PROGNOST F

Basic diagnostic X-ray system table, non-powered

Model/ID: 7041-5-87xx
Basic UDI-DI: 426050264X008ZR

Instructions for use

Ident. Nr. 5041-0-8002

CE

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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 to the PROTEC Technical Service Organisation.

Revision Status

Revision	Date	Updated pages	Comments	Author
1.0	2019-05-14	all	Newly created. Replace document 5041-0-0002_Rev05	
2.0	2019-08-07	Page 21 chap. 3.2 Chap. 8.2	Intended use updated Changed illustration dimension renamed Identification label updated	
3.0	2020-08-11	Front page, Cap. 5.3.3	Maintenance updated	
4.0	2020-11-24	Front page	Model ID revised	
5.0	2021-05-26	all	V4.0 transferred to new layout (MDR)	MB
6.0	2022-12-07	Chap. 1.2.1	Optional Accessories corrected	ML
7.0	2024-04-08	Chap 4.2.1	Positioning of the tabletop optimised	DP

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 and routinely inspected in accordance with the manufacturer's recommendations contained in the equipment accompanying documents.
Maintenance and service is only to be performed by customers authorized by PROTEC GmbH & Co. KG.
Live electrical terminals are deadly.
Do not remove flexible high-tension cables from X-ray tube cover or high-tension generator and/or access covers from X-ray generator.
For all components of the equipment protective earthing means must be provided in compliance with the national regulations.
Failure to comply with the foregoing may result in serious or fatal bodily injuries to the operator or those in the area.

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 "Technical Description" of the product and to observe the points it contains.

NOTE

The use of the product with add-on or accessory parts not authorized by PROTEC or other unapproved components 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 describe the performance characteristics and operation required for efficient and effective use of the PROGNOST F.

Before you work with the PROGNOST F, the complete instructions for use must be read, especially the Safety Instructions and the chapter Handling.

1.2 Description

The PROGNOST F X-ray system table consists of a moving grid table with a floating tabletop. It is designated for the installation of a running grid device that can be manually moved in longitudinally direction with an electronic drive for an anti-scatter grid and a 3-field measuring chamber for operation with automatic exposure control.

Non-operated the floating tabletop of the X-ray system is locked in longitudinal and transverse directions by highly effective pedo-mechanical brakes. Both directions of movement can be released by an ergonomically easy to reach braking bracket. The ease of movement of the tabletop and its large adjustment range allow comfortable positioning of the patient.

1.2.1 Versions

PROGNOST F 7041-5-87xx

Tabletop versions

Model ID	Material	L	W	Tabletop colour
7301-0-5900	carbon fibre	200 cm	75.5 cm	white
7301-0-2200	carbon fibre	226 cm	75.5 cm	white
7301-0-6000	composite fibre	200 cm	75.5 cm	white
7301-0-6010	composite fibre	226 cm	75.5 cm	white
7301-0-6020	composite fibre	200 cm	65.5 cm	white

Optional Components

- X-ray cassette holder (Bucky or Grid entity)
- Measuring chamber (ionization or solid state)
- Anti-scatter grid

Optional Accessories

- Mattress
- Ball knob grab handle, for a fine positioning of the patient on the 4-way tabletop
- Handle long, for facilitating the positioning and descending of the patient
- Shock protection profile, for rear tabletop accessory rail
- Compression band
- Detector holder lateral, incl. 2 handles*

*Accessories with medical purpose

Accessories that can influence the EMC conditions

- Network cable (note the max. cable length in the component documentation)
- WiFi router (Only use devices approved by PROTEC)

1.2.2 Hardware and Network System Requirements

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

1.2.3 Installation

NOTE

The installation of the PROGNOST F must be performed by PROTEC service department or a service company authorized by them.

For more information, please see separate "Installation manual PROGNOST F."

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

The PROGNOST F has a weight of 132kg.

Every technician is obliged to check the floor load. Raised floors and hollow floors must also be considered.

1.3 Performance Characteristics

1.3.1 X-ray system table

- Variable tabletop size
  - Standard: 226 x 75,5 cm
  - Optional: 220 x 75.5 cm
- Wide range of applications
- Table height of 70 cm, suitable for patients
- Center marking for the transverse movement on the tabletop
- Floating tabletop
- Tabletop colour – white
- A low (optimized) distance between the tabletop surface and the film (detector) surface
- Large adjustment range of the tabletop for position of the patient
- Side profile rails on the long sides of the tabletop for attaching accessories
- Designated for the installation of a Bucky with anti-scatter grid and 3-field measuring chamber intended for the use with automatic exposure control
- Extensive cassette program including Format 13 cm x 18 cm up to Format 43 cm x 43 cm
- High reliability

1.4 Intended Use

The PROGNOST F stationary 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 Benefit

Considered in isolation, no clinical benefit can be shown for X-ray system tables.

As components of diagnostic X-ray systems in human medicine, they contribute to the clinical benefit of X-ray systems, which consists of the generation of conventional two-dimensional X-ray images for creation or specification of findings as a basis for treatment decision.

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 Medical Conditions to be diagnosed

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

1.8 Indications and Contraindications

As standalone products, X-ray system tables have no intended main effect in or at the human body. Therefore, considered in isolation, no indications and contraindications can be shown for them

1.9 Intended User Group

As a component of a diagnostic X-ray system, PROGNOST F is intended exclusively for use by professional users who are trained in the operation of diagnostic X-ray systems in accordance with the respective national regulations and who are familiar with the proper handling, use and operation and also have been instructed in the permitted conjunction with other medical products, objects and accessories.
Appropriate users can be, for example: X-ray technicians, X-ray assistants, medical technical X-ray assistants, surgeons, casualty surgeons, orthopaedists and other trained medical personnel.

1.10 Declaration of Conformity

CE

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

The declaration of conformity is available upon request from PROTEC:

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2 Safety Instructions

	**NOTE** xxx	Contains information that must be observed during operation.
	**CAUTION!** **xxx**	Contains information which, if not observed, can cause property damage.
	**WARNING!** **xxx**	Contains information which, if not followed, can cause personal injury.
	**WARNING!** **xxx**	Warning of radioactive substances or ionizing radiation. Contains information which, if not observed, can cause personal injury.

Settings and calibrations that are not described in these instructions for use must be carried out using the technical description of the device by PROTEC service department or a service company authorized by them.

NOTE

All instructions supplied with the PROGNOST F must be observed and the safety instructions contained therein must be carefully read and adhered to.

NOTE

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

NOTE

The PROGNOST F may only be commissioned if all safety measures for operator protection have been met and checked. These protective measures can include door contact, designated area, dosimeter, protective clothing, etc.

CAUTION!

The instructions for use contain all the information relevant to safety in order to generally put the PROGNOST F into operation. The device may only be operated by appropriately trained and trained personnel. In this context, operation is ensured by clear symbols on the control elements. All further information and instructions can be found on the supplied data carrier (USB, CD or DVD). This information applies in its entirety as an appendix to these instructions for use and must be observed.

NOTE

All control elements are described again in detail in these operating instructions.

2.1 General Safety Instructions

2.1.1 Device Operation

In case of a malfunction, do not use the PROGNOST F anymore and notify PROTEC service department or a service company authorized by them.

2.1.2 Operating Personnel

NOTE

Only trained and authorized personnel are allowed to work on the PROGNOST F.

NOTE

The operating personnel must be familiar with all warning signs attached to the PROGNOST F. They are used for your own safety and that of others and ensure proper operation.

2.1.3 Crushing and Collision Hazard

WARNING!

It must be ensured that when operating the moving parts of PROGNOST F, no persons or objects are in the obvious danger area of the device. If not observed, it can result in personal injury or damage to the PROGNOST F or other objects.

2.1.4 Explosion Protection

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

2.1.5 Interaction with Other Devices

Interactions with other devices are not known.

2.1.6 Electromagnetic Environment and Influencing of Devices

CAUTION!

The use of the PROGNOST F immediately next to other devices or with other devices in a stacked form should be avoided, as this could result in defective operation. If use in the manner described above is nevertheless necessary, the PROGNOST F and the other devices should be observed to ensure that they are working properly.

NOTE

The properties of this device, determined by emissions, allow its use in industrial areas and in hospitals (CISPR 11, class A). When used in residential areas (for which class B is usually required by CISPR 11), this device may not provide adequate protection for radio services. The user may need to take remedial measures such as relocating or realigning the device.

The PROGNOST F is intended for use in an environment in professional health care facilities (e.g., clinics, surgery centres, physiology practices ...).

3 Control Elements and Displays

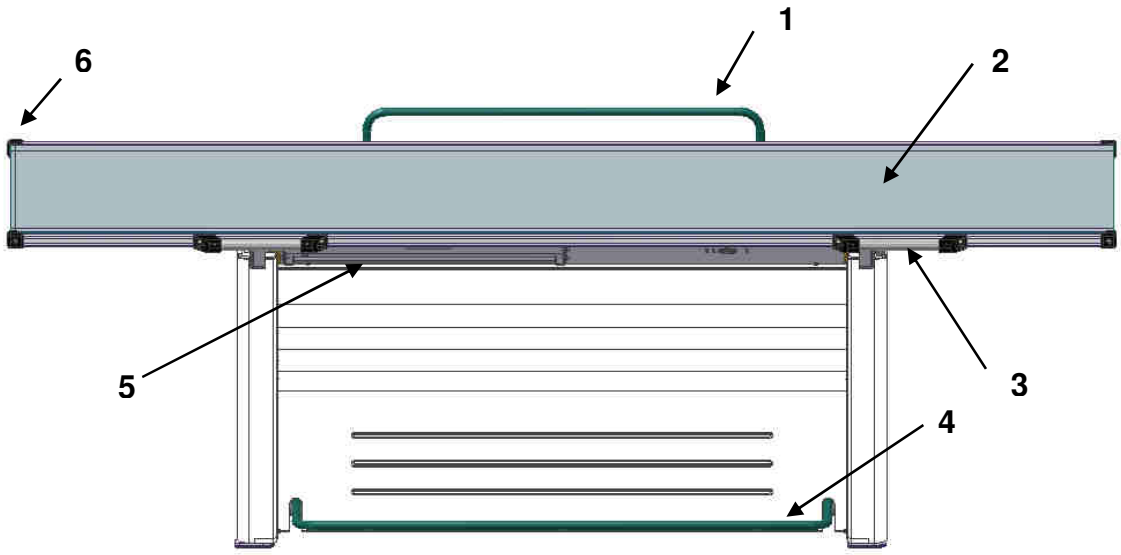
3.1 Main Switch of the PROGNOST F

The PROGNOST F does not have a main switch.

3.2 Emergency Stop Switches of the PROGNOST F

The PROGNOST F does not have an emergency stop switch.

3.3 Control Elements and Display of the PROGNOST F



1 Long handgrip RAL 6021 (optional)
2 Tabletop
3 Short handgrip (optional)
4 Brake bar
5 Bucky unit
6 Corner protection (optional)
7 Compression band (optional)

3.3.1 Brake bar

By actuating the brake bar (**4**) with the foot, the brakes of the tabletop are released and the tabletop can be moved floating by hand.

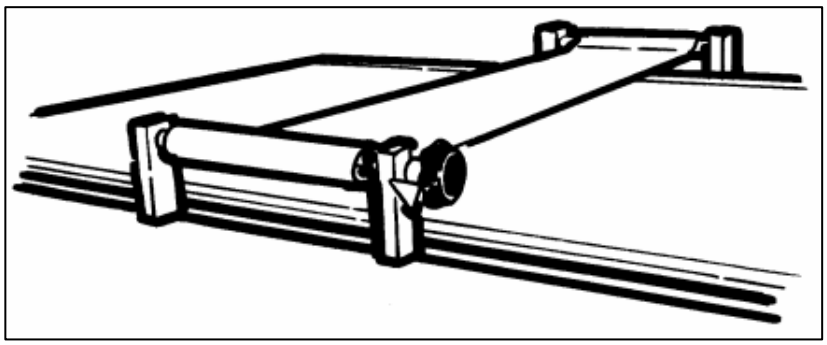
3.3.2 Handgrips (optional)

A long handle (**1**) for the back of the tabletop and 2 handles (**3**) for the front of the tabletop are available as options. Both handles can only be removed with tools. The long handle is intended for easier ascending and descending of the patient. The tabletop can be better shifted with the short handles.

CAUTION!

Before ascending and descending of the patient, move the tabletop to the front position.

3.3.3 Compression Band (optional)



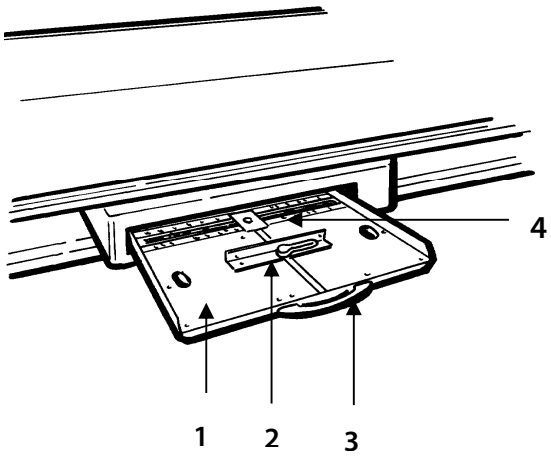
The compression band (**7**) is inserted into the PA profile rails of the tabletop. The transparent band-shaped compressorium can be used to apply pressure to the body part to be examined or to hold the body in rest position. The tensile force is adjusted self-locking.

3.3.4 Bucky Cassette Tray

The cassette tray is used to hold the X-ray film cassettes.

The cassette tray (**1**) can be pulled out of the Bucky by the handle (**3**) until the limit stop to insert the cassette. The cassette is locked by the clamping device (**2**). The cassette is automatically centred in transverse direction. In the longitudinal direction, the cassette can be positioned manually by aligning it according to the center markings (**4**) or by setting the cassette positioner to the corresponding cassette size.

The movement range of the Bucky is 545 mm.



4 Handling

4.1 Requirements before and during Operation

It must be ensured that the surfaces in contact with patients are disinfected before the X-ray examination of each patient (see chapter 5.3.2).

4.2 Operation of the PROGNOST F

4.2.1 Releasing the tabletop brake and positioning the tabletop

NOTE

Prior to patient positioning, the X-ray unit must be brought into the required exposure position.

WARNING!

The tabletop may only be locked when the tabletop is in the rest position, not while it is being moved.

1. Release the tabletop brakes by pressing the brake bar with your foot.
2. Move the floating tabletop to the desired position by hand while keeping the brake bar pressed.
3. When the tabletop is in the rest position, release the brake bar and the tabletop will be locked again by the brakes.

Tabletop displacement from the central position:

Transverse direction	± 150 mm
Longitudinal direction	± 330 mm (2m tabletop)
	± 460 mm (2.26 m tabletop)

4.2.2 Operation at the PROGNOST F

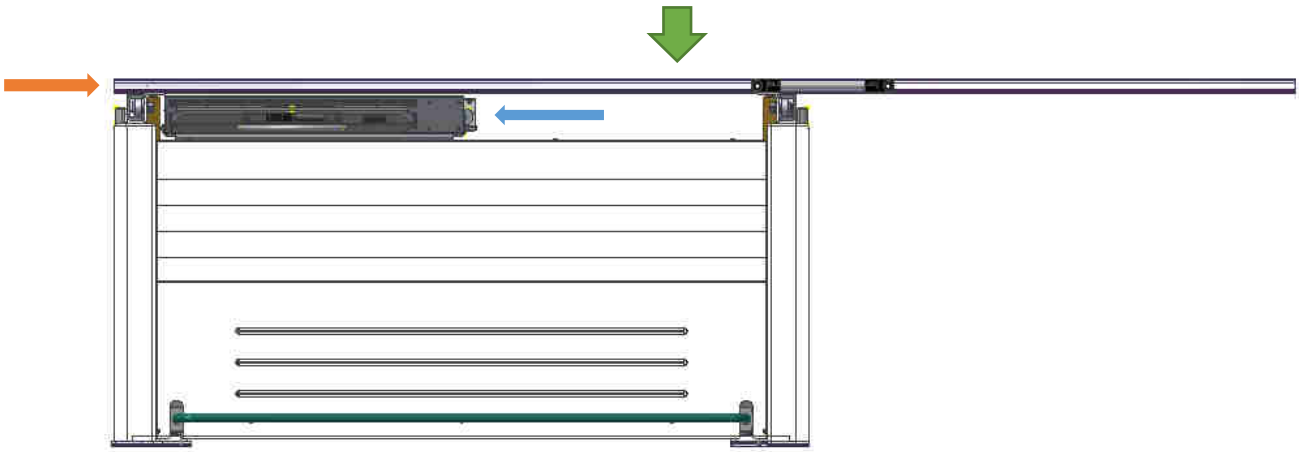
- Move the tabletop to a position where the patient can climb onto the table surface as easily as possible.

NOTE

The PROGNOST F is only used for positioning the patient during the examination. The Patient may only ascend and descend under the supervision or assistance of the examiner, otherwise there is risk of injury!

If the patient weighs more than 150 kg, the user should always follow the steps for ascending and descending the patient:

- Move the tabletop completely to one side (left or right).
- Slide the Bucky cassette drawer to the other side.
- Position the tabletop as centred as possible (back/front).
- The patient should ascend and descend in the middle of the tabletop (green arrow).



- Position patients for the exposure. If necessary (e.g., open wounds), cover the table surface with suitable cloths or disposable care pads.

WARNING!

Danger of crushing at the table edges and danger of trapping on and below the tabletop!
When the tabletop is moved horizontally, extremities can be trapped between the edge of the table and a fixed obstacle (wall, tube column, X-ray equipment).
Therefore, when using the PROGNOST F, make sure that neither the patient nor the personnel are standing in the direction of movement.
In particular, make sure that no extremities of the patient protrude over the edge of the tabletop. The patient must also be informed that all body parts should remain unmoved on the tabletop.

4.3 Function of the PROGNOST F

4.3.1 Switching the PROGNOST F on and off

The PROGNOST F does not have a separate on and off switch.

5 Safety and Maintenance

5.1 Introduction

In this chapter you will find information about safety and maintenance that are necessary to ensure the correct and reliable function of the device after installation.

5.2 Reusability

The PROGNOST F can be reused without any special preparation procedures.
However, it must be ensured that the surfaces in contact with patients are disinfected before the X-ray examination of each patient (see also chapter 4.1).

The PROGNOST F must no longer be used with patients if it shows signs of wear (e.g., metal abrasion, wear of insulations) or dangerous technical defects (e.g., bent parts) or if the resulting image quality (e.g., artifacts in the image) is insufficient.
In this case, please contact PROTEC service department or a service company authorized by them immediately.

5.3 Cleaning and Disinfection

NOTE

Caution!

Possible material changes!

5.3.1 Cleaning

The cleaning of the PROGNOST F is very easy due to the very good quality surface coating. This is usually only done with a dry cloth.
Do not use corrosive, dissolving or abrasive cleaning agents, which could damage the device surfaces or the coating.
Clean the 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 woollen cloth.

5.3.2 Disinfection

The disinfection must be performed in accordance with the current applicable legal requirements and guidelines corresponding for 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 parts of the PROGNOST F, including accessories, may only be cleaned with a wipe disinfection with suitable surface disinfectants (e.g., Melsept® SF, 15 min. application time at 2% concentration). The information provided by the disinfectant manufacturer on concentrations and application times must be observed.

5.4 Inspection and Maintenance

WARNING!

No maintenance or repair work may be performed while the PROGNOST F 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

Prior to operation, the operator must ensure that all safety related mechanisms, indicators and/or switches described within the user manual are fully functional and that the device is overall operationally ready.

- Check that the tabletop moves smoothly when the tabletop brake is released.
- Check the tabletop brake if it is not released.

5.4.2 Regular Monitoring

5.4.2.1 Quality control by the operator

Quality checks for X-ray components must be performed at regular intervals in accordance with the relevant national guidelines.

5.4.2.2 Safety-related controls

In the interest of the patient, operator and external third parties, it is necessary that all checks regarding operational safety and/or functionality of the device are performed regularly every 12 months by the PROTEC customer service department, or a service provider authorized by PROTEC.

All components within the PROGNOST F, which may pose a risk due to wear and tear 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 intended safety-related checks are not carried out, PROTEC GmbH & Co. KG accepts no liability for damage to the operator 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 service department or a service company authorized by them in order to ensure the safe and reliable functionality of the device. The maintenance intervals depend on the frequency of use. The required specifications can be found in the corresponding Technical Description in chapter 3 *Maintenance and Safety Inspection*.
In the event that the planned maintenance is not carried out, PROTEC GmbH & Co. KG assumes no liability whatsoever for damage to the user and third parties if damage results from inadequate or not carried out maintenance.
Prior to the examination operation, the user must satisfy himself that all appliances listed in the operating instructions and serving safety are in working order and that the product is ready for operation.
See the technical descriptions of the device.
Wear parts must be replaced with original components.

5.4.4 Warranty

NOTE

You will find the current warranty conditions in your order documents or in the price list valid at the time of purchase.

Repairs and spare parts in the event of improper use are also excluded.
Warranty work may only be carried out by trained specialists.

5.4.5 Product Service Life

The PROGNOST F is designed for a service life of 10 years when used in accordance with the specifications and regular maintenance by PROTEC service department or a service company authorized by them. After the product has reached the end of its service life, further use is at your own risk.

5.4.6 Further Information

Detailed information to the individual chapters and for a safe operation, transport or storage can be found in the Technical Description of the PROGNOST F.

5.4.7 Applied Parts and Parts Considered as Applied Parts

Part	**Definition** Applied part or part that is treated like an applied part but is not defined as an applied part.
Tabletop	Applied part
Handle (optional, mounted at the tabletop)	Part, considered as an applied part
Mattress (optional)	Part, considered as an applied part

5.4.8 Disposal Notes

The PROGNOST F contains various plastics and heavy metal. When disposing exchange and spare parts, or if necessary, the entire device, the valid rules and regulations must be observed. Please contact your contractual partner or service company or commission a company specialized in disposing the respective components.

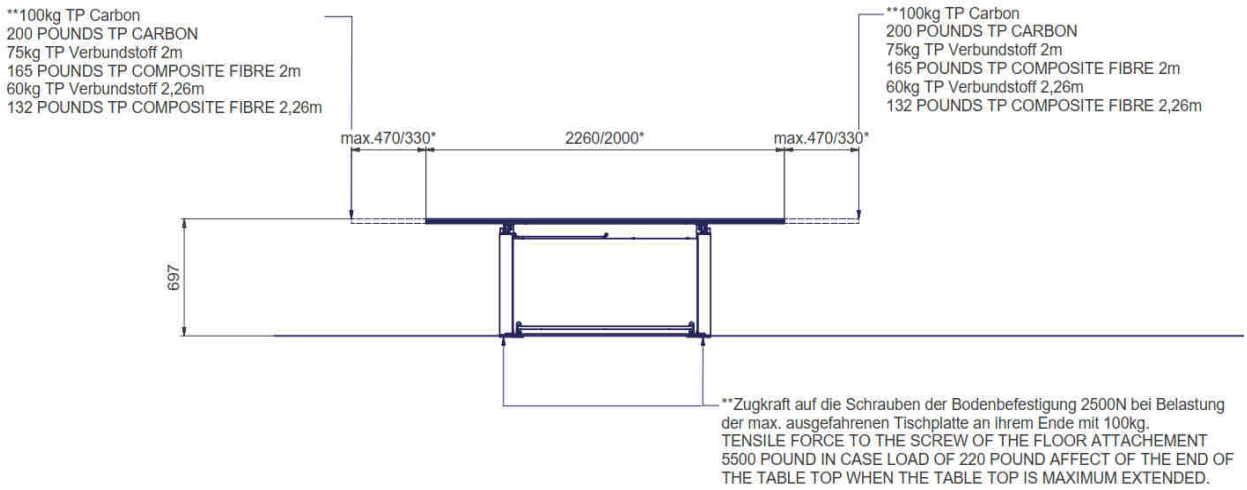
6 Power Supply

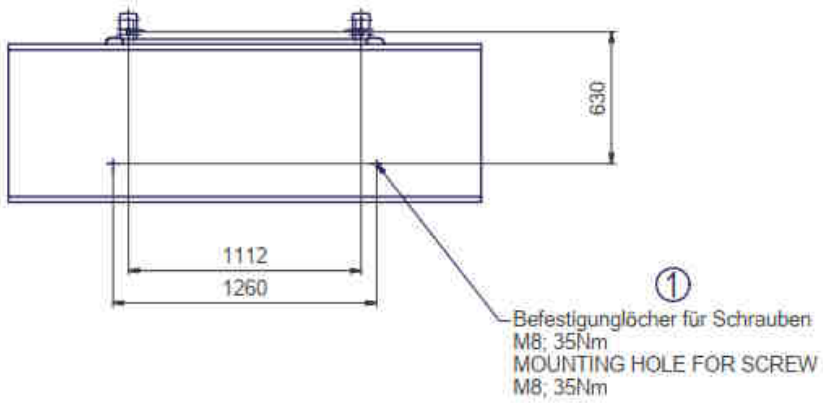
NOTE

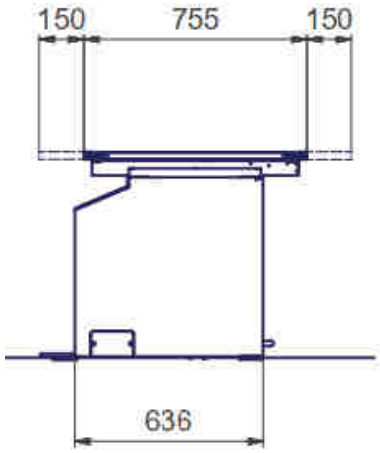
The PROGNOST F does not require a power supply.

7 Technical Data

7.1 Dimensions







Tabletop dimensions (L x W):	226 cm x 75.5 cm or 200 cm x 75,5cm
Max. Patient weight (line load)	230 kg (standard) 250 kg (optional)
Table height:	697 mm
Tabletop transverse movement from center pos.:	± 150 mm
Tabletop longitudinal movement from center pos.:	± 330 mm (200 cm tabletop)
Tabletop longitudinal movement from center pos.:	± 470 mm (226 cm tabletop)

The brakes of the tabletop are actuated by a Bowden cable.

7.2 Attenuation Equivalent

CAUTION!

The attenuation equivalent of the PROGNOST F may have to be considered during the acceptance test of the X-ray system.

The tabletop is defined as an applied part.
The aluminium attenuation equivalent of the tabletop is typically 0.7 mm Al and <0.8 mm Al for carbon; 0.85 mm Al for composite material according to EN 60601-1-3 at 100 kV and a first half-value layer thickness of 3.6 mm Al and typically 0.6 mm Al and <0.8 mm Al according to 21CFR § 1020.30 (m) at 100 kV and a first half-value layer thickness of 3.6 mm Al.

7.2.1 Protection Type and Protection Class

The PROGNOST F corresponds to protection class 1 and contains applied parts type B (according to EN 60601-1).

7.3 Environmental Conditions

7.3.1 Environmental Conditions during Operation

Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

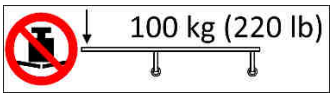
7.3.2 Environmental Conditions for Shipping and Storage

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

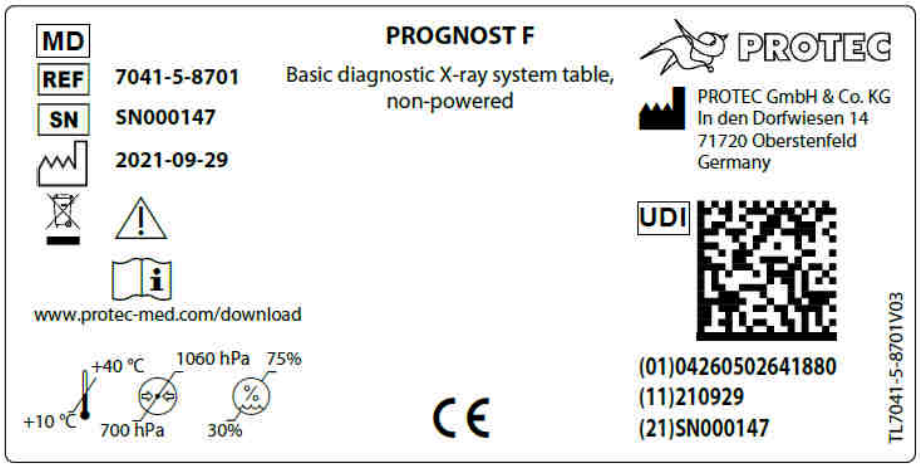
8 Description of Symbols, Labels and Abbreviations

8.1 Symbols

	Atmospheric pressure limit
	Temperature limit
	Humidity limit
	Keep dry
	Fragile, handle with care
	This way up
	Attention, observe accompanying documents
	Refer to Instructions for use
	CE marking
	Manufacturer
	Medical Device
	Order reference
	Serial number
	Unique Device Identification
	Production date
	Caution: pinch-/crushing hazard for hands and fingers

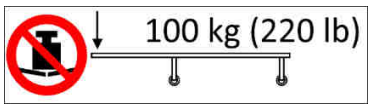
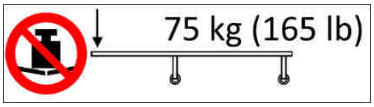
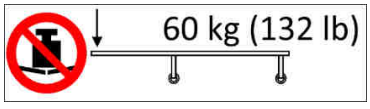
 www.protec-med.com/download	This symbol indicates the need to observe the instructions for use. This is provided in an electronic format (eIFU) on our website.
	Notes on disposal; WEEE , Waste of Electrical and Electronic Equipment
	Protective ground (Earth)
	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight

8.2 Type Label



8.3 Labels

Labels on the front side of the different tabletops

	Carbon fibre tabletop
	Composite fibre tabletop 200cm
	Composite fibre tabletop 226cm

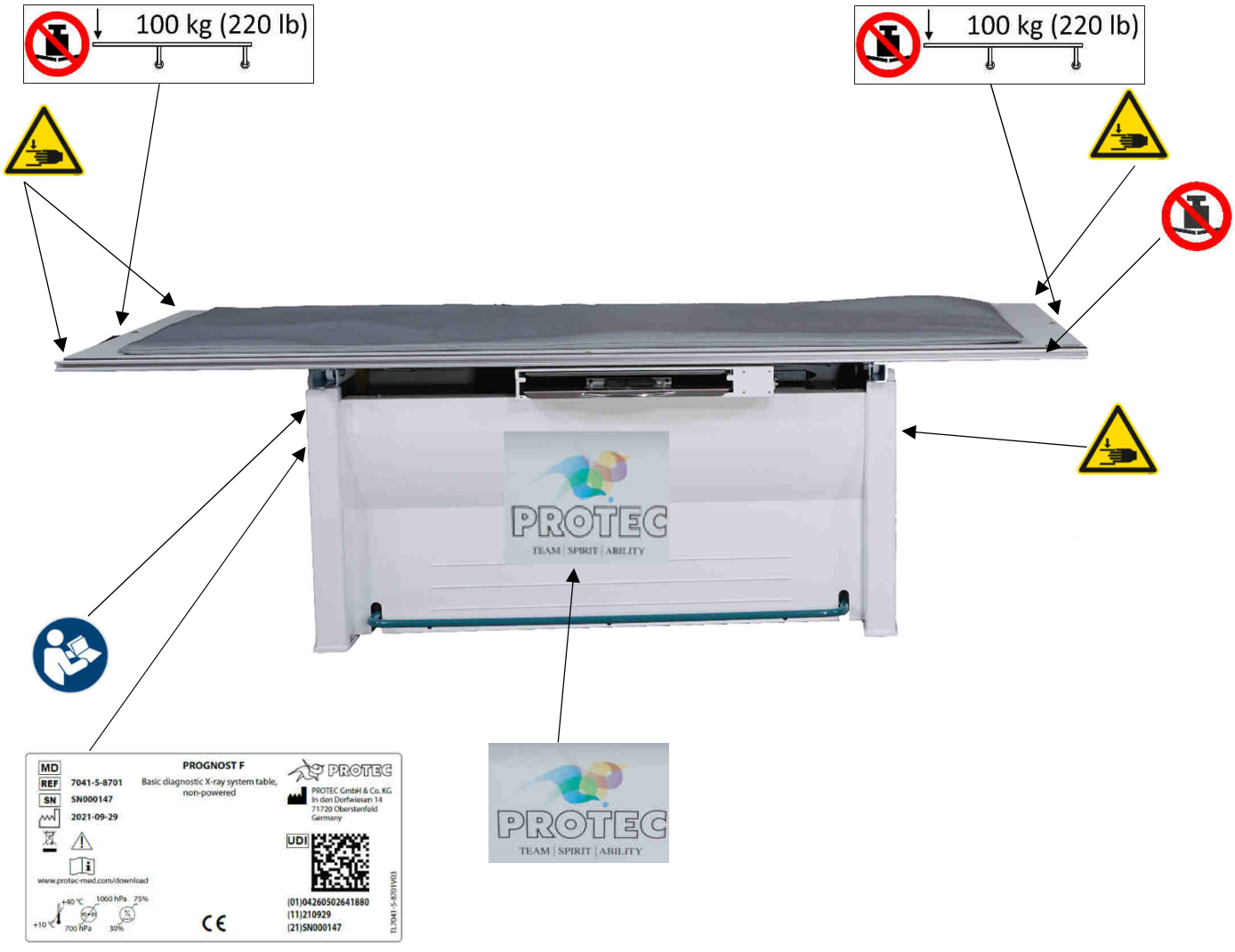
Labels on the tabletop

	Caution: Watch out for possible crushing hazards to fingers or hands while moving the tabletop, table or X-ray unit.
	Maximum allowed patient weight (distributed load) for the tabletop (Composite fibre tabletop).
	Maximum allowed patient weight (distributed load) for the tabletop (Carbon tabletop).

Label on the front plate

Company label

8.4 Positions of the Sings 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
V AC	Volt (alternating current)
V DC	Volt (direct current)
inch	Inches