SIEMENS Healthcare

Siemens AG, H IM AX QM, Siemensstr. 1, 91301 Forchheim

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Contact Person:
Name Claus Kolbert
Abteilung H IM AX MK IPM
E-Mail Claus.kolbert@siemens.com
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To all Users of AXIOM Artis, Artis zee or Artis Q systems

Important Safety Information **UI-S AX053/13/S**

Important information regarding a safety relevant corrective action for your AXIOM Artis, Artis zee or Artis Q system in conjunction with a wireless footswitch.

This letter is being distributed to all affected customers via Update AX 057/13/S.

Dear Customer,

With this letter we are informing you about a potential problem with your AXIOM Artis, Artis zee or Artis Q system.

When does this problem occur and what are the risks?

A problem can occur, if by mistake the wireless footswitch gets disconnected from the loading station due to an unintentional pull of the plug connection. In this case it is necessary to loosen the interlocking mechanism. However, if this does not happen properly, the plug can become damaged. As a consequence, this could have the implication that the wireless footswitch can no longer be charged.

What are the measures that are taken to avoid possible risks for the future?

The cabling that is currently being used will be replaced for all affected systems that are installed. The new solution has a coupling device that automatically unlocks upon draw. It will be distributed via the corrective measure AX053/13/S. In addition, we will provide to all our customers an addendum for our operating manual that describes the appropriate handling required by the user.

What are the risks for the patients that have previously been examined with the system?

This matter has no consequences for patients who have previously been examined or treated using this system. We do not consider it necessary to re-examine these patients due to this hardware issue.

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. Please observe this safety notice, and comply with the corresponding measures until the update has been fully completed.

If the device has been sold and is therefore no longer in your possession, please forward this safety note 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

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Dr. Heinrich Kolem
CEO H IM AX

i.V.

Wolfgang Hofmann
Safety Officer Medical Devices