To all users of the following software products:

syngo.via RT Image Suite
with _syngo_.via VB30, VB40, VB50 and VB60

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Customer Safety Advisory Notice SY052/21/S

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Subject: Potential loss of unsaved results when using _syngo_.via RT Image Suite

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: when editing a structure set after saving and re-opening the study, sporadically the edited countours 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 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 verfication is important because the system will not display any error message.

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How can the user help to avoid a potential risk?

For *syngo*.via VB30 and VB40, no workaround is available.

For *syngo*.via VB50 and *syngo*.via VB60, the following workaround is available: before clicking "complete", save the data using the RT navigator "Save" button (see Figure 1).
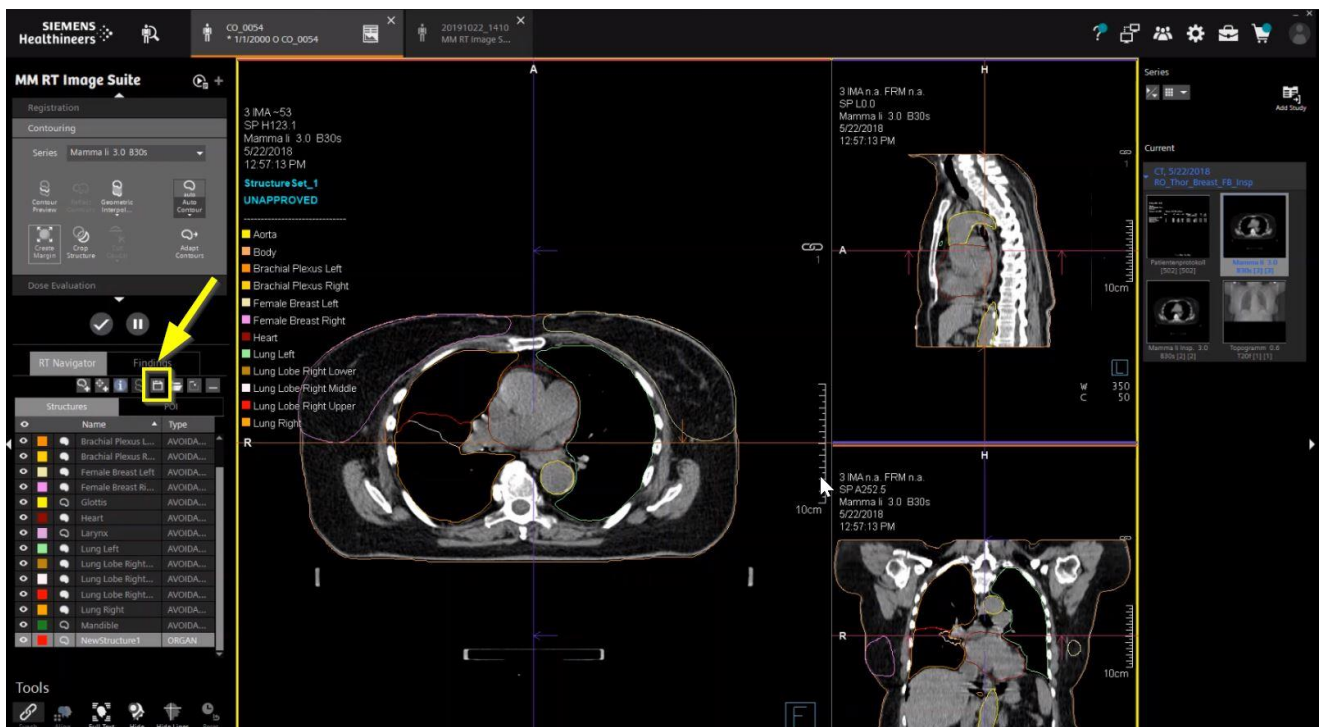
Figure 1: Save Structure Set from RT Navigator (screenshot taken from *syngo*.via VB60)

Note for *syngo*.via VB50: this workaround might result in two structure sets in the patient browser. Please check the latest timestamp to identify the most recent structure set to be sent to the archive (PACS) or your treatment planning system (TPS).

How will the issue be permanently resolved?

A solution for the issue described will be developed and distributed with high priority for the affected *syngo*.via VB30, *syngo*.via VB40, *syngo*.via VB50 and *syngo*.via VB60 systems. Depending on your current software version, the corresponding update will be performed as soon as it is available.
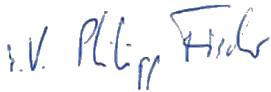
Your local service organization will contact you in due course to schedule an appropriate date for the installation. The solution will be provided to you free of charge.

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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

Electronically signed by: Markus Nagel Reason: I am approving this document Date: Jul 22, 2021 12:13 GMT+2

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