To all user of the following systems AXIOM Artis / Artis zee / Q / Q.zen

Product/Trade Name:	*see Attachment 1*	E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Model Number:	*see Attachment 1*	Date	March, 2021
		Corrective Action ID	AX068/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Addendum of the tooth belt cleaning for AXIOM Artis, Artis zee, Artis Q and Artis Q.zen

Dear Customer,

We would like to inform you about a potential issue with your AXIOM Artis, Artis zee, Artis Q and Artis Q.zen system and a corrective action that will be performed.

What is the issue and when does it occur?

Due to inappropriate cleaning, some Artis systems show unexpected corrosion of visible belts, which are needed to move system parts (e.g. C-Arm). This issue occurs sporadically and is not considered as a systematic issue.

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

Increased corrosion may lead to a malfunction of the belts. This might cause a limited functionality of the Artis system up to system failure. Unintended movement of the C-Arm may cause hazardous situation to patient, operator or staff members. In this case, it might be necessary to stop clinical treatment or to continue treatment on an alternative system.

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

The issue was detected during regular field observation. The root cause of the issue is an inappropriate cleaning of the system e.g. letting fluids enter the interior of system or using harsh cleaning agents.

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

Use only substances for cleaning and disinfection, which are recommended.
Do not let cleaning liquids seep into the openings of the system, e.g., air openings, gaps between covers.

Observe the attached cleaning and disinfection instructions.

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

An addendum to the system Operator Manual explains appropriate cleaning in detail and is attached to this letter.

This letter and the attached addendum are distributed as update AX068/20/S and have both to be filed with the system documentation.

What is the efficiency of the corrective action?

The addendum will increase the awareness concerning the cleaning process and mitigate the occurrence of the issue if considered.

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

There are no 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 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)

i.V. Reinmar Killmann

Electronically signed by: Reinmar Killmann
Reason: I am approving this document
Date: Mar 22, 2021 07:10 GMT+1

Dr. Reinmar Killmann

Vice President Project & Portfolio Management

i.V. Johann Böck

Electronically signed by: Johann Boeck
Reason: I am approving this document
Date: Mar 22, 2021 07:05 GMT+1

Johann Böck

Safety Officer Medical Devices AT

Attachment 1

Product/Trade Name	Model number
Artis zee floor	10094135
Artis zee floor MN	10094142
Artis zee ceiling	10094137
Artis zee biplane MN	10094143
Artis zee biplane	10094141
Artis zee multi-purpose	10094139
Artis zee III floor	10502501
Artis zee III ceiling	10502502
Artis zee III multi-purpose	10502503
Artis zee III biplane	10502504
Artis zee III floor MN	10502506
Artis zee III biplane MN	10502507
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
AXIOM Artis FC	5904433
AXIOM Artis BC	5904649
AXIOM Artis MP	5904466
AXIOM Artis FA	5904441
AXIOM Artis BA	5904656
AXIOM Artis TC	7728350
AXIOM Artis TA	7007755
AXIOM Artis dFC	7412807
AXIOM Artis dFC MN	7727717
AXIOM Artis dBC	7728392
AXIOM Artis dTC	7413078
AXIOM Artis dBC MN	5917054
AXIOM Artis dFA	7555373
AXIOM Artis dBA	7555357
AXIOM Artis dTA	7008605
AXIOM Artis dMP	7555365