

Siemens Healthcare GmbH, SHS DI MR QT, Allee am Roethelheimpark 2,
91052 Erlangen

To all users of the following software products:
syngo.via RT Image Suite

with NUMARIS X A11 and A20 software

Name	██████████
Department	SHS DI MR QT
Telephone	+49 (9131) 84-██████████
Fax	+49 (9131) 84-██████████
Mobile	+49 (162) ██████████
E-mail	██████████@siemens-healthineers.com
Date	June, 2020

Customer Safety Advisory Notice MR020/20/S

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 option *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 at your MAGNETOM system and/or *syngo.via* RT Image Suite on your *syngo.via* server (for this please refer to Customer Safety Advisory Notice SY038/20/S) 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), it cannot be excluded that this results in an incorrect calculated radiation treatment plan. The occurrence of this case is very unlikely and has never been reported so far.

Siemens Healthcare GmbH
Management: Bernhard Montag, President and Chief Executive Officer;
Jochen Schmitz, Christoph Zindel

Allee am Roethelheimpark 2
91052 Erlangen
Germany

Tel.: +49 (9131) 84 0
siemens.com/healthcare

Chairman of the Supervisory Board: Ralf P. Thomas
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105

An example of a visibly distorted image is shown in Fig. 1.

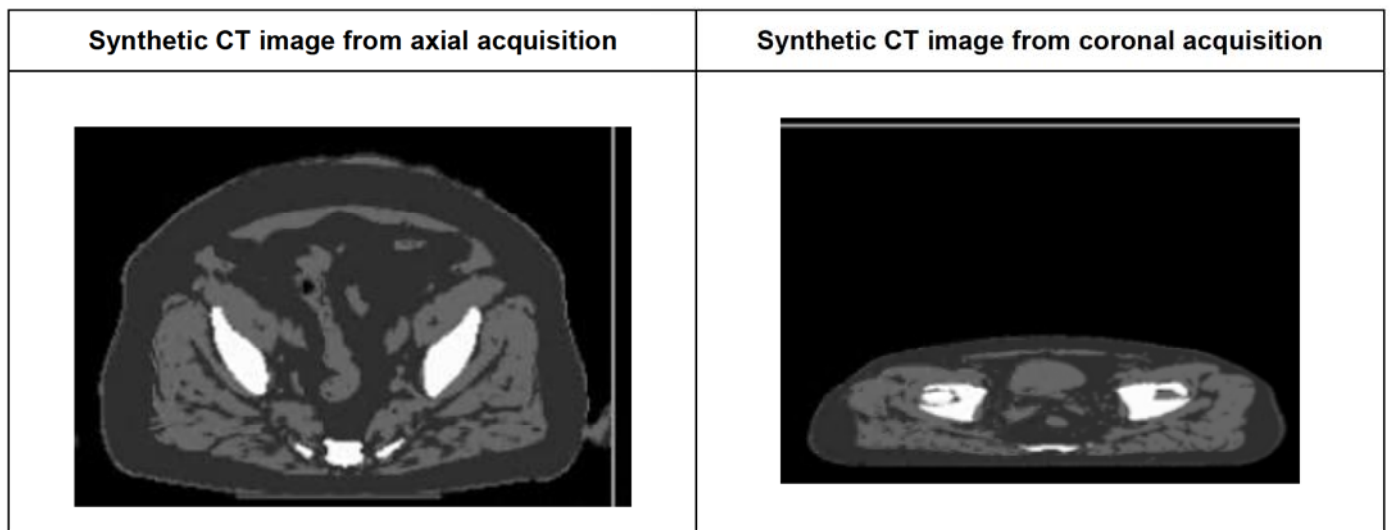


Fig. 1: Comparison of Synthetic CT image calculated from axial acquisition to Synthetic CT image calculated from coronal direction.

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, always 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* server: *syngo.via* VB30 with update SY039/20/S and *syngo.via* VB40 with SY040/20/S
- MAGNETOM systems: NUMARIS X A20A with service pack 04 provided with MR021/20/S.

Customers with NUMARIS X A11 software version will be upgraded to NUMARIS X A20A.

Your local service organization will contact you for update of your system (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. Please make sure that everybody affected in your organization is informed accordingly.

If you have sold your MAGNETOM system or your *syngo.via* server 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.

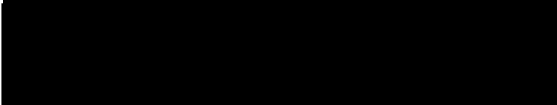
If you have any unresolved questions or you require technical support, please contact your local application specialists or your local service/sales organization.

Sincerely yours,

—

Siemens Healthcare GmbH

Signature:



Email:

