

CC: Chairman of Medical Board & Heads
of Departments



Customer Safety Advisory Notice CAN 002-2018

To: Director of the Radiology Department
Director of the Nuclear Medicine
Risk Management Officer
Users of Siemens Healthineers' Symbia T and Symbia Intevo SPECT/CT systems

Re: CARE Dose4D algorithm – Risk of unnecessary radiation exposure in CT scans based on PA/AP topograms

Dear valued Siemens Healthineers customer,

This letter is to inform you about an issue that could potentially impact the CARE Dose4D algorithm in CT scans that include the head. Based on data calculated by our computed tomography (CT) business line (BL), it is now evident that an increase in dose is possible when scanning the head region with CARE Dose4D using a posterior-anterior (PA) or anterior-posterior (AP) topogram.

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

Siemens Healthineers is aware of potential, incorrect tube-current calculations by the CARE Dose4D algorithm when utilizing PA or AP topograms. Depending on the geometrical shape of the skull, rare cases may occur in which the calculated dose distribution is not appropriate. The CARE Dose4D software may select the maximum tube current for the uppermost part of the skull, which incidentally leads to unnecessary radiation exposure.

How can you help to avoid the potential risk of this issue?

The described issue does not occur when using a lateral topogram. Accordingly, we strongly recommend the utilization of topograms in the lateral position for all CT and SPECT/CT scans that include the entire head. Alternatively, if you choose to perform both a lateral topogram in conjunction with a PA or AP topogram you must ensure that you perform the lateral topogram last as CARE Dose4D is based on the last topogram. If you do not utilize a lateral topogram for scans including the entire head, we strongly recommend that you deactivate the CARE Dose4D feature (Figure 1).

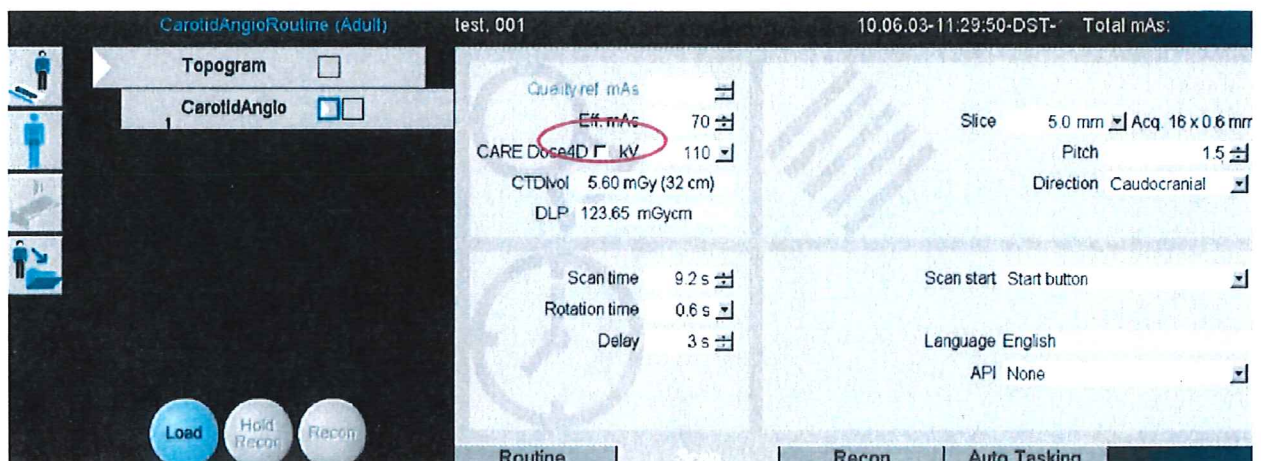


Figure 1 deactivate the check box for CARE Dose4D

Are there any additional safety features currently present?

To prevent any possible deterministic effects on the patient's skin or eye lenses, Siemens Healthineers implemented a dose alert in accordance with IEC 60601-2-44 in Symbia software versions VB10 or newer. The system displays a warning which must be confirmed 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, you can configure dose notification thresholds for every scan range (please refer to your Symbia Operators Manual for your corresponding software version). If a dose notification threshold is configured and is bound to be exceeded, a notification requesting a confirmation pops up prior to the scan (Figure 2).

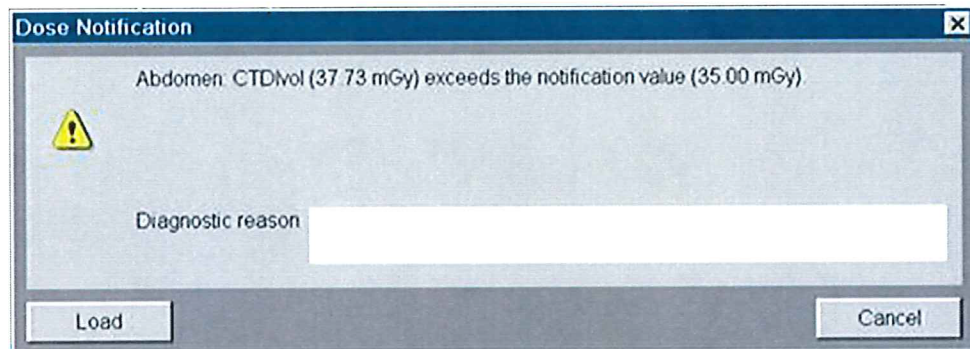


Figure 2. Pop up window "Dose Notification" in case a configured threshold is exceeded

What are the next steps for this issue?

Molecular Imaging is developing appropriate solutions to address the problem with high priority.

Please ensure that this customer safety advisory notice is placed in the *Symbia Operator's Guide* and disseminated to all operators of the system. If this equipment is no longer in your possession, we kindly ask that you forward this letter to the new owner of the equipment and please inform Siemens Healthineers about the change in ownership.

Adverse events or quality problems experienced with the use of this product should be reported to Siemens Healthineers through the contact information provided below and may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

If you have any questions regarding this safety advisory notice, please contact your local Siemens Healthineers representative at the contact numbers provided below.

- America: 1-800-888-7436
- Europe, Middle East, and Africa: +49 9131 940 4000
- Asia and Australia: +86 (21) 3811 2121

Sincerely,

[Redacted Signature]

Matt Shah
Vice President, RA/QA & EHS
Molecular Imaging
CAN 002-2018