

PROGNOST XS

Basic diagnostic X-ray system table, non-powered

Model/ID: 7034-0-0000

Basic-UDI-DI: 426050264X023ZM

Instructions for use

Ident. No. 5034-0-0002



CE



NOTE

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**NOTE**

The information contained in this document conforms to the configuration of the equipment as of the date of manufacture. Revisions to the equipment subsequent to the date of manufacture will be addressed in service updates distributed of the PROTEC GmbH & Co. KG Technical Service Organisation.

Revision Status

Revision	Date	List of effective pages	Comments	Author
4.0	2021-05-26	all	REV03 transferred to the new layout (MDR)	MB

General Notes



WARNING!

In order to maintain the set and tested requirements of the 60601 series of standards, the ME system must not be modified during its actual operating life.

Mechanical and Electric Warning



WARNING!

All of the movable assemblies and parts of this equipment should be operated with care. They must be routinely inspected in accordance with the manufacturer's recommendations contained in the accompanying documents. Maintenance and service is only to be performed by personnel authorized by PROTEC GmbH & Co. KG.

Touching live electrical terminals and connections can be deadly.

Do not remove the flexible high-tension cables from the X-ray tube cover or high-tension generator or open the housing of the X-ray generator.

Protective conductor connections must be provided in compliance with the national regulations for all components of the equipment.

Failure to comply may result in serious or fatal injuries to present persons.

To the User



NOTE

The user of these accompanying documents is required to carefully read through and carefully consider the instructions, warnings and cautions contained therein before starting operation.

Even if you have already operated similar systems, changes in the design, production and functional routine of the system described here may have been made, which have a significant influence on the operation.

Assembly and service works on the system described here must be carried out by authorised and qualified personnel from PROTEC GmbH & Co. KG. Assembly personnel and other persons who are not employees of the technical service department of PROTEC GmbH & Co. KG are requested to contact the local branch of PROTEC GmbH & Co. KG before assembly or service work is started.

For assembly and service works, it is necessary to use the description of the product and to observe the points it contains.



NOTE

The usage of the product in combination with attachments, accessories or other non-approved components not authorized by PROTEC is not permitted.



NOTE

According to regulation (EU) 2017/745 of medical devices, all serious incidents related to the device must be reported to the manufacturer and the responsible authority of the member state where the user and/or the patient is established.

1 Device Description

1.1 Introduction

The instructions for use describes the performance characteristics and operational aspects, required for efficient and effective use of the PROGNOST XS.

Prior to working with the PROGNOST XS, the operator is required to read through the instructions for use, especially the safety notes as well as the chapter regarding operation.

1.2 Description

The PROGNOST XS X-ray exposure tables are lightweight, mobile patient positioning tables with solid laminate table top with melamine resin layer for easy cleaning.

1.2.1 Types

PROGNOST XS

Table frame colour RAL 9003

7034-0-0000

Table top

1963mm x 655mm x 6mm

Optional Accessories

- Mattress 1900mm x 600 mm x 15mm

1.2.2 Hardware and Network System Requirements

As a stand-alone product, the PROGNOST XS has no hardware or network connection and therefore no hardware or network requirements.

1.2.3 Installation



NOTE

The installation of the PROGNOST XS must be performed by the PROTEC Customer Service Department or a service authorized by them.

For more information, please see the separate "Installation manual" of the PROGNOST XS.

Contact information of persons qualified to perform installations are available upon request at:

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1.2.3.1 Floor Loading Capacity



NOTE

The PROGNOST XS is primarily made of metal pieces. This has a corresponding effect in the weight of the device.

The **PROGNOST XS has a weight of 48kg.**

Every technician is obliged to check the floor loading capacity. Also raised floors and hollow floors have to be taken into account.

1.3 Performance Characteristics

1.3.1 X-ray positioning table

- Wide range of applications
- High reliability
- Mobile, easy manoeuvrability
- Table top colour white
- Large radiolucent working area

1.4 Intended Use

The PROGNOST XS mobile X-ray system table is intended to be used as a component of a diagnostic X-ray system for patient positioning for various routine applications in planar X-ray imaging in human medicine.

1.5 Clinical Use

In isolated observation no clinical use can be shown for X-ray system tables.

As components of diagnostic X-ray systems in human medicine, they contribute to the clinical utility of the X-ray systems, which is the generation of conventional two-dimensional X-ray images for diagnosis or the specification of findings as the basis for treatment decisions.

1.6 Patient Target Group(s)

The intended patient group includes all people for whom a justifying indication for a medical X-ray has been given by a physician with the necessary expertise in radiation protection.

There are no general or fundamental restrictions on the patient group regarding age, gender, origin and patient condition.

1.7 Diagnosable Medical Conditions

As stand-alone products, X-ray system tables, have no function to diagnose, treat and/or monitor medical conditions.

1.8 Indications and Contraindications

As stand-alone products, X-ray system tables have no intended main effect in or on the human body. Therefore, when viewed in isolation, no indications and contraindications can be identified for them.

1.9 Intended User Group

The PROGNOST XS is exclusively designated for use by professional users who have been trained in the operation of diagnostic X-ray systems in accordance with the corresponding national regulations, and who have been instructed in the proper handling, application and operation as well as in the permissible connection with other medical devices, objects and accessories.

Suitable operators could include the following: X-ray technicians, radiologists, medical-technical radiologists, surgeons, trauma surgeons, orthopaedists and other trained medical personnel.

1.10 Conformity



This product complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 concerning medical devices, including all applicable corrigenda.

The declaration of conformity is available upon request from PROTEC:

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2 Safety Instructions

**NOTE**

Contains information that are relevant to the usage.

xxx

**CAUTION!**

Contains information that can cause damage to properties at nonconformity.

xxx

**WARNING!**

Contains information that can cause personal injuries at nonconformity.

xxx

**WARNING!**

Warning of radioactive substances or ionising rays. Contains information that can cause personal injuries at nonconformity.

xxx

**NOTE**

All manuals supplied with the PROGNOST XS must be observed and any contained safety instructions must be read carefully and complied with.

**NOTE**

After the initial installation, the commissioning must be recorded with the PROTEC acceptance protocol FB-04-07A4.

**NOTE**

The commissioning of the PROGNOST XS can only be done if all safety notes and operator security measures have been met. These operator safety measures can be: door contact, marked area, dosimeter, safety clothing ...

**CAUTION!**

The manual contains all safety relevant information for the commissioning of the PROGNOST XS. Operating the device is exclusively for specially trained staff. In this context, there are relevant safety symbols on every operating element. Further information and instructions can be found on the provided medium (USB, CD or DVD). This serves as additional information and has to be observed.

**NOTE**

All operating elements are described in detail again in this instructions for use.

2.1 General Safety Instructions

2.1.1 Operating of device

In the event of malfunctions, the PROGNOST XS must no longer be used and the PROTEC customer service department or a service department authorized by PROTEC must be notified.

2.1.2 Operating Personnel



NOTE

Only properly trained and authorized personnel are permitted to operate the PROGNOST XS.



NOTE

The operating personnel must familiarize themselves with all warnings signs located on the PROGNOST XS. They serve to ensure their own safety and that of others and guarantee proper operation.

2.1.3 Crushing and Collision Hazards



WARNING!

Ensure that while operating the moving parts of the PROGNOST XS, no persons or objects finds themselves in the obvious danger zone of the device. Failure to do so may result in bodily injury to persons or damage to the PROGNOST XS or other objects.

Crushing of fingers and hands is possible at the points marked with arrows in the picture below. Please ensure that neither the patient nor the personnel are staying uncontrolled in the movement area when moving the table.



2.1.4 Explosion Protection

The PROGNOST XS is not designated for use within areas with explosive hazards.

2.1.5 Interaction with External Devices

Interaction with external devices is not known.

2.1.6 Electromagnetic Environment and the Interference of Devices

Electromagnetic influence by devices is not known.

3 Control Elements and Device Displays

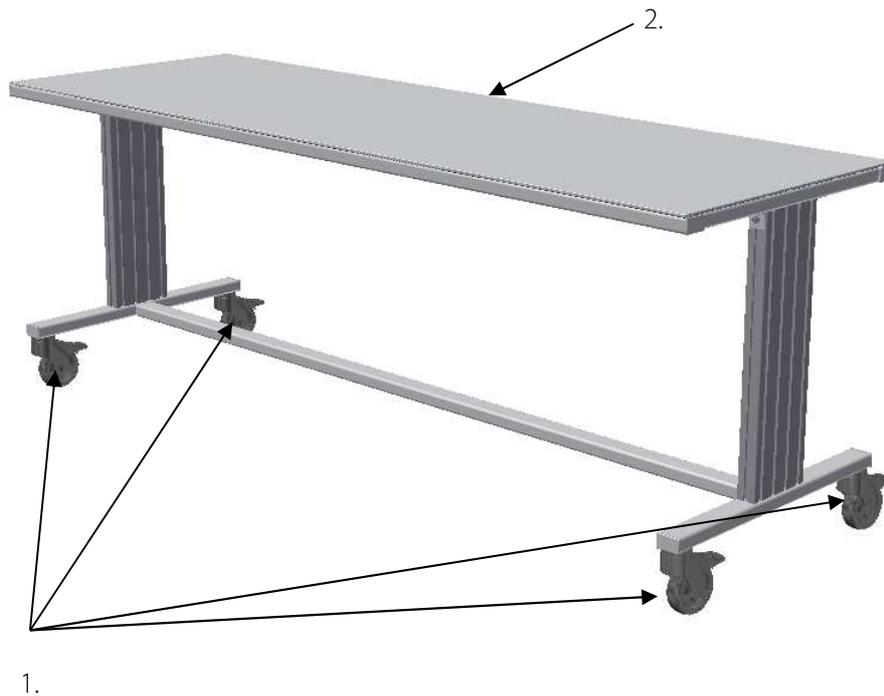
3.1 Main switch of the PROGNOST XS

The PROGNOST XS does not have a main switch, as it is a non-active medical device.

3.2 Emergency stop switch of the PROGNOST XS

The PROGNOST XS does not have an emergency stop switch, as it is a non-active medical device.

3.3 Control elements and displays of the PROGNOST XS



1. Brake rolls
2. Table top

3.3.1 Brake rolls

To fix the positioning table in all directions on the ground, it has 4 total locking devices, which must be locked on the left and right side before the patient is descending or ascending.

4 Handling

4.1 Requirements before and during Operation

It must be ensured that the surfaces that come into contact with patients are disinfected before the X-ray examination of each patient (see chapter 5.3).

4.2 Operation of PROGNOST XS

4.2.1 Exposures with the PROGNOST XS

Following procedure must be observed to prevent collisions with the PROGNOST XS, the image receiver or other furniture.

- X-ray device, e.g. swivel arm system, to the 0 degree position
- Set the height of the X-ray image receptor to match the height of the table
- Move the table to the intended exposure position for inspection
- Move the table to a position in which the patient can climb onto the surface as easily as possible
- Operate the brake wheel locks and check that the wheels are effectively braked



WARNING!

Before ascending or descending of the patient, the brake rollers must be locked. All rollers can be braked, but at least two rear rollers (furthest away from the ascending patient) must be locked.



NOTE

The PROGNOST XS is not suitable for patient transport. It is only used for positioning the patient during examination. The ascending and descending of the patient has only be done while fixed brakes and in the center of the table top, under supervision or assistance of the examiner as otherwise there is a risk of tipping over! Provide patients with assistance when ascending.

- Provide patients with assistance when ascending. In order to achieve the best possible support of the table, the patient should climb onto the table in the middle of the table top
 - Position the patient for the exposure. If necessary (e.g. open wounds), cover the table surface with suitable cloths or disposal care pads
-



WARNING!

Danger of squeezing at the table edges and danger of trapping on and below the table top!

When the table is moved horizontally, extremities can be squeezed between the edge of the table and a stationary obstacle (wall, column, X-ray unit). Therefore, when moving the PROGNOST XS, make absolutely sure that neither the patient nor the personnel are standing in the direction of the movement. Pay particular attention that none of the patients extremities protrude over the table top.

- Release the brake wheel locks and move the PROGNOST XS to the exposure position
 - Lock the brakes again
 - Perform exposures according to the operating instructions of the X-ray unit
 - After the examination, release the fixing brakes and move the table to a position where the patient can easier get off the table
 - Lock the brakes and assist the patient in getting off the table
-

4.3 Function of the PROGNOST XS

4.3.1 Switching the PROGNOST XS ON and OFF

The PROGNOST XS does not have a main switch, as it is a non-active medical device.

5 Safety and Maintenance

5.1 Introduction

In this chapter, you will find details regarding safety and maintenance, which is required to ensure the correct and reliable function of the device following initial installation.

5.2 Reusability

The PROGNOST XS can be reused without any special reprocessing procedures. However, it must be ensured that the surfaces that come into contact with patients are disinfected between patients (see also Chapter 4.1).

The PROGNOST XS must no longer be used with patients if it shows signs of attrition (e.g., metal abrasion, abrasion of insulations) or dangerous technical defects (e.g., torn cable, bent parts) or if the resulting image quality (e.g., artefacts in the image) is insufficient. In this case, please contact PROTEC customer service or a service authorized by PROTEC immediately.

5.3 Cleaning and Disinfection



NOTE

Caution!
Changes to material are possible!

5.3.1 Cleaning

The PROGNOST XS can be cleaned with ease due to the high quality surface coating. This is usually done only with a dry cloth.

Do not use any corrosive, dissolving or abrasive cleaning agents as this may damage the surfaces of the unit or the coating.

Clean device surfaces and painted parts with a damp cloth and a mild to slightly alkaline cleaning solution (e.g. RBS® Neutral T) and wipe dry.

Chrome parts may only be wiped with a dry wool cloth.

5.3.2 Disinfection

Disinfection must be performed in accordance with the current applicable legal requirements and guidelines corresponding to disinfection and explosion protection.

For disinfection of surfaces in contact with patients, we recommend commercially available medical rapid disinfection wipes (e.g. Dr. Schumacher Descosept Sensitive Wipes).

All mechanical components of the PROGNOST XS, including accessories, may only be subjected to wipe disinfection with suitable surface disinfectants (e.g. Melsept® SF, 15 min. residence time at 2% concentration). The information provided by the disinfectant manufacturer on concentrations and residence times must be observed.

5.4 Inspection and maintenance



WARNING!

No maintenance or repair work may be performed while the PROGNOST XS is being used with a patient!
All maintenance and repair work may only be performed by personnel trained or authorized by PROTEC.

5.4.1 Daily monitoring before and during the examination operation

The locking of the rolls must be checked by operating the fixation brakes.

5.4.2 Regular Monitoring

In case of heavy contamination, the rolls must be cleaned to ensure sufficient floor adhesion. The rolls must be cleaned once a week. Clean the rolls with a damp cloth and a soap-free cleaning agent, or commercially available medical rapid disinfection wipes and wipe dry.

5.4.2.1 Safety-related checks

In the interest of patients, operators and external third parties, it is necessary that all checks regarding operational safety and/or functionality of the unit are carried out regularly every **12 months** by **PROTEC** customer service or a **PROTEC** authorized service provider.

All components within the PROGNOST XS that may pose a risk due to attrition must be inspected and, if necessary, replaced every 12 months by the PROTEC service department or a PROTEC authorized service provider.

In the case that the scheduled checks are not carried out, PROTEC GmbH & Co. KG will not be liable for damage to the user and third parties if and insofar as damage results from insufficient or non-performed checks.

5.4.3 Maintenance

The required maintenance must be carried out by PROTEC customer service or a service authorized by PROTEC to ensure the safe and reliable functioning of the device. The maintenance intervals depend on the frequency of use. In the event that the scheduled maintenance is not carried out, PROTEC GmbH & Co. KG will not be liable for damage to the user and third parties if and insofar as damage results from insufficient or non-performed maintenance.

Prior to test operation, the user must satisfy himself that all safety relating devices listed in the instruction manual are in working order and that the product is ready for operation.

Attrition parts must be replaced with original components.



NOTE

The maintenance checklist must be printed out from the instruction manual and recorded.



NOTE

After maintenance and service work, the recommissioning must be recorded with the PROTEC acceptance protocol FB-04-07A4.

5.4.3.1 Maintenance checklist

This maintenance checklist serves as a working aid for maintenance on a "PROGNOST XS" and should be performed every 6 months for more than 100 patients/day and every 12 months for less than 100 patients/day, depending on the use of the device.

This procedure does not replace the mandatory acceptance test or other procedures for checking X-ray equipment specified by European standards or internal country standards. This procedure is intended for the periodic inspection of the X-ray components and its maintenance in accordance with the requirements of the manufacturer PROTEC GmbH & Co. KG.

PROTEC Dealer:								
Service Technician Name:								
Service Technician No.:								
Customer:								
Customer No.:								
Place of Installation:								
PROGNOST XS No.: 7034-0-0000		Serial Number:						
		Annually for systems with less than 100 patients/day		Every 5 years for systems with less than 100 Patients/day				
		Semi-annually for systems with more than 100 patients/day		Every 4 years for systems with more than 100 patients/day				
		Visual control	Functional control	Exchange	Exchange			
1	Safety Inspection					OK	Not OK	Note
1.1.	Check the parts of the X-ray system table for damages	x						
1.2.	All labels are still fixed and readable	x						
1.3.	Check the 70Nm tightening torque of the guide rolls fixing screws		x					
1.4.	Brake functionality of all 4 guide rolls are working properly		x					
1.5.	Check all fixing screws, tighten if necessary (see installation manual)		x					
1.6.	The table top has no relevant damage. If necessary perform control exposures	x						

Final Report:

- No safety or function-relevant problems detected
- Next maintenance in 6 / 12 / ____ months

Remarks, notes:

.....

.....

.....

Inspector:

Date:

Signature:

Doctor/Doctors office/clinic:

Date:

Signature:

5.4.4 Warranty



NOTE

The current conditions of guarantee are deposited in the order papers or in the pricelist valid at the time of purchase.

All repairs and spare parts are excluded from the warranty in event of improper operation.

Warranty service may only be performed by trained specialists.

5.4.5 Product life

The PROGNOST XS is designed to have a product life of 10 years when used in accordance with the specifications and is regularly maintained by PROTEC customer service or an authorized service provider. After the product has reached the end of its product life, further use is at the operator's own risk.

5.4.6 Parts with direct patient contact

Part	Definition: The components listed below are components that have direct contact with the patient during intended use
Table top	Direct patient contact
<i>Optional accessories</i>	
Mattress	Direct patient contact

5.4.7 Disposal notes



The PROGNOST XS contains different plastics and heavy metal. When disposing exchange and spare parts, or if necessary, the whole system, the current rules and regulations must be observed. Please contact your contractual partner or the service company, or a company specialized in disposing the respective components.

6 Power supply



NOTE

The PROGNOST XS does not require power supply.

7 Technical Data

7.1 Dimensions

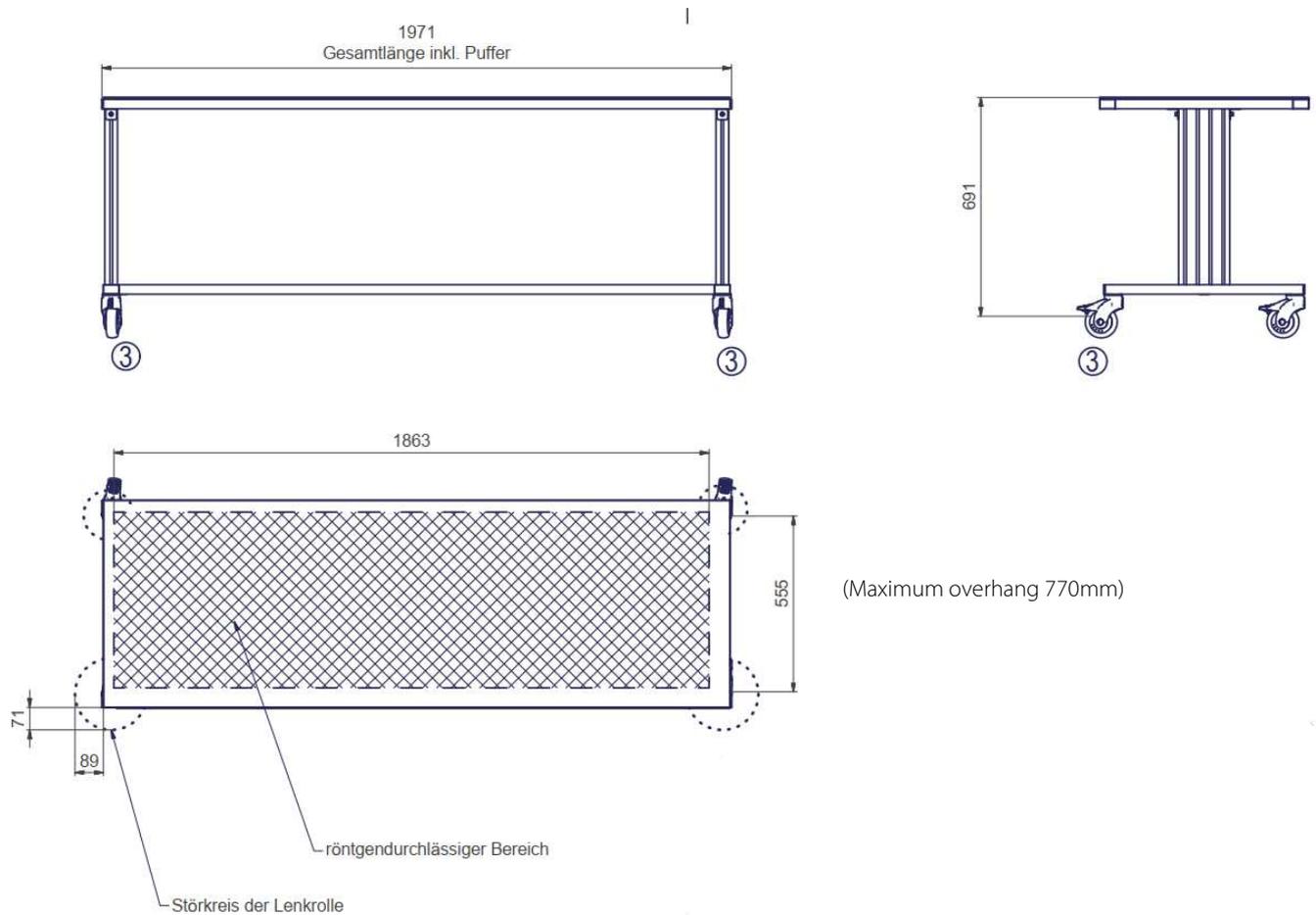


Table top:	1963 x 655 mm
Max. patient weight (distributed load):	180 kg
Total weight without patient:	47 kg
Table height:	760 mm
Dimension of the plane penetrable by X-ray:	1863 x 555 mm

The brakes of the wheels are mechanically operated.

7.2 Attenuation Equivalent



WARNING!

The PROGNOST XS attenuation factor must be considered during the acceptance test.

The aluminium attenuation equivalent of the table top is typically 0,7 and <0,8mm Al according to EN 60601-1-3 at 100 kV with a first half-value layer thickness of 3,7mm Al and typically 0,6mm Al and <0,8mm Al according 21CFR § 1020-30 (n) with 100 kV and a first half-value layer thickness of 1,2mm Al.

7.2.1 Protection Type and Protection Class

The PROGNOST XS does not comply with any protection class and does not contain any applied parts.

7.3 Environmental Conditions

7.3.1 Environmental conditions during operation

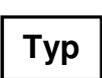
Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 70% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa

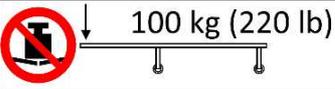
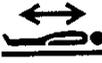
7.3.2 Environmental conditions for shipping and storage

Ambient Temperature	- 10°C to + 70°C
Relative humidity	10% to 95% (non-condensing)
Atmospheric pressure	500 hPa to 1060 hPa

8 Description of Symbols, Labels and Abbreviations

8.1 Symbols

	Air pressure limit
	Temperature limit
	Humidity limit
	Keep dry
	Fragile, Handle with care
	This way up
	Attention, observe warnings and precautions
	Refer to the manual
	CE marking
	Manufacturer
	Order Code
	Order reference
	Serial number
	Production date
	Caution: pinch-/crushing hazard for hands and fingers

 <p>www.protec-med.com/download</p>	<p>This symbol indicates the need to consult the operating instructions. This is provided in an electronic format (eIFU) on our website.</p>
	<p>Disposal instructions; WEEE , Waste of Electrical and Electronic Equipment</p>
	<p>Protective earth</p>
	<p>Do not exceed the maximum indicated weight</p>
	<p>Do not exceed the maximum indicated weight</p>
	<p>Table movements for exposure</p>
	<p>Longitudinal movement of the table</p>
	<p>Transverse movement of the table</p>

8.2 Identification Label

<p>MD</p> <p>REF 7034-0-0000</p> <p>SN SN000136</p> <p>2021-09-29</p>    <p>www.protec-med.com/download</p> <p>+10 °C +40 °C 1060 hPa 70%</p> <p>700 hPa 30%</p>	<p>PROGNOST XS</p> <p>Basic diagnostic X-ray system table, non-powered</p>	 <p>PROTEC GmbH & Co. KG In den Dorfwiesen 14 71720 Oberstenfeld Germany</p> <p>UDI</p>  <p>(01)04260502640357 (11)210929 (21)SN000136</p> <p>TL7034-0-0000V03</p>
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8.3 Labels

Labels on the table top

	<p>Caution: Watch out for possible crushing hazards to fingers or hands during movements of the table or X-ray unit</p>
 <p>180kg 400lb</p>	<p>Maximum permitted patient weight (distributed load) on the table top</p>

Labels on the lower table top frame

 <p>Achtung! Der Tisch ist nur zur Patientenlagerung an Röntgenarbeitsplätzen bestimmt!</p> <p>CAUTION! Table use for patient positioning in radiographic rooms only!</p>	<p>Caution: Watch out for possible crushing hazards to fingers or hands during movements of the table or X-ray unit</p>
--	---

8.4 Position of the Symbols and Labels



8.5 Abbreviations

mm	Millimetre
cm	Centimetre
lb.	Pound
kg	Kilogram
°C	Degree - Celsius
hPa	Hectopascal
DIN	German Industry Standard
EN	European Standard
CE	CE-Mark
Hz	Hertz
ED	Duty Cycle
A	Ampere
SN	Serial number