Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 12129

May 2012

To: Seno Advantage Customers
Hospital Administrators / Risk Managers
Radiology Department Managers

RE: **Seno Advantage Workstation 1.x: Inaccurate measurements on magnification views acquired on non-GE digital mammography systems.**

GE Healthcare has become aware of an issue associated with the magnification images acquired on non-GE digital mammography systems and the Seno Advantage Workstation that 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 Issue
The measurement values provided by the Seno Advantage Workstation may be incorrect when applied to magnification images acquired on non-GE digital mammography systems. If not noticed by the caregiver, this could lead to an overestimate of the size of the breast lesion. The measurement values for GE images are not affected.

Safety Instructions
The Seno Advantage 1 workstation was designed for diagnostic reading of GE Senographe 2000D and Senographe DS images, and should not be used to read any other images.

Affected Product Details
All versions of SenoAdvantage 1.x are affected.

Product Correction
Please place the enclosed warning sticker on the lower right of the top surface of your Seno Advantage keypad.

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.

Sincerely,

[redacted]
Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

[redacted]
Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 12129

May 2012

To: Seno Advantage Customers
Hospital Administrators / Risk Managers
Radiology Department Managers

RE: **Seno Advantage Workstation 2.x: Inaccurate measurements on magnification views acquired on non-GE digital mammography systems.**

GE Healthcare has become aware of an issue associated with the magnification images acquired on non-GE digital mammography systems and your Seno Advantage Workstation that 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 Issue

The measurement values provided by the Seno Advantage Workstation may be incorrect when applied to magnification images acquired on non-GE digital mammography systems. If not noticed by the caregiver, this could lead to an overestimate of the size of the breast lesion. The measurement values for GE images are not affected.

Safety Instructions

For all digital mammograms, GE Healthcare recommends that the user perform the necessary measurements on the standard contact images on the Seno Advantage Workstation, and not rely on measurements made on the acquired magnification images.

Affected Product Details

All versions of SenoAdvantage 2.0 and 2.1 are affected.

Product Correction

GE Healthcare will install new software to correct this issue with the release of Field Modification Instruction (FMI) 12129 in the near future. This correction will not affect the performance or any other functionality of your current equipment. A GE Healthcare service representative will contact you to arrange for this modification. This activity will be performed at no cost to you.

Contact Information

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Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 25404

May 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Aneurysm length measurement in AW Volume Viewer 2 and 3**

GE Healthcare has become aware of a potential safety issue due to over-estimation of aortic aneurysm length associated with the **Advanced Vessel Analysis** (AVA) option on AW systems using **Volume Viewer 2** (**version6.4 to version6.8**) or in **Volume Viewer 3** (**version7.2 & version7.3**) when using migrated protocols created in version6.4 to version6.8. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

It has been reported that the length indicated by the measurement of an aneurysm in Abdominal Aortic Protocol may be longer than the actual length of the aneurysm. Centerline-length measurements use a sequence of line segments to calculate distance in the image. Even with manually editing to smooth the tracking, the application calculates the length based on an "internal" representation of the centerline, and thus the measurement centerline can vary from the displayed centerline.
As a result of this length over-estimation, it is possible that a user could choose a stent with a longer length than needed for the aneurysm

Safety Instructions

Until this application is updated to the newer version, GE recommends that you do not use Centerline-length measurements for Abdominal Aorta Stent planning to avoid the risk of overestimation in stent length.

Affected Product Details

Advantage Windows Workstations running Advanced Vessel Analysis (AVA) option on Volume Viewer 2(version6.4 to version6.8), or in Volume Viewer 3 (version7.2 & version7.3) when using migrated protocols created in version6.4 to version6.8

Product Correction

The new application version which addresses this issue is going to be installed on all systems with impacted versions.
In case you need more information on this topic, please contact a GE Application Specialist or your GE Field Service representative. We sincerely apologize for any inconvenience that may have caused by this issue.

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.

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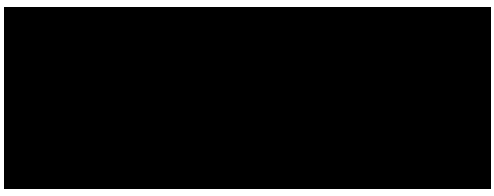
Sincerely,

Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems



Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

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9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 25404

May 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Automatic Interpolation for Missing PET Slices**

GE Healthcare has become aware of a potential safety issue due to the automatic replacement of missing PET slices with interpolated data associated with the Volume Viewer Application of your AW Workstation. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

When loading PET data into the Volume Viewer, if slices are missing in a PET series (i.e., from a networking error, or operator error), the Volume Viewer application will interpolate from neighboring slices to fill these gaps when loading the series without any warning. Thus, if a small lesion is located in any of the missing slices, it may not appear on the interpolated slices.

Safety Instructions

Until the Volume Viewer application can be replaced, users should verify that all PET slices have loaded correctly into the Volume Viewer.

Affected Product Details

Volume Viewer versions 3.0.64 to 3.0.64x, Volume Viewer Plus versions 5.4.46 to 5.9, Volume Viewer 2 versions 6.4.54 to 6.8 and Volume Viewer 3 version 7.3.23. Note that the version number is displayed in the upper left corner of the applications screen or in the Splash screen of the application since AW 4.4.

Product Correction

GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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.

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Sincerely,

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Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

[redacted]

Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 25409

May 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

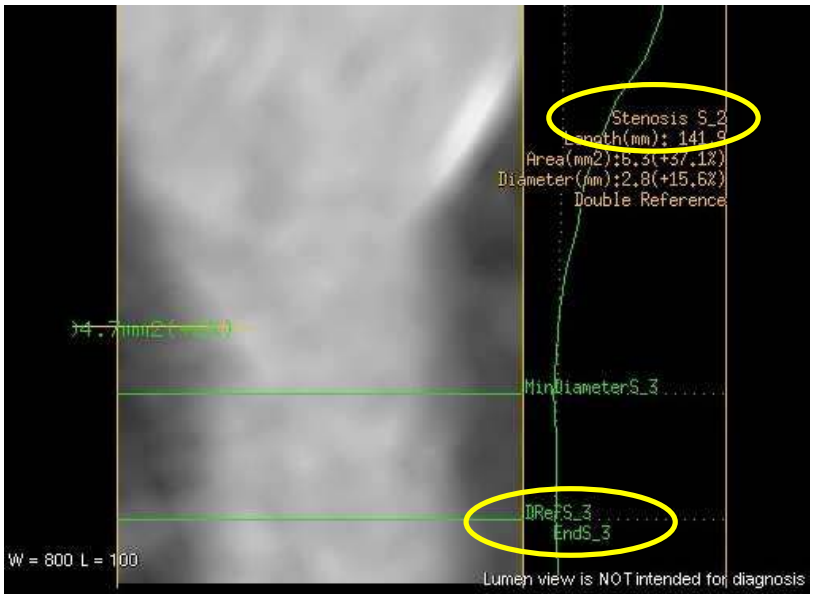
RE: **Advantage Workstation Display of Stenosis / Aneurysm Measurements**

GE Healthcare has become aware of a refresh problem of the stenosis / aneurysm measurement tools associated with the cardio-vascular applications of your Advantage Workstation that may impact patient safety. The refresh problem of the stenosis / aneurysm tools will occur when at least 3 of these measurements are deposited and then the first measurements are deleted. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

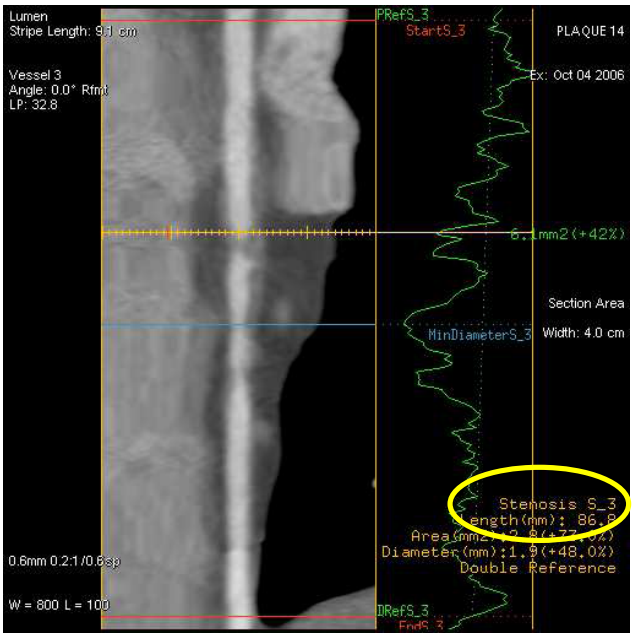
When depositing several (at least 3) stenosis or aneurysms measurements from the tools of the applications listed below, if the user deletes the first measurements, the display of these measurements will not be correctly refreshed on the screen and can be misleading.

On Volume Viewer 3 version vxtl_7.x, the stenosis / aneurysm number corresponding to the measurement values in the lower right corner of the image will not match the number of the stenosis / aneurysm graphically displayed on this same image. As the identification of the finding differs only by one digit, the user can miss this information.



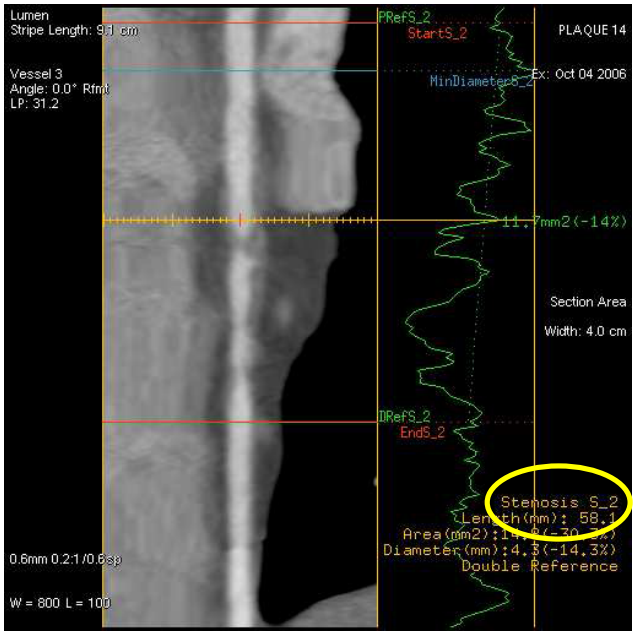
On Volume Viewer 3.1 version vxtl_8.1, the stenosis / aneurysm measurement points will be moved to another vessel location / a different vessel other than the one the user originally selected. The measurements will match the new vessel anatomy, but they will differ from the original intent of the user.

Before the first measurements are removed



After the first measurements are removed:

Stenosis # 2 from Vessel # 2 replaced Stenosis # 3



In the worst case, a mismatch of measurement annotations in Lumen view could lead the caregiver to underestimate vascular diseases (e.g. stenosis and aneurysm), which could lead to a potential missed diagnosis.

Safety Instructions

A new version of the software Is already available. Until new software is installed:

- Deposit only one stenosis / aneurysm measurement at a time.
- When analyzing multiple locations, delete the first stenosis measurement before placing the next stenosis measurement.

Affected Product Details	Advantage Workstations AW Volume Share 2 (AW version 4.4). ONLY IF ONE OF FOLLOWING APPLICATIONS IS INSTALLED: · VesselIQ Xpress or AVA Xpress · CardIQ Xpress Pro or Plus · CardEP · CardIQ Fusion PET or SPECT provided with **Volume Viewer 3** and **3.1** from versions 7.0 to 7.5 and 8.1. To verify the version installed on your system: Select the "Admin" menu from the "Patient list" page. Then select "Display Configuration". You will find the version of your system in "Installed Application(s)". This version will appear as vxtl_7.x or vxtl_8.x.
Product Correction	GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction. We sincerely apologize for any inconvenience that may have caused by this issue.
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.

Sincerely,

[redacted]

Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

[redacted]

Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 25409

May 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Vessel Labeling Mismatch using AW Volume Viewer 3 and 3.1**

GE Healthcare has become aware of a potential safety issue due to a possible mismatch of vessel labeling in applications listed below on systems using **Volume Viewer 2 (version6.0 to version6.11)** and **Volume Viewer 3 and 3.1 (version7.0, version7.5 & version8.1). Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

It has been reported that with Volume Viewer 2 and 3, when multiple branches are used in a vessel analysis, a Save State / Save Tracking can be incorrectly loaded. This may cause the display of an incorrect Vessel Name on the restored images. This happens whenever a branch name has a leading or trailing space in either a predefined or user defined name. In particular, the predefined branches "Right Popliteal Artery" and "Left Popliteal Artery" included in the "Lower Extremity Detailed Analysis" protocol are affected.

It has also been reported that with Volume Viewer 3, a mismatch of vessel labels can occur after depositing a bifurcation point and when a branch is either added, removed or renamed before the "Show Tracking" button is pressed. This results in the incorrect loading of the Saved State.

Mismatched vessel labels have also been reported when a branch defined using several intermediate points has its last extremity points removed. The curved image of the vessel may not be correctly refreshed to reflect this change.
Mismatches can also occur in a multiple-phase cardiac dataset, when a vessel branch is deleted from any phase other than the one on which the vessel was defined.

Safety Instructions

Until corrected software is installed, the Vessel Analysis protocol can be used with the following precautions:

1. Please avoid the use of leading or trailing spaces in Vessel Names
2. Be sure to press "Show Tracking" after depositing new bifurcation points
3. When editing a multi-point vessel tracking, remove and replace the entire branch, not only the final end-point
4. When analyzing multi-phase cardiac images, do not delete vessel branches from a phase other than the one in which it was created.

Affected Product Details

Advantage Workstation Volume Share 2 (versionAW4.4_04) with Volume Viewer 3 and 3.1 (version7.0 to version7.5 and version 8.1) and only when or more of these applications is installed:

- VesselIQ Xpress or AVA Xpress
- CardIQ Xpress Pro or Plus
- CardEP
- CardIQ Fusion PET or SPECT

Advantage Workstations Volume Share (v.AW4.3) and AW4.2 (version4.2-05 and above) provided with Volume Viewer 2(version6.0 to version6.11) and only when one or both of these applications is installed:

- CardIQ Xpress Pro or Plus
- CardEP

Product Correction

The new application version that addresses this issue will soon be installed on all systems.

In case you need more information on this topic, please contact a GE Application Specialist or your GE Field Service representative. We sincerely apologize for any inconvenience that may have caused by this issue.

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.

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Sincerely,

[redacted]

Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

[redacted]

Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80114

May 2012

To: Hospital Administrators
Radiology Department Managers
Radiologists

RE: **Incorrect Alignment of fused CT and PET images**

GE Healthcare has become aware of a potential safety issue due to incorrect alignment of fused CT and PET images associated with the CT/PET fusion capabilities of your Volume Viewer and CT/PET Fusion application. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Volume Viewer allows two studies (one PET and one CT) that are registered in the same spatial domain to be viewed simultaneously in fused mode. The two images should be aligned to the same precision as the scanner. Assuming the two images are acquired with a calibrated machine and there is no patient movement between the CT and PET acquisitions, the two images should be visually aligned to a precision of less than one half PET voxel. However, the problem associated with this version of software may introduce a shift of up to 1.5 PET voxels, which can be as much as 8mm with certain zoom factors.

CT/PET Fusion provides similar functionality and can additionally allow two exams acquired in different spatial domains to be registered either manually or automatically. The same issue as described above will also exist in this application, but **only if the registration step is skipped** and with certain zoom factors.

Safety Instructions

1. PET/CT Review Scenario: When initially displayed, the images are not correctly aligned depending on factors such as the default zoom and view. By adjusting the zoom, the PET image may be shifted with respect to the CT image. This shift can be as large as 8mm.

2. CT/PET Fusion Scenario: In CT/PET Fusion this issue will only occur when the registration step is skipped. RTSS contour boundaries defined with the PET data may be misplaced (up to 8mm) by the user as a result of the display misregistration. Note: The contour reference to the CT image is accurate under all conditions. Until a corrected product is provided, users should ensure that the registration step is completed.

Affected Product Details

Volume Viewer (versions 3.0.64 or 3.0.64m) using any PET Protocols or layouts containing fused views.
CT/PET Fusion (versions 1.0.48C, 1.0.52, 1.0.56 on AW 4.0 or 1.0.50, 1.0.52, 1.0.56 on AW 4.1 or 1.0.52, 1.0.56 on AW 4.2

Product Correction

GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

Contact Information

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Sincerely,

[redacted]

Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

[redacted]

Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80115-80116-25361

May 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Display/Printing Error for Curved and Navigator Images**

GE Healthcare has become aware of a potential safety issue due to a display and printing problem for Curved and Navigator images associated with the Volume Viewer. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The problems are limited to certain filmed Curved and Navigator images.

- With versions 3.0.64m, 3.0.64q, 3.0.64s of Volume Viewer and versions 5.2.0k, 5.2.13h, 5.3.25 of Volume Viewer Plus: When Curved or Navigator images are sent to the Filmer directly from the Volume Viewer application, orientation annotations to the left and right of the images arrive inverted on the Filmer. This can be seen by opening the Filmer in full-page mode and comparing it to the original image.
- With versions 3.0.64m, 3.0.64q, 3.0.64s, 3.0.64t of Volume Viewer and versions 5.2.0k, 5.2.13h, 5.3.25, 5.4.46 of Volume Viewer plus within Filmer, Curved or Navigator images can be flipped or rotated. In this case, the orientation annotations do not follow the new orientation of the image.

It should be noted that other views (Axial, Sagittal, Coronal, Oblique, 3D, etc.) are not affected by the problem. Likewise, direct printouts (Film Sequence or Cine Loop) that do not go via the Filmer, along with images saved from Volume Viewer, are not affected.

Safety Instructions

For Volume Viewer versions 3.0.64m, 3.0.64q, 3.0.64s and Volume Viewer Plus 5.2.0k, 5.2.13h, 5.3.25:

Printed Films and their Electronic Backup from the Filmer are reliable only if The Curved and Navigator images are saved on disk (screen saved) from the Volume Viewer, then sent to the Filmer from the 2D Viewer. A screen save of an image can be done in Volume Viewer by using the "S" key or by the "save image" function selection from the viewport contextual menu (right mouse button when over the image in Volume Viewer).

For Volume Viewer versions 3.0.64m, 3.0.64q, 3.0.64s, 3.0.64t and Volume Viewer Plus versions 5.2.0k, 5.2.13h, 5.3.25, 5.4.46:

Printed Films and their Electronic Backup from the Filmer are reliable only if the images are not flipped or rotated inside the Filmer.

Affected Product Details

Volume Viewer 3.0.64m, 3.0.64q, 3.0.64s, 3.0.64t and Volume Viewer Plus 5.2.0k, 5.2.13h, 5.3.25 and 5.4.46 installed in AW 4.1 or 4.2. Other versions of Volume Viewer or Volume Viewer Plus do not present any annotation problem. When the software is running, the version number is displayed at the top left of the application screen.

Product Correction

GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

Contact Information

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GE Healthcare Systems

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Chief Medical Officer
GE Healthcare

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9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80115-80116-25361

May 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Inaccurate measurements when using "Edit Contour" tool in AW 4.0, 4.1 and 4.2.**

GE Healthcare has become aware of a potential safety issue due to possible inaccurate measurements associated with the "Edit Contour" tool of Advanced Vessel Analysis **AVA** in **CardIQ, CardIQ2**, **CardEP** on the **AW 4.0** VolumeAnalysis v3.0.40-3.054 or **AW 4.1/4.2** VolumeViewer v3.57-3.64 of your Advantage Windows system. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

When using the "Edit Contour" tool along a tracked vessel to perform a significant manual edit of one cross-section, the automatic measurements attached to this edited contour may be inaccurate. This applies to the Dmin and Dmax values displayed on the screen and all of the automatic Diameter and Area measurements potentially attached to the edited contour in the report images and tables.
Values displayed by the Vessel Analysis software will be an interpolation between the true value associated to the edited contour, and the values associated to the adjacent (non-edited) cross sections. The amount of under- or over-estimation will be proportional to the difference between edited and non-edited contours. Therefore, a problem may occur if the contour was significantly edited while the two adjacent contours have not been edited in a similar way.

Safety Instructions

1. Discontinue use of the "Edit Contour" feature until this software functionality is corrected or replaced.

2. Manual measurements of the thrombus, or vessels (in the case of AVA quantification failure), can safely be used in the affected versions.

3. Please note the following system capabilities:
   - Accuracy of cross-section distance measurements should be +/- 10% for vessels with a diameter between 10 and 20 mm. It should be +/- 5% for vessels with a diameter greater than 20 mm.
   - Accuracy of cross-section area measurements should be +/- 40% for vessels with a diameter between 10 and 20 mm. It should be +/- 20% for vessels with a diameter greater than 20 mm.
   - Accuracy of volume measurement should be +/- 40% for vessels with a diameter and length between 10 and 20 mm. It should be +/- 20% for vessels with a diameter and length greater than 20 mm.
   - Accuracy should be better than +/- 10 degrees for angle measurements.

Affected Product Details

Models Affected	Software Releases Affected
AW 4.0	Volume Analysis 3.0.40h and 3.043e 3.0.51g to 3.0.54eta 3.0.54kappa
AW4.1	Volume Viewer 3.0.57, 3.0.58
AW4.1/4.2	Volume Viewer 3.0.64 to 3.0.64m 3.0.64q, 3.0.64s 3.0.64t

Product Correction GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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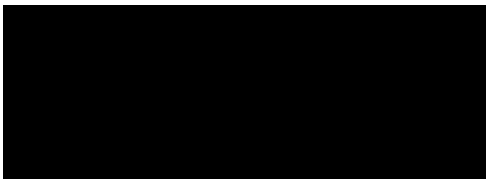

Chief Medical Officer
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9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80115

May 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Distortion of MRI oblique planes on AW workstation**

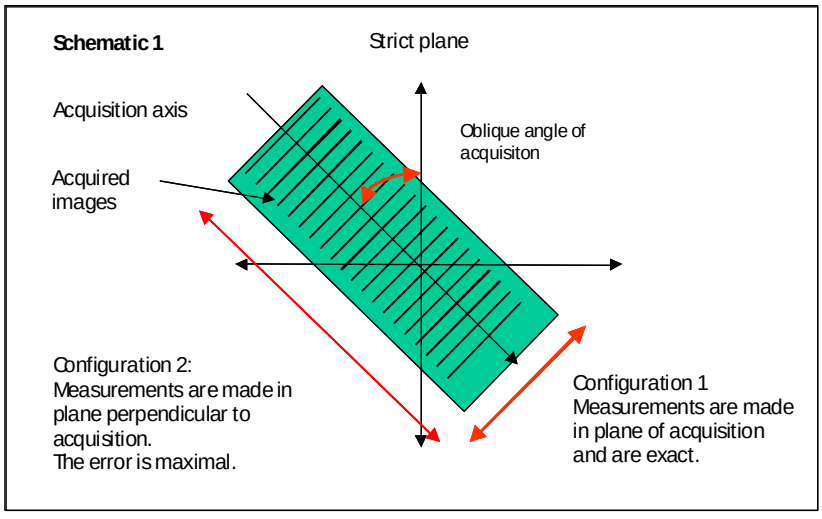
GE Healthcare has become aware of a potential safety issue due to distorted reconstructions created from MRI oblique images associated with the Volume Analysis application on AW 3.1 or AW 4.0 or the Volume Viewer application on your AW 4.1. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The problem concerns only MRI exams acquired on an oblique plane in relation to axial, sagittal, coronal planes, and for measurements made in a plane different from the acquisition plane.

Reconstruction in 3D made from this type of acquisition using Volume Analysis or Volume Viewer has the following fault: reconstructed volumes appear compressed in comparison to their real size. This causes an error in the measurements made on a plane that is different from the acquisition plane. This error does not appear on the native images.

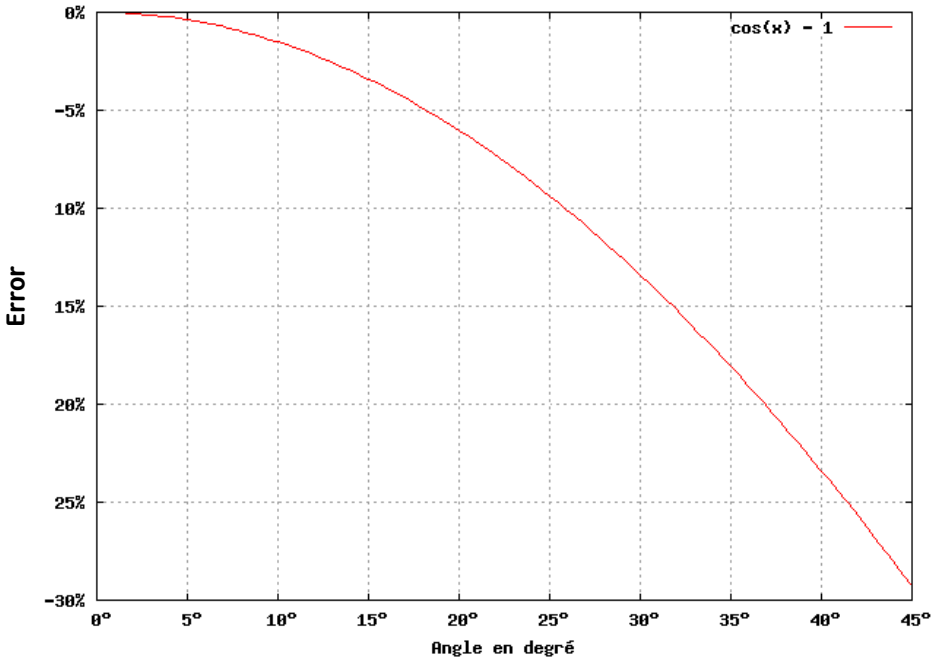
Note that the deformation depends on the acquisition angle in relation to the closest axial, sagittal or coronal plane according to the formula 1- cosine (angle), as well as by the orientation of the reformatted images in relation to the acquisition axis. The maximum value of the deformation is 30%: this is reached for an acquisition angle of 45 degrees in relation to a main plane, and the measurement error is maximum when the measurement plane is perpendicular to the acquisition plane.



Curve C: Variation of the error as a function of the angle of obliquity of acquisition

Graph showing the percentage error as a function of the angle of the acquisition plane and in the most penalizing condition of measurement that is, for a measurement made on a plane perpendicular to the plane of acquisition.

Error as a function of acquisition obliquity



Safety Instructions

Recommendations for New MRI Oblique Exams:

Before the problem is corrected on your workstation, we recommend the following:

- Make acquisitions in the strict axial, sagittal or coronal planes, i.e., without incline in relation to the reference planes.
- For therapeutic follow-up with comparison of exams, if it is necessary to make exams in the oblique plane, specify the angle of acquisition in relation to the table to the same value as used in the reference exam. This approach is not recommended, however, because it is difficult to find exactly the same angle from one exam to another.

Following correction of the problem:

Great care must be taken when comparing a new exam with an old exam. We recommend only the comparison of images processed with versions unaffected by the problem. If necessary, volume reconstruction of old exams should be redone using the new version.

The table below summarizes our recommendations for oblique MR exams.

	Before correction	**After correction**
Absolute measurement	Incorrect outside the acquisition plane. See the error curve as a function of the angle.	Correct
Exam comparison	Incorrect outside the acquisition plane. Not recommended, but possible if the acquisition angle is the same as when using the reference exam.	Correct Providing that the exams to be compared were processed with a non-affected version.

Recommendations for Stored Exams:
Images generated from screen captures are only reliable if:

- The acquisition was not oblique in relation to the strict axial, sagittal or coronal reference planes.
  OR
- The version of the Volume Analysis or Volume Viewer software that was used to reconstruct these images is not one of the versions affected by the problem.

Affected Product Details

Volume Analysis 3.0.34, 3.0.40, 3.0.43, 3.0.51, 3.0.54a through 3.0.54z, and 3.0.54alpha through 3.0.54eta. Volume Viewer 3.0.57, 3.0.58, 3.0.58d, and 3.0.63.
When the software is running, the Version No. is displayed at the top left of the application screen.

Product Correction

GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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.

Sincerely,

[redacted]

Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

[redacted]

Chief Medical Officer
GE Healthcare

[redacted]

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80125

May 2012

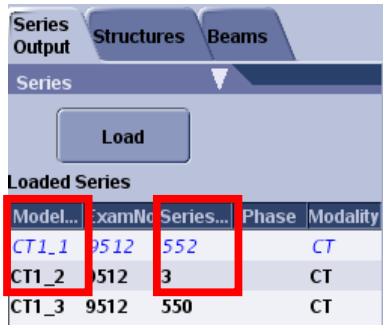
To: Hospital Administrators
Radiology Managers
Risk Managers

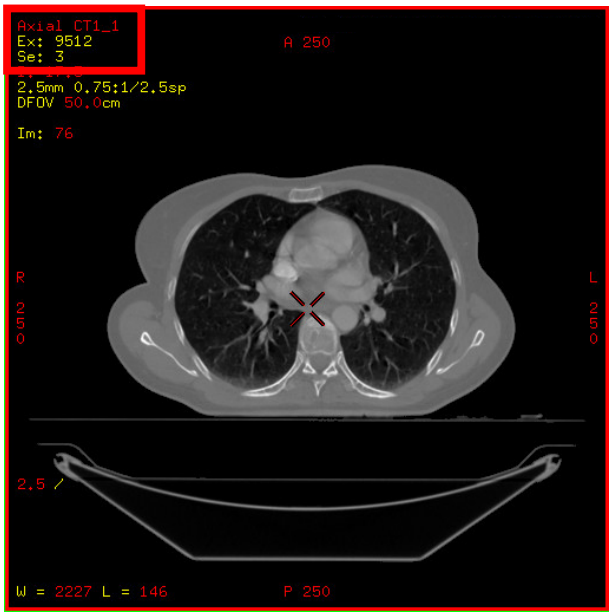
RE: **Advantage Workstation: AdvantageSim MD – Mislabeling of series in the image view**

GE Healthcare has become aware of an issue associated with the AdvantageSim MD application of your Advantage workstation that 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 Issue

AdvantageSim MD supports loading multiple image sets from an examination at the same time. When several non-phased series are loaded simultaneously, there is a possibility that they can be mislabeled, with the result being that incorrect model and series numbers are on the displayed images. The Radio Therapy Structure Sets (RTSS) generated using mislabeled series will most likely be rejected by the radiation treatment planning system. If they are not rejected by the system, the non-phased data used for treatment planning might be confused with each other, causing errors in radiation treatment planning.





In the right image above, the "CT1_1" Model Number (top left corner, line 1 in red) is shown as corresponding to Series Number "3" (top left corner, line 3 in yellow) instead of "552" as shown in the Series Panel (left image above). This is incorrect.

Safety Instructions

As a preventive action, GE Healthcare recommends that the user load non-phased series one-by-one into AdvantageSim MD.

Once all image series are loaded into AdvantageSim MD, use the "Series Panel" data to visually verify that the Model Numbers and corresponding Series Numbers are correctly matched in the "Image Panel".

Note: 4D Phases are not affected by this issue and can be loaded simultaneously using multiple selection.

There is a potential that the issue may have had an impact on images loaded on dose planning systems using AdvantageSim MD 7.4 through 7.6, i.e., November 2006 or later. Please take this into account when patient treatment may be affected by an RTSS created on or after this time based on data transferred from your Advantage Workstation to another device such as a treatment planning workstation or a PACS.

Affected Product Details

AdvantageSim MD versions 7.4 through 7.6 inclusive are affected.
The version is displayed in the top left corner of the AdvantageSim MD left user interface panel.

Product Correction

GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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.

Sincerely,

Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80128

May 2012

To: Hospital Administrators / Risk Managers
Oncology Department Managers / Radiation Oncologists
Radiation Physicists / Dosimetrists / Therapists

RE: **Advantage Workstation: AdvantageSim – Inconsistent DRR (Digitally Reconstructed Radiographic) Visualization**

GE Healthcare has become aware that inconsistent DRR (Digitally Reconstructed Radiographic) visualization may occur when the blended DRR feature or the Isocenter Move mode feature is used in combination with specified other functions of the AdvantageSim application on Advantage Workstation. These inconsistencies may affect patient safety. Other AdvantageSim functions are not affected. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The following issues have been identified in the AdvantageSim application. Please see Appendix for a detailed explanation.

1. When using the **Center on Cursor** feature in combination with a blended DRR in certain AdvantageSim versions, the captured DRR will remain fixed in the original position while the active DRR will move to a position where the 3D cursor is centered on the screen.
2. When using the **Isocenter Move** mode feature in combination with a blended DRR in certain AdvantageSim versions, the captured DRR will remain fixed in the original position while the active DRR is correctly recalculated and shown.
3. When the image series is changed (on the top left corner of a DRR view) while using DRR blending, the captured DRR is not recalculated or cancelled.
4. When using the blended DRR function the visualization of the captured DRR may change without the visualization parameters (MIXING and DEPTH CONTROL) being updated on-screen after choosing a DRR preset for the active DRR.
5. When a new beam is created after using DRR blending on a previous beam, switching back to the previous beam may cause annotations for BLENDING, MIXING and DEPTH CONTROL to not be shown.

Affected Product Details

Safety Issue #1 affects all Advantage Workstations with AdvantageSim versions 5.x, 6.x and 7.x (AdvantageSim MD) up to and including version 7.7.0. These products were distributed from August 2000.

Safety Issues #2 through #5 affect all Advantage Workstations with AdvantageSim versions 7.x (AdvantageSim MD) up to and including version 7.7.0. These products were distributed from October 2005.
The version is displayed on the top left corner of the AdvantageSim left user interface panel.

Safety Instructions

Safety issues 1-3 and 5 can be corrected by turning the DRR “off” and then back “on” to force it to recalculate and display correctly. Safety issue 4 requires manual setting of the DRR parameters instead of using a preset. Please see Appendix for detailed instructions for each safety issue.

Product Correction

GE Healthcare will correct all affected workstations by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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.

Sincerely,

Vice President QARA
GE Healthcare Systems
9900 Innovation Drive
Mail Stop: RP2130
Wauwatosa, WI 53226, USA
[redacted]@ge.com

Safety Issue

1. When using the **Center on Cursor** feature in combination with a blended DRR in certain AdvantageSim versions, the captured DRR will remain fixed in the original position while the active DRR will move to a position where the 3D cursor is centered on the screen.

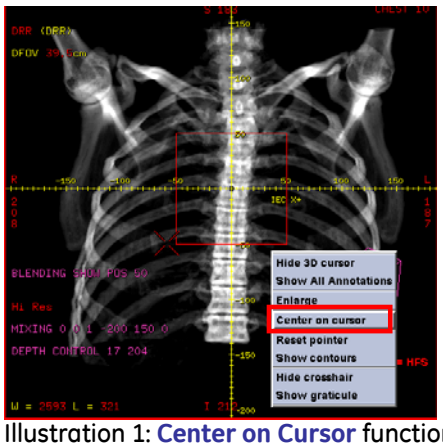


Illustration 1: **Center on Cursor** function

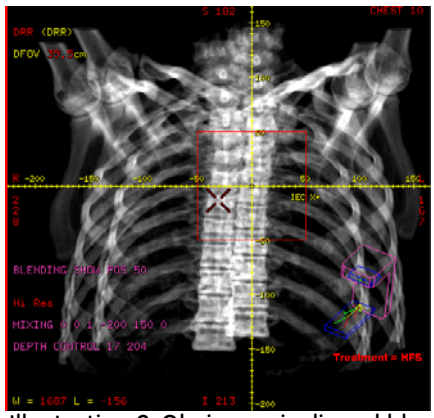


Illustration 2: Obvious misaligned blended DRR using the **Center on Cursor** feature

Lung DRR with airway pulled out and blended. Note the location of the carina just above the cross-hairs.

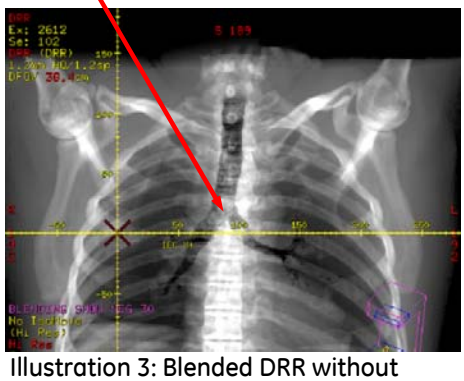


Illustration 3: Blended DRR without misalignment

Lung DRR with airway pulled out and blended. After **Center on Cursor**, location of the misaligned carina below the cross-hairs.

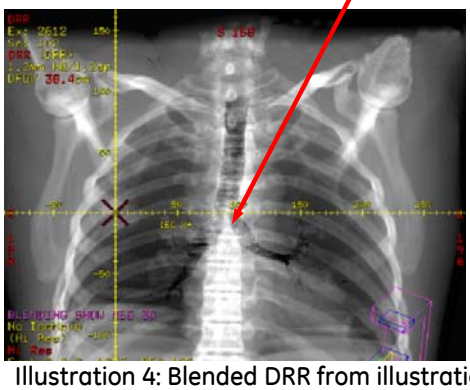
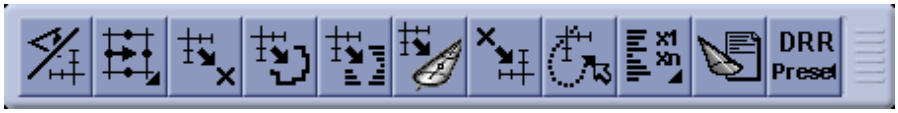


Illustration 4: Blended DRR from illustration 3 after **Center on Cursor** with non-obvious misalignment

Safety Instructions

The blended DRR can be re-aligned to show both DRRs in the correct position by switching the DRR off/on once using the leftmost button of the beam toolbar (see below).



Use the leftmost button to switch the DRR off/on.

Safety Issue

2. When using the **Isocenter Move** mode feature in combination with a blended DRR in certain AdvantageSim versions, the captured DRR will remain fixed in the original position while the active DRR is correctly recalculated and shown.

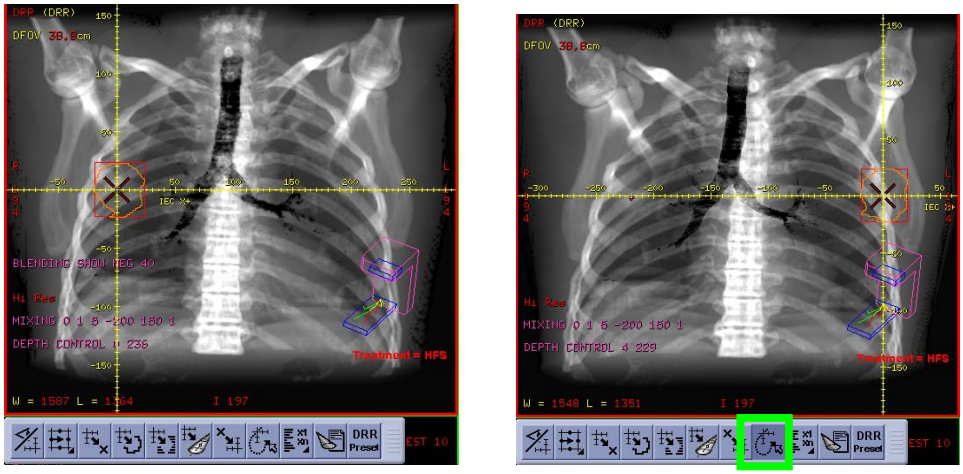


Illustration 5: Blended DRR before (left side) and after (right side) **Isocenter Move** mode (green highlighted button) is used to change isocenter. The example represents an extreme isocenter movement to illustrate the effect.

Safety Instructions

The blended DRR can be re-aligned to show both DRRs in the correct position by switching the DRR off/on once using the leftmost button of the beam toolbar (see below).

Use the leftmost button to switch the DRR off/on.

Safety Issue

3. When the image series is changed (on the top left corner of a DRR view) while using DRR blending, the captured DRR is not recalculated or cancelled.

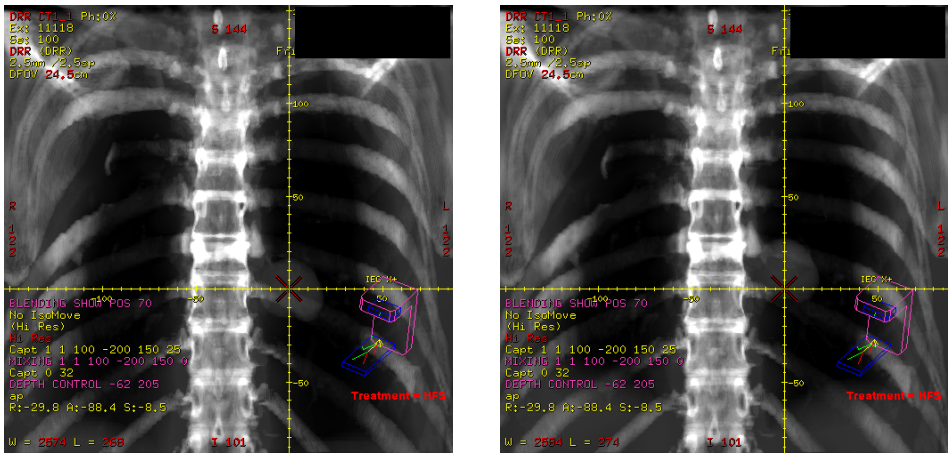


Illustration 6: 0% phase blended with 0%phase (left side) and 50% phase blended with 0%phase (right side). Both show 0% phase in upper left corner

Safety Instructions

The blended DRR can be re-aligned to show both DRRs in the correct position by switching the DRR off/on once using the leftmost button of the beam toolbar (see below).

Use the leftmost button to switch the DRR off/on.

Safety Issue

4. When using the blended DRR function the visualization of the captured DRR may change without the visualization parameters (MIXING and DEPTH CONTROL) being updated on-screen after choosing a DRR preset for the active DRR.

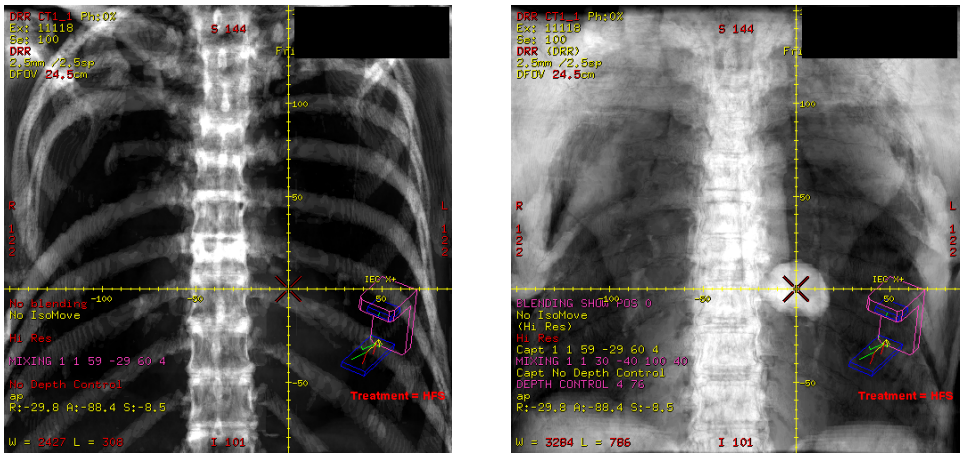


Illustration 7: Initial DRR with bone preset (left side), Incorrect visualization after blending with a different preset (right side)

Safety Instructions

In order to properly visualize the DRR, it is important that a preset is not used for the 2nd DRR of the blended pair. If the issue has already occurred, follow the sequence below to restore correct visualization:

1. Turn off blending
2. Select a preset for the 1st DRR
3. Capture DRR
4. Manually apply mixing and/or blending
5. Turn blending on

Safety Issue

5. When a new beam is created after using DRR blending on a previous beam, switching back to the previous beam may cause annotations for BLENDING, MIXING and DEPTH CONTROL to not be shown.

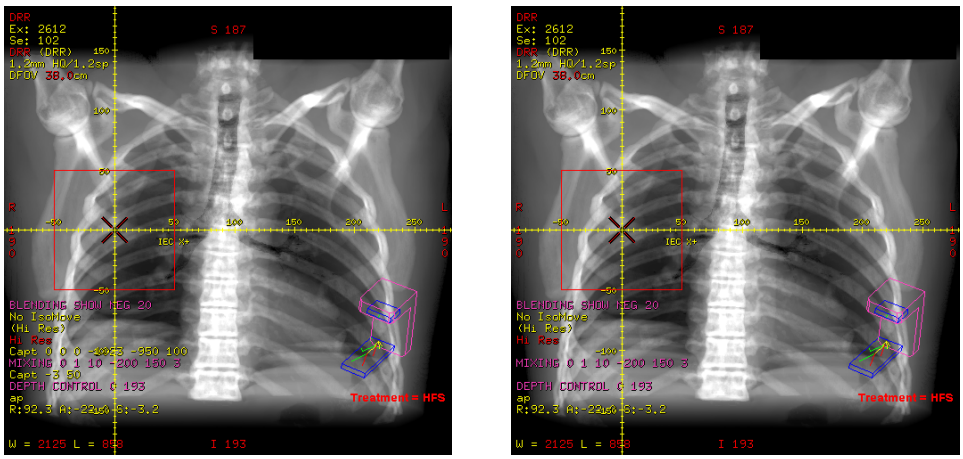
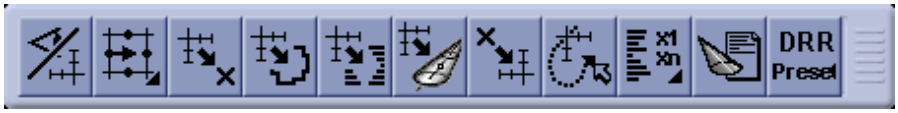


Illustration 8: Initial Blended DRR with all annotation shown (left side), after adding another beam blended annotation is not shown (right side)

Safety Instructions

The annotation can be restored by switching the DRR off/on once using the leftmost button of the beam toolbar (see below).



Use the leftmost button to switch the DRR off/on.

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

May 2012

GE Ref: FMI 80130

To: Hospital Administrators / Risk Managers
Radiology Managers
Radiologists

RE: **Advantage Workstation Reporting Tool: Edits made on a report can be saved into incorrect reports**

GE Healthcare has become aware that edits made on a report in Reporting tool can be saved into incorrect reports. This issue 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 Issue

When two or more reports are opened in the Reporting Tool, edits made on one report/exam can be saved into incorrect reports/exams. Scenario that can lead to this problem:

1) User opens Reporting Tool with at least 2 editable DICOM structured reports
2) User opens the first report in edit mode
3) User switches to the second report in edit mode
4) User switches back to the first report
5) User edits data in the first report
6) User saves the result and this will create a new report based on the patient identification and measurements data of the second report with some of the edits entered for the first report

No injury has been reported related to this issue.

Affected Product Details

All Reporting Tool versions 2.5 or earlier on Advantage Workstation are affected. The software version is displayed in the upper left corner of the Reporting Tool user interface window.

Safety Instructions

Open only one patient report at a time when editing a report in Reporting tool.

Product Correction

GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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 the appropriate Regulatory Agencies have been notified.

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.

Sincerely,

Vice President QARA
GE Healthcare Systems
9900 Innovation Drive
Mail Stop: RP2130
Wauwatosa, WI 53226, USA
[redacted]@ge.com

Chief Medical Officer
GE Healthcare
3000 N Grandview Blvd
Mail Stop: W440
Waukesha, WI 53188, USA
[redacted]@ge.com

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref. : FMI 80131

May 2012

To: Hospital Administrators
Radiology Managers
Risk Managers

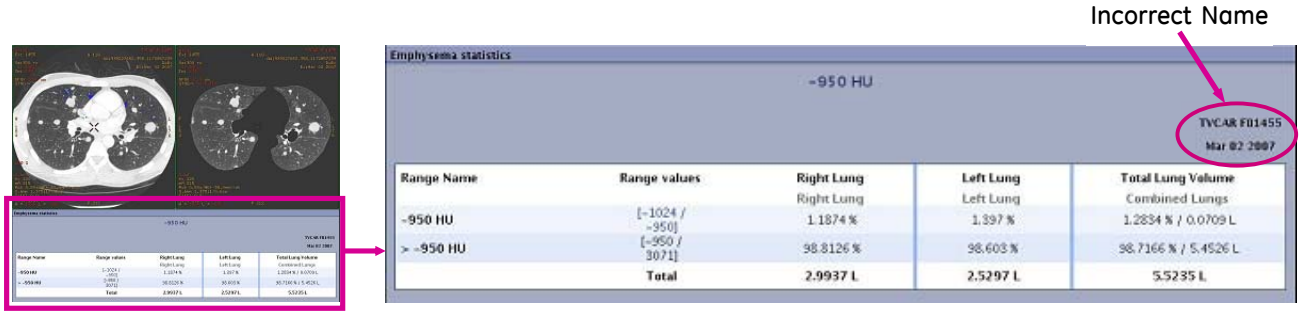
RE: **Advantage Workstation Thoracic VCAR: Incorrect patient name may be displayed on the data summary table if a specific workflow is followed**

GE Healthcare has become aware that when analyzing CT images using the Thoracic VCAR application software, incorrect patient name may appear in the summary table if the user does not exit the application in between the analysis of two consecutive patients. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

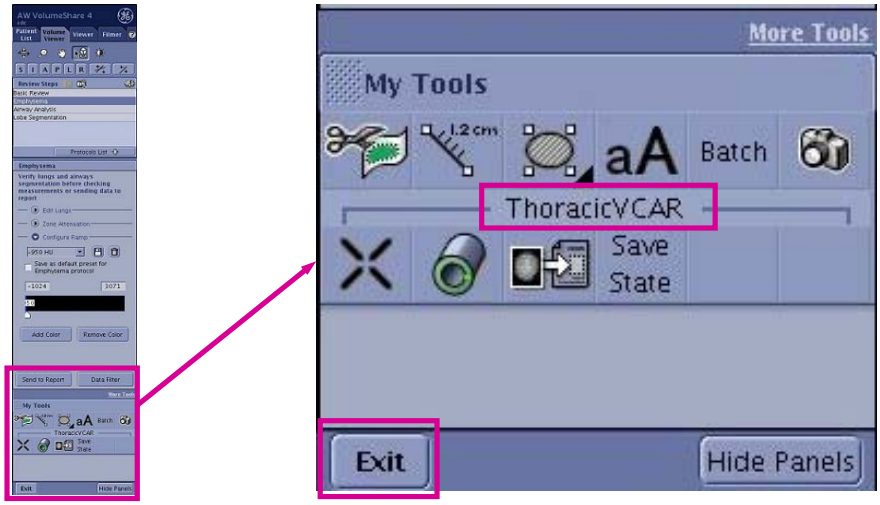
When using the summary table feature on Thoracic VCAR to display data, incorrect patient name will be displayed if the user does not exit the application in between the analysis of two consecutive patients. This only affects the summary table information, whereas the individual DICOM information and actual data itself is not affected and the data integrity is intact.

If the user did not exit the application, the correct imaging study will appear and the data on the summary table will contain the results of the current patient imaging study; however, the previous patient name will be displayed on the summary table. This summary result may be separated from the remainder of the CT imaging exam if it is printed on film or paper and incorrectly inserted in another patient's file. This issue may cause confusion and possible incorrect assessment. No adverse event has been reported related to this issue. The figure below illustrates where the incorrect name may be displayed.



Safety Instructions

Ensure that the Thoracic VCAR software is properly exited using the exit application key prior to loading a new patient.



Affected Product Details

Thoracic VCAR versions 9.3 through 9.6.24 are affected. The version is displayed by clicking the "?" on the upper left Thoracic VCAR user interface panel and selecting "About...".

Product Correction

GE Healthcare will correct all affected workstations by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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 the appropriate Regulatory Agencies have been notified.

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.

Sincerely,

[redacted]

[redacted]

Vice President QARA
GE Healthcare Systems

Chief Medical Officer
GE Healthcare

Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80137

May 24, 2012

To: Hospital Administrators
Radiology Managers
Risk Managers

RE: **Advantage Workstations and Seno Advantage workstations previously issued Field Safety Corrective Actions.**

GE Healthcare recently completed a comprehensive review of the core software and optional applications installed on Advantage Workstations and Seno Advantage workstations at customer sites.
Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue As a result of the comprehensive review, it has been determined that one or more workstations at your institution should have received one or more previously issued Field Safety Corrective Actions.

Safety Instructions The corrections applicable to your institution are described in the attached notice(s).

Affected Product Details Advantage Workstations and Seno Advantage workstations.

Product Correction GE Healthcare will correct all affected AW server installations by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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.

Sincerely,

Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Systems

Chief Medical Officer
GE Healthcare