

Siemens Healthcare GmbH, SHS DI CTQT, Siemrnsstr 1, 91301 Forchh m

Name
Department SHS DI CTQT

To all users of the following software products:

Telephone
E-mail

syngo.via RT Image Suite
with syngo.via VB30 and syngo.via VB40 software
with licence for patient marking with external lasers
(technical name of the license:
"CTRRT IMAGE SUITE PAT MARK")

Date
August 2020

Customer Safety Advisory Notice SY051/20/S

SOMATOM go. CT Scanners with
syngo.RT Image Suite
with syngo.CT VA20A, syngo.CT VA30A
with licence for patient marking with external lasers
(technical name of the license:
"CT RT IMAGE SUITE PAT MARK")

Customer Safety Advisory Notice SY051/20/S

Subject: Incorrect calibration offset between CT central image plane and external lasers after update/upgradepotentially resulting in an unprecise cancer treatment

Dear Customer,

This letter is to inform you about an incorrect parameter in the laser bridge configuration of your syngo.via RT Image Suite after performing one of the below listed updates or upgrades. Please follow the provided workaround to avoid a potentially incorrect patient treatment.

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

The calibration offset between the central CT image plane and the external RT lasers has been set automatically to the factory default of 50.00 cm, if your syngo.via RT Image Suite has been updated or upgraded to one of the following software versions:
- syngo.CT VA20A to syngo.CT VA30A
- from any lower syngo.via SW-version to syngo.via VB40

New installations with the listed software versions are not affected since the initial calibration has been performed already based on this current software version.

If the misadjustment of the offset value is not recognized during the subsequent treatment planning process or remains undetected during the position verification at the treatment system (e.g. linear accelerator,) this can potentially result in an unprecise treatment (dose applied to the wrong location).

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

How can the user help to avoid a potential risk?

In addition to the already provided recommendation in your user manual (see warning in Figure 1 below), we highly recommend performing the laser calibration and the quality assurance procedure for the laser offset after every RT Image Suite software update.

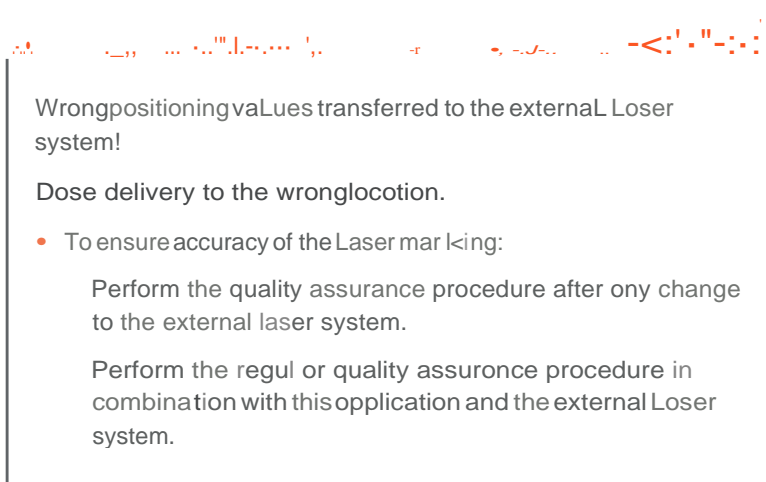


Figure 1: Warning on page 28 (English version) of user manual *syngo.via RT Image Suite* (Print No. C2-via-RT.621.03.03.02)

Please update the calibration offset in the MM RT Image Suite Configuration dialog accordingly as shown below in Figure 2. Details of this procedure are documented in Chapter 13.2 (Laser configuration) of your user manual.

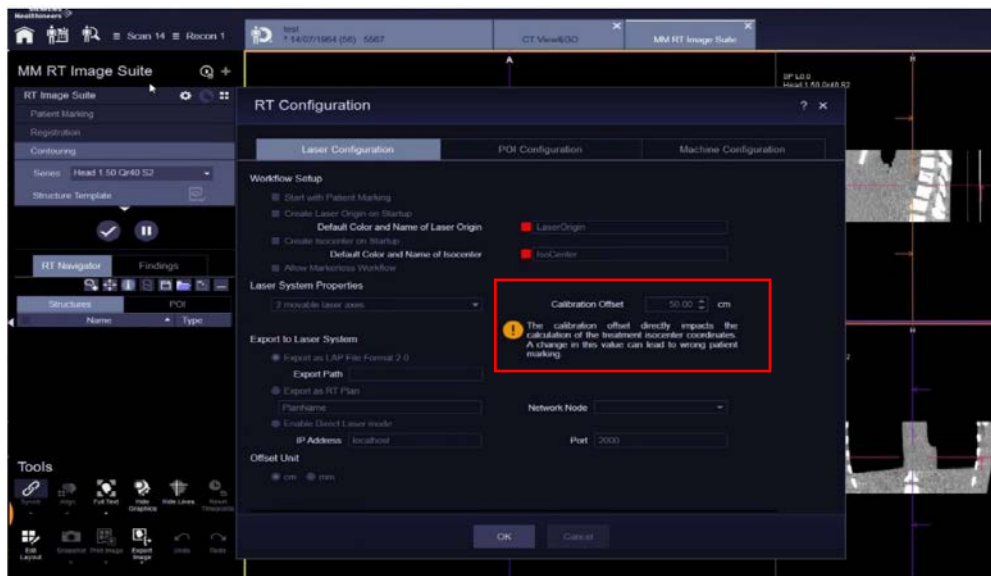


Figure 2: MM RT Image Suite Configuration dialog with the marked parameter

If you need any further support during the calibration, please contact your local service center.



How will the issue be resolved permanently?

The rollout of the update/upgrade packages has been stopped for affected systems.

The described issue has already been corrected with the update package to syngo.via VB408_HF01. All other update packages will not be rolled out via remote connection anymore, but with support by your local service organization.

If the calibration of the laser system has already been performed after the SW update and the offset value is correctly adjusted, please ignore this letter.

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,

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