Siemens Healthcare GmbH, HC DI CT QT, Siemensstr. 1, 91301 Forchheim

Name Dr. Markus Nagel
Department HC DI CT QT

Telephone +49 (0)9191 18-7231
E-mail markus.nagel@siemens-healthineers.com

Date October 26, 2017

To all users of the

SIEMENS SOMATOM Definition AS
SIEMENS SOMATOM Definition DS
SIEMENS SOMATOM Definition Edge
SIEMENS SOMATOM Definition Flash
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!

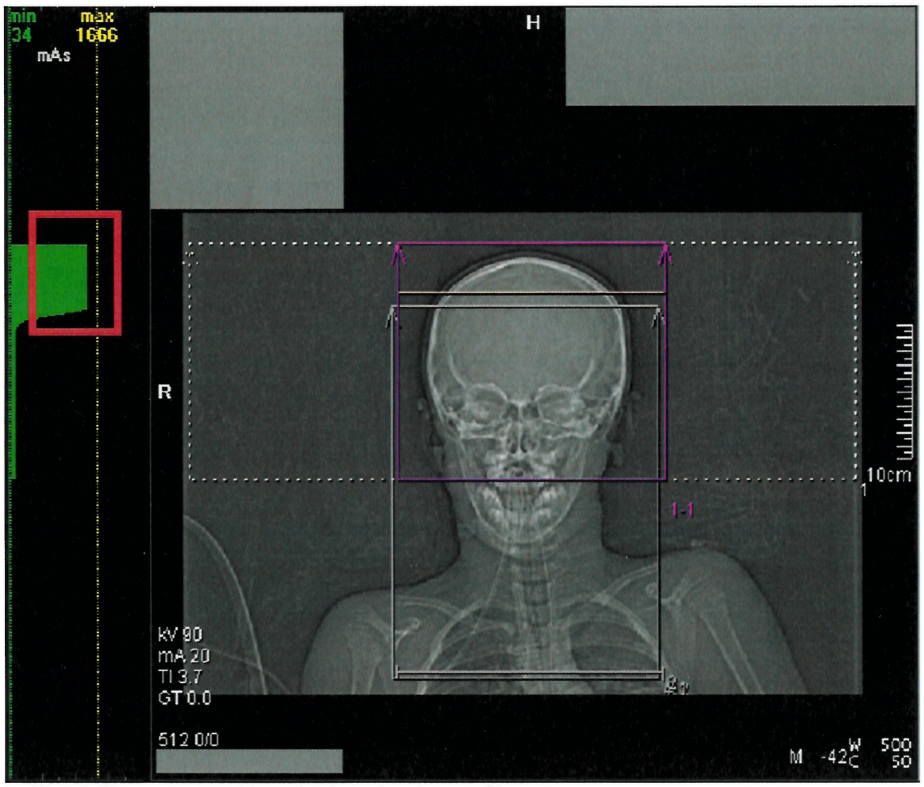

Fig. 1 Topogram with calculated mAs profile

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)

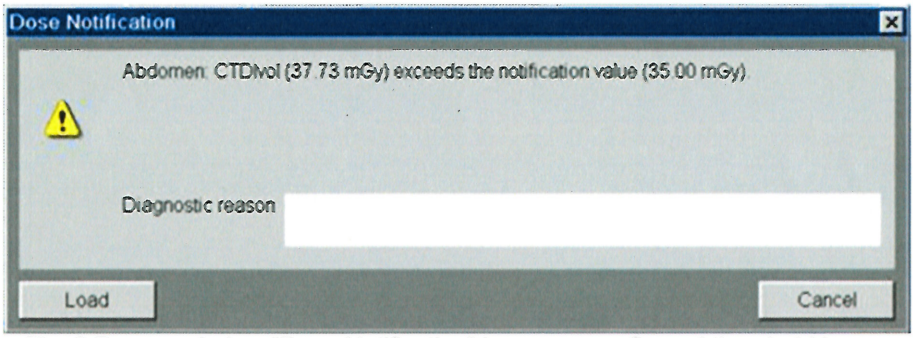

Fig. 2 Pop up window "Dose Notification" in case a configured threshold is exceeded

SIEMENS Healthineers

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,

Uwe Rückl
Head of Research & Development CT
Computed Tomography
Siemens Healthcare GmbH
Forchheim
Germany

Dr. Markus Nagel
Head of Quality&Technology CT
Computed Tomography
Siemens Healthcare GmbH
Forchheim
Germany

SIEMENS Healthineers

Definit./AS/Edge/Flash/Force

Update Instructions
Safety Update - CT053/17/S

CUSTOMER SAFETY ADVISORY NOTICE

Update within deadline	3 months				
Mandatory	☑ Yes	☐ No			
Affected	☑ Warranty	☑ Contract	☑ Others		
Update by	☐ Customer	☐ Informatics	☐ RSC	☐ Apps	☐ CSE
Remote update	☐ Yes	☑ No			
Intranet download available	☑ Yes	☐ No			
Update material required	☐ Yes	☑ No			
Material free of charge	☑ Yes	☐ No	☐ No, credit if returned		
Return of parts	☐ Yes	☑ No			
Application training needed	☐ Yes	☑ No	☐ Recommended		
Application training time	0 h				
Estimated completion time	0,25 h	Number of CSEs: 1			

Remarks: This Update requires the download, print-out and distribution of a Customer Safety Advisory Letter CSAN. See sections 1-2 for details.

Scope

Material number	7740769, 8098027, 10430603, 10590000, 10742326
Software version	n.a.
Related to customer advisory letter	667492-EAE-01S-01

Change reference no.: 667492
Name: S. Reiche
Department: HC SV CS SLM CT

Document Version

Siemens reserves the right to change its products and services at any time.

In addition, manuals are subject to change without notice. The hardcopy documents correspond to the version at the time of system delivery and/or printout. Versions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens office to order a current version or refer to our website http://www.healthcare.siemens.com.

Disclaimer

Siemens provides this documentation “as is” without the assumption of any liability under any theory of law.

The content described herein shall be used by qualified personnel who are employed by Siemens or one of its affiliates or who are otherwise authorized by Siemens or its affiliates to use such documents.

Assemblers and other persons who are not employed by or otherwise directly affiliated with or authorized by Siemens or one of its affiliates are not entitled to use this documentation without prior written authority.

Copyright

1.1 General Information

1.1.1 Systems/Products Affected

See page 1.

The list of affected systems is not part of these Update Instructions.

Obtain the material and serial numbers from your local Update Management or Dispatch.

1.1.2 Reason for the Update

Distribution of customer safety advisory notice (CSAN).

This update is in conjunction with: Customer Advisory Notice CT053/17/S DocLink - 667492-EAE-01S-01

1.1.3 Prerequisites

The latest version of this document can be found in the Services Knowledge Base (SKB).

1.1.4 Special Tools

n.a.

1.2 Material Information

1.2.1 Ordering Information

n.a.

1.2.2 Preparations for Intranet Download

The required file: "**Customer Advisory Notice CT053/17/S**" has to be downloaded from the Siemens Healthcare Intranet -> Customer Services.

- Go to (➔ Product Information, https://productinformation.healthcare.siemens.com/)
- Follow the path:
  CT -> Software Download -> UIs 2017
- Click the left mouse button on the file to be downloaded: "Customer Advisory Notice CT053/17/S"
- Save the file on the hard drive D:\...
- When finished saving close the window

1.2.3 Return of Parts

n.a.

2.1 Work Steps

- Open the zip file “Customer Advisory Notice CT053-17-S.zip”.
- Select the customer advisory notice in the correct language and print it out.
  The local update management may want to add a personalized cover sheet.
- Send the letter to the customer via certified mail and with a prove of delivery.
  (The reception needs to be acknowledged.)
- When you have received the prove of delivery report the update.
  See Final Work Steps.

2.1.1 Final Check

n.a.

2.1.2 Final Work Steps

- The update has to be reported by authorized employees, either via:
  - Automated data transfer (only in countries connected to SAP via an Update Handling Interface)
  - The “ Update Handling ” on the Siemens Healthcare Intranet/Extranet -> Customer Services application (for countries NOT connected to SAP via the Update Handling Interface)
  - the Completion Protocol (for countries that do not have one of the connections indicated above)

The update is not considered to have been performed until the IVK structure in the Installed Base is updated.

2.1.3 Customer Information

n.a.

2.1.4 Changes to Previous Version

n.a.

3.1 CUSTOMER SAFETY ADVISORY NOTICE

3.1.1 Reason for the Update

Distribution of customer safety advisory notice (CSAN).

3.1.2 Protocol

This update has been completed successfully. The customer was informed of the solution to the “Customer (Safety) Advisory Notice”: **CT053/17/S (667492-EAE-01S-01)**.

Customer:	.....		
Customer No.:	.....	Func. Location	.....
Material No. of the system:	.....	Serial number of the system:	.....
Notification:	.....		
Remark:	.....		
Remark:	.....		
Country:	.....	Site:	.....
Performed by:	.....	Telephone:	.....
Date:	.....	Signature:	.....

File the protocol in the corresponding binder.

4 List of Hazard IDs

There are no Hazard IDs in this document.

healthcare.siemens.com/services

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Telephone: +49 9131 84-0
siemens.com/healthineers

Print No.: CT00-000.897.98.01.02 | Replaces: n.a.
Doc. Gen. Date: 10.17 | Language: English

siemens.com/healthineers