SIEMENS

Healthcare

To all users of Artis systems running software version Artis VC1x

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Important customer safety notice

Update AX026/13/S

Safety-related information regarding corrective measures for Artis systems running Artis VC1x software

Dear Customer,

We would like to draw your attention to a possible problem with Artis systems that are running Artis VC1x software.

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

If a network problem arises that puts the system into the operating mode "Bypass Fluoro" while the function "Block radiation" is activated, this function cannot be deactivated again by once more pressing the "Block Radiation" key on the **TSC (Touch Screen Control)**. Even in positions which are different from the patient transfer position and the park position, the system then displays the message "XRAY manually disabled".

Risk: The system's image generation function is not available, even to a limited extent, for patient examinations without switching the system off and back on again manually in the meantime.

What measures are to be taken to avoid possible risks?

If the fault described above occurs, we urgently recommend switching the system OFF manually ("System shutdown") and then back ON again. The fault cannot generally be rectified sufficiently, either by executing the "System Restart" or "Application Restart" functions. A corresponding supplement to the Operator Manual is enclosed with this letter.

The problem will be solved when the next Service Update is available (currently scheduled for 2014).

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

We do not consider it necessary in this case to re-examine patients.

We thank you for your cooperation in dealing with this safety notice and request that you promptly notify and instruct accordingly all the staff at your organization who have to be aware of this problem. Please also forward this safety information to other organizations that could be affected by this measure. Please observe this safety notice, and comply with the corresponding measures until the update has been fully completed.

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

Best regards,

SIEMENS AG Healthcare Sector

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