SIEMENS Healthineers

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All customers with Sensis systems

Date June 7, 2017

Important customer safety notice regarding corrective field action:

AX034/17/S

Information about corrective action for Sensis systems.

Dear Customer,

This letter is to inform you of the implementation of the action announced in Customer Safety Advisory Notice AX005/17/S.

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

In Sensis systems, substantial contamination of the computer with dust can lead to problems with system startup. In rare cases this has led to the failure of the Sensis.

What is the impact on system operation and what is the potential risk?

If the system fails, the functions of the Sensis can no longer be used. This may result in a situation in which it is necessary to cancel or restart clinical treatment or transfer it to a functioning system.

What actions will be taken?

Our service organization will clean the computer and other relevant hardware now and during maintenance at regular intervals in future.
You will also be provided with an annex to the user manual which describes functional and safety checks.

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How was the issue detected and what is the cause?

The issue was detected in the clinical environment. It was caused by a computer being contaminated with dust.

How effective are the corrective actions?

The cause is eliminated after cleaning the computer. Recurrence of the error is prevented through cleaning.

How will the corrective action be implemented?

Our service organization will contact you shortly to arrange a date to perform this corrective action. Please feel free to contact our service organization to arrange a convenient appointment. This letter will be distributed to affected customers as Update **AX006/17/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 is a possible defect that had no influence on the treatment of patients.

We thank you for your cooperation in dealing with this customer safety notice, and request that you promptly notify and instruct accordingly all the staff at your organization who need to be aware of this problem. Please forward this safety information to any other organizations that could be affected by this measure.

If the 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 you to inform us of the identity of the device's new owner where possible.

Best regards,

Siemens Healthcare GmbH
AT Business Area

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