Name	Dr. Markus Nagel
Department	SHS DI CT QT
Telephone	+49 (9191) 18-7231
E-mail	markus.nagel@siemens-healthineers.com
Date	December, 2020

Customer Advisory Notice CT086/20/S

To all users of SIEMENS SOMATOM:

Force
Definition AS
Definition Edge
Definition Flash
Drive
Confidence
EdgePlus

running on *syngo*.CT VB20A_SP3

Customer Advisory Notice CT086/20/S

Subject: Technical issue during interventional workflow with several SOMATOM CT scanners running on *syngo* CT VB20A_SP3, solved with the new servicepack VB20A_SP4

Dear Customer,

This letter is to inform you about a software issue we have identified in the current *syngo* CT VB20A_SP3 software running on your SOMATOM CT scanner and a planned software update to correct this issue.

What is the problem and when does the malfunction occur?

When performing an interventional procedure using an i-Sequence or i-Fluoro mode under the specific conditions described below, the RTD (Real Time Display) images will potentially not be displayed during the subsequent i-Sequence or i-Fluoro scans or any other following examinations, regardless of the scan mode (e.g.: volume scan). This can occur immediately or at a later point in time.

In this situation, any i-Fluoro scans will be canceled automatically after 2 seconds with an error message stating that the RTD images cannot be shown in time (see Fig. 1).
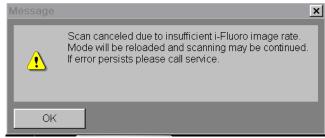

Fig. 1 i-Fluoro error message

The following sequence of operations will trigger the described issue:
- An i-Sequence or i-Fluoro mode has been loaded and used at least once.
- More than 50 images have been interactively scrolled through by the user within the same scan protocol.

How can the operator help to avoid the above-mentioned issue?

When performing interventional examinations using the i-Sequence or i-Fluoro mode, please do not scroll through more than 50 images between two scans.

If an interventional examination has already been performed and the correct display of RTD images is impaired, please restart the application via System → End → Restart Application. After a successful restart, standard operating conditions are restored.

How will these issues be permanently resolved?

This issue will be resolved with an improved software version, *syngo* CT VB20A_SP4. A service pack will be rolled out free of charge with the CT087/20/S update for all affected systems. Its release is planned for the end of Q1/2021. All future service packs will also contain the fix.

We appreciate your cooperation with this Customer 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 SOMATOM CT scanner and/or it is no longer in your ownership, we kindly ask you to immediately forward this Customer Advisory Notice to the new owner of the CT scanner. Please also inform us of the identity of the new owner of the CT scanner.

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

Sincerely yours,

Electronically signed by:
Philipp Fischer
Reason: I am approving
this document
Date: Dec 22, 2020 19:28
GMT+1

Electronically signed by:
Markus Nagel
Reason: I am approving
this document
Date: Dec 22, 2020 14:46
GMT+1

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

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