

Siemens Healthcare GmbH, SHS DI CT QT, Siemensstr. 1, 91301 Forchheim

To all users of the following software products:

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

Name Department

artment SHS DI CT QT

Telephone E-mail @siemens-healthineers.com

Date

Customer Safety Advisory Notice SY052/21/S

August 2021

Customer Safety Advisory Notice SY052/21/S

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.

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

WEEE-Reg.-No. DE 64872105

Chairman of the Supervisory Board: Ralf P. Thomas Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821 Siemensstr. 1 91301 Forchheim Germany Tel.: +49 (9191) 18 0 siemens-healthineers.com



## 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).

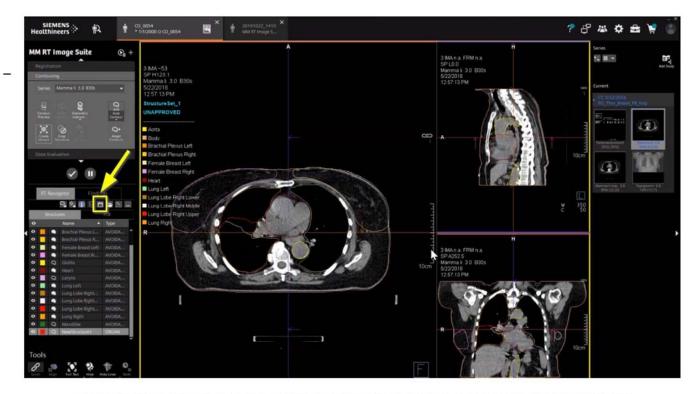


Figure 1: Save Structure Set from RT Navigator (screenshot taken from syngo.via VB60)

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,

Siemens Healthcare GmbH Forchheim Germany	Siemens Healthcare GmbH Forchheim Germany

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

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To all users of the following software products:

Name Department

SHS DI CT QT

Telephone E-mail

@siemens-healthineers.com

MAGNETOM Systems with syngo.via RT Image Suite with syngo MR VA20A, VA30A and VA31A with licence SW-Key
CT\_RT\_IMA\_SUITE\_SYNTHETIC\_CT

Date August 2021

Customer Safety Advisory Notice MR019/21/S

Customer Safety Advisory Notice MR019/21/S

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

Chairman of the Supervisory Board: Ralf P. Thomas Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821 WEEE-Reg.-No. DE 64872105 Allee am Roethelheimpark 2 91052 Erlangen Germany Tel.: +49 (9131) 84 0 siemens-healthineers.com



#### How can the user help to avoid a potential risk?

For affected scanners running on software version syngo MR VA20A, no workaround is available.

For affected scanners running on software versions syngo MR VA30A and VA31A, 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 affected scanners running on software versions syngo MR VA30A and VA31A: 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).

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Sincerely yours,



## 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 MR VA20A, VA30A and VA31A. 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.

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Siemens Healthcare GmbH
Forchheim
Germany

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Forchheim
Germany

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Siemens Healthcare GmbH, SHS DI CT QT, Siemensstr. 1, 91301 Forchheim

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

Name
Department SHS DI CT QT

Telephone E-mail @siemens-healthineers.com

Date August 2021

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 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 / 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 verfication is important because the system will not display any error message.

Siemens Healthcare GmbH

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

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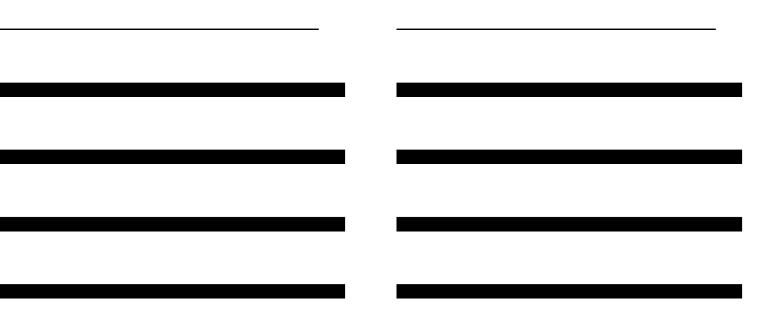
# How can the user help to avoid a potential risk?

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)



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## 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.

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Sincerely yours, Siemens Healthcare GmbH Siemens Healthcare GmbH Forchheim Forchheim Germany Germany

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