Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.215**.. dated** 9.7.2012 **Regarding NCMDR FSN of Artis zee/Q/Q.zen systems with software version VD11E from (SIEMENS).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 245/ 2020

12 -05 -1442 H

27 -12-2020

Field Safety Notice of Artis zee/Q/Q.zen systems with software version VD11E from SIEMENS.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15470
Product	Artis zee/Q/Q.zen systems with software version VD11E.
Description	Radiological technology - radiological equipment for vascular diagnostics.
Manufacturer	SIEMENS.
Local Agent	Muscat Pharmacy.
The affected products	Part numbers: 10094135, 10094137, 10094141, 10280959, 10502501, 10502502, 10502504, (Please see attachment 1 in the attached FSN).
Reason	Blocked or limited table movement may occur.
Action	1. The software of the affected systems will be updated. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

SIEMENS Healthineers

To all user of the following systems Artis zee/Q/Q.zen sytems with Siemens Healthineers table (Tilt/Step, OR) and with software version VD11E

Product/Trade Name: *see Attachment 1*

Part number: *see Attachment 1*

E-mail advancedtherapies-fsca.team@siemens-healthineers.com

Date November 2020

Corrective Action ID AX056/19/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Blocked or limited table movement in case of a defective Safety Limit Switch

Dear Customer,

We would like to inform you about a potential issue with your Artis zee/Q/Q.zen systems with Siemens Healthineers table (Tilt/Step, OR) and with software version VD11E system and a corrective action that will be performed.

What is the issue and when does it occur?

Blocked or limited table movement may occur in case of a defective Safety Limit Switch which is activated by default as long as the table has not reached the end position. The function of the Safety Limit Switch is to prevent table movements beyond defined limits.

What is the impact on 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.

How was the issue 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.

SIEMENS Healthineers

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

We strongly recommend to establish appropriate emergency procedures until the corrective action 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.

What actions are being taken by the manufacturer to mitigate possible risks?

The software of the affected systems will be updated.

What is the efficiency of the corrective action(s)?

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 AX057/19/S.

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.

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

Please forward this safety information to any other organizations that could be affected by this measure.

Letter of November 2020
To all user of the following systems Artis zee/Q/Q.zen sytems with Siemens Healthineers table (Tilt/Step, OR) and with software version VD11E

SIEMENS Healthineers

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.

With best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies (AT)

[redacted]

[redacted]

Letter of November 2020
To all user of the following systems Artis zee/Q/Q.zen sytems with Siemens Healthineers table (Tilt/Step, OR) and with software version VD11E

SIEMENS Healthineers

Attachment 1

Product/Trade Name	Part number
Artis zee floor	10094135
Artis zee ceiling	10094137
Artis zee biplane	10094141
Artis zeego	10280959
Artis zee III floor	10502501
Artis zee III ceiling	10502502
Artis zee III biplane	10502504
Artis Q floor	10848280
Artis Q ceiling	10848281
Artis Q biplane	10848282
Artis zeego	10848283
Artis Q.zen floor	10848353
Artis Q.zen ceiling	10848354
Artis Q.zen biplane	10848355