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**To all users of SIEMENS SOMATOM On.Site:
running on syngo CT VA35A**

Customer Advisory Notice CT023/21/S

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Subject: Technical issues with SOMATOM On.Site CT scanners running on syngo CT VA35A, solved with the new service pack V35A_SP1

Dear valued Customer,

This letter is to inform you about software issues we have identified in the current syngo CT VA35A software running on your SOMATOM On.Site CT scanner and a planned software update to correct these issues.

When does the malfunction occur and what is the problem?

Sporadically, the USB communication between the Lenovo tablet and the drive camera can be disturbed, and the touch UI application may therefore be terminated unexpectedly.

In addition to this malfunction, we would like to inform you about recently noticed deviations of the SOMATOM On.Site CT scanner from its descriptions in the datasheet and user documentation:

Field of View (FoV):

For recon orientations other than axial, the scanner software only allows a limited FoV. The maximum FoV depends on the pitch setting. For example, a pitch of 0.55 allows a FoV of 224 mm, rather than the specified 260 mm. For axial reconstructions, the specified FoV of 260 mm is available. As a consequence, if optimal patient positioning is not possible (due to anatomical or specific disease-related reasons), certain scan areas may not be correctly visualized at the edge of the CT image.

FAST 3D:

Furthermore, image reconstructions based on our "FAST 3D" functionality might be limited* and the automatic alignment of images is impaired, so the alignment must be done manually.

* The FAST 3D algorithm might not detect the respective landmarks needed for automatic image rotation, compromising subsequent postprocessing steps.

How can the operator help to avoid the above-mentioned issue?

Termination of Touch UI application:

On syngo CT VA35A, the scanner can be used without the drive camera. Thus, to avoid the described issue, the camera device can be deactivated in the Windows 10 device manager. Your local service engineer will support you with this workaround.

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WEEE-Reg.-No. DE 64872105

Field of View (FoV):

Special attention needs to be paid to the correct patient positioning to prevent potential shortcomings of a limited FoV. Please find more information on patient positioning and scan planning in the scanner's Instructions for Use / Chapter 8.

The attending physician should be advised to pay particular attention to the correct positioning of patients during scanner operation, as this will reduce the potential effects of a limited FoV.

FAST 3D:

The scanner can be used without FAST 3D. Until *syngo* CT VA35A_SP1 software version is released, FAST 3D must be manually deactivated in scan protocols. With *syngo* CT VA35A_SP1 software version, FAST 3D will be deactivated automatically. To compensate for the missing functionality, Inline Results parallel ranges can be activated. An alternative is to reconstruct series offline in the Advanced Mode or with local postprocessing/PACS solution (e.g., *syngo.via*).

Your local application specialist will support you with this workaround.

- These measures aim to enable the attending physician to make a careful decision on the appropriateness of scanning a patient with a certain clinical image using SOMATOM On.Site despite limited FoV and avoiding multiple scans of one patient because of the currently limited FoV.

How will these issues be permanently resolved?

This issue will be solved by an improved *syngo* CT VA35A_SP1 software version. A service pack will be rolled out free of charge with the update CT017/21/S for all affected scanners. Its release is planned for the end of Q3/2021. All future service packs will contain this fix as well.

We appreciate your cooperation with this Customer Advisory Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this Customer 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 SOMATOM CT scanner and/or it is no longer in your ownership, we kindly ask you to immediately forward this Customer Advisory Notice to the new owner of the CT scanner. Please also inform us of the identity of the new owner of the CT scanner.

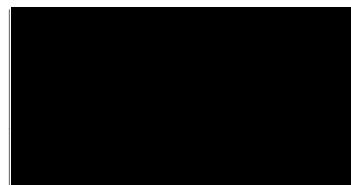
If you have any questions or if you require technical support, please contact your local application specialists or your local service/sales organization.

Sincerely yours,



*Electronically
signed by: Philipp
Fischer
Reason: I am
approving this
document
Date: Jun 16,
2021 11:11
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Head of CT
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