To all user of following ARTIS pheno systems

Product/Trade Name:	ARTIS pheno	EU-SRN	DE-MF-000006122
Model Number:	10849000	E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
		Date	January, 2023
		Corrective Action ID	AX040/22/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Software update of ARTIS systems with software version VE10B

Dear Customer,

We would like to inform you about potential issues with your ARTIS system in combination with a Siemens Healthineers table or a 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
ARTIS pheno	with Siemens Healthineers table		x	
	with Trumpf or MAQUET table	x	x	x

Issue 1: Detection of wrong table movement direction

What is the issue and when does it occur?

In case of any unintended table movement, the system may not detect the wrong direction. Such a situation may occur, for example, if there was any potential additional failure of the table software leading to a movement in the wrong direction.

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

If such error occurs, the unintended direction of the movement could lead to crushing of patient, staff member, operator or equipment. This may cause injuries to persons or damage to equipment.

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

The problem was identified during internal code review in the development department. 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?

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

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

The software will be updated.

Issue 2: Adjust C-arm to Ref

What is the issue and when does it occur?

If during the procedure X-ray has been released and a reference image has been stored, the following issue may occur: If "Adjust C-arm to Ref" is activated when the C-Arm is positioned outside of the working range (that means that the C-Arm is not close to the table), the C-Arm will reach the target position with an inaccuracy of 5-10 mm. Nonetheless, the message “Endposition reached” will be displayed.

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

Live images might not match the previously stored reference images.
Overlay images might be shown inaccurate on anatomy (e.g. DSA Roadmap workflow does not match real anatomy). This may cause e.g. a vessel perforation in DSA roadmap.

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

The issue was identified during system testing in the development department. 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?

Position the C-Arm in the working range before activating "Adjust C-arm to Ref".
If "Adjust C-arm to Ref" has been activated while the C-arm is outside the working range at the table it needs to be re-activated when the C-arm is at the table.

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

The software will be updated.

Issue 3: 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 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?

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

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 1-3.

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 AX041/22/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. If measurement have already been performed in the past for diagnostics, please verify the results and diagnostic evaluation if applicable.

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)

[redacted]
President Advanced Therapies

[redacted]
Person Responsible for Regulatory Compliance