

Siemens Shanghai Medical Equipment Ltd., HC DI CT QT CN
No. 278 Zhou Zhu Rd. Pudong New Area, Shanghai P.R.China

To all users of the

SIEMENS SOMATOM go.Up
SIEMENS SOMATOM go.Now

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CC: Chairman of Medical Board & Heads
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Safety Advisory Notice CT013/18/S

Customer Safety Advisory Notice CT013/18/S

Re: SOMATOM go.Up and SOMATOM go.Now – Risk: Patient rescan might become necessary

Dear customer:

This letter is to inform you about the potential risk of a patient rescan due to 3 sporadic software issues.

When does the malfunction occur and what is the problem?

Topic 1: We have observed sporadic software stability problems preventing the start of a reconstruction after the CT examination. If these problems occur, this is indicated by a red cross in the "Job Status" table (see example in Fig. 1 on page 2).

Topic 2: We have become aware of very sporadic problems with an impact on image quality. If the detector is still in adjustment mode at the time the scan command is provided from the control box, severe streak artifacts may occur. We were able to reproduce this issue with the following workflow: Within only 12 seconds we changed the kV/mA settings repeatedly and immediately pressed the "Start" button on the control box.

Topic 3: Only for customers using *syngo* Osteo CT: If the scan/recon tab card is closed after an osteoporosis scan of a patient but before the intended Osteo reconstruction has been completed, the Osteo reconstruction cannot be continued or completed at a later point in time. In this case, a rescan would be necessary to complete the Osteo reconstruction.

Depending on your specific workflow, aborting the scan process, image quality or reconstruction issues may require an additional scan that exposes the patient to an additional X-ray dose. It cannot be excluded that (additional) X-rays will have a negative effect on patients.

How can the operator help to avoid a potential risk of the system?

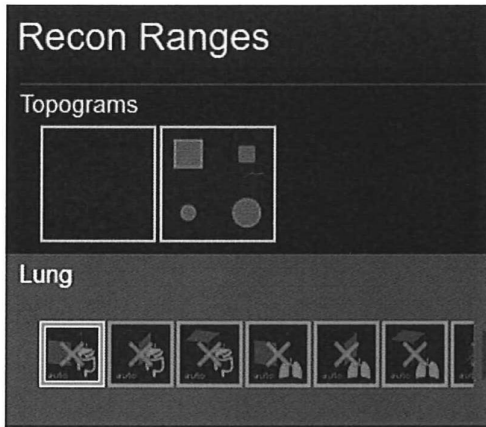
To avoid an unnecessary additional X-ray dose to patients please observe the following instructions:

Topic 1: If a reconstruction cannot be started after an examination, please reboot the system and repeat the aborted reconstruction. If the error persists, please contact your local Siemens Healthineers service support team. They can help you to decide whether a rescan is necessary or not.

Topic 2: If you change the scan parameters kV or mA (tube HV or current), please wait for at least 12 seconds before you trigger a scan command on the control box. If artifacts are visible in the topogram, please repeat the topogram before starting the volume scan. If you have started a volume scan and detect artifacts in the real time display, please stop the scan immediately to avoid an unnecessary X-ray dose.

Topic 3: After an osteoporosis scan has been completed, the Osteo reconstruction needs to be started and completed directly after the scan. Therefore the images should be loaded and checked in "CT View&Go" – before the scan/recon tab card is closed. Please do not close the scan/recon tab card before you have reconstructed and checked all Osteo images.

A successful and complete Osteo reconstruction is visualized by full green bars in the column "Recon Progress" of the "Job Status" table and by images including the Osteo phantom in the tab card "CT View&Go" (for details please see Fig. 3 below). An example of a correct Osteo reconstruction is provided in Fig. 2. After checking the successful and complete Osteo reconstruction you may close the scan/recon tab card.



[Fig. 1]
Screenshot example "Job status" – no reconstruction possible



[Fig. 2]
Example of a successful reconstruction for later use in syngo Osteo CT



[Fig. 3]
GUI screenshot with Recon Progress bar

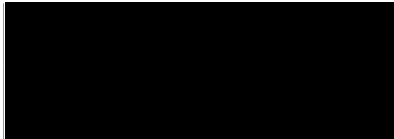
What has been done to address these issues? What actions shall be taken by the user?

The stability and image quality issues mentioned are solved by the software updates VA10A_SP2 and VA20A. The Osteo reconstruction issue is solved with the VA20A software update. The respective upgrade of your system is scheduled for the second half of this year 2018. You will be informed as soon as the update(s) are available for your system.

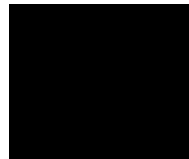
We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is included in the medical device's instructions for use. Your personnel should maintain awareness of these issues until your system has been upgraded.

If you have sold this medical device and it is no longer in your possession, we kindly ask you to forward this safety advisory notice to the new owner of this device. In addition, please inform us about the new owner of the device.

Sincerely yours,



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