

CC: Chairman of Medical Board
& Heads of Departments



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To all users of the following software products:

SOMATOM Force
SOMATOM Definition AS
SOMATOM Definition Edge
SOMATOM Definition Flash
SOMATOM Drive
SOMATOM Confidence
SOMATOM Edge Plus
with software *syngo* CT VB10A

Customer Safety Advisory Notice CT035/19/S

Customer Safety Advisory Notice CT035/19/S

Subject: Potential safety related software issues in *syngo* CT VB10A software running on several types of SOMATOM CT scanners – Potential safety related issues solved in *syngo* CT VB20 software

Dear Customer,

This letter is to inform you about four safety related software issues we have identified in the current *syngo* CT VB10A software version running on your SOMATOM CT scanner. We would also like to inform you about a planned software update to correct these issues.

When do the malfunctions occur and what are the problems?

The following technical issues have been identified in the *syngo* CT VB10A software running on your SOMATOM CT scanner. Each of them might result in a scan abort with the necessity to perform a rescans and/or in a delayed diagnosis:

- 1.) Due to a software error the local database capacity reaches its limits faster than this was the case with previous software versions. We have identified some elements that remain on the hard drive even though a user has cleaned (deleted) outdated patient data. Furthermore, the complete database deletion can only be performed via a command prompt with administrator privileges as the security measures in the *syngo* CT VB10A software have been increased.
- 2.) For SOMATOM Force users only: When planning a "Turbo Flash" spiral scan, the examination task card may lock up. This can occur if a "Care Contrast" scan contains a pre-monitoring scan, a contrast sequence monitoring scan and a "Turbo Flash" spiral scan with a high pitch (>2.3).
Details: After the pre-monitoring scan, the operator selects a ROI and clicks <Accept>. Due to the high pitch (or the high table speed) of the "Turbo Flash" spiral scan, a table test move is proposed to the operator. After clicking <Start>, the system issues a request to press the <Move> button. When the <Move> button is pressed, nothing happens but the table test move dialog pops up again. The exam task card then locks up, if the <Start> button is pressed a second time.
- 3.) The series description changes unexpectedly very sporadically.
Details: For example, the operator performs a head examination followed by an abdomen scan. After the scans are completed, the abdomen series description is sometimes overwritten with the description

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of the previous examination . If the operator does not recognize this change and starts the recon job immediately, the series description cannot be changed back again.

- 4.) The systems may sporadically crash during an interventional workflow using the cut functionality. Details: This issue can happen when the following conditions are fulfilled. An Intervention examination is already started and an i-mode (i-spiral, i-sequence, i-fluoro) is loaded. In this situation the chronicle context menu option <Cut> will lead to a software crash. For details see Fig. 1 below.

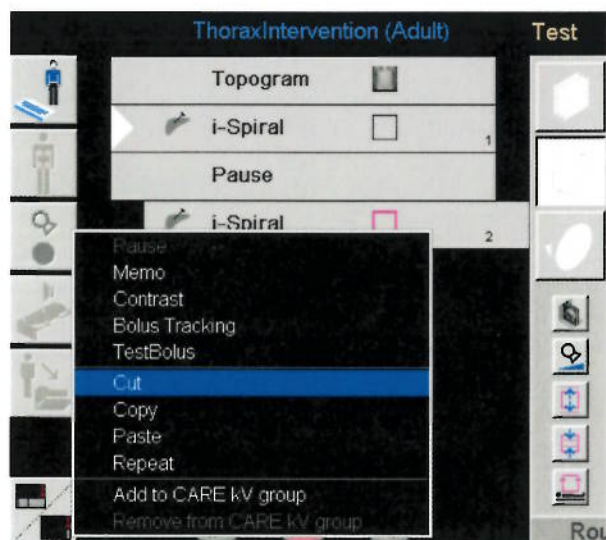


Fig. 1: Example of how issue 4 may occur.

How can the operator help to avoid potential risks?

We can provide the following recommendations to avoid the issues mentioned above:

- 1.) Local database capacity reaches its limits: Please schedule an appointment with your local service organization to delete the local database on a regular basis. The recommended frequency of this task depends on the individual workload.
- 2.) The examination task card may lock up during a "Turbo Flash" spiral scan. In order to avoid such a lock-up, two solutions exist:
 - a. The pitch can be reduced so that the table test move becomes obsolete and is not proposed to the operator any more. This consequently means the examination is no longer a real "Turbo Flash" spiral scan.
 - b. The table test move is not a must and can be skipped. If this workaround is chosen, the operator must be particularly cautious and make sure that there are no obstacles in the way of the table top movement. The high table top speed during such examinations makes it impossible to stop the movement within the usually required 25 mm. The travel distance before and after the scan may be up to 400 mm. The corresponding dialog is shown in Fig. 2 below.

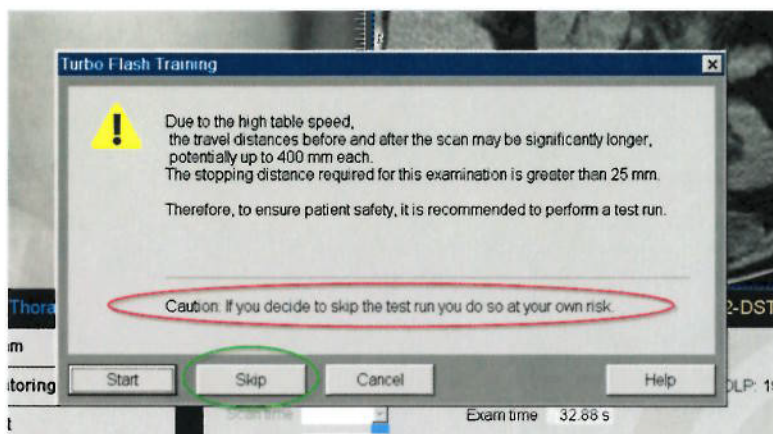


Fig. 2: Table test dialogue with warning if skipped

- 3.) The series description changes unexpectedly: To avoid this highly sporadic issue, the operator should check the series description for any unexpected changes after the scans have been completed and before the recon jobs are started. It can be changed back manually if the recon has not yet started.
- 4.) Crash during interventional workflow: After the software crash, a system restart is needed. To prevent this happening, the loaded Intervention examination has to be canceled (press <Cancel> button) before a chronicle entry is cut.

How will these issues be permanently resolved?

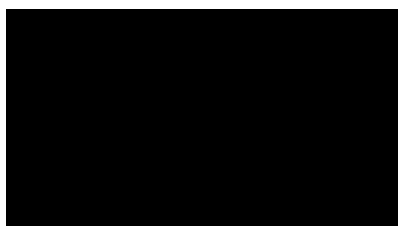
These issues will be resolved with the next *syngo* CT VB20 software version. Its release is planned for Q4/2019.

We appreciate your cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the medical device's Instructions for Use. Your personnel should remain aware of the situation until the solution has been implemented.

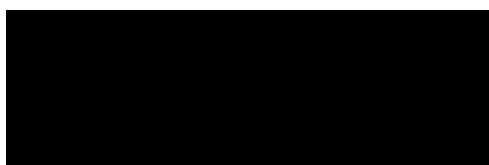
If you have sold your SOMATOM CT scanner and/or it is no longer in your ownership, we kindly ask you to immediately forward this safety advisory notice to the new owner of the CT scanner. Please also inform us of the identity of the new owner of the CT scanner.

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

Sincerely yours,



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