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To all users of *syngo*.via Version VB50

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CUSTOMER SAFETY ADVISORY NOTICE

To all affected users of syngo.via
Affected versions: VB50 with license MI_ONCO_LUNGCAD or MI_ONCO_LUNGCAD_EXP

LungCAD navigation tool - Correction pen may be applied to wrong nodule

Dear customer,

This letter is intended to inform you of a potential safety issue when using the correction pen of the LungCAD navigation tool in *syngo*.via.

What is the issue and when does it occur?

Corrections that are performed via the "correction pen tool" always affect nodule on which the correction tool has been activated.

If you activate the correction pen on a Lung nodule and you accept this nodule, then the system navigates to the next lung nodule and displays it. If you now correct the nodule currently displayed, then the changes are applied to the already accepted nodule, but not to the displayed nodule.

This is not as the user would expect.

The incorrect nodule is getting corrected in the LungCAD navigation tool after accepting the currently edited nodule for the 2nd time. Correction focus does not switch to the new nodule but affects previous nodule on which correction pen was invoked.

What are the possible risks to health?

The user may not realize that values are changed for an already accepted finding.

A wrong diagnosis may be possible; A wrong nodule assessment might contribute to inadequate clinical patient management.

What steps can the user take to avoid the potential risk associated with this issue?

1. Until a final solution is in place on your system, please deactivate the “correction pen” tool immediately after each single correction. Please check additionally if the volume measurement of the respective nodule has been modified. The measured volumes are displayed in Findings Assistant.

2. Please also consider, whether you have already used this functionality in MM Reading workflows. In such case please verify the affected report for the correct diagnosis and patient recommendation.

How will the issue finally be resolved?

Siemens Healthineers will resolve this issue in next version VB50B_HF02 planned to be available by June 2021.

Dissemination of the content of this notice

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein. We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

What if you no longer have this device/equipment?

If this device/equipment is no longer in your possession, please forward this Safety Advisory Notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

We regret any inconvenience that this may cause, and we thank you in advance for your understanding.

Sincerely yours,

Siemens Healthcare GmbH

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