

SIEMENS

Medical Solutions

To all users of the SIEMENS

AXIOM Artis products - Quantification Software
<To the person in charge of the unit where
the SIEMENS product is operated
and the administrative head of organization>

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Date2008-08-29

Customer Safety Advisory Notice

Re: AXIOM Artis systems regarding Quantification Software

Dear customer,

This letter shall inform you about a potential problem regarding the quantification SW QVA, QCA or LVA in combination with certain AXIOM Artis software versions. When performing a specific workflow images can be generated which are misleading or which contain clinically useless measurement results.

When does this problem occur and what are the potential risks?

This problem happens on AXIOM Artis systems with SW versions VB23A, VB23B, VB23C, VB23D or with SW Versions VB31A, VB31B, and VB31C. If the image on which the quantification shall be performed is exchanged (e.g. by advancing the acquired scene) after selection of one of the quantification methods QVA, QCA or LVA, and then the "Catheter calibration" is performed and confirmed, the result can be misleading or clinically useless.

How can the operator recognize the problem?

To perform "catheter calibration" it is required to select a catheter size as well as also to mark the catheter along its axis. As soon the marking of the catheter is finished (marking of the catheter endpoint has been performed), the calculated contour will be displayed. This contour must fit the contour of the catheter in the image. In case the above mentioned problem has occurred, catheter and contour will not match.

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

In case of catheter calibration method shall be used as a base for QVA, QCA or LVA quantification, the user may not alter the selected image after entering calibration method. This means the calibration image has to be selected before starting catheter calibration. Once catheter calibration is selected, the image in the scene must not be changed anymore.

How will the issue finally be resolved?

The problem is solved with the AXIOM Artis software versions VB23E and VB31E. Both versions are in the meantime released for clinical use.

Siemens will upgrade all installed AXIOM Artis systems with the concerned SW versions VB23A, VB23B, VB23D or VB31A, VB31B, and VB31C to the corrected versions VB23E and VB31E during the next months.

This upgrade is free of charge and does not need to be ordered separately.

We appreciate your understanding and cooperation with this safety advice and ask you to immediately instruct your personnel accordingly. Please ensure that this Customer Safety Advisory Notice is placed in the System's instructions for use. Your personnel should maintain awareness of this issue during this time.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

We ask you to confirm that you received this letter by signing the attached form and sending it back to us.


~~Local contact information within the respective RO:~~

Sincerely Yours

2008-08-29



Director Solution Segment Cardiology



Safety Officer

Siemens AG
Healthcare Sector
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Hermann Requardt, Siegfried Russwurm, Peter Y. Solimssen
Sitz der Gesellschaft: Berlin und München; Registergericht: Berlin Charlottenburg, HRB 12300, München, HRB 6684
WEEE-Reg.-Nr. DE 23691322

Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of the AXIOM Artis with the Serial number _____ that I received the following document:

Customer Safety Advisory Notice

AXIOM Artis with reference to Quantification Software
Version VB23A, VB23B, VB23C, VB23D, VB31A, VB31B or VB31C

Place, Date _____

Name _____

Signature _____

Siemens AG
Healthcare Sector
Leitung: Jim Reid-Anderson

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Hermann Requardt, Siegfried Russwurm, Peter Y. Solmsen
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