SIEMENS Healthcare

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To all users of Simens Artis one systems with the IO-BOX below version 4

Important customer safety notice regarding corrective field action:

AX063/15/S

Information regarding corrective action for Artis one system with the IO-BOX version below version 4.

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent a possible hazard to persons and equipment.

What is the underlying issue requiring this corrective action and when does the issue occur?

The issue is caused by a component called IO-BOX (It is a signal input/output module, which also provides the housing for the image pre-processing component) rebooting on its own due to an error pattern. IO BOX reboot may happen in rare cases. In such cases the x-ray may be not available.

What effect does this system behavior have on the operation of the system and what potential risks are associated with this?

Generally when above situation has happened, the system needs a reboot to recover. In the worst case, the system may reboot more than once in a short time and the outcome could be system cannot be used at that time. The procedure may be delayed or even interrupted.

What action will be taken?

This issue will be remedied with hardware update AX063/15/S. Following the installation of this update, the IO-BOX will be updated to version 4 or above.

How was the issue detected?

The issue was identified during regular field observation.

How effective are the corrective actions?

Following the installation of the hardware update, the cause of the undesired system behavior is remedied and the error is prevented from recurring.

How will the corrective action be implemented?

Our service organization will contact you to arrange a date for the installation of the hardware update. Please feel free to contact our service organization for an earlier appointment. This letter will be distributed to affected customers as Update AX066/15/S.

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

We do not consider it necessary to re-examine any patients in this case. This system behavior had no influence on the treatment of patients.

Please forward this information to all the staff at your organization that needs to be aware of this problem. If you have sold the device, 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.