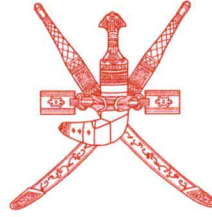


# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للأدوية  
والرقابة الدوائية  
مسقط

To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No. 205.... dated 25/11/21. Regarding NCMDR FSCA of SOMATOM Confidence, SOMATOM Definition Edge, SOMATOM Definition Edge Plus, SOMATOM Definition AS from ( mrf: Siemens Healthcare GmbH).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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مسقط

Circular No. 205 / 2021

20 -04-1443 H

25 -11-2021

Field Safety Corrective Action of SOMATOM Confidence, SOMATOM Definition Edge, SOMATOM Definition Edge Plus, SOMATOM Definition AS from Siemens Healthcare GmbH.

Source	NCMDR-National Center for Medical Devices Reporting <a href="http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15922">http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15922</a>
Product	SOMATOM Confidence, SOMATOM Definition Edge, SOMATOM Definition Edge Plus, SOMATOM Definition AS.
Description	Scanning Systems, Computed Tomography.
Manufacturer	Siemens Healthcare GmbH.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	SOMATOM Confidence, SOMATOM Definition Edge, SOMATOM Definition Edge Plus, SOMATOM Definition AS, with syngo.CT VB20A_SP5
Reason	Possible degradation of image quality in head scans.
Action	1. It is mandatory to change to the new cupping correction setting CC = 4 immediately, restart the application, and (if applicable) reconstruct the raw data again (See attached FSN for more details) 2. Contact the local agent for remedial action
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL



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

To all users of the following software products:

**SOMATOM Confidence**  
**SOMATOM Definition Edge**  
**SOMATOM Definition Edge Plus**  
**SOMATOM Definition AS**  
with *syngo*.CT VB20A\_SP5

Name  
Department

Dr. Markus Nagel  
SHS DI CT QT

Telephone  
E-mail

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healthineers.com

Date

November 2021

**Customer Advisory Notice CT067/21/S**

## **Customer Advisory Notice CT067/21/S**

**Subject: Possible degradation of image quality in head scans with *syngo*.CT VB20A\_SP5**

Dear Customer,

This letter is to inform you about a possible degradation of image quality in head scans when using your CT scanner with software *syngo*.CT VB20A\_SP5.

### **When does the malfunction occur and what is the problem?**

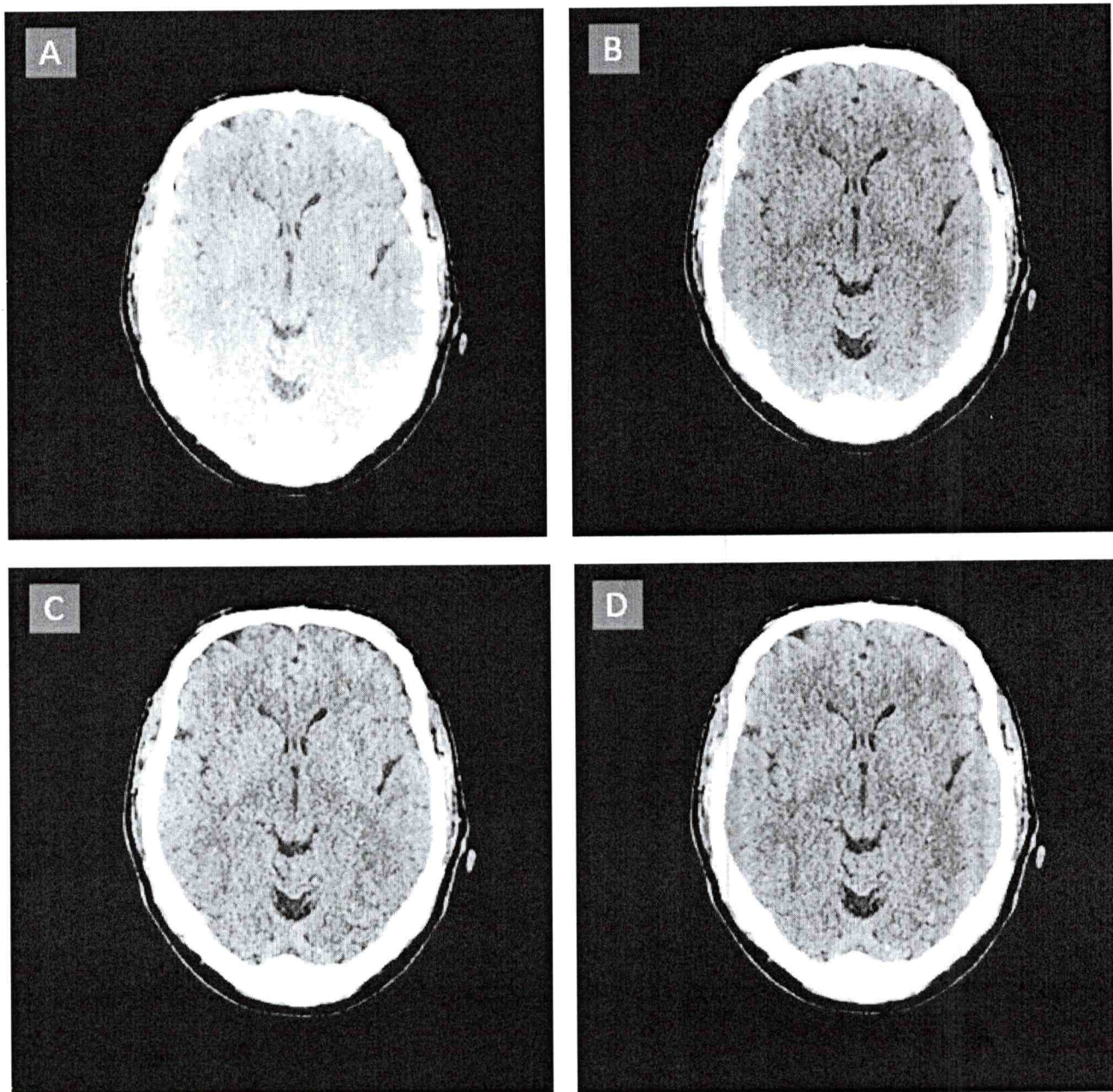
Relevant degradation of head image quality has been reported, which depends on the configuration of your CT scanner and your reconstruction settings. The problem occurs only in cases where an H-kernel is used in combination with the iBHC-Setting (beam-hardening correction) "Bone" or "Iodine", the standard for most native cranial CT studies. To date, no related misdiagnosis has come to our attention, however, we would like to make you aware of such degradation to avoid a possible future misinterpretation.

Technically, the issue is related to the so-called cupping correction. With *syngo*.CT VB20A\_SP5, a new cupping correction setting (CC = 4) has been introduced featuring an improved algorithm to reduce artifacts. This new algorithm works properly for CC = 4, but unexpectedly degrades image quality for the other cupping correction factors:

- CC = 0 (called "Standard" in Application Specific Configuration)
- CC = 1
- CC = 2

In Figure 1 below, the issue (hyperdense extended areas) can be seen in the upper left image (A).  
For a direct comparison, the situation is also shown for a correct reconstruction based on the settings

- CC = 0 / < SP5 (upper right): (B)
- CC = 1 / < SP5 (lower left): (C)
- CC = 4 / SP5 (lower right): (D)



**Figure 1:** Sample images of a native cranial CT scan with reconstruction kernel Hr38 and iBHC=Bone:  
(A): degraded image quality with CC = 0, SP5  
(B): normal image quality with CC = 0, < SP5  
(C): normal image quality with CC = 1, < SP5  
(D): normal image quality with CC = 4, SP5

### How can the user help to avoid the issue?

The issue is an effect of the reconstruction only and raw data itself is not affected. A re-scan is not required. Instead, the data can be reconstructed again with the new cupping correction setting CC = 4.

**In any case, to avoid possible misdiagnosis, it is mandatory to change to the new cupping correction setting CC = 4 immediately, restart the application, and (if applicable) reconstruct the raw data again.**

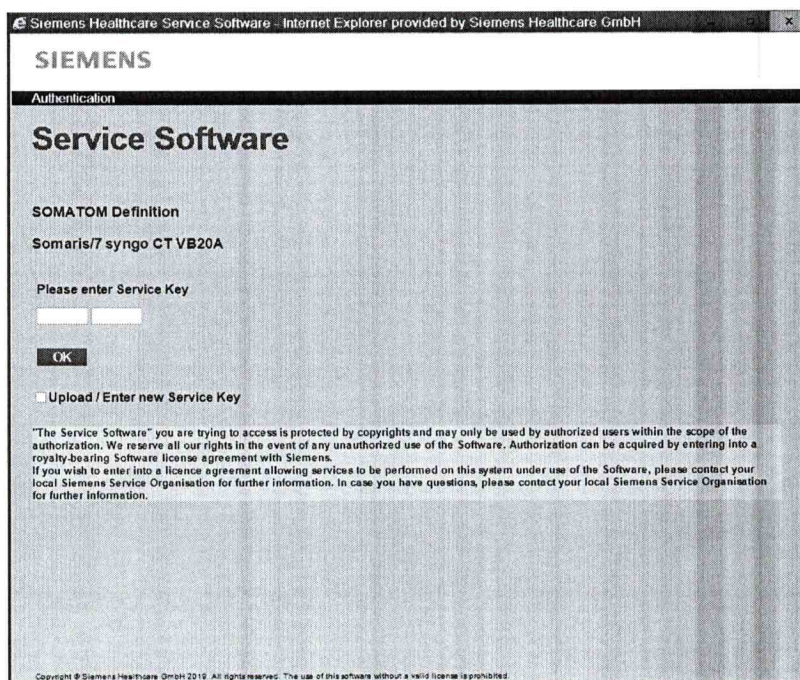
Cupping correction setting CC = 4 is a further development of CC = 1: The Image impression is very similar to setting CC = 1 but an important improvement reduces possible artifacts. For customers that have routinely been using CC = 0 and CC = 2 instead of CC = 1, the image impression with CC = 4 will be different from what they are used to.

- Please note that the use of cupping correction CC = 4 may cause slightly altered CT numbers of non-water equivalent body materials or tissues in reconstructions with H-kernels and enabled iBHC (i.e., setting “Bone” or “Iodine”) compared to results obtained with settings CC = 0, 1, or 2. **For any quantitative interpretation of CT numbers, e.g., the mapping of HU to electron density, a recalibration is necessary.**

Please find below a detailed description, how to change the cupping correction:

- 1) Please make sure, that no patient is open in the chronicle. If a patient is still open, close it before proceeding!
- 2) Choose **Options → Service → Local Service**

Local Service window appears:



- 3) Click **OK** without entering a service key

4) Click **Configuration** and change the setting as described

Configuration window appears:

A. Choose **Application**

B. Choose **"4"** for cupping correction

C. Click **Save** Button

After a few seconds a message window "Site data successfully saved" appears → Click **OK**

D. Click **Home** Button

After a few seconds a message window "a restart of application SW..." appears. → Click **OK**

Result: Your system will be restarted automatically. The cupping correction change will be active after the restart.

**How will the issue be permanently resolved?**

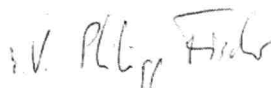
We are working with high priority on a solution for the described degradation.  
Your local service organization will contact you in due time and schedule an appropriate date for the installation of the solution, which will be provided to you free of charge.

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

If you have sold your system and/or it is no longer in your ownership, we kindly ask you to immediately forward this Advisory Notice to the new owner of the system. Please also inform us of the identity of the new owner of the system.

If you have any unresolved questions or technical support is required, please contact your local application specialists or your local service/sales organization.

Sincerely yours,



Dr. Philipp Fischer  
Head of CT  
Computed Tomography  
Siemens Healthcare GmbH  
Forchheim  
Germany

Electronically  
signed by: Philipp  
Fischer  
Reason: I am  
approving this  
document  
Date: Oct 26,  
2021 20:11  
GMT+2



Dr. Markus Nagel  
Head of CT QT  
Computed Tomography  
Siemens Healthcare GmbH  
Forchheim  
Germany

Electronically  
signed by:  
Markus Nagel  
Reason: I am  
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GMT+2