

To all users of SIEMENS SOMATOM:

**go.Now
go.Up
go.All
go.Top**

running syngo CT VA20A SP4a

or syngo CT VA20A SP5

Regional Unit Contact

Name: [Last name, First name]
Department: [department]
Telephone: [your phone number]
Email: [your e-mail address]
Date: [date of signature]

Customer information letter CT050/21/S

Customer Notification

Dear Customer,

This letter is to inform you of new device software update on CT products.

CT049/21/S is remote update for the following products running with software versions *syngo CT VA20A SP4a* or *syngo CT VA20A SP5*:

SOMATOM go.Now	(Model #11061610, #11061612, #11061613, #11061618),
SOMATOM go.Up	(Model #11061620, #11061622, #11061623, #11061628),
SOMATOM go.All	(Model #11061630, #11061632, #11061638),
SOMATOM go.Top	(Model #11061640, #11061642, #11061648) without dual energy post-processing.

CT022/21/S is onsite update for the following product running with software versions *syngo CT VA20A SP4a* or *syngo CT VA20A SP5*:

SOMATOM go.Top (Model #11061640, #11061642, #11061648) with dual energy post-processing

What is the problem?

Some technical issues have been identified in certain software versions mentioned above, and these issues may result in sporadic problems causing scanning workflow interruptions and unexpected user notifications. Sporadic software errors may also occur during interventional workflows.

What are the potential patient issues?

Delay in diagnosis or scan abort and patient rescan during interventional procedure may occur with the mentioned software versions.

What steps can the user take to avoid the issue?

There are no workarounds available for the identified issues.

How will the issue finally be resolved?

Siemens Healthineers has developed software update CT VA30A_SP4 to ensure uninterrupted scanning workflows and reduce the number of user notifications.

This update will also provide workflow improvements, bug fixes for performance and stability problems observed in installed base.

The corrective action will be provided free of charge and will be distributed via one of the following update packages:

CT049/21/S, CT022/21/S.

How will the corrective action be implemented and how effective is the corrective action?

The update **CT022/21/S** will be performed onsite and the update and **CT049/21/S** will be performed remotely. The software update process will require approximately 180 minutes for completion.

Please make sure the system and power are stable before and during the process. Please do not switch off the system during the update process. Siemens highly recommends starting the installation when the scanner is not in use or when the necessary time for the update to be completed can be scheduled.

If you have any questions, please contact our service organization at **[local service phone-number]**.

We appreciate your understanding and cooperation and request that you promptly notify and instruct accordingly all the staff at your organization who need to be aware of this notice. In addition, if you have further distributed this product, please identify your customers and notify them at once of this product advisory notice. If the device has been sold and is therefore no longer in your possession, please forward this notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

This recall is being made with the knowledge of your national competent authority (e.g. TGA or FDA).

Thank you for your continued support.

[This information letter has been created digitally and is valid without signature.]