To all users of the following systems: Cios VA30

Product/Trade Name:	Cios Spin, Cios Alpha, Cios Flow	EU-SRN	DE-MF-000006122
		E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
UDI-DI:	04056869153506, 04056869153490, 04056869246628	Date	September, 2023
		Corrective Action ID	AX036/23/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Fulfillment of new requirements from DIN and IEC standards for Cios VA30 Systems

Dear Customer,

We would like to inform you about a potential issue with your Cios VA30 system(s) as well as a corrective action that will be performed.

What is the issue and when does it occur?
Potentially affected system: Cios Spin VA30

With respect to DIN 6862-3:
So far, in 3D mode, information about image orientation regarding "laterality" (i.e., L = left / R = right) cannot be defined and saved with the clinical image by the user.

Potentially affected systems: Cios Alpha VA30, Cios Spin VA30, Cios Flow VA30

With respect to IEC 60601-2-54:
So far, in radiography modes SUB, DR, and DCM, the autostore function can be deactivated by the user; however, in 3D mode, the autostore function is activated by default and cannot be deactivated by the user.

What is the impact on the operation of the system and what are the possible risks?

With respect to DIN 6862-3:

In 3D mode, the user could mix up the patient orientation regarding "laterality". Therefore, the user could carry out a wrong diagnosis and/or wrong treatment based on the acquired clinical images, which does not show clear information about patient orientation.

With respect to IEC 60601-2-54:

The user could deactivate autostore mode for radiography modes SUB, DR, and DCM. Consequently, user could accidentally forget to save the images manually and be forced to repeat image acquisition and double the radiation dose originally required.

How was the issue identified and what is the root cause?

As part of continuous system maintenance, new and already delivered systems have been continuously monitored regarding compliance with applicable standards and regulations as well as regarding changes to standards.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

With respect to DIN 6862-3:

In 3D mode and if "laterality" information is important in the procedure, the user should place a marking aid in the radiation path to clearly define patient orientation (i.e., left or right marker) before the procedure begins.

With respect to IEC 60601-2-54:

The user should not deactivate autostore mode for radiography modes SUB, DR, and DCM.

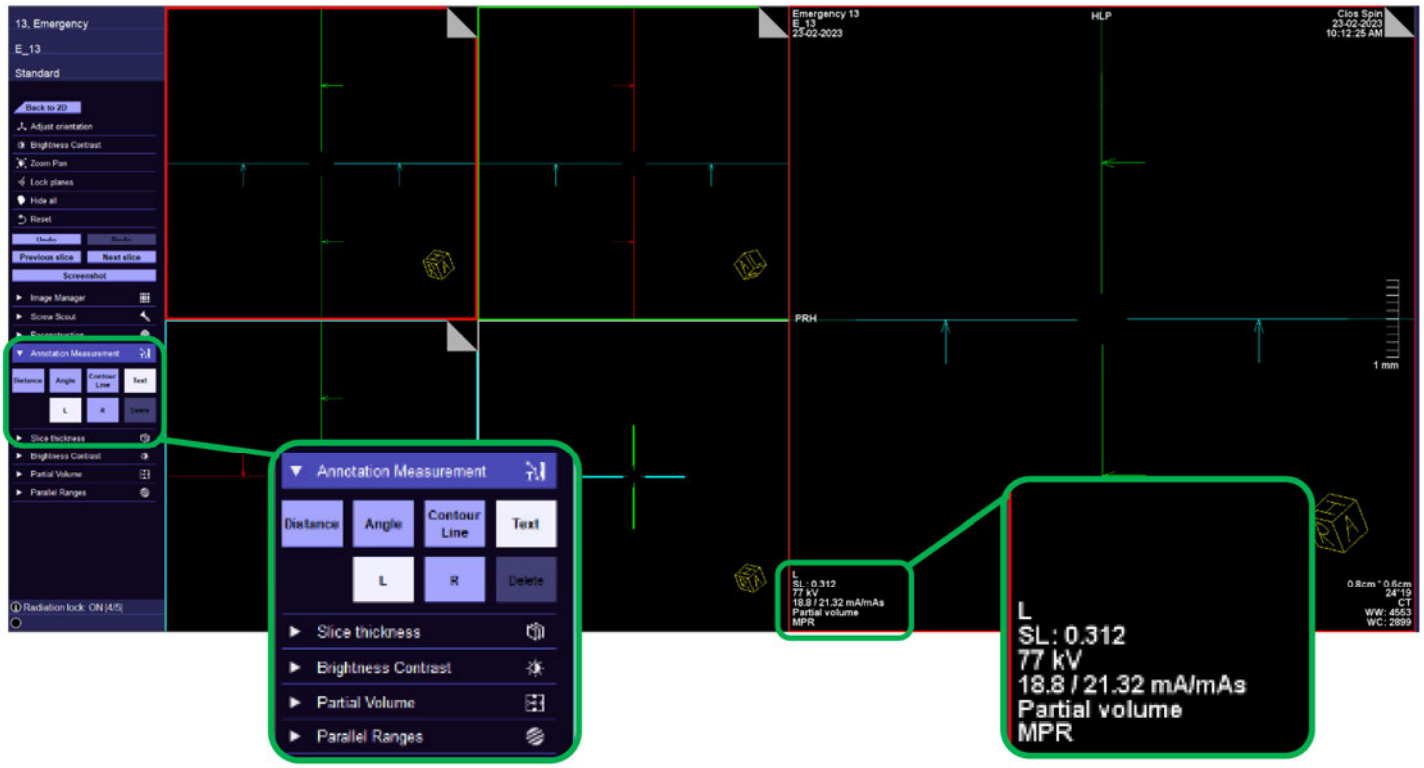
What actions are being taken by the manufacturer to mitigate possible risks?

Our service organization will install a new software version VA30K.

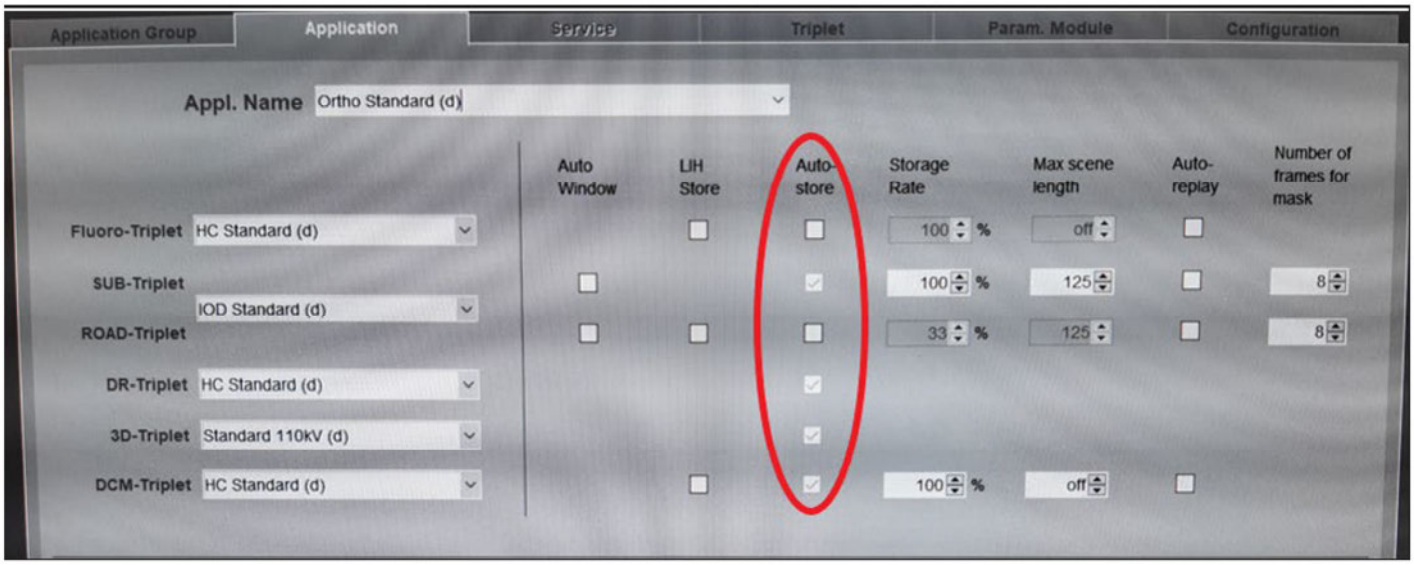
With software version VA30K, the user interface of Cios VA30 systems will be changed to consider the current standards DIN 6862-3 and IEC 60601-2-54.

With respect to DIN 6862-3:

In 3D mode and if patient orientation information is important in a procedure, the user can predefine the patient orientation "L/R" (left/right), and therefore "laterality" information will additionally be saved in the clinical image (see screenshot of user interface below).



With respect to IEC 60601-2-54:
In radiography modes SUB, DR, DCM as well as in 3D mode, the autostore function is selected/activated by default and cannot be deactivated by the user.



What is the efficiency of the corrective action(s)?

With respect to DIN 6862-3:

With the corrective action, the probability of mixing up the patient orientation regarding "laterality" (i.e., left/right) will be minimized.

With respect to IEC 60601-2-54:

With the corrective action, the user will no longer be able to deactivate autostore mode for radiography modes SUB, DR, and DCM.

In summary, the corrective action minimizes the probability of occurrence of nonconformity with international standards.

How will the corrective action be implemented?

The corrective action will be implemented with the upcoming software version VA30K as measure AX036/23/S. Our service organization will contact you to schedule an appointment to perform the corrective action. Please feel free to contact our service organization for an earlier appointment.
This letter will be distributed to all affected customers as update AX035/23/S.

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

The manufacturer does not consider risks for patients who have previously been examined or treated.

Please ensure that all users of the affected products within your organization and others who may need to be informed receive the safety-relevant information provided with this notice and comply with the recommendations therein.
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 retained in your product-related records appropriately. Please keep this information at least until the measures have been finalized.
Please forward this safety information to any other organizations that could be affected by this measure.

If the device has been sold on and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner, where possible.

With best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies (AT)

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