

## Urgent security information

**Field Safety Correction Action (FSCA)  
Regarding your Womed-X-ray system  
Information for the customer / end user**

Type: \_\_\_\_\_

Serial number: \_\_\_\_\_

Postanschrift :

eMail

Internet :

Telefon :

Telefax :

Geschäftsführer

Handelsregister

Ust.-IDNr.  
Bankverbindung  
IBAN  
BIC

*Ihre Zeichen*

*Ihre Nachricht vom*

*Unsere Zeichen*

*Datum*

24.01.2020

### **Sender:**

WOLF-Medizintechnik GmbH  
Am Wachtelberg 15  
D – 07629 St. Gangloff

Contact partner:

**Concerning technical questions:** Mr. Thomas Frank

E-Mail: [thomas.frank@womed.net](mailto:thomas.frank@womed.net); Tel.: +49 (0) 36606 60441

**Medical security officer:** Mr. Sebastian Müller

E-Mails: [sebastian.mueller@womed.net](mailto:sebastian.mueller@womed.net); Tel.: +49 (0) 36606 60441

### **Addressee:**

This information applies to end users of the above-mentioned products of the affected serial numbers

### **Dear end user of aforementioned product,**

You have bought a high-quality X-ray system from one of our authorized and qualified sales and service partners and have been in operation for some time.

**With this urgent safety information, we inform you about the need for prompt product modification, which affects the product you have installed.**

Affected products are therapeutic X-ray systems of the models **T-200** and **T-160** with the **PROGNOST SH** X-ray tube column sold by us.

Based on a complaint, we have received the knowledge that in very special cases of fatigue of material screw connections to fix the column could lose their close fit. This could be caused by very rough handling of the column (e.g. by strongly movements of the column into the end stops of the floor rail). In the worst case this could result in falling over of the tube stand. **In extreme case, the occurrence of the damage can endanger the life and limb of the patient or user.**

For this reason, we have decided to retrofit the affected systems in the field by a Field Safety Corrective Action (FSCA).

There are two corrective measures required:

**Corrective measure 1 (immediate action):**

- Secure the cantilever by attaching additional screws

**Corrective measure 1 (retrofitting):**

- Installation of T-slot nuts in the fastening keyways of the X-ray tube column
- Installation of two support angle brackets on the X-ray tube column

Together with your sales and service partner, we ask you to carry out the immediate action **until January 31, 2020 at the latest** and the **retrofit, where appropriate together with the next planned maintenance, but latest until September 30, 2020**. Of course, this is free of charge for you. Please make an appointment promptly with our qualified service partner, who has contacted you by sending of this letter. Our service partner will carry out the retrofitting for you.

You can continue to use the system without restrictions until the modification.

Please pay attention to the careful handling of the X-ray tube column on the guide rails. In particular, please avoid unrestrained driving into the end stops, but brake the column manually before reaching the end stops.

Please make sure in your organization that all users of the aforementioned product and other relevant persons to be informed about this **Urgent Safety Information**. If you have given the products to third parties, please forward a copy of this information or inform the above-mentioned contact person.

Please keep this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices in Germany has received a copy of this "Urgent Safety Information".

As a manufacturer of high-quality medical products, we pay attention on user / patient safety. We apologize for the inconvenience this measure may cause you and thank you for your understanding.

Best regards  
Your WOmed Team