ITH icoserve
technology for healthcare

A Siemens Healthineers Company

ITH icoserve technology for healthcare GmbH I Innrain 98 I A-6020 Innsbruck

To all users of the following software product:

syngo.share view diagnostic in the versions
VA24, VA25, VA26, VA27, VA28

Name	Florian Öhlschläger
Department	Quality and Documentation
Phone	+43 (512) 89059 442
E-Mail	florian.oehlschlaeger@ith-icoserve.com
	Florian.oehlschlaeger@siemens-healthineers.com
Subject	Field Safety Notice QM-533
Date	10 July 2020

Field Safety Notice QM-533

Notice Regarding the Calculation of Slice Thickness for Multiplanar Reconstruction (MPR) in *syngo*.share view diagnostic

Dear customer,

The problem described in this field safety notice only affects customers who use the diagnostic function "Multiplanar Reconstruction (MPR)" for radiological DICOM slice images from CT, PET and MR in the product *syngo*.share view diagnostic.

This notice is intended to inform you about a software bug in our product *syngo*.share view diagnostic. Under rare circumstances and certain conditions, this bug can lead to the erroneous calculation of slice thickness when using multiplanar reconstruction (MPR). There have been no known incidents or cases of harm to a patient. This bug was discovered through our internal quality assurance process. Other products in the *syngo*.share product family such as *syngo*.share webview, *syngo*.share webview diagnostic or *syngo*.share view are not affected by this bug.

What is the nature of the problem and when does it occur?

The product *syngo*.share view diagnostic contains a function for multiplanar reconstruction (MPR). The uncovered bug occurs in rare circumstances and under certain conditions when performing length, area and angle calculations in multiplanar reconstructions (MPR).

The calculation error only occurs when the patient is not positioned parallel to the image level during image capture. The angle of the patient relative to the image level (DICOM tag: Image Orientation Patient) can lead to deviations in the calculation of lengths, areas and angles in multiplanar reconstructions (MPR). These deviations are listed in Table 1.

These deviations in length, area and angle calculations occur in relation to the angle of the calculation relative to the image level. The maximum possible deviation for length, area and angle calculations occurs at a right angle relative to the image level.

Angle of patient relative to image level	Maximum possible deviation
Angle of patient relative to image level 0°	No error in length, area and angle calculations
Angle of patient relative to image level less than 1°	Less than 0.03% error in length, area and angle calculations
Angle of patient relative to image level less than 6°	Less than 1% error in length, area and angle calculations
Angle of patient relative to image level less than 10°	Less than 3% error in length, area and angle calculations
Angle of patient relative to image level less than 20°	Less than 10% error in length, area and angle calculations
Angle of patient relative to image level greater than 20°	Less than 43% error in length, area and angle calculations

Table 1: Overview of maximum possible deviations in relation to the angle of the patient relative to the image level

What can the user do to minimize the potential risk?

Avoid using length, area and angle calculations in multiplanar reconstructions when the patient is not oriented parallel to the image level.

How will this problem be fixed permanently?

A technician will contact you and perform a hotfix to permanently fix the problem.
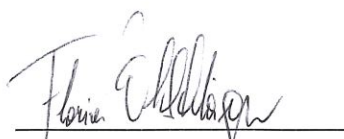
We sincerely apologize for any inconvenience caused by this measure, however, we believe that taking this preventative measure is necessary to ensure patient safety.

We thank you for your cooperation in the matter outlined in this field safety notice and ask you to pass this information on to your employees without delay. Your employees should be made aware of this potential problem and act with caution until the permanent fix is in place.

Sincerely,

Dr.Bernhard Hirsch
Managing Director

Mag. Florian Öhlschläger
Quality Manager