To all user of ARTIS pheno systems with Large Display

Product/Trade Name:	ARTIS pheno
Model Number:	10849000

EU-SRN	DE-MF-000006122
E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Date	June, 2022
Corrective Action ID	AX021/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Transmission failure concerning ARTIS pheno systems with Large Display

Dear Customer,

We would like to inform you about a potential issue with your ARTIS pheno system with Large Display and a corrective action that will be performed.

What is the issue and when does it occur?

Due to several technical issues within the two video transceivers a video signal from one of the transceivers of the Large Display may be lost.
In very rare cases it can happen that both transceivers of the Large Display fail which can lead to the loss of both video signals.
This issue can sporadically affect the Large Display in the examination room as well as the displays in the control room.

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

If the issue occurs there can be a malfunction within the video transmission which might lead to a situation where the Large Display will not work properly anymore.
If only one of the two video transceivers is affected, one half of the Large Display will still be active and can be used. In the very rare case that both video transceivers are affected the Large Display will not show any signal and cannot be used anymore.

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

The issue was detected by regular field observation. The issue was caused by the manufacturing process of our former supplier of the affected video transmission components.

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

We strongly recommend to establish appropriate emergency procedures until the corrective action has been performed. 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?

Our service organization will exchange the affected video transmission links.

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

The corrective action will mitigate the probability of occurrence of the non-conformity.

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 AX022/20/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 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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