CC: Chairman of Medical Board &
Heads of Departments

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To all users of the following software products:

***syngo*.CT Cardiac Function**
used in *syngo*.via VA20A, VA30A or VB10A
***syngo*.CT Cardiac Planning**
used in *syngo*.via VB20A or VB30A

Safety Advisory Notice SY015/19/S

Customer Safety Advisory Notice SY015/19/S

Subject: *syngo*.CT Cardiac Function / Planning – Risk of wrong measurement in the annulus-plane

Dear Customer,

This letter is to inform you about the potential risk of a wrong measurement in the annulus plane during a TAVI planning procedure using *syngo*.CT Cardiac Function or *syngo*.CT Cardiac Planning. This risk is due to a software issue found in the TAVI algorithm in the above listed *syngo*.via software versions.

When does this malfunction occur and what is the problem?

The software *syngo*.CT Cardiac Function and the software *syngo*.CT Cardiac Planning define the annulus plane based on three automatically or manually set hinge points (lowest points of the aortic valve cusps). Furthermore a centerline, defined by the geometrical center of the aorta, is automatically determined by the software. By definition this centerline is initially perpendicular to the annulus plane.

During the automatic procedure a smoothing algorithm subsequently adjusts the shape of the centerline. In unfavorable conditions this smoothing algorithm can result in a slight distortion of the centerline and ultimately in a tilting of the measurement plane compared to the previously defined annulus plane. Any measurements of annular parameters taken under the described conditions might be incorrect due to the tilted measurement plane.

The magnitude of the deviation depends on the initial shape of the individual centerline related to the patient's anatomy. The stronger the initial bend in the centerline, the stronger the correction level of the smoothing operation. Please note that the bending of the centerline may be influenced by potential massive calcifications of the aortic root.

How can the operator help to avoid this potential risk?

When evaluating the annular dimensions the operator has to ensure that the measurement plane is optimally aligned with the annulus plane. This can be checked in the VRT segment as shown in Fig. 1. For this check, the operator has to move to the annulus plane by pressing the button "Annulus Plane". By activating the vessel diameter measurement tool a blue measurement plane will be displayed and can be compared with the white annulus plane. If they are not aligned, as seen in Fig. 1, any measurements using the cross-sections of the curved planar reformation may not be accurate.

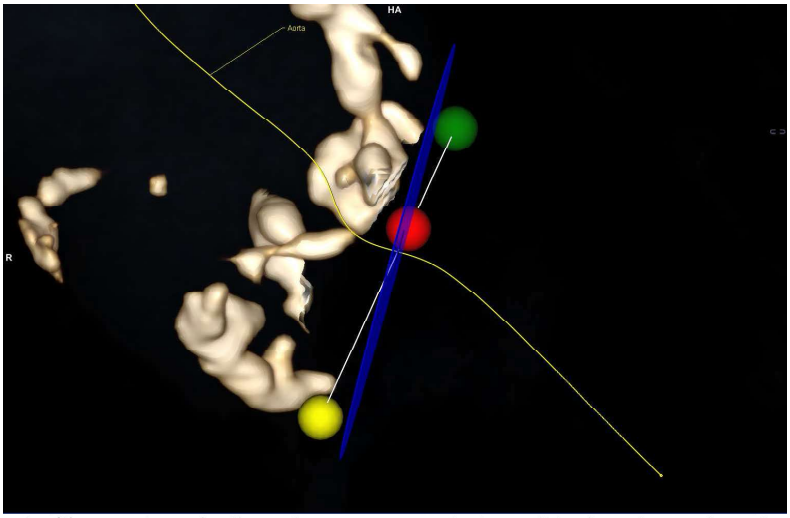

Fig. 1: VRT segment with angular misaligned measurement-plane (blue) and annulus-plane (white) in a worst case situation

Important: If the operator recognizes a significant deviation of two planes as shown in Fig. 1, it is absolutely essential to avoid any measurements in the CPR segments using the cross-sections at the annulus plane.

Workaround: As shown in Fig. 2 any annular measurement shall be performed manually in the MPR segment showing the annulus plane instead. The ROI Polygonal and/or Distance Line tools can be used.

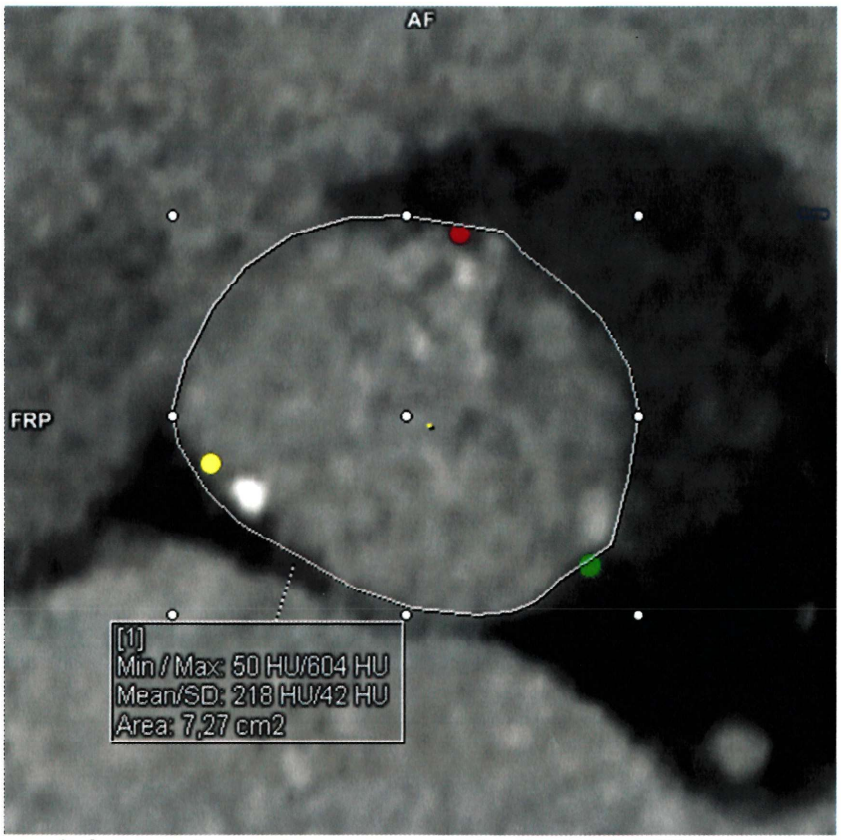

Fig. 2: MPR example for correct manual measurement using the function "ROI Polygonal Measurement"

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How will the issue be permanently resolved?

Our experts are working on a technical solution with the highest priority.

If your system technically qualifies for a future software solution your local service organization will inform you as soon as the technical update is available. In the meanwhile, please follow the workaround described above to avoid the risk of an incorrect measurement as communicated in this letter. If your system does not technically qualify for a future software solution (e.g. end of support has been communicated), please maintain the workaround described above permanently to avoid incorrect annular measurements.

In case you have any unresolved questions, please contact your local application specialists or your local service/sales organization.

We will inform the relevant National Competent Authorities about this field safety corrective action (FSCA).

- We appreciate your cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the medical device's Instructions for Use. Your personnel should maintain awareness until the solution has been implemented.

In case your system shares the license CT_Cardiac_Function_TAVI_ADV with other systems (through Multi Server Licensing) please forward a copy of this letter to all other users of this license.

If you have sold your syngo.via system and/or it is no longer under your ownership, we kindly ask you to forward this advisory notice to the new owner of the *syngo*.via. Please also inform us of the identity of the new owner of the *syngo*.via system.

Sincerely yours,

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