To all user of following ARTIS icono / pheno system in combination with a Siemens Healthineers VE OR Table

Product/Trade Name:	ARTIS pheno, ARTIS icono biplane, ARTIS icono floor
UDI-DI:	4056869046877, 4056869063317, 4056869149325

EU-SRN	DE-MF-000006122
E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Date	December, 2023
Corrective Action ID	AX044/22/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Possible hardware issue during transversal movement of Siemens Healthineers VE OR Table

Dear Customer,

We would like to inform you about a potential issue with your ARTIS icono / pheno system in combination with a Siemens Healthineers VE OR Table.

We have already informed you about this issue by CSAN AX002/23/S.

What is the issue and when does it occur?

During transversal table movement, it could happen that the rolling bearing may get dislocated; it is part of the linear guide rail and enables the transversal table movement. As a consequence of this unlikely event the rolling bearing may fall out of the linear guide rail. As a further consequence the mechanical connection between table top and table base may get lost.
It has not yet been reported to us that this issue occurred during clinical use of the system.

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

In the very unlikely case of occurrence, it cannot be excluded that the patient may fall off the table and the patient and/or the user may be injured. This may result in a situation where it may be necessary to cancel clinical treatment or to continue treatment on an alternative system.

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

The issue was identified during internal system tests. The root cause is an inadequate preload force of the linear guide rail during the manual manufacturing process preventing the correct positioning of the linear guide rail.

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

To mitigate the potential risk, please perform a visual inspection of the tabletop bearings on each side of the patient table (four locations) on a daily basis according to Artis Addendum instructions.

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

An inspection will be performed to check the correct positioning of the linear guide rails of the Siemens Healthineers VE OR Table.
An updated Artis Addendum will be distributed with the corrective action.

What is the efficiency of the corrective action?

This measure is intended to mitigate the risk in connection with this issue.

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 AX045/22/S.

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

The manufacturer does not consider any 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 advise 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. Please inform Siemens Healthineers about then new owner accordingly.

With best regards,

Siemens Healthineers AG
Business Area Advanced Therapies (AT)

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Electronically signed by: Carsten Bertram
Reason: I am approving this document
Date: Dec 8, 2023 11:07 GMT+1

Carsten Bertram
President Advanced Therapies

i.V.

Electronically signed by: Christian Dittmar
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Date: Dec 8, 2023 10:18 GMT+1

Christian Dittmar
Person Responsible for Regulatory Compliance