SIEMENS Healthineers

To all user of ARTIS icono systems with Quantification Application SW (QVA/QCA) on a standalone XWP computer

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Customer Safety Information (CSI) for Field Safety Corrective Action:

AX034/20/S

Subject: Customer Safety Information for ARTIS icono systems with Quantification Application software (QVA/QCA) running on a standalone XWP computer.

Dear Customer,

We would like to inform you about a potential problem of your ARTIS icono system in combination with Quantification Application (QVA/QCA) running on a standalone XWP computer.

What problem is behind this corrective action and when does the problem occur?

When using Quantification Application (QVA/QCA) on DSA images the results of various physiological properties of arteries, such as vessel diameter might be wrong. This problem does not occur when using Quantification Application (QVA/QCA) on native (non-DSA) images.

What is the impact on the operation of the system and what are the possible risks?

Besides the above described problem there is no other impact on the operation of the system. Using Quantification Application (QVA/QCA) on DSA images might lead to a failure in vessel detection or incorrect quantification of vessel detection which could result in a wrong diagnosis and in an inappropriate treatment of the patient.

How was the problem identified and what is the root cause?

The problem was identified by regular field observation. The root cause of this problem is a software error.

What measures are being taken by the manufacturer to mitigate possible risks?

The software of the affected systems will be updated.

Which steps has to be taken by the user to avoid the possible risks associated with the problem?

We recommend urgently not to use Quantification Application (QVA/QCA) on DSA images until the software problem has been solved.

What is the efficiency of the corrective actions?

The software update will mitigate the occurrence of the problem.

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How will the corrective action be implemented?

Our service organization will get in contact with you for an appointment to perform the corrective action. Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as update AX035/20/S.

What about new Products?

Measures for production have already been implemented. The software update will directly be installed on new products.

What risks are there for patients who have previously been examined or treated using this system?

If Quantification Application has already been used on DSA images in the past, please verify the results and diagnostic evaluation if applicable.

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.

Please forward this safety information to any other organizations that could be affected by this measure.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

With best regards,

i.V. Reinmar Killmann

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