SIEMENS

Healthcare Sector

To all users of Artis zeego systems

BU contact:

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Important customer safety notice regarding field measure: AX055/13/S

Information regarding a safety-related corrective action for Artis zeego systems. This letter will be distributed to affected customers as Update AX 010/14/S.

Dear Customer,

We would like to draw your attention to a possible problem with your Artis zeego system.

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

In the course of our product monitoring activities, a supplier informed us of its internal discovery of an installation problem. In isolated cases, the crimping of a drive motor cable was found not to have been performed correctly. This improper cable crimping could lead to a poor contact and, as a result, increased transfer resistance. The possibility of a fire being caused by the build-up of heat has been ruled out.

We strongly recommend that you arrange an appointment with our customer service department regarding the installation of Update AX 055/13/S.

What measures will be taken to avoid possible risks?

To establish which systems are affected by improper crimping, the installed base will be examined and instances of improper crimping corrected.

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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 to re-examine patients in this instance, as this is a possible hardware fault that had no influence on the treatment of 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.

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

With best regards,
SIEMENS AG Healthcare Sector
Business Unit AX

[redacted]
CEO H IM AX

[redacted]
Safety Officer Medical Devices