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To all users of IONTRIS

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Customer Safety Advisory Notice

PT027/18/S

IONTRIS (10013851, Siemens AG) – Possible wrong understanding derived from a hint in IFU regarding the authorization of QA procedures in „Technical Mode“.

Dear Customer,

with this letter we would like to inform you about a possible wrong understanding of the authorization in the QA procedure in the "technical mode" of the IONTRIS (10013851, Siemens AG) and, as a result, the unlikely but possible risk to the medical staff.

When can this malfunction occur and what are the potential risks?

Within the QA procedure in the "technical mode", the user name and password will be used to authorize the application of radiation. For the operating of the beam within the procedure, at least one precondition is that the room is in the status released „The treatment room is closed and empty since...“. This is done by room 'searching' and closing the door to the treatment room, functionally controlled by the Person Safety System (PSS). The PSS is not part of the IONTRIS.

If, after authorization and release by the PSS, the user enters the treatment room again, opening the door will in any case release the precondition stated above. In order to resume the interrupted application of radiation, at least this precondition must be restored. A solely opening of the door does not require a renewed authorization by the user.

The prerequisites for authorization are given in the user documentation "IONTRIS IT, Operator Manual PT QA & Service" (print number PT02-MPA.621.02.09.02) under chapter 4 "General QA Workflow". The note on page 85 (100) of Chapter 4, "Your authorization remains valid until the door to the room is opened." states that the sequence of multiple automated procedures does not require re-authorization each time the door to the treatment room is opened. On the other hand, the possible conclusion that an interim opening of the doors always leads to the expiry of the authorization, would not apply.

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The wording and context of the note could mislead the user into believing that after reconditioning the prerequisite room status, "searched" by the PSS, the QA procedure will in no case be automatically resumed, but a renewed authorization is always necessary.

In the unlikely, but depending on the technical design of the PSS possible case, that a person returns into the treatment room whilst the closing of the door in a current 'searching' process (generally, however, an illegal procedure), there is a possibility that in this respect radiation without renewed authorization is applied. Depending on the beam alignment and location of the person in the treatment room, the application of radiation can lead to serious physical long-term damage.

What steps can the user take to prevent the potential risk to the user?

Compliance with the valid person safety concept:

Operating personnel must ensure that no persons are present in the treatment room as part of the room 'searching'.
Even after an interruption and a new scan no one should be in the treatment room.

What adjustments are made by the manufacturer?

It is a modification of the IONTRIS (10013851, Siemens AG) user documentation in preparation, which describes more clearly the necessary conditions in case of interruption of the QA procedure. This modification will be available from the end of 2019.

Passing on the information described here:

Please make sure in your organization that all users of the above-mentioned products and other persons to be informed of this safety information. If you have given the products to third parties, please forward a copy of this information or inform the contact person listed below

Please retain this information at least until the action is completed.

The German National Competent Authority has received a copy of this safety advisory notice.

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With best regards,



Siemens Healthcare GmbH

Acknowledgment of receipt

Address:

As the responsible operator of _____ we hereby confirm that we have read and understood the safety information "**Possible wrong understanding derived from a hint in IFU regarding the authorization of QA procedures in 'Technical Mode'**".

Place, Date: _____

Name: _____

Signature: _____