

To all users of SIEMENS SOMATOM:

go.Now
go.Up
go.All
go.Top
go.Fit
go.Sim
go.Open Pro
X.cite
running *syngo CT VA30A SP4*

Regional Unit Contact

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Date: [date of signature]

Customer information letter CT010/22/S

Customer Notification

Dear Customer,

This letter is to inform you of a new device software update to software version VA30A_SP5 on CT products.

CT008/22/S is remote update for the following products running with software versions *syngo CT VA30A SP4*:

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),
SOMATOM go.Fit	(Model #11061788),
SOMATOM go.Sim	(Model #11061660, #11061668),
SOMATOM go.Open Pro	(Model #11061670, #11061678),

CT088/21/S is remote update for the following product running with software version *syngo CT VA30A SP4*:

SOMATOM X.cite (Model #11330001)

What is the problem?

Some technical issues have been identified in software version *syngo CT VA30A SP4*, and these issues may result in sporadic problems causing scanning workflow interruptions, unexpected user notifications and image artifacts. Sporadic software errors may also occur during interventional workflows.

What are the potential patient issues?

Technical issues found in current software might lead to the following potential patient issues:

- possible rescan due to degraded image quality. No misdiagnosis has been reported to Siemens regarding this issue until today;
- unexpected radiation and additional contrast media due to repeated intervention scan caused by inaccurate position;
- delay in diagnosis, scan abort and patient rescan.

What steps can the user take to avoid the issue?

Please install the update as soon as possible.

How will the issue finally be resolved?

Siemens Healthineers has developed software update *syngo* CT VA30A SP5 to ensure a more stable scanning workflows, to reduce the number of user notifications, to further improve the image quality and to reduce image artifacts.

This update will 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, depending on your systems:

CT008/22/S, CT088/21/S.

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

The remote 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.]