Leiden, December 10, 2024

Our ref. : 24M0001
Re. : FIELD SAFETY NOTICE: Important notification for users of QAngio XA and QAngio XA 3D

Dear Customer,
Recently, it has been brought to our attention that for certain Siemens XA image acquisitions, the isocenter calibration value calculated by Medis applications can be incorrect due to an unexpected value for “distance source to patient” that is saved by Siemens in the standard DICOM attribute (0018,1111). The appropriate value to be used by the Medis applications is “distance source to isocenter” which is stored in a Siemens private attribute (0021, xx17, “SIEMENS SMS-AX ACQ 1.0”) in the DICOM data.

All relative results (%diameter stenosis) are not affected. The derived result QFR is only slightly affected.

However, this deviation of the calibration value will directly impact all absolute measurement results of the Medis applications (in mm, vessel diameter, lesion length, etc.). In house testing by Medis on a set of 51 (clinical) Siemens data sets (102 images) show an average difference of the absolute results of 2-3%, with a few outliers of max 15% (both under and over estimation).

In absolute terms, a deviation of 2-3% represents +/- 0.1 mm (not clinically relevant) but a 15% deviation represents +/- 0.5 mm. We have discussed this issue with a practicing clinician who stated that the +/- 0.5 mm can be clinically relevant for the choice of stent or balloon.

Conditions under which the error can occur: Siemens equipment used, table height changed during procedure, operator activates the creation of an updated DICOM image with new distance information, QCA analysis performed using isocenter calibration (instead of the more accurate catheter calibration) that produces an outlier result (2 out of 51 cases in our study), clinician takes wrong decision based on the QCA results, wrong decision results in patient harm.

No reports related to this issue have been received from the field.

Although simultaneous occurrence of these conditions is rare in practice, out of an abundance of caution, we want to inform our customers through this Field Safety Notice of this situation and will offer them a corrected version of the Medis application. However, when you have experienced any measurement on a patient that might have been negatively influenced by this issue, please contact Medis directly (see for contact details below).

This issue has been reported to the Dutch Health and Youth Care Inspectorate (IGJ) and other regulatory authorities where applicable.

If you work with QAngio XA 8.0 / 8.1 or QAngio XA 3D 2.0, 2.1 or 2.2, we request you to install the new version of the software as soon as possible. We apologize for the inconvenience this may cause.
NB. Please take care to distribute this Field Safety Notice to all employees in your organization that work with any of these Medis products!

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If you have any questions, you can contact the Medis support desk by mail (support@medisimaging.com) or by telephone (North America and Mexico: +1 919 278 7888, other countries: +31 (0)71 522 32 44).

Yours sincerely,

[redacted]
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M. Munassor, M.Sc.
QA Manager

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Bob Goedhart, Ph.D.
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