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To all users of syngo.via CUT Version VB40A

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Customer Safety Advisory Notice

Structured Reporting, Findings Assistant: Automatic calculation of CAD-RADS proposes incorrect patient management recommendation for patients with acute chest pain

(CAD-RADS: "Coronary Artery Disease - Reporting and Data System")

Dear customer,

With this letter we would like to inform you of the potential safety issue 'Miscalculated CAD-RADS Management recommendation proposed by syngo.via might contribute to inadequate clinical patient management'.

Who is affected by the issue?
Users of *syngo.via* version VB40A_CUT, when using the automatic calculation functionality of CAD-RADS in the Findings Assistant.

What is the issue and when does it occur?
When using the body part "Cardiac Coronaries" provided by *syngo.via* VB40A_CUT Findings Assistant for the assessment of a "Coronary Artery Disease" (CAD) case, the automated calculation for the recommended Management of the patient is incorrect.
The 'Patient State' attribute indicates whether the patient has stabie or acute chest pain and is one of the major criteria for the recommended management of the patient.
However, the 'Patient State' attribute value is not correctly processed by the calculation of the management proposal: The calculation always presents the value which belongs to the stable chest pain, even when the 'Patient State' has been set to 'Acute chest pain'.

What is the possible impact?
The miscalculated CAD-RADS Management recommendation proposed by syngo.via might contribute to inadequate clinical patient management.

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Steps to take to avoid / mitigate the potential risk associated with this issue?
1. We decided to switch off the automated calculation of values for the patient management in the current CUT version installed on your system. Until this change is implemented on your system, we strongly recommend to overwrite the proposed value for the patient management recommendation with the correct management advice, following the CAD-RADS guideline (see on-line help).

2. Please also consider, whether you have already used this functionality since start of the CUT phase.
In such case please verify the affected report for the correct management advice, following the CAD-RADS guideline (see on-line help).

How will the issue finally be resolved?
Siemens Healthineers will solve this product error in the final *syngo.via* VB40A version. As a CUT customer you will automatically receive this version as soon as it is available.

Dissemination of the content of this notice
Please ensure that all users of syngo.via VB40A_CUT within your organization and others who may need to be informed will receive the safety relevant information provided with this notice.
Please add this safety advisory to your product related records.
Please keep this information at least until the VB40A version is installed on your systems.

We appreciate your understanding and cooperation with this safety advisory .
We regret any eventual inconveniences that this may cause.

Sincerely yours,

Siemens Healthcare GmbH

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