



## URGENT FIELD SAFETY NOTICE

April 03, 2009

To: AdvantageSim Customers  
Hospital Administrators / Risk Managers  
Oncology Department Managers

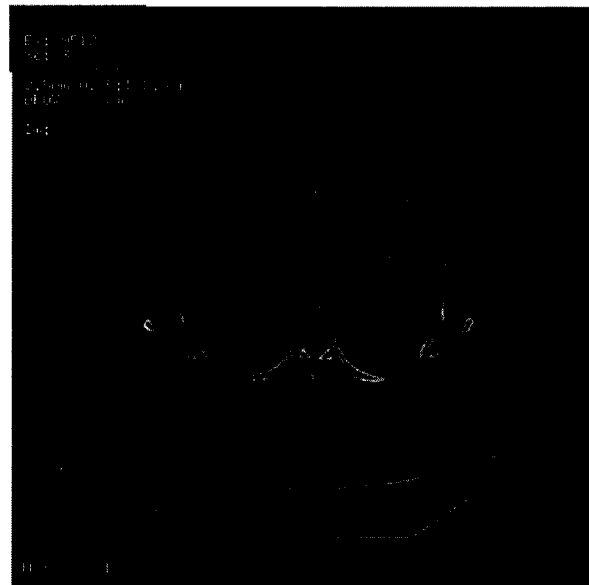
Subject: **Advantage Workstation: AdvantageSim MD – Mislabeling of series in the image view**

GE Healthcare would like to inform you of the following 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.

Model	Series Number	Series	Phase	Modality
CT1_1	9512	552		CT
CT1_2	9512	3		CT
CT1_3	9512	550		CT



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.



**Affected Product** 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.

**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.

**Product Correction** GE Healthcare will install new software (AdvantageSim MD 7.7) to correct this issue with the release of Field Modification Instruction (FMI) 80125 in the near future. This correction will not affect the performance or any other functionality of your current equipment.

**Contact Information** Please contact your local sales or service representative if you need additional information regarding this notification.

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If you have any questions, please contact your local sales or service representative immediately.

Sincerely,

[Redacted signature]

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