

Siemens Healthcare GmbH, SHS AT, Siemensstr. 1, 91301 Forchheim

To all user of systems and Artis zee/Q/Q.zen systems with Siemens Healthineers table (Tilt/Step, OR)

E-mail AdvancedTherapies-FSCA@siemens-healthineers.com
Date February, 2020

Customer Safety Information (CSI):

AX030/19/S

Subject: Important safety information for customers regarding field corrective actions: Artis zeego systems and Artis zee/Q/Q.zen systems with Siemens Healthineers table (Step/Tilt, OR).

Dear Customer,

We would like to inform you about the following potential issues with your ARTIS zeego and Artis zee/Q/Q.zen systems with Siemens Healthineers Table (Step/Tilt, OR).

1. **Potential issue with the Message “Stand battery charging: DO NOT POWER OFF” on Artis zeego systems**

a) What is the problem and when does the problem occur?

The system message “Stand battery charging: DO NOT POWER OFF” might not be visible because it is covered by other system messages.

The above message may be displayed if the system has been switched off for a longer time and the backup battery of the Artis zeego stand needs to be charged or changed.

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

In case the stand battery is empty there is a risk that the patient cannot be removed from the patient table and that in case of a system shutdown, all stand movements are blocked and can only be reactivated by a field service engineer.

Therefore, please consider the need to establish emergency procedures in such cases until the corrective action under section 4 has been performed. In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

c) How was the subject identified and what is the root cause?

The problem was identified during regular field observation. The root cause for suppressing the message is a code setting in the message priorities.

d) What actions do we recommend urgently to mitigate possible risks?

Please check the system messages before power off/shutdown of the system. If possible do not switch off the system while the message "Stand battery charging: DO NOT POWER OFF" is displayed and wait until the battery has been charged or replaced.

2. Potential issue of blocked stand movements concerning Artis zeego systems

a) What is the problem and when does the problem occur?

No stand movement is possible any more in case the system is moved into the supervision area while moving the system in the safety override mode.

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

If this problem occurs, the system performs an immediate safety stop. All stand movements are blocked and can only be reactivated by a field service engineer. Therefore, please consider the need to establish emergency procedures in such cases until the corrective action under section 4 has been performed. In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

c) How was the subject identified and what is the root cause?

The problem was identified by regular field observation. The root cause for the blocked stand movement is a software error of the stand control unit.

3. Potential issue of blocked table movements concerning Artis zee/Q/Q.zen systems with Siemens Healthineers tables

a) What is the problem and when does the problem occur?

Blocked or limited table movement is caused by a defective Safety Limit Switch which is activated by default. The function of the Safety Limit Switch is to prevent table movements beyond defined limits.

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

If this problem occurs, the system performs a safety stop. All table movements are blocked and can only be reactivated by a field service engineer. Therefore, please consider the need to establish emergency procedures in such cases until the corrective action under section 4 has been performed. In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

c) How was the subject identified and what is the root cause?

The problem was identified by regular field observation. The root cause for the blocked tabletop movement (horizontally and vertically) is a software error of the stand control unit.

4. What measures are being taken to mitigate possible risks described under sections 1-3?

The software of the affected systems will be updated.

What is the efficiency of the corrective actions?

The corrective action mitigates the probability of occurrence of the non-conformities.

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 AX031/19/S.

What about new Products?

New systems are already delivered with the current software version.

What risks are there for patients who have previously been examined or treated using this system?

The manufacturer does not consider risks for patients who have previously been examined or treated.

We thank you for your cooperation in dealing with this customer safety notice. Please 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 appreciate your support in informing us of the identity of the device's new owner where possible.

Best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies (AT)



Dr. Michel Therin
President Advanced Therapies



Johann Böck
Safety Officer Medical Devices AT