To all user of the following systems ARTIS icono and ARTIS pheno systems

Product/Trade Name:	ARTIS icono biplane, ARTIS icono floor, ARTIS pheno
Model Number:	11327600, 11327700, 10849000

EU-SRN	DE-MF-000006122
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Date	February, 2022
Corrective Action ID	AX003/22/S, AX004/22/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Software update of ARTIS systems with software version VE20 to VE21

Dear Customer,

We would like to inform you about potential issues with your ARTIS system in combination with Siemens Healthineers table or Trumpf/MAQUET table (OEM) and a corrective action that will be performed.

In the table below the system and table combinations are mentioned which are affected by the corresponding issues.

System with table combination		Issue 1	Issue 2	Issue 3	Issue 4	Issue 5
ARTIS icono Floor	with Siemens Healthineers table	x	x			
ARTIS icono Biplane	with Siemens Healthineers table	x	x	x		
ARTIS pheno	with Siemens Healthineers table	x	x		x	
	with Trumpf or MAQUET table	x	x		x	x

Issue 1: Indication of block movements function

What is the issue and when does it occur?

When the operator activates the functions "Block Movements" or "Block Table Movements" by pressing the Block Movements button on the Pilot Control Module, there will be a dedicated message displayed on the monitor (e.g. “Movement manually disabled - Deselect 'Block Movement'”). However, this message will be displayed for a limited time and will not re-appear when the operator attempts to initiate system movements again.

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

If the operator does not realize the signal on the Pilot Control Module or, if applicable, other indications for blocked movements and does not follow the troubleshooting procedures described in the operator manual, the operator will not be able to move the system or the table.

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

The issue was identified during regular field observation. The root cause is the message concept for the “Block Movement” or “Block Table Movement” function.

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

The operator of the system should consider other indications of the block movement status, e.g., the LED lights on the pilot control module, and follow the troubleshooting procedure described in the OM (14.1 No unit movement possible! → 3 Check the Block Movement function).

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

The software will be updated in order that the block movements-related messages will re-appear every time when the operator attempts to initiate system movements.

Issue 2: Blocked table/stand movement in case of broken drive connection

What is the issue and when does it occur?

In case of a broken drive connection of the table the recovery procedures described in the User Manual are not working sufficiently.

In case of a broken drive connection a drive error occurs impacting one axis of the Siemens table (e.g. tilt or lift). This means the table movement will be blocked entirely, i.e. the desired level of residual functionality will not be maintained.

Also, if a drive error impacts one axis of the plane A stand, the stand movement will also be blocked entirely, i.e. the desired level of residual functionality will not be maintained.

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

If this problem occurs, all movements of the affected subsystem (e.g. table) are blocked and can only be reactivated by a field service engineer. Movement of other subsystems remain available.

Depending on the status of the intervention, the limited functionality may not be sufficient to continue with treatment as planned. This may result in a situation where it is 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 problem was identified during system testing in the factory. The root cause is a software issue.

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

Please consider the need to establish emergency procedures to manage situations related with the failure of your Artis system according to the User Manual.

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

The software will be updated.

Issue 3: 3D run with manually rotated flat detector

What is the issue and when does it occur?

In case it is intended to perform a 3D acquisition and the flat detector (FD) of plane B is pushed out of its position after the test run before the fast 3D acquisition, e.g. by hand, the 3D run will be performed with a non-defined rotated FD of plane B.

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

In this case, the collision check which has been performed during the test run, is not valid anymore. During the fast 3D acquisition run, this could lead to a collision of the plane B detector and patient, operator, staff members, patient table or other room equipment.

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

The problem was identified during system testing in the factory. The root cause is a missing detector supervision after 3D test run.

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

Do not rotate the detector manually by pushing it out of its position after a 3D test run. In case detector rotation happened by accident after having done the 3D test run, please deselect the 3D acquisition protocol, select it again and repeat the 3D test run.

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

The software will be updated in order to exit the 3D test run in case the detector has been rotated.

Issue 4: Stopped and blocked system movements on the ARTIS pheno system

What is the issue and when does it occur?

In special, clinically untypical positions of the ARTIS pheno stand (see figure 1) the robot may move into a so called singularity position, where the movement may get stopped and blocked.

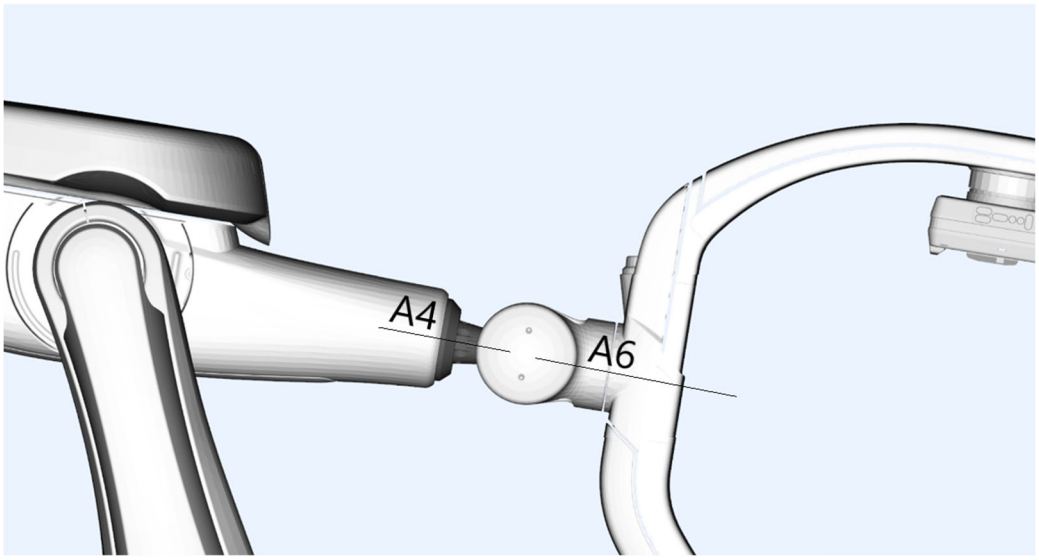

Figure 1: C-Arm position in singularity

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

If this issue occurs, all stand movements are blocked and can only be reactivated by a field service engineer.

Depending on the status of the intervention, the limited functionality may not be sufficient to continue with treatment as planned. This may result in a situation where it is 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 has been identified in the field in combination with a suboptimal system adjustment only.

The root cause for the blocked stand movement is a software issue.

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

Please consider the need to establish emergency procedures to manage situations related with the failure of your ARTIS system according to the User Manual.

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

The software will be updated.

Issue 5: Missing movement stop with multiple collision sensor activation

What is the issue and when does it occur?

In case of a failure in the collision sensor circuit (e.g. a permanently activated collision protection sensor) between the ARTIS pheno and a Trumpf/MAQUET table, which occurs rarely, the table movement may not be stopped when another collision sensor gets activated during a table movement.

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

This may lead to a situation where the activation of a proximity signal (collision sensor) does not trigger a movement stop. This may cause a potential hazard of crushing of patient, operator or staff members.

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

The problem was identified during system testing in the factory. The root cause is a software issue.

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

Please avoid injuries to persons and damage to equipment due to collisions or crushing by performing system movements with adequate care.

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

The software will be updated.

What is the efficiency of the corrective action?

The corrective action mitigates the probability of occurrence of the above mentioned issues 1-5.

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 AX005/22/S.

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

The manufacturer does not consider this system to bare 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)

ppa.

Electronically signed by: Carsten Bertram Reason: I am approving this document Date: Feb 8, 2022 19:15 GMT+1

Carsten Bertram
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Electronically signed by: Johann Boeck Reason: I am approving this document Date: Feb 8, 2022 14:20 GMT+1

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