SIEMENS Healthcare

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To all users of the tabcard „4D" on the X-Workplace with SW version (VD10E)

BU contact:
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Important customer safety notice regarding corrective field action:

AX067/15/S

Information regarding corrective action for X-Workplace with SW version VD10E.

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent a possible hazard to persons and equipment.

What is the underlying issue requiring this corrective action and when does the issue occur?

The issue is caused by a possible wrong, too small measurement in the MPRs of a volume, which got acquired with a CT scanner with a tilted gantry.

What effect does this system behavior have on the operation of the system and what potential risks are associated with this?

In this situation, your "4D" tabcard will show wrong, too small length measurements, if the measurement has been performed at the upper right MPR in a 2x2 layout. This might potentially result in selecting a device with the wrong size, which then needs to get exchanged.

What action will be taken?

This issue will be remedied with software update AX067/15/S. Following the installation of this update, the "4D" tabcard correctly processes CT scans with tilted gantries and therefore also displays correct measurements.

How was the issue detected?

The issue was identified during regular testing in the Siemens factory.

How effective are the corrective actions?

Following the installation of the software update, the cause of the undesired system behavior is remedied and the error is prevented from recurring.

How will the corrective action be implemented?

Our service organization will contact you to arrange a date for the installation of the software update. Please feel free to contact our service organization for an earlier appointment. This letter will be distributed to affected customers as Update AX068/15/S.

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

We do not consider it necessary to re-examine any patients in this case, as potential wrong measurements would have directly been detected and changed when implanting the device. This system behavior had no influence on the treatment of patients.

Please forward this information to all the staff at your organization that needs to be aware of this problem. If you have sold the device, please forward this safety notice to the new owner. We would also request that you inform us of the identity of the device's new owner where possible.

Sincerely,

SIEMENS Healthcare GmbH
Business Area AT

Dr. Heinrich Kolem
President Advanced Therapies

i.V.
Wolfgang Hofmann
Medical Device Safety Officer