To all user with ARTIS pheno systems with software version VE10B

Product/Trade Name:	ARTIS pheno	EU-SRN	DE-MF-000006122
UDI-DI:		E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
		Date	September, 2022
		Corrective Action ID	AX017/22/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Three potential software issues on all ARTIS pheno systems with software version VE10B

Dear Customer,

We would like to inform you about the following potential issues with your ARTIS pheno system and a corrective action that will be performed.

This customer letter is addressing three potential software issues.

Issue 1 (System error management):

What is the issue and when does it occur?

The ARTIS pheno system is provided with a dedicated error management mechanism. In rare cases of specific X-ray tube failures, the system is intended to automatically switch over to “Bypass fluoroscopy” mode. However, in case such a failure occurs while the “Block Radiation” functionality is active, the “Block Radiation” functionality cannot be unlocked, and the system will not switch over to “Bypass fluoroscopy” mode. In “Bypass fluoroscopy” mode a limited imaging functionality (non-subtracted, continuous fluoroscopy with reduced power and without acquisition and storage of images) would remain available.

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

In that case (specific X-ray tube failure while “Block Radiation” is active), the operator is unable to release X-ray in “Bypass fluoroscopy” mode which remains permanently inhibited. 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 inhouse testing at manufacturer site. The root cause is a software issue in the error management.

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

In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

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

The software in the affected systems will be updated to correct the issue.

What is the efficiency of the corrective action?

The software update will mitigate the occurrence of the issue.

Issue 2 (Head holder symbols):

What is the issue and when does it occur?

During the procedure it is not visible to the user whether a head holder has been selected by the user in the system software or not.

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

If a head holder is being used but by mistake not selected on the system in accordance with the Instructions for Use, a possible collision between the C-Arm and the head holder can occur during system movement.

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

The problem was identified by regular field observation. The indication of the selected type of head holder is only visible in the control room and not directly obvious in the examination room.

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

Please ensure that the configuration of the head holder is correct prior to system movements and double-check configuration in the control room in case of uncertainty during the procedure (see Instruction for Use, chapter “Activation of the head holder collision zone”).

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

The software in the affected systems will be updated to correct the issue. A symbol on the display in the examination room will indicate if a head holder is selected and which type of head holder is selected.

Head holder settings

The following head holders can be set (depending on your system configuration):

Icon	Description
-	**None**: No head holder is attached. No collision zone for head holder is set!
	**Head Extension**
	**Head Clamp**
	**Horseshoe Head Rest**
	**Head Rest (tiltable)**
	**Default Head Holder**: A unknown head holder is attached. The collision zone around the head holder is quite big. Unit movement are performed with reduced speed!

For systems not using head holders at all, it is possible to permanently disable the head holder-specific collision zone in service mode.

What is the efficiency of the corrective action?

The software update will mitigate the occurrence of the issue.

Issue 3 (Stand movement):

What is the issue and when does it occur?

After a routine brake test as recommended in the Instructions for Use, in rare cases it may occur that no stand movement is possible.

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

After the occurrence of this issue no stand movement is possible and the system may need to be reset by a service technician. This could lead to a possible delay of a procedure.

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

The problem was identified by regular field observation. 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 carry out a routine brake test with sufficient time before starting any procedure.

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

The software in the affected systems will be updated to correct the issue.

What is the efficiency of the corrective action(s)?

The software update will mitigate the occurrence of the 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 (covering issues 1 to 3 above). Please feel free to contact our service organization for an earlier appointment.
This letter will be distributed to affected customers as update AX018/22/S.

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

We do not consider it necessary to re-examine any patients in relation with the issues (issue 1 to 3) described above. If measurement graphics and annotations have already been used 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)

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Date: Sep 15, 2022 07:58 GMT+2

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President Advanced Therapies

Date: Sep 15, 2022 07:20 GMT+2

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Person Responsible for Regulatory Compliance