

To users of the Cios Alpha VA20 / VA30 and
Cios Fusion systems

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Important customer safety notice regarding corrective field action:

AX033/19/S

**Information about corrective action for Cios Alpha VA20 / VA30 and Cios
Fusion systems from a specific production batch**

Dear Customer,

Your Cios system is a high-quality mobile C-arm that meets all regulatory requirements regarding dose display. For this reason a DAP chamber (DAP=Dose area product) is installed.

What is the issue to be rectified, and when does it occur?

The DAP chamber may be missing an insulating foil on the outside of the carbon electrodes.

How does the problem affect system operation, and what are the potential risks?

The system is not subject to any restrictions and may be operated safely by users for patients. However, there is a potential risk in certain circumstances for a service technician carrying out a service call on the DAP chamber. Due to the missing insulating foil and even though the amperage of the component is low an electrical accident cannot be ruled out.

What action will be taken?

We will check the DAP chamber in your system, and if necessary, replace it with a sound, insulated DAP chamber. This letter will be distributed to affected customers as Update AX032/19/S.

How was the issue detected?

The problem was discovered during production final testing in another, comparable system and was localized to a few installed units by checking the component batches.

How will the corrective action be implemented?

Our service team will schedule an appointment with you to implement the measure. Service personnel specially trained in this problem will be used for this procedure to ensure a safe exchange.

What risks are there for patients who have previously been examined or treated using this system?

The system is not subject to any restrictions and may be operated safely by users for patients. The issue encountered here is a hardware fault that has no effect on patient diagnosis or treatment already carried out.

We thank you for your cooperation in dealing with this customer safety notice, and request that you immediately notify all staff at your facility who need to be aware of this problem, and instruct them accordingly. Please also forward this safety information to any other facilities that could also be affected by this action.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the current owner. If possible, please notify us of the identity of the current owner.

We thank you for your time and cooperation and wish you much continued success with your Cios system.

Best regards,

SIEMENS Healthcare GmbH
Business Area Advanced Therapies

