SIEMENS Healthineers

Siemens Healthcare GmbH, HC AT IR D, Siemensstr. 1, 91301 Forchheim

To all users of Artis Q systems with SW version VD11 and Gigalix X-ray tubes

Name Daniel Seebacher
Department HC AT IR D

Telephone +49 (9191) 18-6427
Fax +49 (9191) 18-9920
Mobile +49 (173) 4310033
E-mail daniel.seebacher@siemens.com

Date October 27, 2016

Urgent: Important customer safety notice regarding corrective field action

AX048/16/S

Information about corrective action for Artis Q systems with SW version VD11 and Gigalix X-ray tubes

Dear Customer,

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

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

For Artis systems with software version VD11, and Gigalix X-ray tubes, the semi-automatic focus switch may in cases of a special type of defect in foci "small" and "micro" (if present), does not work as intended when pressing the footswitch multiple times. This special type of focus defect, that causes the failure of the semi-automated focus switch, becomes more likely as the service life of the X-ray tube increases.

What is the impact on system operation and what is the potential risk to patients?

This can result in the spontaneous malfunction of the active (micro or small) focal spot and a loss of imaging. While we are not aware of any patient injuries, under the circumstances described below this issue can cause a loss of the fluoroscopy functionality and may lead to a situation where the clinical procedure has to be aborted, re-scheduled or the patient needs to be relocated to a functioning system.

We do not consider it necessary to re-examine any patients because the possible defect does not impact the image quality.

What actions can you take?

System operation with a 2-foci Gigalix X-ray tube: It is still possible to perform image acquisition with the large focus after manual selection of a corresponding organ program.

System operation with a 3-foci Gigalix X-ray tube: Fluoroscopy is still possible with the "small" or "micro" focus that is still intact through manual selection of a corresponding fluoro program. In addition, image acquisition with the large focus is still possible.

There should be standard emergency procedures in place in case of system failures. Consider reinforcing these procedures until the update has been effected.

What actions will we take?

A software update will correct the above mentioned issue. After the update, the Artis system will switch again semi-automatically to a functioning focal spot for all focus defects, enabling images to be displayed until the current procedure comes to an end.

How was the issue detected and what is the cause?

The issue was detected during root cause analysis of a customer complaint; the fluoroscopy function was not available although not all foci were defective.

How will the corrective action be implemented?

If your system has a Siemens Remote Service connection, the software will be downloaded to your system as a remote update. If you receive a corresponding notice from the system, you must enable the performance of the update at your earliest convenience. If you have already received the remote software update AX048/16/S this safety notice is outdated and may be disregarded.

If you are not connected to Siemens Remote Service, our service organization will contact you to schedule a manual software update. Please feel free to contact our service organization for an earlier appointment.
This letter will be distributed to affected customers as Update AX049/16/S.

How effective is the corrective action?

The cause will be eliminated by the software update, thus preventing a recurrence of the issue.

We thank you for your cooperation in dealing with this customer safety notice. Please promptly notify and instruct all the staff at your organization who need to be aware of this problem. Please forward this safety information to any other organizations that could be affected by this measure.

If the affected device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request that you to inform us of the identity of the device's new owner where possible.

Best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies

Dr. Heinrich Kolem
President Advanced Therapies

Wolfgang Hofmann
Safety Officer Medical Devices