To all user of the following systems with a 40 kVA UPS

Product/Trade Name: *see Attachment 1*

Model Number: *see Attachment 1*

E-mail advancedtherapies-fsca.team@siemens-healthineers.com

Date February 2021

Corrective Action ID AX026/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Wrongly configured 40 kVA UPS (Uninterruptible Power Supply)

Dear Customer,

We would like to inform you about a potential issue with your Artis Q / Q.zen / pheno / icono system with a 40 kVA UPS and a corrective action that will be performed.

What is the issue and when does it occur?

The Uninterruptible Power Supply (UPS) of your System might not work properly due to a wrong configuration.

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

If the power supply of the hospital is interrupted, UPS would have to step in and to provide power to the system, which is not guaranteed in the present case. In this case, the system might not work anymore so that neither releasing radiation nor imaging will be possible until the hospital power is available again.

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

The issue was identified during an internal inspection by our suppliers.

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.

Siemens Healthcare GmbH
Management: Bernhard Montag, President and Chief Executive Officer;
Darleen Caron, Jochen Schmitz, Christoph Zindel

Chairman of the Supervisory Board: Ralf P. Thomas
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105
SCF V12

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

Our service organization will inspect the potentially affected UPS configuration and will correct the settings if required.

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

This update corrects potentially non-conforming systems and will verify that the systems delivered are according to the specification.

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 AX029/20/S.

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

There are no 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)

i.V. Reinmar Killmann

Dr. Reinmar Killmann
Vice President Project & Portfolio Management

i.V.

Johann Böck
Safety Officer Medical Devices AT

Attachment 1

Product/Trade Name	Model Number
Artis zee floor	10094135
Artis zee ceiling	10094137
ARTIS pheno	10849000
Artis zee multi-purpose	10094139
Artis Q ceiling	10848281
Artis zee biplane	10094141
ARTIS icono biplane	11327600
Artis Q.zen floor	10848353
Artis Q biplane	10848282
Artis Q floor	10848280