

Siemens Healthcare GmbH, HC CP XP MK, Allee am Röthelheimpark 2,
91052 Erlangen

<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
Department HC CP XP MK IN SGU
Telephone 09131 84 8218
Fax
E-Mail gianmarco.antonini@siemens.com
Date

Re: How to avoid patient procedure interruption in case of a potential system failure

Dear customer,

This letter is to inform you of steps required to avoid procedure interruption that may occur due to a potential hardware malfunction of the Siemens Cios Alpha C-arm x-ray system.

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

It has been reported that under certain circumstances, when starting the system up or reconnecting the C-arm cable to the main unit, the error 5000/243 "No X-ray - FD re-initializes" may occur. The error refers to a potential hardware malfunction which requires a part replacement. When this error occurs, the system will become inoperable (i.e. no X-ray) until the affected part is replaced.

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

Please perform the following checks before starting a procedure with Cios Alpha:

- Ensure that the system is ready after the startup
- Ensure that the error 5000/243 is not displayed, neither as message box nor in the FLC status bar (lower left side of the left monitor)
- In general, avoid disconnecting and reconnecting the C-arm cable during or shortly before starting a procedure

In case the error described above is displayed, the Cios Alpha system becomes inoperable; and a backup system is needed to perform the procedure.

Please inform the Siemens Uptime Service as soon as possible.

Siemens Healthcare GmbH
Geschäftsführung: Bernhard Montag, Vorsitzender;
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Sitz der Gesellschaft: München, Deutschland; Registergericht: München, HRB 213821
WEEE-Reg.-Nr. DE 64872105

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 malfunction. As soon as the modification is available, a Siemens service engineer will contact you to schedule implementation of the modification for your 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,



Andre Hartung
CEO HC CP XP



Jürgen Buckow
HC 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 a procedure interruption due to a potential hardware failure in Cios Alpha

Place, Date _____

Name _____

Signature _____