SIEMENS Healthcare

Siemens Healthcare GmbH, HC AT IR MK, Siemensstr. 1, 91301 Forchheim

Name Philip Stenner
Department HC AT IR MK
E-mail philip.stenner@siemens.com

Date May 29, 2017

To all users of Artis systems.

Important customer safety notice regarding corrective field action:

AX043/16/S

Information about corrective action for Artis systems in conjunction with the Artis table

Dear Customer,

This letter is to inform you of a corrective action that will be performed to increase the protection against liquid entry into the Artis table.

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

A corrective field action AX002/15/S was already performed to protect the Artis table against liquid entry at critical locations.
However, larger amounts of liquid can still enter the table. This may result in electric table movement failure.

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

The patient table cannot be moved, or can only be moved to a limited extent.
If function failure occurs, it could 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?

Various gaps and openings on the top of the table will receive additional sealing.

How was the issue detected and what is the cause?

The issue was determined while testing the effectiveness of the prior corrective field action.

How effective are the corrective actions?

The measure eliminates the root cause also for larger amounts of liquid. Recurrence can be excluded.

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 for an earlier appointment. This letter will be distributed to affected customers as update AX065/16/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 hardware fault that had no influence on the treatment of patients.

We thank you for your cooperation in dealing with this customer safety notice. We request you to promptly notify and instruct all staff in 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
Business Area Advanced Therapies

ppa

Dr. Heinrich Kolem
President Advanced Therapies

i.V.

Wolfgang Hofmann
Safety Officer Medical Devices