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To all users of the following software products:

syngo.via RT Image Suite running on servers with syngo.via VB60 software after upgrade CT scanners with syngo.CT VA40A after upgrade

Customer Safety Advisory Notice CT004/22/S

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Subject: Silent change of default Patient Marking workflow setting after upgrading to new RT Image Suite version with syngo.via VB60 or syngo.CT VA40 software

Dear Customer,

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

In RT Image Suite versions prior to syngo.via VB60 / syngo.CT VA40, the Workflow Setup “Allow Markerless Workflow” was deactivated by default in the Laser Configuration settings (c.f. fig.1 below, left column). After upgrading RT Image Suite to VB60, this setting is automatically, and without explicit notification, changed to “Markerless workflow” in the new “Workflow Type” section in the Laser Configuration settings with VB60 (c.f. fig. 1 below, right column).

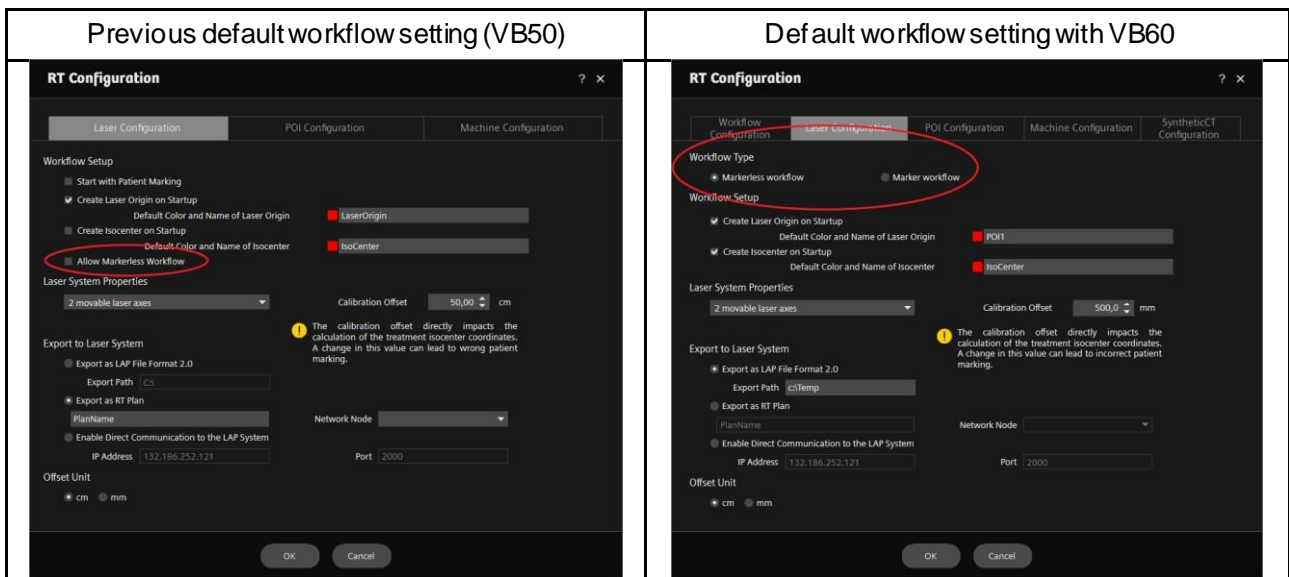


Fig. 1: Comparison of default workflow setting in VB60 and previous versions (example: VB50).

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If a marker-based workflow was used prior to the upgrade, then following the upgrade the laser offset coordinates in the Patient Marking step are no longer calculated based on the marker position. If the radiopaque markers are not placed at the laser zero position as described in the "Instructions for Use" (IFU), this may lead to the wrong laser offset coordinates being displayed in the Patient Marking step.

How can the user help to avoid a potential risk?

After upgrading RT Image Suite to VB60, please check the Laser Configuration settings in the RT Configuration and adjust the Workflow Type according to your actual workflow. Additionally, it is generally recommended that you "perform a quality assurance procedure after any change to the external laser system or any change to the software application" (c.f. IFU chapter 2.6 and 4) to ensure that the laser coordinates are correctly calculated.

How will the issue be permanently resolved?

It is sufficient to check that the default Workflow Type is correct. There is no technical update needed.

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.

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 questions or need technical support, please contact your local application specialists or your local service/sales organization.

Sincerely yours,

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