

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

| | | | |
|---------------------|-------------------------|----------------------|--|
| Product/Trade Name: | <i>see Attachment 1</i> | E-mail | advancedtherapies-fsca.team@siemens-healthineers.com |
| Model Number: | <i>see Attachment 1</i> | 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.

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

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)


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


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 |