



Urgent Field Safety Notice

GE Healthcare

GE Healthcare Systems
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Wauwatosa, WI 53226
USA

GE Healthcare Ref: 40829

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To: Hospital Administrators / Risk Managers
Managers of Radiology/Cardiology
Radiologists/Cardiologists

RE: **Xeleris workstation 1.0, 1.1, 2.0, 2.1, 3.0: Safety Issues.**

GE Healthcare has become aware of safety issues relevant for the Xeleris Workstation:

1. Measurements taken on the CT Images on the CT system are different from the Xeleris Workstation
2. Inaccurate PET SUV values may be calculated when data is retrieved from PACS after being processed in the Xeleris.
3. Wrong marking of "Early" and "Late" result series on display in Brain SPECT when 2 result series are opened in compare mode.

These issues may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issues

1. Erroneous measurements on CT Images have been identified on certain Xeleris workstations, when a single series has multiple sets of slices with differing zoom and pixel sizes. In such cases, the Xeleris will erroneously assign the same pixel size values to all slices in a series, regardless of the individual slice pixel sizes. This assignment of pixel sizes will, in this instance, cause distance measurement errors on those images.

This issue is relevant for all Xeleris systems.

2. There is also possibility for getting wrong SUV values when a PET study is retrieved from a PACS after being processed in the Xeleris. The wrong SUV Values may be calculated only if the patient demographics were changed on the Xeleris before the first processing and data transfer to the PACS. The concern is for Incorrect treatment or mis-diagnosis due to erroneous quantitative measurements.

This issue is relevant only for Xeleris 3.x and Xeleris 2.x systems.

3. A software issue in Brain SPECT application may switch between the display of EARLY and LATE images of dual scan studies. The switch occurs under a specific processing routine during which the user initially processes each image separately, saves each one to a result series and then reviews the data by loading the Brain SPECT application using only these two result series. The concern is for, delay of patient treatment and incorrect treatment or mis-diagnosis due to wrong data labeling.

This issue is relevant only for Xeleris 2.x and Xeleris 1.x systems.

Affected Product Details

Xeleris workstation 1.0, 1.1, 2.0, 2.1 and 3.0.

Safety Instructions

1. To avoid erroneous measurements refrain from measuring distances on CT Images on the Xeleris. If such measurements are required they should be done on the CT system.
2. Do not modify patient demographics in PET Studies on the Xeleris. If such modification is required, perform it on the PET before sending the data to the Xeleris.
3. Be aware that brain SPECT result series should be loaded for review together with the raw data in order to avoid the image label switching.

Product Correction A GE Healthcare Service representative will perform the required software update on each affected system. This activity will be performed at no cost to you.

Contact Information If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/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.

Thank you,

