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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 VB20 or *syngo* CT VB10

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Customer Safety Advisory Notice CT070/19/S

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Subject: Several types of SOMATOM CT Scanners running on *syngo* CT VB20 or *syngo* CT VB10 – Potential safety-related issues solved in *syngo* CT VB20 Service Pack 1 and *syngo* CT VB10 Service Pack 2

Dear Customer,

This letter is to inform you about two safety-related software issues we have identified in the current software version *syngo* CT VB20 or *syngo* CT VB10 running on your CT scanner. We would 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 software version *syngo* CT VB20 and *syngo* CT VB10. Potentially all the issues can result in scan aborts, necessary rescans or in delayed diagnosis:

1.) The system may sporadically crash during a 3D interventional procedure when using a 3D I-spiral or a 3D I-sequence scan with an active 3D layout. After the software crash, a system restart is needed.

2.) The system may crash during an interventional workflow using the "Cut functionality". This issue was already present in the previous software version *syngo* CT VB10, was improved with software version *syngo* CT VB20 but unfortunately was not completely rectified. It can occur if the following conditions are fulfilled: An interventional examination has already been started and either an I-sequence or an I-fluoro scan has been loaded and scanned at least once. Additionally, the entry which should be removed (Cut) must be an interventional one and it has to be the last entry in the chronicle. In this situation the menu option "Cut" will lead to a system crash. After the software crash, a system restart is needed. For details see Figure 1 below.

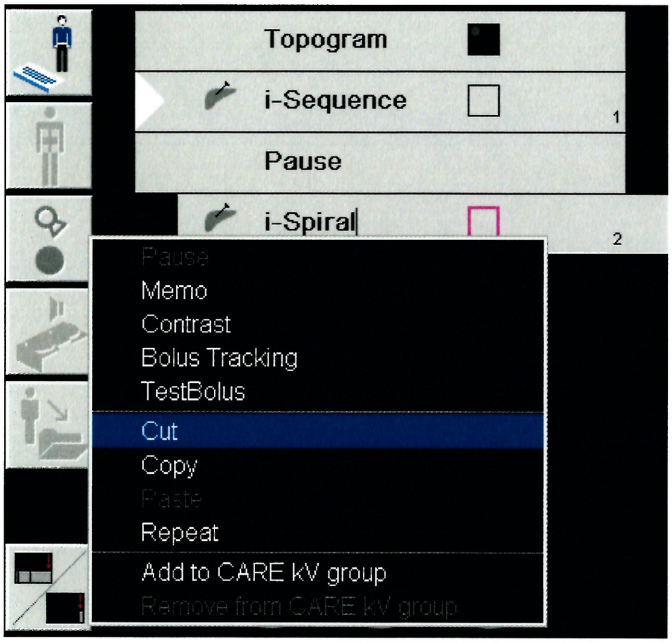

Figure 1: Example demonstrating how issue No. 2 will occur.

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

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

1.) Crash during a 3D interventional workflow:
To avoid this issue, 2D interventional scans can be used (I-fluoro scans, 2D I-sequence scans or I-spiral scans in combination with a 2D layout). Please do not use 3D I-spiral or 3D I-sequences, if they are not absolutely required for your workflow.

2.) Crash during an interventional workflow when using the “Cut” functionality:
To avoid this issue, the loaded interventional examination must be canceled (press "Cancel" button) before a chronicle entry is cut.

How will these issues be permanently resolved?

These issues will be solved with the next software version *syngo* CT VB20 Service Pack 1 and *syngo* CT VB10 Service Pack 2. Depending on the software version your system is running on and your region you will receive one of the mentioned technical updates free of charge.

We appreciate your cooperation with this Safety Advisory Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this Customer Safety 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 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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