

To all users of the following systems with software version
VD12 Artis zee / Artis Q / Artis Q.zen

Product/Trade Name: See attachment 1

Model number: See attachment 1

E-mail advancedtherapies-fsca.team@siemens-healthineers.com

Date June, 2021

Corrective
Action ID AX044/21/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Sporadic failure during startup procedure of the Image Acquisition System (IAS)

Dear Customer,

We would like to inform you about a potential issue with your Artis system with software version VD12 and a corrective action that will be performed.

What is the issue and when does it occur?

Due to a software error, the IAS (Image Acquisition System) may sporadically fail during startup/restart.

What is the impact on the operation of the system and what are the possible risks?

In case it might be necessary to manually restart the system during procedure, the IAS may not boot and the IAS of the Artis system remains in the Bypass fluoroscopy mode. The following message is displayed: "BYPASS" / "BYPASS FLUORO". This means that continuous fluoroscopy only (in plane A) is possible. It is not possible to release acquisitions. Depending on the status of the procedure, the limited functionality may not be sufficient to continue with treatment as planned. This might result in a situation where clinical treatment may be delayed until an additional restart is performed.

How was the issue identified and what is the root cause?

The issue was detected during system testing in the factory. The main issue is a sporadically occurring software bug.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

If the "BYPASS" / "BYPASS FLUORO" message does not disappear after approximately four minutes, an additional restart of the Artis system is necessary.

Siemens Healthcare GmbH
Management: Bernhard Montag, President and Chief Executive Officer;
Darleen Caron, Jochen Schmitz, Christoph Zindel

Chairman of the Supervisory Board: Ralf P. Thomas
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105
SCF V12

What actions are being taken by the manufacturer to mitigate possible risks?

The software of the affected systems will be updated.

What is the efficiency of the corrective action(s)?

The corrective action mitigates the probability of occurrence of the non-conformities.

How will the corrective action be implemented?

Our service organization will get in contact with you for an appointment to perform the corrective action. Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as update AX045/21/S.

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

The manufacturer does not consider risks for patients who have previously been examined or treated.

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

Please forward this safety information to any other organizations that could be affected by this measure.

If the 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 you to inform us of the identity of the device's new owner where possible.

With best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies (AT)



Letter of June, 2021
To all users of the following systems with software version VD12 Artis zee / Artis Q
/ Artis Q.zen



Attachment 1

Product/Trade Name	Model number
Artis zee floor	10094135
Artis zee ceiling	10094137
Artis zee multi-purpose	10094139
Artis zee biplane	10094141
Artis Q floor	10848280
Artis Q ceiling	10848281
Artis Q biplane	10848282
Artis Q.zen floor	10848353
Artis Q.zen ceiling	10848354
Artis Q.zen biplane	10848355