To all users of the following systems Artis one with hybrid cable

Product/Trade Name:	Artis one	EU-SRN	CN-MF-000013436
UDI-DI:	04056869009964	E-mail	at_szn_fsca.team@siemens-healthineers.com
		Date	March, 2023
		Corrective Action ID	AX061/22/S

[redacted]

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Artis one hybrid cable replacement

Dear Customer,

We would like to inform you about a potential issue with your Artis one system and a corrective action that will be performed.

What is the issue and when does it occur?
Due to a potential malfunction, the examination room monitor connected with the hybrid cable may have a display issue.
The issue occurs sporadically and might occur during procedure.

What is the impact on the operation of the system and what are the possible risks?
In most cases when the issue occurs, system can enter into "Bypass fluoroscopy" mode by itself or after a reboot. 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.

In rare cases when system may not enter into "Bypass fluoroscopy" mode, which would mean that no image function is available for the system and may result in a situation where it is necessary to cancel clinical diagnostic/treatment or continue diagnostic/treatment on an alternative system.

How was the issue identified and what is the root cause?
The issue was detected by regular field observation. The root cause is determined as signal transmission issue between the examination room monitor and the PC, which is caused by quality issue of laser of TX module integrated in hybrid cable.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?
It is strongly recommended to establish appropriate emergency procedures until the corrective action has been performed. In any case, please make sure that diagnostic/treatment can be continued in other ways if there is any possible safety issue for involved patient.

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

The possible risk is mitigated by realization of the field corrective action AX061/22/S. The measure is to replace current hybrid cable by a succeeding solution as a design improvement to enhance stability and quality of signal transmission.

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 AX065/22/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 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,

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