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91301 Forchheim

Contact person of
the Regional Unit
Department

<To the person in charge of the unit where the SIEMENS
product is operated, and the administrative head of
organization>

Telephone
Fax
E-mail

Date 9th of February 2021

Safety Advisory Notice

To all users of the SIEMENS YSIO X.pree

Contact person of
the Business Unit
Department

Telephone
Fax
E-Mail

Re: Incorrectly assigned image

Dear customer,

This letter is to inform you of a potential hazard and a software update intended to correct this issue. The system is safe to use when observing the instructions provided below until the correction is performed.

What is the problem, when can it occur and what are the potential risks?

Siemens has received a complaint about an image assigned to a different patient during image recovery process. In the unlikely event of an interrupted connection to a MAX detector during an initiated image recovery, the previously acquired image (possibly belonging to the previous patient) might be displayed to the user instead of the currently acquired image. If this error remains undetected by the user, it could potentially impact diagnosis of the patient examined when the connection was interrupted.

The prior examination is not affected by this issue.

Does this problem impact already examined patients?

We have no knowledge of any cases where the described behavior resulted in misdiagnosis. In the notified event the user noticed the error.

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What steps can the user take to avoid the potential risk of this issue prior to final resolution?

It is advised for the user to check the image displayed following image recovery to ensure that it is the newly acquired image and it belongs to the current patient. If this is not the case, the user should delete the image and notify Siemens customer service.

How will the issue finally be resolved, and the corrective action be implemented?

This safety advisory notice will be distributed to all affected customers via XP051/20/S. With the field safety corrective action XP052/20/S, a modified software version will be installed by Siemens Healthineers. The software update will correct the described issue and prevent its reoccurrence. The update is planned to be available starting in the second quarter of 2021.

Apart from the described correction, the updated software contains further stability, usability and performance improvements and is provided free of charge.

Our service organization will get in contact with you for an appointment to perform the corrective action. Please also feel free to proactively contact our service organization to schedule your preferred appointment.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this Field Safety Notice is placed in the system's instruction for use. Your personnel should maintain awareness until the modification has been implemented.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely yours,

