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To all users of the following software products:

syngo.via RT Image Suite / Sim&GO
with SOMATOM go.Now
SOMATOM go.Up
SOMATOM go.All
SOMATOM go.Fit
SOMATOM go.Top
SOMATOM go.Sim
SOMATOM go.Open Pro
SOMATOM X.cite and
SOMATOM X.ceed
with software *syngo* CT VA20A, VA30A and VA40A

Customer Safety Advisory Notice CT42/21/S

Customer Safety Advisory Notice CT42/21/S

Subject: Potential loss of unsaved results when using *syngo.via* RT Image Suite / Sim&GO

Dear Customer,

This letter is to inform you about a potential data loss when using the contouring or patient marking workflow in *syngo.via* RT Image Suite / Sim&GO: when editing a structure set after saving and re-opening the study, sporadically the edited contours or points may not be saved as intended and an incomplete structure set may be sent to the treatment planning system (TPS). If this is not recognized in the TPS, an incorrect treatment plan might be created.

When does the malfunction occur and what is the problem?

The following technical issue has been identified in a user scenario, when a structure set has already been saved in *syngo.via* RT Image Suite / Sim&GO and is then saved again after further edits: The workflow is marked as completed, but sporadically the RT structure set might not have been saved into the local database.

The user can recognize the issue as follows:

Please reopen the completed workflow and check whether all recently edited contours are present. This verification is important because the system will not display any error message.

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Management: Bernhard Montag, Chairman;
Darleen Caron, Jochen Schmitz, Christoph Zindel

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WEEE-Reg.-No. DE 64872105

How can the user help to avoid a potential risk?

For affected scanners running on software versions *syngo* CT VA20A and VA30A, no workaround is available.

For affected scanners running on software version *syngo* CT VA40A, the following workaround is available: before clicking “complete”, save the data using the RT navigator “Save” button (see Figure 1).

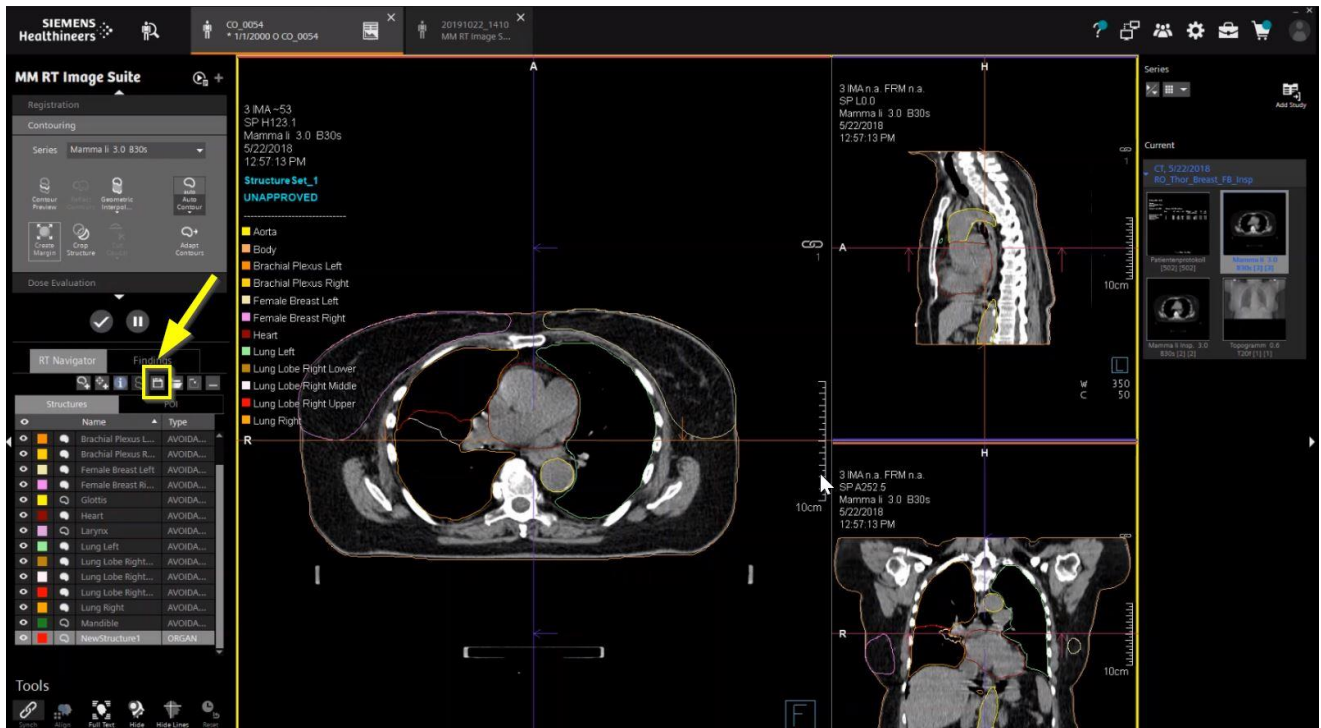


Figure 1: Save Structure Set from RT Navigator (screenshot taken from *syngo* CT VA40A)

How will the issue be permanently resolved?

A solution for the issue described will be developed and distributed with high priority for the affected scanners running on software versions *syngo* CT VA20A, VA30A and VA40A. Depending on your current software version, the corresponding update will be performed as soon as it is available.

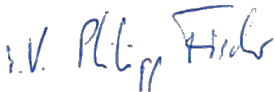
Your local service organization will contact you in due course to schedule an appropriate date for the installation. The solution will be provided to you free of charge.

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 remain vigilant until the solution has been implemented.

If you have sold your system 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 questions or technical support is required, please contact your local application specialists or your local service/sales organization.

Sincerely yours,



*Electronically
signed by: Philipp
Fischer
Reason: I am
approving this
document
Date: Jul 22,
2021 16:02
GMT+2*



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