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<To the person in charge of the unit where the SIEMENS product is operated, and the administrative head of organization>

Contact person of the Regional Unit Department ADD MY INFORMATION

Telephone
Fax
E-Mail

Date

Safety Advisory Notice

To all users of the SIEMENS Cios Alpha mobile C-arm x-ray system

Contact person of the Business Unit Department H CP XP MK IN SGU
Telephone 09131 84
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E-Mail @siemens.com
Date

Re: How to avoid potential system freezes of the Cios Alpha mobile C-arm x-ray system and resume full system operation

Dear customer,

This letter is to inform you of how to avoid system freezes that may potentially lead to hazard to patients and how to resume operation of Cios Alpha mobile C-arm x-ray system in a fast and reliable manner.

When does this malfunction occur and what are the potential risks?

It has been reported that under certain circumstances the following user actions may cause the system to freeze. The system may become temporarily inoperable.

- When images were transferred from the left monitor to the right monitor (function A to B) during image acquisition (i.e. radiation on) or shortly before starting image acquisition
- When acquisition of image was started while storing of scenes initiated by pressing the Store button was still in progress
- When scene replay was initiated either automatically or by pressing the "play" button (especially when pressing the "play" button more than once) while the storing of those scenes was still in progress
- When image acquisition was initiated again before automatic replay of the last scene started
- When finalized CD/DVDs were used to store additional data
- When radiation summary reports with more than 190 entries were being exported

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Sitz der Gesellschaft: Berlin und München, Deutschland; Registergericht: Berlin Charlottenburg, HRB 12300, München, HRB 6684
WEEE-Reg.-Nr. DE 23691322

- When system restart was initiated when the error message "System blocked. Turn system off/on" (error codes 215/80 and/or 208/80) was displayed

If a system freeze occurs, a system reset is required to resume fully operation. This process may take approximately 4 minutes.

During the reset process no x-ray imaging is available at Cios Alpha mobile C-arm x-ray system.

What steps can the user take to avoid the potential risk of this issue?

- Avoid to transfer images with the A to B function either shortly before starting or during image acquisition and allow a minimal time delay (up to 5 seconds) between A to B and the start of the next image acquisition
- Allow storing of scenes to be completed (i.e. the progress bar "Fluoro loop storage in progress" is not displayed anymore) before you initiate next image acquisition
- Allow replay of the 'Last Scene Hold' (LSH) to be completed before you start next image acquisition, do not press the "play" button more than once.
- Allow storing of scenes to be completed (i.e. the progress bar "Fluoro loop storage in progress" is no longer displayed) before starting play/replay of the scene
- Ensure that CDs/DVDs used to store data have not been previously finalized
- Avoid exporting studies with radiation summary reports containing more than 190 entries to CD/DVD/USB media and to DICOM nodes
- If the error message "System blocked. Turn system off/on" (error codes 215/80 and/or 208/80) is displayed do not turn off the system. The system is able to recover automatically without a restart. Please wait up to 50 seconds and simply acknowledge the message by pressing the OK button

In general, if a system freeze occurs during an intervention, act according to the emergency procedure (please refer to the highlighted Section "Resetting the Cios Alpha" at the end of this letter): Reset the Cios Alpha mobile C-arm x-ray system by pressing the RESET button located on the right side of the monitor cart and press the ON button on the monitor cart.

The system restart will take up to 4 minutes.

Please be advised that the emergency procedure is available as a magnetic board and should be attached at the system monitor cart.

Please, do not try to turn the system off and on, as this will not restart the system in the above mentioned cases and may unnecessarily delay resumption to full operation.

How will the issue finally be resolved?

Siemens is planning to release a modification for the Cios Alpha mobile C-arm x-ray system that will resolve the above mentioned potential malfunctions. The modification will be available by the end of June 2015. As soon as the modification is available a Siemens service engineer will get in touch with you to schedule implementation of the modification for your Cios Alpha mobile C-arm x-ray system.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is placed in the system's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely Yours



CEO H CP XP

H CP XP QM

Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of the Cios Alpha mobile C-arm x-ray system with the Serial number _____ (optional) that I received the following document:

Safety Advisory Notice

How to avoid potential system freezes of the Cios Alpha mobile C-arm x-ray system and resume full system operation

Place, Date _____

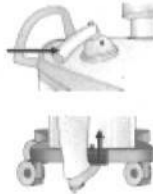
Name _____

Signature _____

Cios Alpha – Emergency procedure

For interventional applications, always keep a second unit at hand for emergencies

Cardiopulmonary resuscitation (CPR) procedure



- ◆ Release the electric brakes and move the C-arm into a position from where it can be removed from the patient table without causing a collision.
- ◆ In case of power failure/emergency stop: Override the brakes.
- ◆ If necessary, remove the remote control unit from the patient table and attach it to the monitor trolley.
- ◆ Release the brake lever and remove the Cios Alpha from the treatment area. Watch out for cables leading to the monitor trolley, remote control unit and foot switch!
- ◆ If necessary, release the foot brake and remove the monitor trolley from the treatment area.

Unlocking radiation release



- ◆ Press this button in the PREPARATION tab.
- ◆ Enter the password "0000" to enable radiation release.

Emergency stop

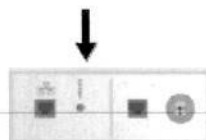


The emergency stop button is located on the control unit of the Cios Alpha.

- ◆ Press the emergency stop button.
 - All motorized movements are disabled.
 - Radiation is interrupted.
- ◆ Release radiation again: Press the foot switch or hand switch again.

Resetting the Cios Alpha

If the computer fails to shut down or no longer responds to inputs, a system reset may be necessary:

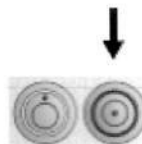


- ◆ Press the reset button with a pointed object, then press the ON button on the monitor trolley.
- ◆ Wait until the system has rebooted.

The following information will be lost as the result of a reset: Collimator position, set dose values, image orientation, position memory.

Resuming operation after a power failure

In the case of a power failure, the unit is switched off.



- ◆ Wait until the computer has shut down.
- ◆ Restart the system by pressing the ON button on the monitor trolley as soon as power has been restored.
- ◆ Wait until the unit has fully rebooted. Pay attention to any error messages that may appear during booting.
- ◆ Resume treatment:
 - Reselect the last patient.
 - Make the necessary settings, e.g. dose, collimator, image parameters, etc.
 - Check/correct the C-arm position.

Total time until resumption of operation: approx. 4 minutes.

For detailed information please refer to the System Operator Manual.
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