

Urgent Field Safety Notice (FSN)

about Field Safety Corrective Action (FSCA)
PROTEC FSCA-2021-01
concerning your PROGNOST XS x-ray system table
To the attention of end users

Product name: PROGNOST XS

Serial number: _____

Date: 28th Oct. 2021

Sender:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14
D - 71720 Oberstenfeld

Contacts:

Contact person for completing this process: Mrs. Elisabeth Haag
E-Mail: elisabeth.haag@protec-med.com; Tel.: 07062-9255-41
Responsible Person / PRRC according to article 15 MDR: Mr. Frank Baisch
E-Mail: frank.baisch@protec-med.com; Tel.: 07062-9255-27

Addressee:

This information concerns PROTEC customers und end-users with products of defined serial numbers.

Dear end users of the above products made by our company,

you have bought a PROTEC X-ray system table through our authorized and qualified sales and service partner and have been using it for some time.

With this urgent safety information we inform you about the need of a prompt product upgrade that affects your PROGNOST XS.

In addition, we unfortunately have to point out that you may no longer use your table until it has been completely retrofitted with our retrofit kit!

With the PROGNOST XS table, the welded connection to the table top frame of the patient table can tear partially or completely as a result of the insufficient weld, and the table top can break off on one side or completely which could result in the patient falling from the table on the floor or the unit below and sustaining possible injury.

A retrofit kit is available with which the connection of the table top frame to the side profiles is reinforced using additional support plates. A safe working load of up to 180kg is then again possible without restriction.

We also provide you with the current instructions for use with the retrofit kit and ask you to observe the information and safety instructions contained therein when continuing to operate.

We refer you to this again:

Further use of the table must be temporarily suspended until the retrofit is complete, and any infringement on your part is your own responsibility.

We will start distributing the retrofit kits to our sales and service partners at the soonest so that you can resume operation with the PROGNOST XS table as soon as possible. Please have the retrofit carried out on your X-ray system table. Of course, this is done free of charge for you. Please make an appointment as soon as possible with our qualified service partner, who will contact you with this letter. Our service partner will implement the retrofitting for you.

Please reply with the form on the next page (page 3) and send to the PROTEC email address mentioned below to confirm that you have received this notice, arranged temporarily decommissioning and whether you still have the table in your possession and in use. If the PROGNOST XS table is no longer in your possession, please reply with the form on the next page part C) that you have disposed the table or the information to the current owner of the PROGNOST XS table. Please send the filled form (page 3) signed back to us on your earliest convenience (within 5 days). After the conversion with the retrofit kit, please sign page 4 of this letter and return it to us.

Please make sure in your organization that all users of the above product and other applicable persons are informed of this urgent filed safety notice. If you have given the products to third parties, please forward a copy of this information or inform our contact person mentioned above.

Please keep this information at least until the measure has been completed. The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Field Safety Notice".

As a reputable and dutiful manufacturer, our focus is on quality and user-patient safety. We apologize for the inconvenience associated with this measure and thank you for your understanding.

With best regards
Your PROTEC team

Confirmation of receipt of the URGENT FIELD SAFETY NOTICE and the temporarily decommissioning of your PROGHOST XS or other information:

| | |
|----------------------|-------------|
| Product name | PROGNOST XS |
| Serial number | |

A) The location (end user / operator) of the product is:

| | |
|---|--|
| doctor's office/ clinic with address and e-Mail: | |
|---|--|

B) Confirmation of serial number, receipt of this letter and temporarily decommissioning:

| | |
|---|--|
| Contact person (name, function/title) at final at end user / operator: | |
| Authorised signature at end user: | |
| Date: | |

C) Other information- if needed:

| | |
|---|--------------------------|
| Table not in use anymore; disposed of in accordance with regulations: | Date of disposal: |
| Table not in use at our site anymore; Current Owner with address and e-Mail: | |
| Contact person (name, function/title) at former end user / operator: | |
| Authorised signature at former end user: | |
| Date: | |

Please send the completed and signed form back to:

PROTEC GmbH & Co. KG
Customer Service
Fax: +49(0)7062/ 92550 60 oder
E-Mail Elisabeth.Haag@protec-med.com

Confirmation of the successful implementation of the conversion with our retrofit kit by an authorized sales and service partner.

| | |
|----------------------|-------------|
| Product name | PROGNOST XS |
| Serial number | |

The location (end user / operator) of the product is

| | |
|---|--|
| doctor's office/ clinic with address | |
|---|--|

The retrofitting with the above serial number has been carried out properly and we hereby confirm the completion of the conversion.

Authorized sales and service partner:

| | |
|---|--|
| Company: | |
| Street and No.: | |
| City: | |
| ZIP Code | |
| Country: | |
| Contact Person: (name, function, title) | |
| Stamp/ Date / SIGNATURE: | |

End user / operator:

| | |
|---|--|
| Contact person (name, function/title) at final at end user / operator: | |
| Authorised signature at end user: | |
| Date: | |

Please send the completed and signed form back to:

PROTEC GmbH & Co. KG
Customer Service
Fax: +49(0)7062/ 92550 60 oder
E-Mail Elisabeth.Haag@protec-med.com