

Siemens Healthcare GmbH, SHS DI SY QT RC, Hartmannstr. 16, 91052 Erlangen

To all users of syngo.via CUT Version VB40A

Name
Department

Telephone
E-mail

Our reference
Date

PM00186366
June 19, 2019

Customer Safety Advisory Notice

syngo.via VB40A_CUT reporting functionality calculates wrong LI-RADS scores for liver reporting

Dear customer,

With this letter we would like to inform you of the potential safety issue 'reporting functionality calculates wrong LI-RADS scores for liver reporting'.

What is the issue and when does it occur?

When using the automated calculation for the LI-RADS Score evaluation inside the reporting functionality in any syngo.via workflow for liver reading and reporting, syngo.via VB40A_CUT may present too low LI-RADS score values for certain combination of input values.

What is the possible impact?

The underestimated LI-RADS score proposed by syngo.via might contribute to inadequate patient management.

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

1. We recommend to not use this functionality in the syngo.via version VB40A_CUT.
2. Please also consider, whether you have already used this functionality since start of the CUT phase. In such case please verify the original report following your clinical workflow without using the new functionality (automated LI-RADS calculation) in syngo.via VB40A_CUT version.

How will the issue finally be resolved?

Siemens Healthineers will solve the 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.

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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

