SIEMENS

Healthcare

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Date March 25, 2015

To all users of Artis systems

Important customer safety notice regarding the field corrective action:

AX002/15/S

Information regarding a field corrective action for Artis systems used in conjunction with the Artis table

Dear Customer,

This letter is to inform you of a corrective action required to better protect the Artis table against penetration of liquids.

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

If the tabletop is approximately fully extended at the head end and there is a large amount of liquid on the table surface, the liquid can make its way from the foot end of the tabletop onto the top cover of the table column where it can seep into the table through a gap. If this causes electronic components to become contaminated, table movements may no longer be possible.

What action will be taken?

The gap in the top cover of the table column will be sealed. This will ensure protection against entry of liquids.

How was the issue detected and what causes it?

The issue was detected during regular field observation. When a table was exposed to a large amount of liquid for an extended period of time while in the above-described position, table movements were no longer possible with this system.

What effect will the corrective action have?

The corrective action will eliminate the cause of the problem and thereby prevent recurrence of the malfunction.

How will the corrective action be introduced?

Our service organization will contact you to arrange a date to perform the corrective action. Please feel free to contact our service organization for an earlier appointment. This letter will be distributed to affected customers as Update AX 003/15/S.

What are the risks for patients who were previously examined or treated with this system?

We do not consider it necessary to re-examine any patients in this case.
This issue involves 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 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 you have sold this device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of the device. We would also request that you inform us of the identity of the new owner where possible.

Yours sincerely

Siemens Aktiengesellschaft
Healthcare Sector
AX Business Unit

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Chief Executive Officer

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Sicherheitsbeauftragter Medizinprodukte