SIEMENS Healthcare

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To all customers using

SOMATOM Definition Flash running software version syngo CT2012B SOMATOM Definition Edge running software version syngo CT2012B SOMATOM Definition AS running software version syngo CT2012B SOMATOM Definition running software version syngo CT2012B

SOMATOM Definition AS running software version syngo CT2013B

CUSTOMER SAFETY ADVISORY NOTICE

Dear Customer,

Your SOMATOM CT is equipped with one of the above-mentioned software versions. We would like to inform you about a malfunction which may lead to a system display freeze during interventional procedures.

When does this problem occur?

If the function "Auto save last displayed images as key images" is activated during an interventional procedure, your software configuration allows conflicting access to the CT system image database. In such situations a system display freeze might occur. Normal interaction with the system is then no longer possible. No error message is issued and only a system restart resolves the problem. In case of a sudden system display freeze the interventionalist will potentially not immediately recognize the malfunction and continue the interventional procedure.

In view of the misleading information shown on the display an injury of the patient cannot be fully ruled out.

How will this problem be corrected?

We have carefully analyzed this issue and developed a solution, which will be implemented in our next Service Pack. The release of this Service Pack is scheduled for February 2014.

Siemens AG

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SCF 10/2013 V13.06 Page 1 of 3

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What steps can the user take to avoid or minimize the problem?

To avoid this error until you receive the next Service Pack the interventionalist must deactivate the option "Auto save last displayed images as key images". (System Configuration → Intervention, see Fig. 1)

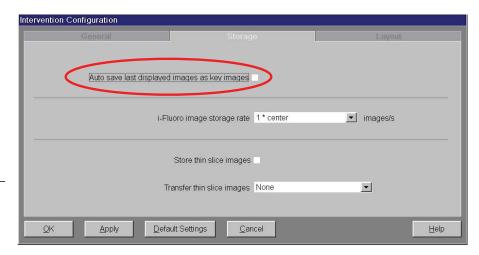


Fig. 1: The "Auto save last displayed images as key images" function has been disabled. The error no longer occurs

The interventionalist can still save manually the key images displayed on the monitor without any problems. (Fig. 2). The possibility to document interventions is therefore still granted.

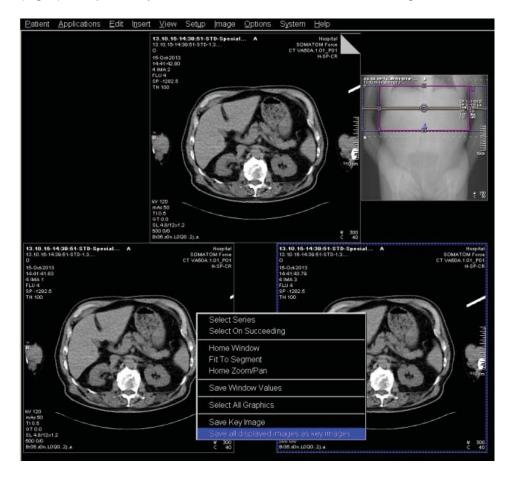


Fig. 2: Key images can still be saved for documentation purposes manually

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We kindly request you to comply with this safety advisory notice and ask respectfully that you instruct your personnel accordingly. Please ensure that this safety advisory notice is filed with the SOMARIS operating instructions until the corrected Software has been installed on your SOMATOM CT System.

We apologize for any inconvenience this technical problem may have caused, and hope that this information proves helpful in avoiding potential problems in the future. More information is available on request from your local Siemens application specialist.

Best regards,

signed
Vice President
Quality Management
Computed Tomography

vice President
Customer Excellence
Computed Tomography

This document is valid without an original signature.