

Siemens Healthcare GmbH, SHS DI CT QT QA, Siemensstr. 1, 91301 Forchheim, Germany

To all users of the following software products

myNeedle Guide 2D license
myNeedle Guide 2D AWP only Workflow license
myNeedle Guide 3D license on a

SOMATOM X.cite,
SOMATOM go.Up,
SOMATOM go.All,
SOMATOM go.Sim,
NAEOTOM Alpha.

SOMATOM X.ceed,
SOMATOM go.Open Pro,
SOMATOM go.TOP,
SOMATOM go.Now or

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 Date December 2022

Customer Safety Advisory Notice CT083/22/S

Subject: myNeedle Guide intervention application swaps orientation labels

Dear Customer,

This letter is to inform you about a potential problem which may occur in the myNeedle Guide CT Intervention application:

When does the issue become a problem and what is it about?

In the *syngo*.CT VA40 and *syngo*.CT VA50 myNeedle Guide application, the order of the orientation labels “head”, “center”, and “feet” in the axial thick slice segments are erroneously swapped in the following two cases:

- if the Recon parameter “Image order” is changed by the user from the default setting “Head to Feet” to “Feet to Head”, or
- if the Recon parameter “Mirroring” is changed by the user from the default setting “none” to any other value, this influences the parameter “Image order”, which is switched from the default setting “Head to Feet” to “Feet to Head” so that above-mentioned condition applies.

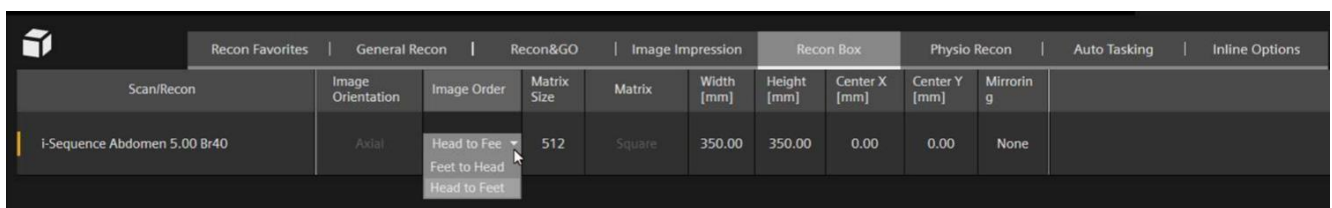


Fig. 1: Recon Parameter “Image Order” in the parameter panel.

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 WEEE-Reg.-No. DE 64872105

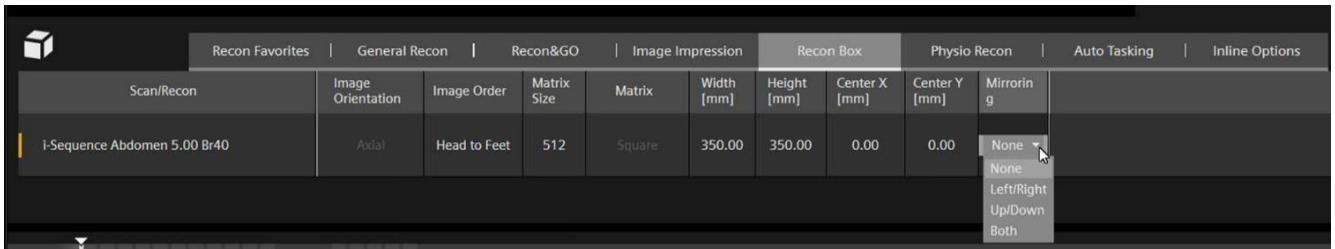


Fig. 2: Recon Parameter “Mirroring” in the parameter panel.

As a consequence, the head segment might mistakenly be labeled as “feet” and vice versa. If the wrong orientation labels are used by the interventionalist to determine the direction in which the needle has to be tilted (towards the head or towards the feet), this might result in the wrong placement and angulation of the needle, leading to potential unwanted damage to sensitive anatomical structures.

- In addition, if the “move to selected axial slice position” functionality is used to position the patient table for the next scan, and the user’s selection of segment is based on the wrong orientation label, this could lead to a scan being performed at the wrong position.

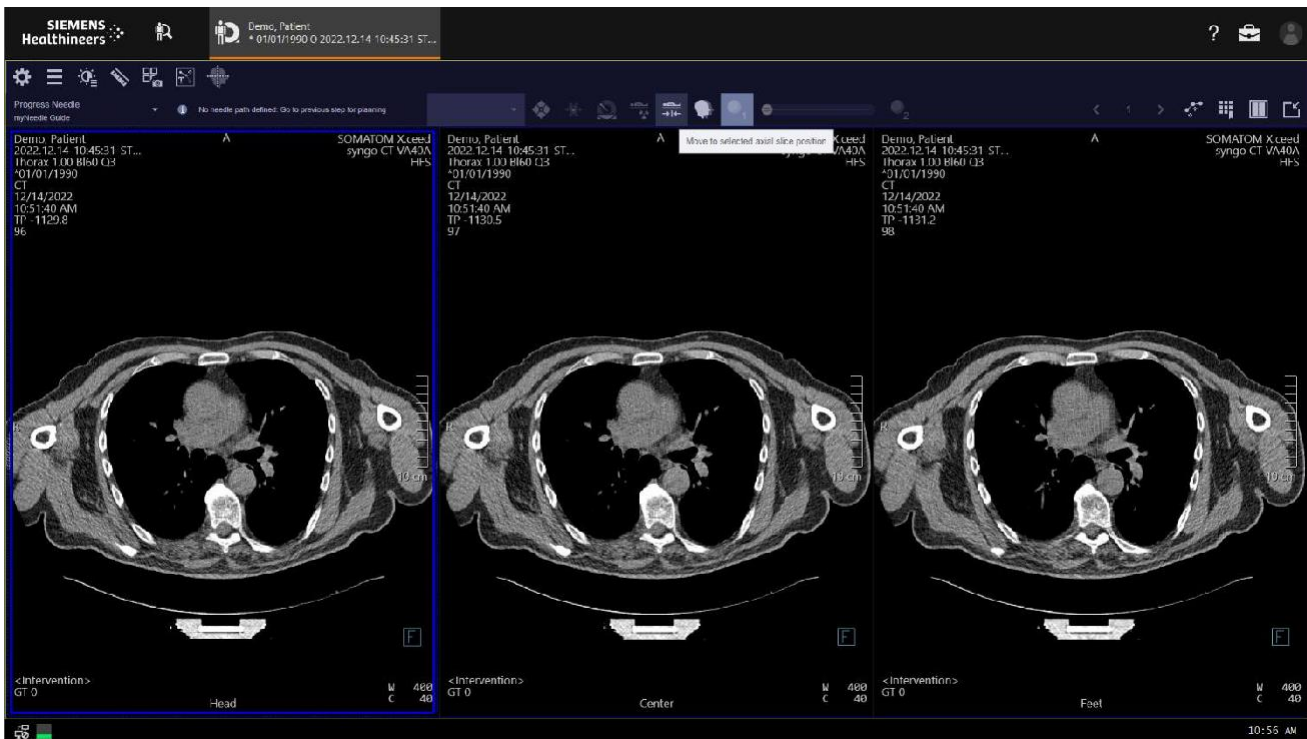


Fig. 3: Axial thick slice segments with orientation labels “Head”, “Center”, “Feet” (example shown: 2D layout) and “Move to selected axial slice position” button

How can the user help to avoid a potential risk?

When performing a CT intervention study, please make sure that the Recon parameter “Image order” is set to “Head to Feet”.

How will the issue be permanently resolved?

We are currently working on a permanent solution for this malfunction. This solution will be rolled out as a software update to your CT. Our service organization will contact you as soon as the update is available.



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.

If you have sold your system running the above-mentioned licenses and/or it is no longer in your ownership, we kindly ask you to forward this Safety Advisory Notice to the new owner of the system immediately. Please also inform us of the identity of the new owner of the system.

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

Sincerely yours,

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Signature:

*Reason: I am approving this document
Date: Dec 21, 2022 09:54 GMT+1*

Email:

Signature:

*Reason: I am approving this document
Date: Dec 21, 2022 10:54 GMT+1*

Email: