

**Contact person**

<To the person in charge of the unit where the SIEMENS product is operated, and the administrative head of organization>

Department: [REDACTED]

Telephone: [REDACTED]

E-mail: [REDACTED]

Date August 2nd, 2018

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**(URGENT) SAFETY ADVISORY NOTICE / (URGENT) FIELD SAFETY
NOTICE**

Important safety information for customers regarding a field corrective action:

XP021/18/S and XP023/18/S

To all users of the System Ysio and Ysio MAX

Re: Ysio and Ysio MAX with a potential malfunction of lifting column (Tube stand 3D V).

Dear customer,

This letter is to inform you of a potential issue and possible hazard to persons associated with the operation of the following products:

Ysio (model number 10281013 or 10281163) with Tube stand 3D V (model number 7042018 or 7042034)

Ysio MAX (model number 10762470) with Tube stand 3D V (model number 7042018 or 7042034)

When does the issue occur?

Due to a problem with the steel cables inside the lifting column of the overhead tube, the steel cables may rupture. The probability of occurrence depends on the degree of usage of the system and is rated as extremely rare. In case the cables break, the tube arm may fall down unexpectedly during movement in vertical direction.

What are the possible risks to health?

Persons may be seriously injured.

What steps can the user take to avoid the potential risks associated with this issue ?

To avoid above mentioned risk until the implementation of the modification mentioned below, it is strongly recommended not to perform up/down movements of the lifting column directly above the patient, but to complete the vertical movement beside the patient and then move the system horizontally to the patient.

How will the issue finally be resolved?

This below mentioned update affects only systems which have not already been updated.

Siemens Healthineers is preparing a Field Safety Corrective Action that will resolve this potential issue. The Field Safety Corrective Action (XP023/18/S) is planned to be available August 21st, 2018.

Dissemination of the content of this notice

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

What If you no longer have this device/equipment?

If this device/equipment is no longer in your possession, please forward this Safety Advisory Notice to the new owner of this device/equipment. If applicable, please inform us about the new owner of the device/equipment.

The relevant National Competent Authority will be informed of this notice, if required.

Sincerely Yours

August 2nd, 2018

