

CUSTOMER (SAFETY) ADVISORY NOTICE

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To all customers using
CT syngo Dual Energy Viewer

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Your letter
Abbr.
Date 10/08/2008

CT syngo Dual Energy Viewer **Important safety advisory notice regarding saving procedure of result images**

To all customers using the *syngo* Dual Energy Viewer.

This letter is intended to inform you of a problem with the *syngo* Dual Energy Viewer based on *syngo* multi modality workplaces (MMWP) and on CT workplaces with the following affected Versions:

software version
<i>syngo</i> MMWP 2007C
<i>syngo</i> MMWP 2008A
<i>syngo</i> MMWP 2008B
<i>syngo</i> MMWP 2008C
<i>syngo</i> CT 2007A
<i>syngo</i> CT 2008G

Within the framework of various Dual Energy applications (e.g. BoneRemoval, LiverVNC...) the *syngo* Dual Energy Viewer allows to calculate new image data sets based on the information of the original 80 and 140 kV data sets. After saving these newly calculated images they can be loaded into other *syngo* applications (e.g. InSpace, 3D ...). In context with the saving procedure ("SaveSets CT"-button) of the resulting images based on non-supine data sets (i.e. patient procumbent or in lateral position) as well as on supine-scans reconstructed with the Mirror-Option ("Left/Right", "Bottom/Up" or "Both") the following error occurs:

The orientation indicated by the orientation cube does not match the actual patient orientation

The error is limited to the generated image data, which are calculated in the *syngo* Dual Energy Viewer from non-supine data sets as well as from supine data sets reconstructed with the Mirror-Option ("Left/Right", "Bottom/Up" or "Both"). In other applications (e.g. InSpace, 3D, ...) the images are displayed under a rotation angle, i.e. in the scans mentioned above the indicated directions of the

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orientation cube and the markings are not adjusted to the actual patient positioning. Hence, the object in the image is displayed in wrong orientation that is distorted by the angle that the patient position differs from a supine position (prone 180°; lateral position: 90°/ 270°). The error occurs with all calculated image data based on non-supine and mirror-option data sets, which were saved via "SaveSets CT"-button.

Error prevention:

Currently there is no possibility known to avoid this error. In general the following course of action should be considered:

No saving of calculated Dual Energy data sets from non-supine and mirror-option scans via "Save Sets CT"-button.

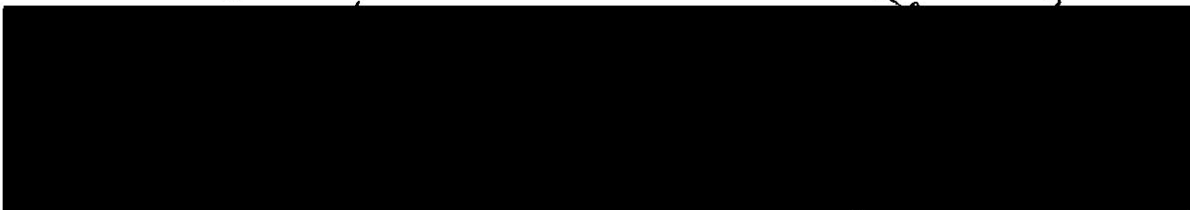
It is highly recommended to check the correct display of "left", "right", "anterior" and "posterior" markings, e.g. by checking the position of the spine with respect to the posterior marking in the image.

The error described above will be fixed within the following activities on the affected software:

software version	action	scheduled release
<i>syngo</i> MMWP 2007C	Upgrade to MMWP 2008 B/C & Installation from sMMWP IKM SP1 service Pack	Upgrade in progress Release of Upgrade Instructions 10/20/2008
<i>syngo</i> MMWP 2008A	Upgrade to MMWP 2008 B/C & Installation from <i>syngo</i> MMWP IKM SP1 service Pack	Upgrade in progress Release of Upgrade Instructions 10/20/2008
<i>syngo</i> MMWP 2008B	Installation from <i>syngo</i> MMWP IKM SP1 service Pack	Release of Upgrade Instructions 10/20/2008
<i>syngo</i> MMWP 2008C	Installation from <i>syngo</i> MMWP IKM SP1 service Pack	Release of Upgrade Instructions 10/20/2008
<i>syngo</i> CT 2007A	Upgrade via VA20 SP2 Service Pack	11/15/2008
<i>syngo</i> CT 2008G	Upgrade via VA20 SP2 Service Pack	11/15/2008

We would appreciate your compliance with this (safety) advisory notice and ask that you instruct your personnel accordingly. Please ensure that this (safety) advisory notice is filed with the Somaris operating instructions until the completeness of the **actions mentioned above**.

Siemens Aktiengesellschaft



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