

Siemens Healthcare GmbH, HC AT SU MK, Siemensstr. 1, 91301 Forchheim

Name
Department

Michael Martens
SHS AT SU M&S-M PMK

To all users of ARTIS pheno systems

E-mail
Date

Michael.Martens@siemens-healthineers.com
23th April 2018

Important safety information for customers regarding a field corrective action:
AX015/18/S

Important safety information for customers regarding a field corrective action: ARTIS pheno systems

Dear Customer,

We would like to inform you about a potential issue with your ARTIS pheno system.

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

If the C-arm is moved manually longitudinal to a fully extended position it may occur rarely, that the system's safety stop mechanism may be activated.

As a result, the C-arm of ARTIS pheno stops the movement and can drop up to 20 mm (0.8"). This can happen during an ongoing procedure.

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 C-arm movements are blocked and can only be reactivated by a field service engineer.

Under certain circumstances, the cover of the detector or collimator can touch and possibly injure the patient due to the C-arm drop.

This can lead to a situation in which it is necessary to stop the clinical treatment or continue the treatment on an alternative system.

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

The problem was identified by regular field observation. The cause is a movement of the C-arm into a complete extension, which may activate the safety monitoring in the system control in rare cases.

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Jochen Schmitz, Michael Reitermann

Siemensstr. 1
91301 Forchheim
Germany

Tel.: +49 (9191) 18 0
siemens.com/healthcare

Chairman of the Supervisory Board: Michael Sen
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105

What action can you take to mitigate possible risks?

As an immediate measure, the operator shall avoid to drive the C-arm into a fully extended longitudinal position.

Figure 1 shows such a fully extended C-arm position.

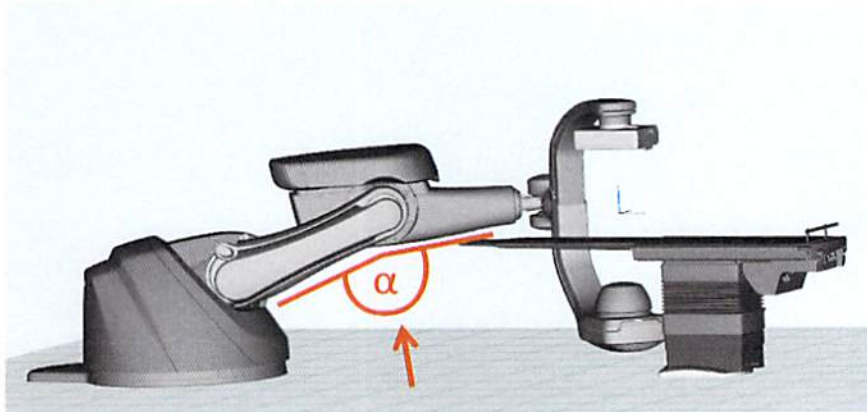


Figure 1: Depiction of C-arm in a fully extended longitudinal position

A fully extended longitudinal position is reached when the stand arms are almost completely stretched out. In this case the angle α between these arms becomes maximal, as can be seen in the figure above. Angular values of α greater than 170 degrees shall be avoided.

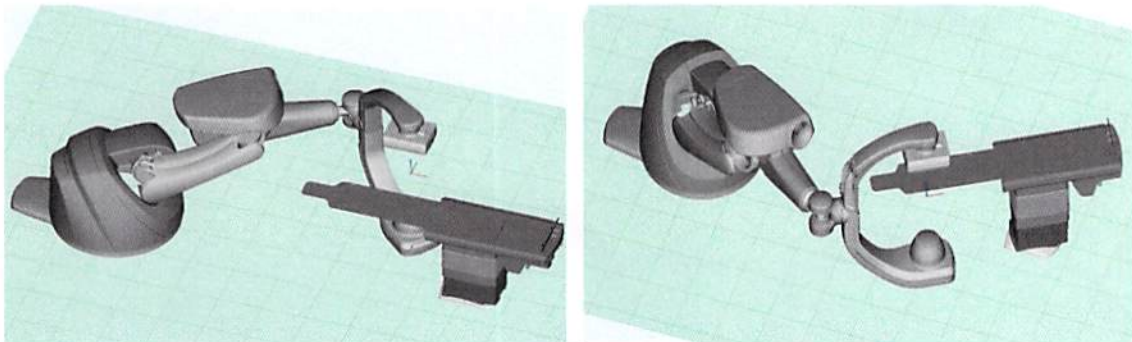


Figure 2: Exemplary depiction of two fully extended C-arm positions

To illustrate this further, Figure 2 shows two examples of system positions with a fully extended longitudinal C-arm, which shall be avoided.

What actions will we take?

We are working on a solution to eliminate the root cause of this problem.

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. We request you to promptly 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 also request you to inform us of the identity of the device's new owner where possible.

Best regards,

- Siemens Healthcare GmbH
Business Area Advanced Therapies



Dr. Heinrich Kolem
President Advanced Therapies



Siegfried Quinger
Safety Officer Medical Devices