

CC: Chairman of Medical Board & Heads  
of Departments



## Customer Safety Advisory Notice CAN 001-2018

**To:** Director of the Radiology Department  
Director of the Nuclear Medicine/PET Imaging Department  
Risk Management Officer  
Users of All Siemens Healthineers' Biograph systems

**Re:** CARE Dose4D algorithm – Risk of unnecessary radiation exposure in CT scans that include the head, 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 PET/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.

### **How can you recognize and correct a possible miscalculation of the tube current when using a PA or AP topogram?**

For customers that have a Biograph mCT or Biograph mCT Flow, the calculated mAs profile (dose profile) of the planned scan range displays on the left side of the screen after the topogram completes (Figure 1).

Any unusual dose distribution, similar to the graph reflected in Figure 1, indicates a possible miscalculation of the CARE Dose4D algorithm. You can easily recognize the very sudden and strong increase of the tube current in the upper part of the skull (Figure 1, red rectangle). In the event you become aware of the described behavior, do not start the scan, run a new lateral topogram, and check the dose distribution again.

For all other Biograph systems, the dose profile is not available. Owners of these systems should use lateral topograms when conducting examinations that include the entire head, as describe in the previous section.

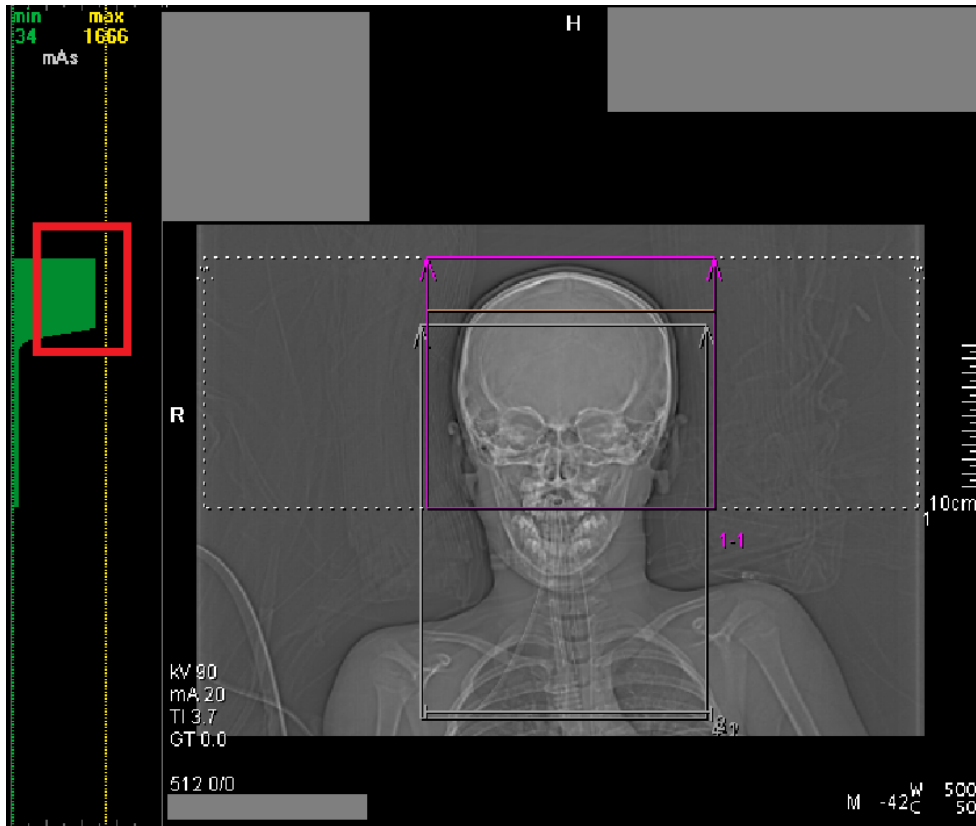


Figure 1. Topogram with calculated mAs profile

**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. 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 Biograph 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).

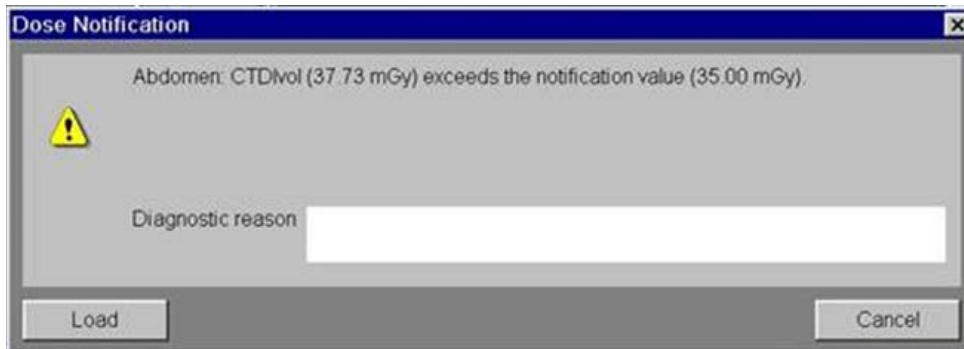


Figure 2. Pop-up window "Dose Notification" in case a configured threshold is exceeded

### **What are the next steps for this issue?**

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

#### **Customers of Biograph mCT and Biograph mCT Flow**

Please ensure that this customer safety advisory notice is placed in the *Biograph Operator's Guide* and disseminated to all operators of Biograph mCT and mCT Flow. 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.

#### **Customers of Biograph Horizon**

Please ensure that this customer safety advisory notice is placed in the *Biograph Horizon Operator's Manual for Examination and Acquisition* and disseminated to all operators of Biograph Horizon. 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.

#### **Customers of Biograph TruePoint**

Please ensure that this customer safety advisory notice is placed in the *Biograph TruePoint PET-CT Operator's Manual* and disseminated to all operators of Biograph TruePoint. 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.

#### **Customers of all other Biograph Systems**

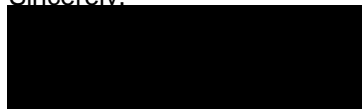
Please ensure that this customer safety advisory notice is placed in the *Biograph PET-CT Operator's Guide* and disseminated to all operators of your Biograph system. If this equipment is no longer in your possession, we kindly ask that you forward this letter to the new owner of the equipment and please 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,



Matt Shah  
Vice President, RA/QA & EHS  
Molecular Imaging  
CAN 001-2018