To all users of the following systems ARTIS icono and ARTIS pheno (Software VE20C)

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

E-mail	qara.med.gb@siemens-healthineers.com
Date	24/03/2021
Corrective Action ID	AX023/21/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Important safety information for customers regarding field corrective actions for ARTIS icono systems and ARTIS pheno systems running with VE20C software version.

Dear Customer,

We would like to inform you about a potential issue with your ARTIS icono / pheno system with software version VE20C and a corrective action that will be performed.

What is the issue and when does it occur?

Due to a software error, the IVS (image evaluation system) and/or IAS (image acquisition system) may sporadically perform an unintended self-recovery during operation.

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

If the software error occurs, the IVS and/or IAS self-recovery functionality starts automatically.

During the self-recovery of the IVS, the Artis system remains in the Backup mode and the following message is displayed: "BACKUP MODE - No connection to image database. Limited imaging and review". This means that during the recovery phase of the IVS only limited imaging functionality will be available (unsubtracted fluoroscopy and CARD, DR, DSA acquisition). After showing the message, the IVS needs up to 4 minutes for recovery of full functionality.

During the self-recovery of the IAS, the Artis system remains in the Bypass fluoroscopy operating mode and the following message is displayed: "BYPASS/BYPASS FLUORO." This means that during the recovery phase of the IAS continuous fluoroscopy is possible only in plane A. It is not possible to release acquisitions. After showing the message, the IAS needs up to 1 minute for recovery of full functionality.

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

The issue was detected by regular field observation. The main error is a sporadically occurring software error of an application running on the IVS PC and also on the IAS PC.

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

Please be aware of the limited system functionality in Backup mode and Bypass fluoroscopy operating mode (see also operator manual chapter 6.7 System operating modes).

In some rare cases the automatic recovery phase may not be successful within 4 minutes. In such a case the system can be manually recovered according to operator manual instructions Chapter 3.13 “Recovering functions in case of system failures”.

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

The software of the affected systems will be updated.

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

The corrective action mitigates the probability of occurrence of the non-conformities.

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 AX024/21/S.

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

The manufacturer does not consider 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,

Eric Donnachie

Regulatory Affairs Manager GB&I

Siemens Healthcare Limited