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To all users of the following software products:

syngo.via RT Image Suite
with syngo.via VB30 and syngo.via VB40 software

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Customer Safety Advisory Notice SY038/20/S

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Subject: Potential incorrect geometry in resulting Synthetic CT images created by the software option “Synthetic CT” of syngo.via RT Image Suite when using input MR images

Dear Customer,

This letter is to inform you about a missing geometry check of the software option “Synthetic CT” running on the syngo.via RT Image Suite.

When does the issue become a problem and what is it about?

The following technical issue has been identified, if MR images have been acquired with customized scan protocols and loaded into syngo.via RT Image Suite for postprocessing with the option “Synthetic CT”:

If the user modifies for any reason (e.g. reduction of artifacts) the original image orientation of a standard MR protocol to acquire images in a different orientation for further processing in “Synthetic CT”, the software does not recognize the adapted acquisition plane. This may result in images with wrong geometry. When this distortion remains unnoticed and the images are subsequently exported to a treatment planning system (TPS), an incorrect calculated radiation treatment plan cannot be excluded. The occurrence of this case is very unlikely and has never been reported so far.

An example of a visibly distorted image is shown in Fig. 1 (next page).

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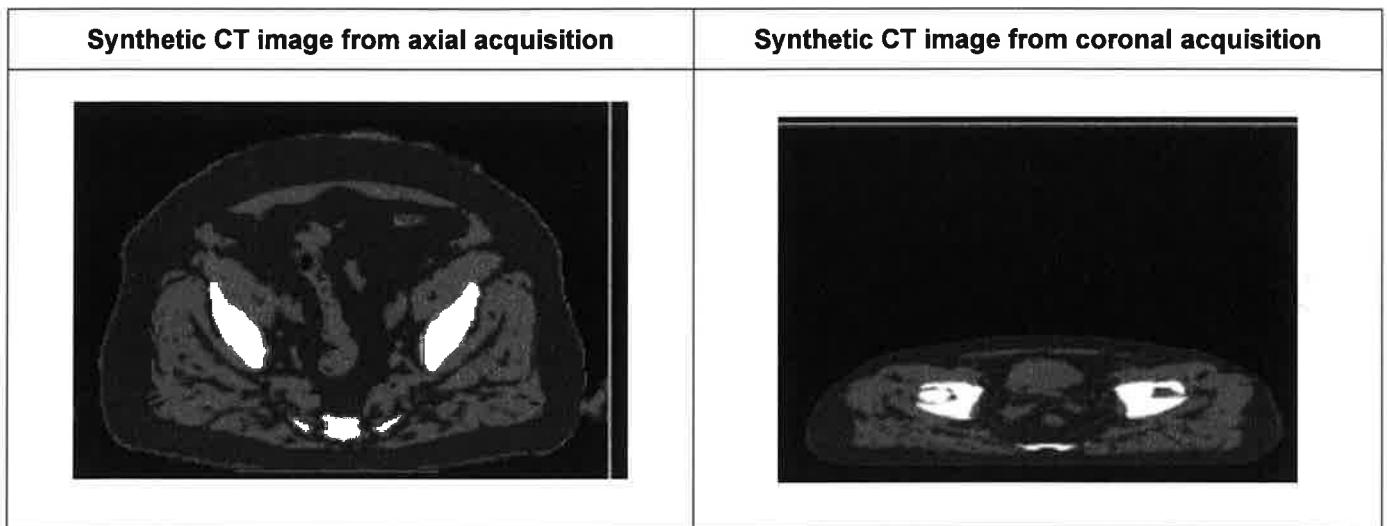


Fig. 1: Comparison of Synthetic CT image calculated from axial acquisition to Synthetic CT image calculated from coronal direction.

How can the user help to avoid a potential risk?

The user should observe the following rules of conduct:

1. Use MR data acquired in axial orientation as input for Synthetic CT calculation only.
2. Use protocols validated by Siemens Healthineers only.
3. In any case, perform a pretreatment verification to compare the actual treatment position with the target position.

How will the issue be permanently resolved?

The described issue will be solved with a service pack for software versions *syngo.via* VB30 and *syngo.via* VB40. Depending on your current software version, the service pack VB30A_HF08 will be installed with update SY039/20/S or the service pack VB40B_HF01 with update SY040/20/S as soon as it is available.

Your local service organization will inform you when it is ready to install and the solution will then be provided to you free of charge.

We appreciate your cooperation with this Safety Advisory Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this Customer Safety Advisory Notice is placed in the medical device's Instructions for Use. Your personnel should maintain awareness until the solution has been implemented.

If you have sold your system running *syngo.via* RT Image Suite and/or it is no longer in your ownership, we kindly ask you to immediately forward this Safety Advisory Notice to the new owner of the system. Please also inform us of the identity of the new owner of the system.

If you have any unresolved questions or you require technical support, please contact your local application specialists or your local service/sales organization.

Sincerely yours,

