

Urgent Device Notification

This document contains important information for the continued proper use of your equipment. Please pass this on to technologists, reading physicians and other persons who need to be aware of the contents of this update, and maintain a copy with the system instructions for use.

September 10, 2007

RE: When using Cardiac Viewer or Pulmonary Viewer, incorrect measurements in derived images which are zoomed and saved in a batch file can occur.

Affected Products: The Cardiac Viewer or Pulmonary Viewer Application that can be run on all Gemini TFs, GXLs and all EBW workstations.

Dear Customer:

Philips Medical Systems would like to inform you of incorrect measurements that can occur when the Cardiac Viewer or Pulmonary Viewer is used to zoom and save derived images in a batch file.

WARNING: Failure to follow these instructions may lead to misdiagnosis and possibly improper treatment.

When the operator uses the distance or area measurement functions (such as the Graphic Tool Line or ROI) on zoomed and batched saved images from the Cardiac Viewer or Pulmonary Viewer, and then views them in the CT Viewer or on a PACS System, the measurements will be incorrect.

The use case described below is the only known scenario where the issue can occur in the Cardiac Viewer or Pulmonary viewer:

- Load a series of images into the Cardiac Viewer or Pulmonary Viewer in slab view.
- Select and measure the diameter of the aorta for example. Record the measurement.
- Zoom appropriate selected images containing the same object.
- **Create and save a batch series from the zoomed images. These images are labeled as derived.**
- Load the images into the CT Viewer
- Perform a measurement on the same object in the derived images.
- Measurements performed on the derived images will be incorrect in proportion to the amount of the zoom.

If the batched zoomed images are enlarged by a factor of 2, the measurements will be increased by a factor of 2.

Two dimensional measurements, such as an area of an ROI will also be incorrect. Using the example in the paragraph above, a zoomed area of an ROI will be incorrect by a factor of four.



PSN 07-002

PHILIPS

RE: When using Cardiac Viewer or Pulmonary Viewer, incorrect measurements in derived images which are zoomed and saved in a batch file

To prevent incorrect measurements, do not save any zoomed images to a batch file. Make all measurements of zoomed images in the CT viewer, which provides correct measurements. Do not perform measurements on any zoomed batched images that have been stored on a PACS system.

This issue does not occur when displaying derived zoomed images in either the CCTA (Cardiac CT Angiography) or CCA (Comprehensive Cardiac Analysis) packages.

Please ensure that this letter is distributed to all affected users including referring physicians, that it is posted appropriately, and that a copy is kept with the Instructions for Use until otherwise notified in writing by Philips that a corrected software version has been installed on your system.

Patient, technologist, and product safety continues to be our overriding concern. As a valued customer of Philips Medical Systems, we want to ensure that your Philips equipment is being used in a safe manner.

Philips is currently investigating methods to correct this issue and will provide updates free of charge to our customers.

Please direct questions to our Customer Care Center (1-800-722-9377) or to your local Philips Medical Systems office.

Sincerely,


Director, PET Regulatory Affairs & Quality Assurance
Philips Medical Systems

