



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80128

December 2010

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,



[Redacted]
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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.

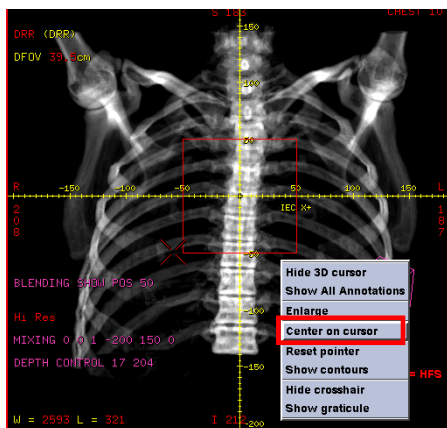


Illustration 1: **Center on Cursor** function

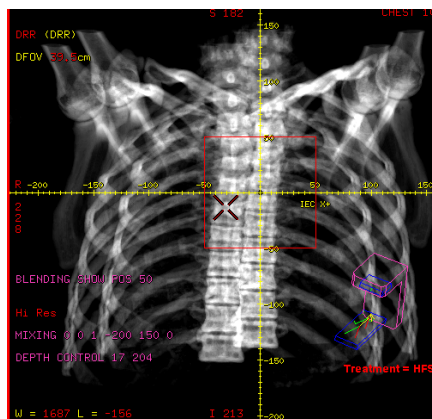


Illustration 2: Obvious misaligned blended DRR using the **Center on Cursor** feature

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

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



Illustration 3: Blended DRR without misalignment

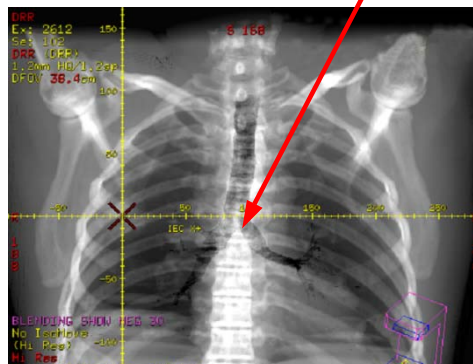
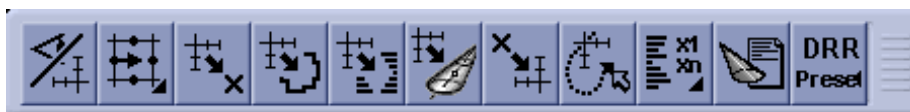


Illustration 4: Blended DRR from illustration 3 after **Center on Cursor** with non-obvious misalignment

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

- 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.

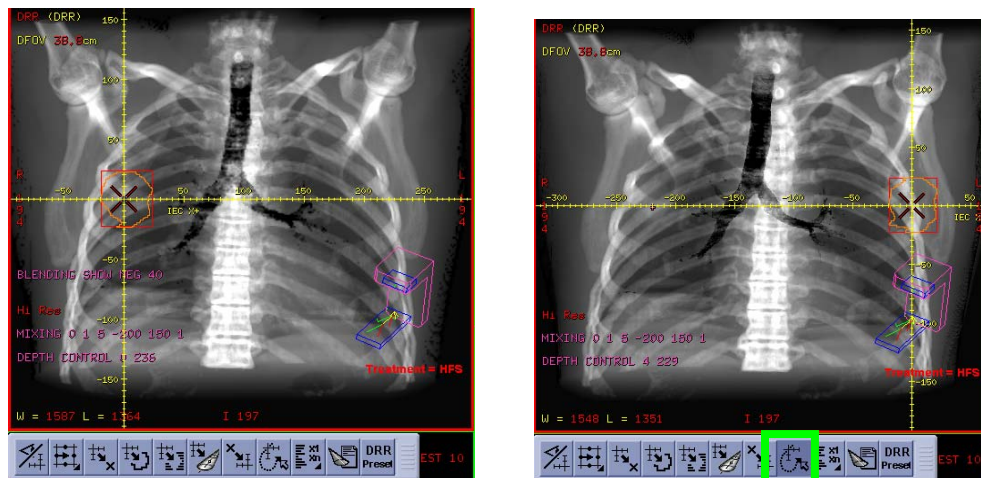


Illustration 5: Blended DRR before (left side) and after (right side) **Isocenter Move** mode (green highlighted button) is used to change isocenter. The example represents an extreme isocenter movement to illustrate the effect.

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

- 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.

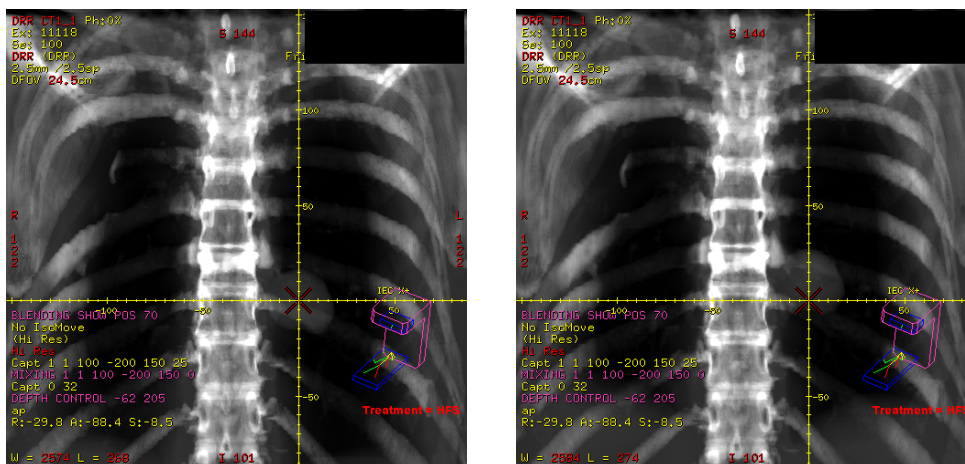


Illustration 6: 0% phase blended with 0%phase (left side) and 50% phase blended with 0%phase (right side). Both show 0% phase in upper left corner

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.

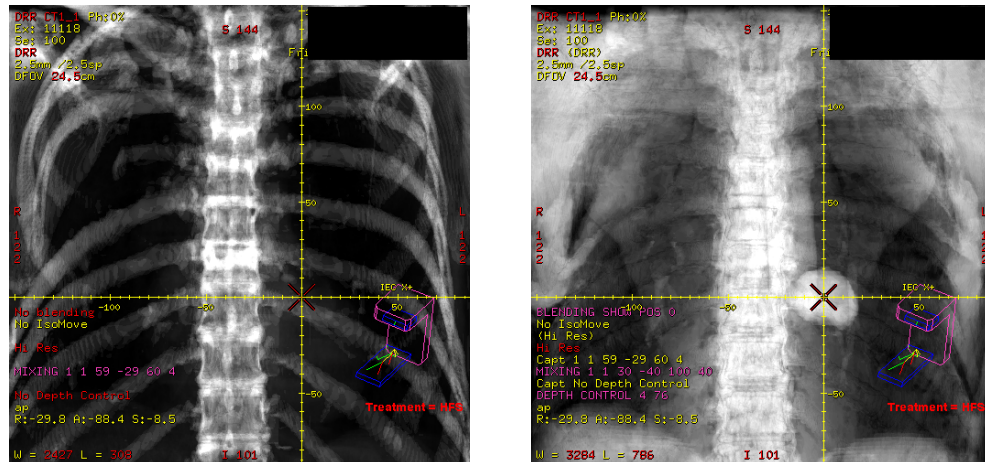


Illustration 7: Initial DRR with bone preset (left side), Incorrect visualization after blending with a different preset (right side)

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

- 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.

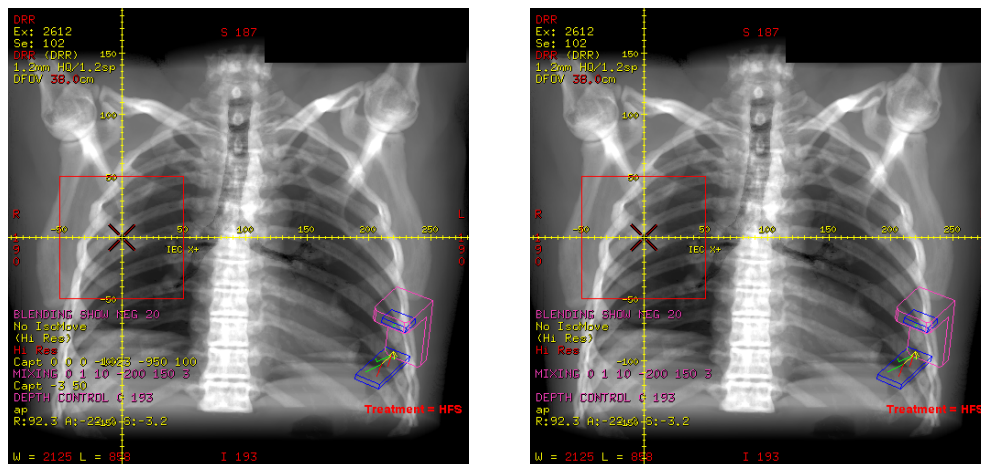


Illustration 8: Initial Blended DRR with all annotation shown (left side), after adding another beam blended annotation is not shown (right side)

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.