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 Date February 10, 2019

To all users of the following
SIEMENS SOMATOM products:
 SOMATOM Confidence
 SOMATOM Definition Edge
 SOMATOM Edge Plus or
 SOMATOM Definition AS
 with Option *syngo* DE Scan for Single Source
 (Dual Spiral Dual Energy® scan mode)

Safety Advisory Notice CT0061 9/S

Customer Safety Advisory Notice CTOOG/19/S

Subject : *syngo* CT VB10A with Option Dual Spiral Dual Energy® - Risk of scan aborts and rescans

Dear Customer,

This letter is to inform you about the potential risk of scans being aborted when using the optional Dual Spiral Dual Energy® mode due to a software issue found in *syngo* CT VB10A for above listed Siemens Healthineers CT scanners with a single X-ray tube.

When does this malfunction occur and what is the problem?

In cases in which the planned Recon (Begin/End) positions for a Dual Spiral Dual Energy® scan are not specified on a 0.5 mm grid (i.e. rounded to half a millimeter), the first scan will be aborted shortly after starting and both scans will be automatically reloaded. If the operator continues the examination in this condition, the repeated Dual Spiral Dual Energy® scan will not yield the desired results. This may result in a rescan being necessary, entailing an additional X-ray dose to the patient.

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

When using Dual Spiral Dual Energy® scan protocols, the operator shall use only 0.5 mm steps for the Recon (Begin/End) positions for **all** recon jobs of the first spiral, do not use any values in between! For example, a value of 400.5 mm is OK, but a value of 400.3 mm will result in the described problem. The Recon (Begin/End) positions for the second spiral will be synchronized with the values of the first spiral. Therefore, only **all** the recon jobs of the first spiral shall be aligned to a 0.5 mm grid. As a reference, you can find the corresponding fields on the recon tab card below in Fig. 1.

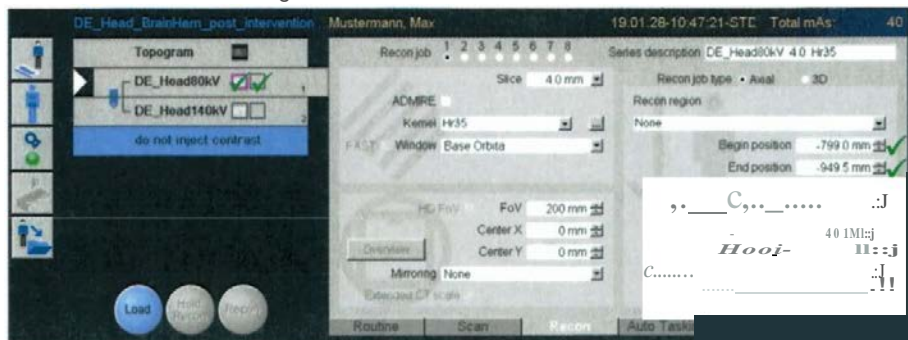


Fig. 1 Good example respecting the 0.5 mm grid (0.0 or 0.5 mm values only)

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Workaround: In the event the operator has used an invalid Recon (Begin/End) position and the first spiral has already been aborted (see Fig. 2), the operator can avoid the necessity of rescanning the second spiral by using the following workflow:

Instead of continuing, the operator shall cut the reloaded autorange (cutting the first scan is sufficient)!

Afterwards the operator shall append the desired autorange from the patient model dialogue! The topogram can be skipped in this case. Before starting the scan process again, the operator shall check that all Recon (Begin/End) positions are on a 0.5mm grid (see Fig. 3).

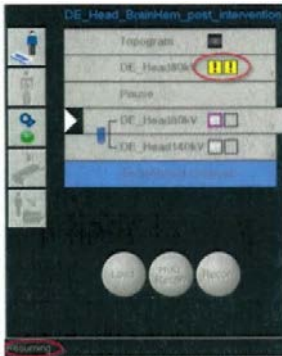


Fig. 2 - Abort situation

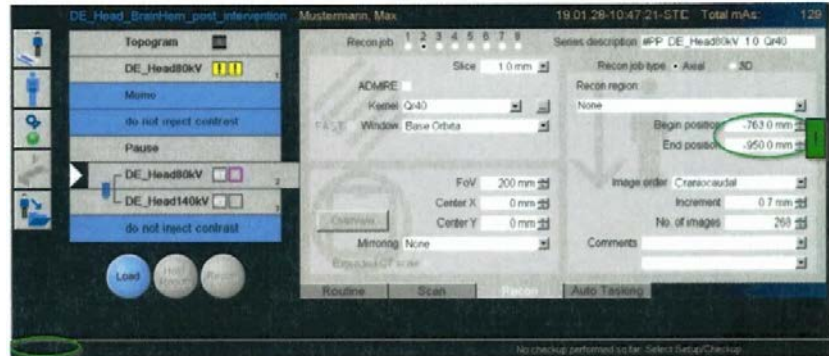


Fig. 3 - Appended Recon range with 0.5 mm aligned Begin/End positions

How will the issue be permanently resolved?

The issue will be resolved by the software update *syngo* CT VB10A_SP1 (Service Pack 1), which is scheduled to be released in March, 2019. You will be informed as soon as the update is available for your system.

We appreciate your cooperation with this advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this 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 under your ownership, we kindly ask you to forward this 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.

Sincerely yours,