

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

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

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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).

Previous default workflow setting (VB50)	Default workflow setting with VB60
RT Configuration ? ×	RT Configuration ? ×
Laser Configuration POI Configuration Machine Configuration	Workflow Each Configuration POI Configuration Machine Configuration SyntheticCT Configuration
Workflow Setup Start with Patient Marking Create Laser Origin on Startup Default Color and Name of Laser Origin Create Loser origin and taser of Laser Origin Create Loser origin of Laser Origin Create Loser or Startup Create Laser System Properties Zmovable laser aves Calibration Offset 50,00 ° cm The calibration offset directly impacts the	Workflow Type
Export to Laser System Coordinates. Calculation of the treatment isocenter coordinates. A change in this value can lead to wrong patient marking. Export Path Col Export Path Col	Export to Laser System A clarage in this value can lead to incorrect patient Export as LAP File Format 2.0 Export as LAP File Format 2.0 Export as IT Phate Export as IT Phate Export as IT
Plantkame Network Node Enable Direct Communication to the LAP System	Plantame Plantame Plantame Plantame Enable Direct Communication to the LAP System
P Address 132.186.252.121 Port 2000 Offset Unit € cm ● mm	IP Address 132.186.252.121 Port 2000 Offset Unit
OK Canel	OK Cancel

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

Siemens Healthcare GmbH

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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 *synga* 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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