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To all users of the

SIEMENS SOMATOM Definition AS
SIEMENS SOMATOM Definition DS
SIEMENS SOMATOM Definition Edge
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SIEMENS SOMATOM Force

Customer Safety Advisory Notice CT053/17/S

Re: CARE Dose4D algorithm – Risk of unnecessary radiation exposure for head scans based on p.a./a.p. topograms

Dear customer:

This letter is to inform you about a potential risk of unnecessary radiation exposure due to a software issue we found in the CARE Dose4D algorithm implemented in the Siemens Healthineers CT scanners specified above.

When does this malfunction occur and what is the problem?

Siemens Healthcare became aware of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate. Potentially, the CARE Dose4D software will select the maximum tube current for the uppermost part of the skull, thus leading to unnecessary radiation exposure.

How can the operator help to avoid a potential risk of the system?

The described issue will not occur when using a lateral topogram instead of a p.a. or an a.p. topogram. Accordingly, we strongly recommend using topograms in lateral position for all head scans.

The following section describes how you can recognize a possible miscalculation of the tube current when still using a p.a. or an a.p. topogram and how to correct it prior to starting the scan:

The calculated mAs profile (= dose profile) of the planned scan range is displayed after performing the topogram on the left side of the screen (Fig. 1).

Any unusual dose distribution similar to the graph reflected in Fig. 1 indicates a possible malfunction of the CARE Dose4D algorithm. The very sudden and strong increase of the tube current in the upper part of the skull is easily recognized (Fig. 1, red rectangle).
In case the operator becomes aware of the described behavior of the system, the scan should not be started. If the dose distribution appears to be incorrect, please run a new lateral topogram and check the dose distribution again!

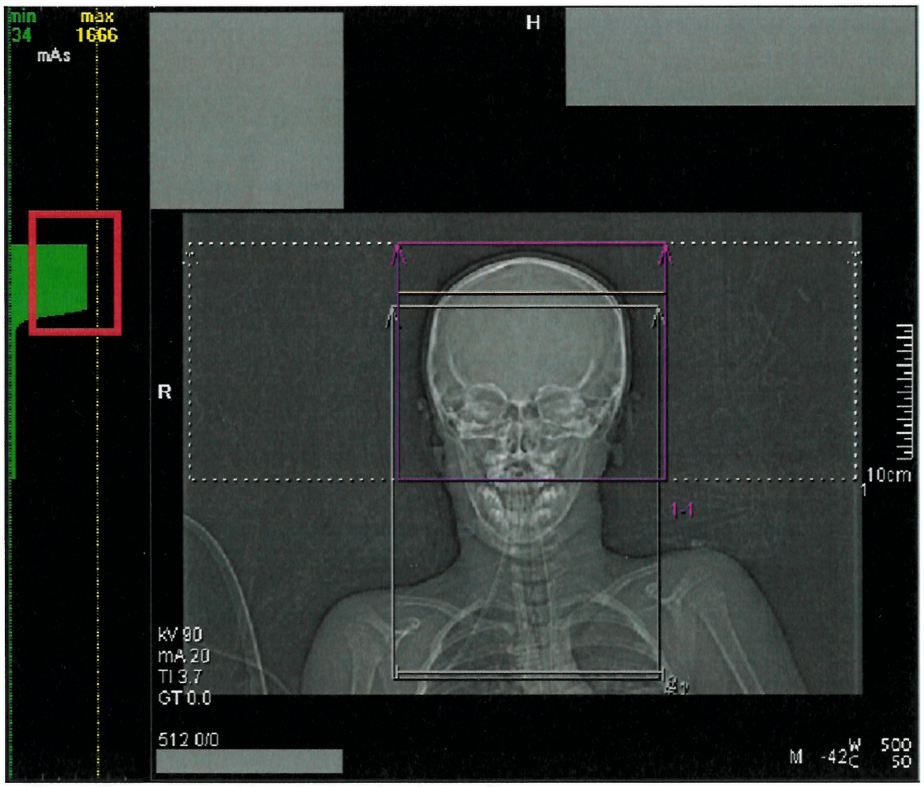

Fig. 1 Topogram with calculated mAs profile

The following part describes additional safety features already implemented in current systems:

To prevent any possible deterministic radiation effects on the patient's skin or eye lenses, Siemens Healthcare implemented a dose alert according to the technical standard IEC 60601-2-44. A warning will be shown and has to be confirmed by the user if the accumulated CTDIvol for the ongoing examination exceeds the alert threshold in any z-position. The default setting for the threshold is adjusted to 1000 mGy.

Furthermore, the user can configure dose notification thresholds for every scan range (please refer to the "Instructions for Use", chapter 9 "Dose management and optimization", subchapter 9.1.1 "Dose Notification"). If a dose notification threshold is configured and is bound to be exceeded, a notification requesting a confirmation by the user pops up prior to the scan (Fig. 2)

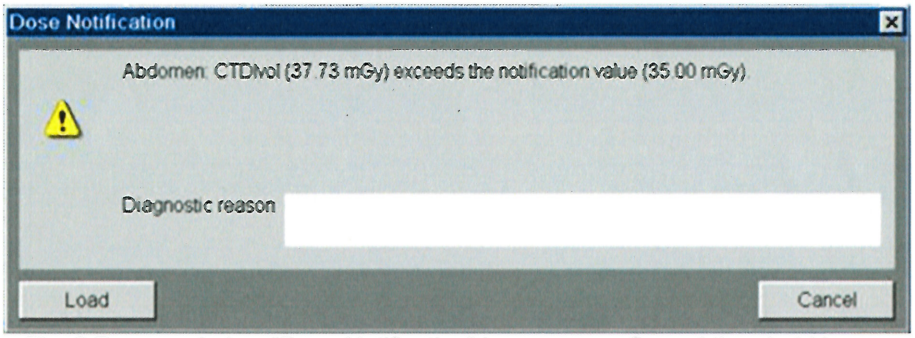

Fig. 2 Pop up window "Dose Notification" in case a configured threshold is exceeded

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How this issue will be solved

Our experts will develop a solution to correct the problem with top priority. As soon as we release the correction, we will inform you concerning the start of the measure and when this correction has been successfully implemented.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the medical device's Instructions for Use. Your personnel should maintain awareness until a solution has been implemented.

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

– The relevant national competent authority has been informed of this notice.

Sincerely yours,

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