CC: Chairman of Medical Board &
Heads of Departments

SIEMENS Healthineers

To the users of Cios Alpha VA20 systems

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Important customer safety notice regarding corrective field action:

AX013/19/S

Important customer safety notice AX013/19/S regarding Cios Alpha VA20

Dear customer,

Your Cios Alpha is a high-quality mobile C-arm, which offers you excellent image quality with high generator performance and extensive protection against overheating at high power levels. Nevertheless, we would like to inform you that with the Cios Alpha, permanent operation at very high tube outputs results in increased wear of the radiation generation components.

What is the problem to be corrected and when does it occur?
The organ programs pre-installed ex works enable safe operation within the specified performance limits.
However, it is possible to overwrite the organ programs with higher performance parameters.

How does the problem affect system operation and what is the potential risk?
Permanent operation at very high tube output results in increased attrition of the radiation generation components.
This is the case, for example, when tube voltages of 125 kV are used over a longer period of time, e.g. more than 30 minutes. There is a risk of premature failure of the monoblock and thus a loss of the imaging X-rays.

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What measures are being taken?
We therefore recommend avoiding overwriting the organ programs, as this can lead to more frequent operation with the performance parameters mentioned above. Please read the operating instructions in general and in this context especially the new Addendum which we have now delivered to you. Please forward this information to your employees or organizations that are affected.

How was the problem detected?

The problem was detected during our field observation.

How is the corrective measure implemented?

This letter and the addendum to the user manual will be distributed as an AX013/19/S update to Cios Alpha VA20 to affected customers.

What are the risks for patients who have been previously examined/ treated with this system?

In this case, we do not consider a follow-up examination of patients to be necessary. The problem at hand here is a possible hardware error without effect on a previous diagnosis and treatment of patients.

We would like to thank you for your cooperation in dealing with this safety notice and ask you to immediately pass this information on to all employees in your institution who need to know about this problem and to instruct them accordingly. Please also forward this safety notice to other entities that may also be affected by this measure.

If the device has been sold and is therefore no longer in your possession, we would like to ask you to forward this safety note to the current owner. If possible, please inform us of the identity of the current owner.

We thank you for your attention and cooperation and wish you continued success with your Cios Alpha.

Best regards,

SIEMENS Healthcare GmbH
Business Area Advanced Therapies

[redacted]

Michel Therin
Head of Business Area AT

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Johann Böck
Safety Officer Medical Devices AT