SIEMENS Healthcare Sector

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

BU-Contact: [redacted]
Name:
Department: H IM AX MK IPM
E-Mail: [redacted]@siemens.com
Date: 2014-09-10

To all users of Artis zeego systems with a C-arm from the serial number range 1000 to 1132

Important safety information for customers regarding the field corrective action:

AX018/14/S

Information regarding the field corrective action for Artis zeego systems with a C-arm from a specified serial number range

Dear Customer,

We would like to inform you that a cable harness shall be replaced on Artis zeego systems equipped with a C-arm in the serial number range from 1000 to 1132.

What problem is behind this corrective action and when does the problem occur

A cable inside the c-arm of systems affected may break within this specific serial number range. The problem will not occur systematically but sporadically in the ongoing life time of a system.

What is the impact to the operation of the system and what are the possible risks

A cable break may cause restricted functionality or even failing of the system. An ongoing procedure may be terminated at this system.

How was the subject identified and what is the root cause

The issue was identified during regular field observation. The root cause is potentially sub-optimal cable routing.

What measures are being taken to mitigate possible risks

Update AX018/14/S will involve the replacement of the affected cable harness with a modified version as well as the modification of the cable routing to prevent wear.

What is the efficiency of the corrective actions

This corrective action will avoid future failures.

How will the corrective action be implemented

Our service organization will get in contact with you for an appointment 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 019/14/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 safety information. We also want you to promptly notify and instruct all the staff at your organization who need to be aware of this problem accordingly. 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.

Yours sincerely,

SIEMENS AG Healthcare Sector
Business Unit AX

[redacted]

Chief Executive Officer

Safety Officer Medical Devices

SIEMENS Healthcare Sector

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

BU-Contact: [redacted]
Name:
Department: H IM AX MK IPM
E-Mail: [redacted]@siemens.com
Date: 2014-09-10

To all users of Artis zeego systems with a C-arm in the serial number range 1000 to 1599

Important safety information for customers regarding a field corrective action:

AX020/14/S

Information regarding the field corrective action for Artis zeego systems with a C-arm from a specified serial number range

Dear Customer,

We would like to inform you about the installation of an improved cable routing on Artis zeego systems with a C-arm in the serial number range from 1000 to 1599.

What problem is behind this corrective action and when does the problem occur

A cable inside the c-arm of systems affected may have been routed in an inappropriate manner. Without additional measure, there is potential that a cable inside the c-arm may break. The problem will not occur systematically but sporadically in the ongoing life time of a system.

What is the impact to the operation of the system and what are the possible risks

In a first instance there is no impact to the operation of the system. Improper routing of the cable may result in increased wear. Without additional measure as supplied by this corrective action, a cable may break resulting in restricted functionality and even system failure. An ongoing procedure may be terminated at this system.

How was the subject identified and what is the root cause

The issue was identified during regular product maintenance. The root cause is a potentially sub-optimal cable routing.

What measures are being taken to mitigate possible risks

Update AX020/14/S will modify the cable routing.

What is the efficiency of the corrective actions

The corrective action does prevent from further wear and damage of cables affected.

How will the corrective action be implemented

Our service organization will get in contact with you for an appointment 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 021/14/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 safety information. We also want you to promptly notify and instruct all the staff at your organization who need to be aware of this problem accordingly. 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.

Yours sincerely,

SIEMENS AG Healthcare Sector
Business Unit AX

[redacted]

Chief Executive Officer Safety Officer Medical Devices