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Healthcare

To all users of
Artis Zeego systems

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Important safety notice

Safety notice for customers **UI-S AX 012/13/S**

Overlay of system information after a functional check

Dear Customer,

We are writing to notify you that, after a functional check of the brakes on the Artis Zeego system, there is a possibility of any output system information being overlaid with different system information. The overlaid information requests users to contact the service department.

To clear this problem, update AX 006/13/S is available for version VC14J and update 007/13/S for version VC21A as of February 21, 2013. By means of this important safety notice, we would therefore urgently recommend you to arrange an appointment with our customer service.

When does this problem arise and what are the possible risks?

The system outputs information if an imminent problem with the brake is indicated after carrying out the regular brake test. This information requests the user to contact the service department to identify further measures to be taken.
The described information may be temporarily hidden by other information, so there is a risk it may be overlooked by the user.
The system remains operational, but the rotary arm can only be moved at a reduced speed.

What measures can users take to mitigate the potential risk arising from this problem?

If, after carrying out the regular brake test, the system can persistently only be moved at a reduced speed, please immediately notify the service department to clarify what further measures need to be taken.

What measures can users take to mitigate possible risks?

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The above updates will modify the system software such that it is no longer possible for this information to be overlaid.

What risks may arise from the scenarios described above for patients that have been previously examined/treated using this system?

There are no risks for patients that have previously been examined or treated using this system.

We thank you for your understanding and cooperation with this safety notice, and invite you to promptly notify the staff at your organization who have to be aware of this problem. Please also forward this safety notice to other organizations affected by this measure. We would ask you to take this safety notice and the corresponding measures into account until the problem has been cleared by running updates AX006/13/S or AX007/13/S.

The national supervisory authorities have been duly notified.

If this device has been sold and is therefore no longer in your possession, please send this safety notice to the new owner. Please also provide us with details of the new owner of the device.

Best regards,

SIEMENS AG Healthcare Sector
Business Unit AX

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CEO H IM AX

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Safety Officer Medical Devices