, or following reboot, do the following steps:

- Perform a PET only acquisition using the same tracer that is intended for the **List Mode Replay**.
- Then, proceed to perform the **List Mode Replay** and subsequent reconstructions.
- Make sure to perform a quality check on any images created after any replay of data.

Affected Product Details

PET Discovery 600 and PET Discovery 690, with software versions pet_mict_plus.44 and pet_velocity.53. The software version is visible on the homepage of the service desktop.

To determine the software version currently on your system, do the following:

1. On the right monitor upper left corner select the Service Icon.
2. Verify that the Service window is under Home.
3. Locate the SW Build Version listed in the center of the page.

All manufacturing dates of the above products are included. You are being contacted because you have been identified as an owner of one or more of these systems.

**Product
Correction**

GE Healthcare will provide a software update for all affected systems to address the issue. A GE Healthcare service representative will contact you to arrange for this correction. This activity will be performed at no cost to you.

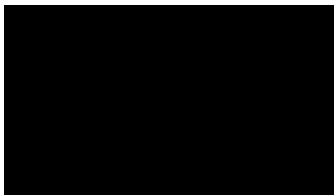
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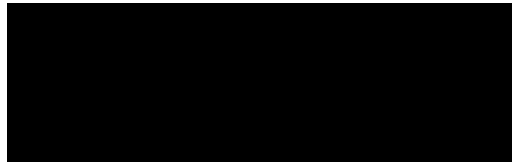
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare