PROGNOST E

X-ray system table

Model/ID: 7043-5-8707L

User Manual

Ident. Nr. 5043-0-8002

CE

PROTEC GmbH & Co. KG
In den Dorfwiesen 14, 71720 Oberstenfeld, Germany
Telephone: +49 (0) 7062/92 55-0 E-Mail: protec@protec-med.com

Version: 2.0
Issued: 2019-08-27
Subject to alterations

NOTE

All sheets of this document contain proprietary and confidential information of PROTEC GmbH & Co. KG and is intended for exclusive use by current PROTEC GmbH & Co. KG customers. Copying, disclosure to other or other use is prohibited without the express written authorization of PROTEC´s law department. Report any violations of this requirement to PROTEC GmbH & Co. KG.

© 2019 PROTEC GmbH & Co. KG, Oberstenfeld

These accompanying documents were created and distributed by the documentation department. Comments and questions about the documentation, please contact:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14 | 71720 Oberstenfeld
Deutschland
Phone: (+ 49) 7062 – 92 55 0
Fax: (+ 49) 7062 – 92 55 60

E-Mail: protec@protec-med.com
Internet: www.protec-med.com

Table of contents

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 Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
1.0	2019-05-14	all	Newly created. Replace document 5045-0-0002_Rev06
2.0	2019-08-27	Page 28, 29 chap. 2.1.7 chap. 3.2 chap. 6.1.1 Chap. 8.2	Changed illustration dimension, changed weight Attention-note inserted Chapter renamed EMC tables removed Identification label updated

General Notes

WARNING!

No changes of the ME device!

Mechanical – 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.
Contact with live parts and connections can be lethal.
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 this Document is directed to read and carefully review the instructions, warnings and cautions contained herein prior to beginning operation, installation or service activities.
While you may have previously operated equipment similar to that described in this Document, changes in design, manufacture or procedure may have occurred which significantly affect the present operation.
The installation and service of equipment described herein is to be performed by authorized, qualified **PROTEC GmbH & Co. KG** Customers.
Assemblers and other Customers not employed by nor directly affiliated with **PROTEC GmbH & Co. KG** technical services are directed to contact the local **PROTEC GmbH & Co. KG** office before attempting installation or service procedures.
For Installations and service procedures it is necessary to read the „technical description“ of the product and to observe any containing point in it.

1 Product description

1.1 Introduction

This user manual describes the special features and operational aspects of the PROGNOST E, knowledge of which are required for efficient and effective use of the X-ray system table.

Prior to working with the PROGNOST E, it is required that the user read the Safety Notes as well as the chapter regarding operation.

1.2 Description

The PROGNOST E consists of a moving grid table with a floating table top. It is prepared for the installation of a running grid device with electronic drive for an anti-scatter grid, which can be moved manually in longitudinal direction, and a 3-field measuring chamber for operation with automatic exposure control. The floating, flat table top of the moving grid table is locked in the resting position by highly effective pedo-mechanical brakes in longitudinal and transverse direction. The motor-operated table top brake and the electrical height adjustment of the table top can be actuated via the foot switch. The ease of movement of the table top and its large adjustment range allow comfortable positioning of the patient.

1.2.1 Models

PROGNOST E	7043-5-8707L

Device components

The X-ray system table PROGNOST E consists of the following components:

- Table base body E
- Front panel E
- Intermediate frame for table top width 755mm
- Table top composite fibre 2260x755mm

Optional variants

- Table top carbon
- Two different table top sizes

Optional accessories

- Long hand grip RAL5021 *(ID: 7301-0-0611)*, for mounting on the back of the table top, as a handle to facilitate patient ascent and descent
- Short hand grip (*ID: 7303-0-1100*)
- short hand grip adjustable (*ID: 7303-0-1150*), for mounting on the front of the table top, as operating aid for easy moving of the table top.
- Corner protection set table top *(ID: 7303-0-1700)*
- Shock protection profile *(ID 7303-0-1510)*, for rear table top accessory rail
- Compression band *(ID 7755-0-4001)*
- Mattress *(ID: 7765-0-402x)*

Integratable components (independent products) and possible combinations

These parts are not supplied with the PROGNOST E but can be combined with it.

- Bucky or Grid entity of the PROTEC series
- 3-field measuring chamber
- Anti-scatter grid

Accessories that can influence the EMC conditions

- Network cable (note the max. cable length in the component documentation)

1.2.2 Installation

See separate "Installation manual" PROGNOST E.
Contact information of persons which are qualified to make installations are requestable at:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14 | 71720 Oberstenfeld
Telephone: +49 (0) 7062 – 92 55 0
Fax: +49 (0) 7062 – 92 55 60
E-Mail: protec@protec-med.com
Internet: www.protec-med.com

1.2.2.1 Floor capacity

NOTE

The X-ray system table PROGNOST E is primarily made of metal pieces. This has a main role in the weight of the device.

The X-ray system table PROGNOST E has a max. weight of 212 kg.

Every technician is obliged to check the ground load. Also double bottoms and hollow floors have to be taken into account.

1.3 Product specific characteristics

- Variable table height
  - PROGNOST E Standard (58.9cm – 87,6 cm)
- Variable table top size
  - Standard: 226 x 75,5 cm
  - Optional: 200 x 75,5 cm
- Floating table top
- Table top colour – white
- Motor activated table top brake for effortless patient positioning
- A low (optimized) distance between the table top surface and the film (detector) surface
- Large adjustment range of the table top for position of the patient
- Reliable construction
- Lateral rails of the table top prepared to accept a number of table accessories
- Prepared 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 35.6 cm x 43 cm

1.4 Intended use

PROGNOST E is a powered X-ray system table with a floating, electronically height adjustable table top for use in medical rooms.
As a component of a stationary basic diagnostic X-ray system PROGNOST E is intended to position and support a patient during a variety of routine planar procedures requiring a diagnostic X-ray system in human medicine.

1.5 Indication and Contraindication

1.5.1 Indication

The X-ray system component PROGNOST F, considered as a single component, has no indication and no contraindication. Since this X-ray system component is intended for connection with other X-ray system components, the indication and contraindication of an entire X-ray system are considered.

A complete list of indications is unrealisable for conventional radiography, because the spectrum of conventional X-rays is very diverse and can vary in the course of medical-technical progress.

Some examples of indications for an X-ray examination may be:

- For the diagnosis of a bone fracture or bony injuries of the skeletal system or pathological changes of hard tissues.
- To control the bone setting.
- For the diagnosis of luxations and ligament ruptures of the locomotor system.
- For the diagnosis of degenerative, inflammatory, traumatic and tumorous diseases and changes of the locomotor system.
- For diagnostic of malformations and malalignments of the skeletal system.
- For the diagnosis of thoracic and pulmonary symptoms (thorax exposures)
- For the diagnosis of sclerotherapy.
- For the diagnosis of inflammatory and expansive processes of the mucosa, cranial bones and paranasal extension.
- For the diagnosis of the abdomen (e.g. acute abdomen, plain abdominal radiography, urethrogram, cystogram).

According to §83 of the German radiation protection law (StrlSchG), an X-ray examination is only justified if the patients benefit from x-ray diagnostics outweighs the radiation risk. The examination method, means the conventional X-ray with the PRS 500 system, must be suitable to answer the diagnostic question and no other more suitable alternative method is available.

1.5.2 Contraindication

- There are no absolute contraindications for conventional X-rays.
- But it is not allowed to make any exposures on humans when they are not medically indicated
- For pregnant women and children it is important to consider if the exposure is really necessary. It should be avoided if possible.

1.6 Intended user group

The PROGNOST E is exclusively designated for use by professional users who are trained to operate diagnostic X-ray equipment, in accordance with the corresponding national regulations, and who were instructed in the proper (certified) use, application and operation as well as in the permissible connection with other medical devices, objects and accessories.
Suitable user groups could include the following: Radiologist, radiology assistants, radiology technicians, doctors and other medically trained personnel.

1.7 Conformity

CE

This product is in conformity with the requirements of the European Community Medical Device Directive 93/42/EEC from 06/14/1993 including all current revision standards.

The declaration of conformity is available directly from PROTEC:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14 | 71720 Oberstenfeld
Telephone: +49 (0) 7062 – 92 55 0
Fax: +49 (0) 7062 – 92 55 60
E-Mail: protec@protec-med.com
Internet: www.protec-med.com

2 Safety Instructions

	**NOTE** xxx	Contains information that are relevant to the usage.
	**CAUTION!** **xxx**	Contains information that can cause damage to properties at non conformity.
	**WARNING!** **xxx**	Contains information that can cause personal injuries at nonconformity.
	**WARNING!** **xxx**	Warning of radioactive substances or ionisating rays. Contains information that can cause personal injuries at non conformity.

Adjustments and calibrations that are not described within the user manual must be made, with the aid of the technical description for the device, by the **PROTEC GmbH & Co. KG** customer service department or a PROTEC GmbH & Co. KG authorized service technician.

NOTE

Every delivered manual has to be read and the safety notes have to be observed.

NOTE

After installation the commissioning have to be recorded with the PROTEC acceptance protocol.

NOTE

The commissioning of the PROGNOST E can only be done if all safety notes and user securities have been met. The user securities can be: end stops, protection covers, brakes, etc.

CAUTION!

The manual contains every safety relevant information for the commissioning of the PROGNOST E. Operating the device is exclusively for special trained staff. In this context there are on every operating element relevant safety symbols. Further information are on the delivered document-CD. Those information count as additional information and have to be observed.

NOTE

Every operating elements are descript in the corresponding manual.

2.1 General safety notice

2.1.1 Requirements for operation

WARNING!

Protection Class I ME device
To reduce the risk of electric shock, this unit is designated exclusively for connection to a supply network with protective earth.
The power for the components of the X-ray system table PROGNOST E is designated to be exclusively supplied through a direct connection to the available X-Ray generator. The X-Ray generator is required to offer a minimum of two connection ports with 230V 50/60Hz.
The X-ray system table PROGNOST E is a Class I ME product (according to EN 60601-1). To reduce the risk of electric shock, this unit is designated exclusively for connection to a supply network with protective earth.
This device contains no on/off switch. The PROGNOST E is directly connected to the X-Ray generator and is switched on/off through the switching on and off of the generator itself. In order to disconnect the PROGNOST E from the power the connected X-Ray generator must be shut off.

2.1.2 Operating of the radiographic system

In case of functional disturbance, e.g. due to electromagnetic interference, the PROGNOST E shall no longer be used and the customer service department of PROTEC or a service company authorized by PROTEC should be informed.

2.1.2.1 Operating type

The PROGNOST E is not designated for continuous use.
Duty Cycle: S3 15% - maximum continuous operation of 1,5 minutes.

2.1.3 Operating personnel

The PROGNOST E should only be operated by personnel who are trained in accordance with the corresponding national regulations in the use and operation of diagnostic X-Ray systems.

NOTE

Only properly trained and authorized personnel are allowed to work with the PROGNOST E.

The user, as well as the service personnel, must pay attention to the warnings, notices and safety instructions located on the device and in the user manual. Failure to comply with the information provided can lead to injury.

NOTE

Operating personnel are required to acquaint themselves with all warnings (warning signs) located on the device. They serve to ensure the safety of the operator as well as others and set a basic for orderly operation.

2.1.4 Pinching and Collision Hazards

CAUTION!

Ensure that while using any product that can be lowered, raised or moved in different directions, neither yourself (operator), the patient or any third party finds themselves in a hazardous position (area of movement). Remove all objects (e.g. chairs, pushcarts) from known collision areas.
Failure to pay attention can lead to damage of the radiographic system as well as external objects.

2.1.5 Explosion protection

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

2.1.6 Interaction with external devices

Unwanted interaction with external devices is not known.

2.1.7 Electromagnetic Environment and the influence of devices

CAUTION!

The usage of other accessories, converter and other cables besides the delivered ones or by PROTEC (or the component manufacturer) established ones can cause increased electromagnetic emissions or a decreased electromagnetic resistance, which will lead to an improper operating mode.

CAUTION!

Avoid using this device directly next to other devices or with other devices in stacked form, as this could result in incorrect operation. If it is still necessary to use it in the manner described above, this unit and the other equipment should be observed to ensure that they are operating properly.

NOTE

The characteristics of this device, as determined by emissions, allow its use in the industrial sector and in clinics (CISPR, Class A). When used in residential areas (for which Class B is usually required by CISPR 11), this unit may not provide adequate protection for radio services. The user must take remedial measures such as implementation or reorientation of the device.

The PROGNOST E is intended for the usage in a professional environment of the medical service (e.g. clinic, surgery centers, physiology offices …)

3 Control elements and device displays

3.1 Foot switch

1 Release the table top brake. The table top can be moved floating by hand.
2 Height adjustment of the table. The table top moves upwards.
3 Height adjustment of the table. The table top moves downwards.
4 Release the table top brake. The table top can be moved floating by hand.

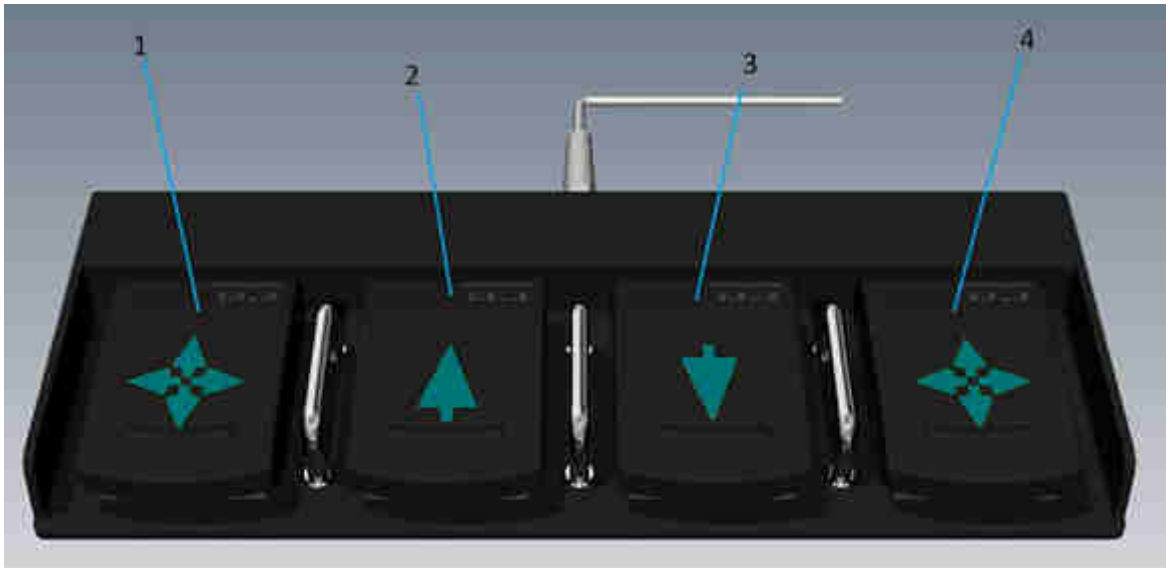


Figure 3-1

Attention: Functions that are controlled by a foot switch are only executed by "double-clicking" the switch.

The switch must be actuated twice within 1.5 seconds and then continuously to perform the function. When the switch is no longer actuated, the movement / function is stopped.

CAUTION!

Functions that are controlled by a foot switch are only executed by "double-clicking" the switch.
The switch must be actuated twice within 1.5 seconds and then continuously to perform the function. When the switch is no longer actuated, the movement / function is stopped.

3.2 Components

1 long hand grip RAL 5021 (accessory)
2 Signal LED
3 Emergency stop switch
4 Table top
5 Foot switch
6 Bucky cassette tray
7 Short hand grip (accessory)
8 Corner protection (accessory)

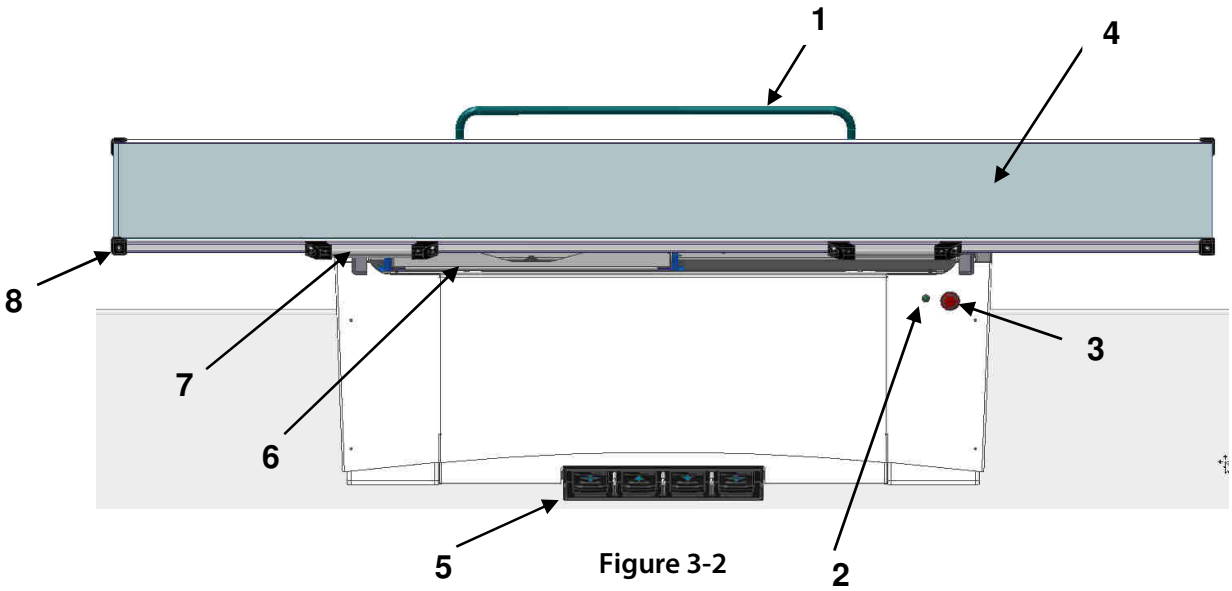


Figure 3-2

3.2.1 Hand grip (optional)

Options include a long hand grip (Fig. 3-2; 1) for the back of the table top and 2 hand grips (Fig. 3-2; 7) for the front of the table top. Both hand grips can only be removed with one tool. The long hand grip facilitates the patient's ascent and descent. With the short hand grip a better shifting of the table top is possible.

3.3 Emergency stop switch, signal LED and acoustic signals

By actuating the emergency stop switch (Fig. 3-2; 3) the control, the drives of the table top brakes and the drive for the height adjustment are switched off.
The emergency stop switch is unlocked by turning it clockwise.

Next to the emergency stop switch there is a two-colour signal LED (Fig. 3-2; 2), which indicates operational readiness and status messages.

CAUTION!

Even if the emergency stop switch has been operated and the signal LED does not light up, voltage may still be applied to the device. Only by switching off the power supply of the generator is the table safely disconnected from the power supply.

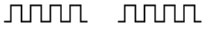
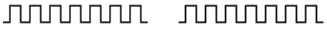
3.3.1 Status message of the signal LED

The following is an overview of the signal LED status display

Signal LED green	Device is ready for operation

Table 3-1

Status messages are generated by cyclic flashing of the signal LED in the colour red.

State	Flashing rhythm red	Description	Measure
1	**1x** 	Overheating of the power output stage. Caused by too frequent raising and lowering of the table with high patient load	Allow the unit to cool at standstill until the signal LED switches from red to bright green again. Reduction of the patient load
2	**2x** 	Drive blocked	• Check whether there is anything between the table top and the floor, move the table upwards and remove the object. • Notify service authorized by PROTEC
3	**3x** 	Overload, too high patient load and thus too high current consumption of the drives	• Reduce patient load and allow device to cool while stationary • Once the cause has been eliminated, the status messages are deleted by briefly pressing the foot switch of the table top brake
4	**4x** 	Unwanted movement, e.g. downwards due to inadmissibly high patient load	Reduction of the patient load. Notify service authorized by PROTEC
5	**7x** 	The controller has recognized that the upper or lower limit switch is out of function	Take device out of operation, notify PROTEC authorized service department

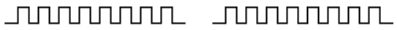
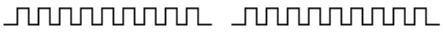
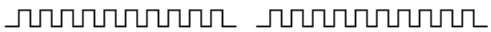
6	**8x** 	Height difference of the lifting columns, there is 1 cm difference in the position (height) of the lifting columns	• Perform zero adjustment (see chapter 4.1.3). • Notify service authorized by PROTEC should the error message reoccur after zero adjustment
7	**9X** 	Blocking the table top brake	Take device out of operation, notify PROTEC authorized service
8	**10X** 	Duty cycle of the lifting columns exceeded	Allow the unit to cool at standstill until the signal LED switches from red to bright green again.

Table 3-2

NOTE

Status messages 2 and 4:

If these status messages can be deleted with the foot switch and then reoccur, the PROTEC authorized service must be informed and the table must be taken out of operation.

3.3.2 Acoustic status messages

For all status messages of the signal LED under chapter 3.3.1 a single acoustic message is given by the built-in beeper.

Beeping sound	Significance
2x 	General Warning

Table 3-3

3.3.3 Acoustic and optical status signals for drive columns blocking

CAUTION!

If a drive is blocked during operation, the movement of the height adjustment must be adjusted and the obvious blocking of the height adjustment (e.g. by resting the table top on an object) must be eliminated.
If the cause of the blockage is not obvious (e.g. internally blocked drive column), the height adjustment must be taken out of operation and the PROTEC authorized service must be notified.

If a drive column is blocked, an optical status signal of the signal LED is given in conjunction with a one-time acoustic warning (see Chap. 3.3.1 & 3.3.2).

If a height difference of >1cm between the drive columns is detected by the control, height adjustment is no longer permitted (height adjustment automatically disabled).

A maximum duty cycle (ED) of 15% is prescribed for the drive columns in order to avoid overloading the column and to achieve a long service life. This is implemented in the control system in such a way that the height adjustment of the table is prevented after the factory-set time and an error message (10x flashing, see table) is displayed. This forces a pause of 4 minutes, as no height adjustment can be made. The internal time is then reset so that the table height can be adjusted again. In order to have the complete travel time available again, the table must be left switched on for at least 15 minutes without making a table height adjustment.

3.4 Bucky from the PROTEC series

The cassette tray (Fig. 3-3) is used to hold the X-ray film cassettes.

After pulling out the cassette tray (Fig. 3-3; 1) from the handle (Fig. 3-3; 3) of the Bucky as far as it will go, the cassette can be inserted. The cassette is clamped by the clamping device (Fig. 3-3; 2). The cassette is automatically centered in the transverse direction. In the longitudinal direction, the cassette can be positioned manually by aligning it with the center markings or by adjusting the cassette positioner (Fig. 3-3; 4) to the appropriate cassette size.

The movement range of the Bucky is 545 mm

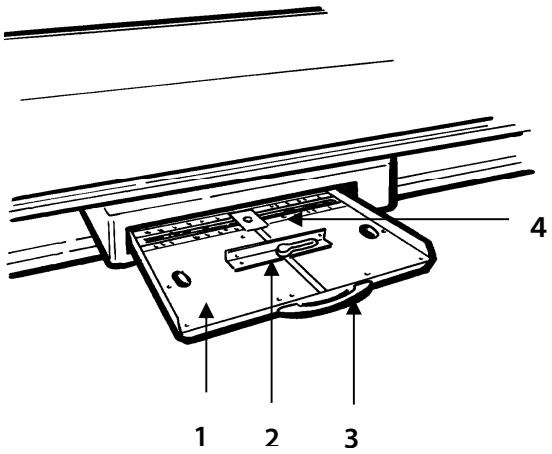


Figure 3-3

4 Handling / Operation

4.1 Operation PROGNOST E

4.1.1 Releasing the table top brakes (positioning the table top)

By double-clicking (see chapter 3.1) on one of the two footswitches intended for controlling the table top brake (Fig. 3-1; 1 & 4), the table top brakes are released, after which the table top can be moved floating by hand.

CAUTION!

The corners of the table top are relatively sharp.

When moving the table top horizontally as well as when getting on and off the patient, the corners of the table top must be observed. Additional protective parts are available as optional accessories (see chapter 3.2).

The table top displacement is from the central position in:

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

4.1.2 Height adjustment of the table top

By double-clicking on one of the two foot switches (Fig. 3-1; 2 & 3) (see chapter 3.1), the table top can be moved up or down. In the end position, the drive is automatically stopped.

CAUTION!

It is recommended to operate the X-ray system table only standing from the front.

The X-ray system table should not be operated while seated, as it is possible for the leg to be trapped between the table top and the foot switch when the table top is lowered. (Only when the table top is in the front position).

If the X-ray system table must be operated while seated, it is essential to ensure that the table top is positioned at the rear (see Fig. 4-1).

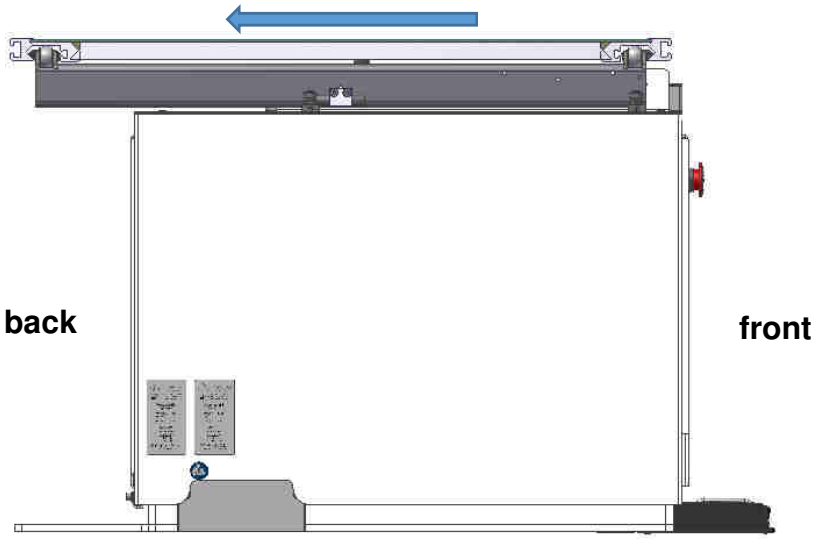


Figure 4-1

4.1.3 Carry out table hight zero adjustment

The control unit must be referenced when it is first put into operation or if differences in the height of the table top are visible.

CAUTION!

If there are visible differences in the table height, the table top could start moving automatically after the brakes have been released.

4.1.4 Zero adjustment with the foot switch

For adjustment, the drive-on foot switch (*Fig. 3-1; 2*) must be actuated and held. After 4 seconds of operation, the control beeps once. Immediately after the sound, the shut-off foot switch (*Fig. 3-1, 3)* must be operated and held. After a few seconds the lifting columns move slowly downwards. The zero adjustment takes place in the lower end position and therefore moves the table all the way down. ***The shut-off foot switch must be actuated until the end of zeroing.*** When both lifting columns are in the end position, the position is set to 0 and the control will beep once for a long time. The zero adjustment has been completed and the foot switch no longer needs to be operated.

CAUTION!

Never carry out the zero adjustment with the patient in position.

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

4.1.5 Operation at the PROGNOST E

- Move the table height to a position in which the patient can climb onto the table surface as easily as possible.

CAUTION!

The PROGNOST E 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 a risk of injury! Help patients to climb up.
If the patient weights more than 150 kg, the user must follow the steps for ascending and descending the patient as described in chapter 4.1.5.

- Ascent and descent of the patient (see Fig. 4-2)
  - Slide the table top all the way to one side (left or right).
  - Push the Bucky cassette tray to the other side.
  - Position the table top as centred as possible (rear/front).
  - The patient should ascend and descend in the middle of the table top (green arrow).

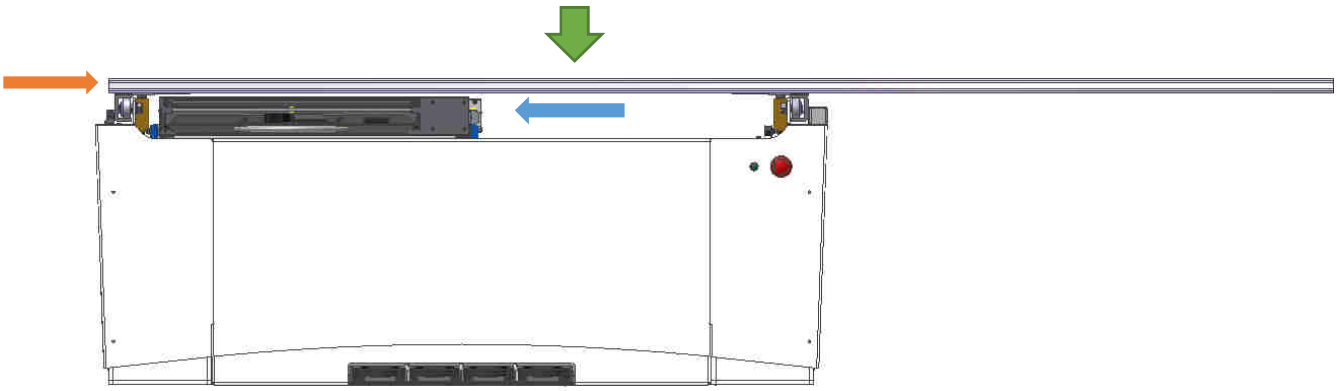


Figure 4-2

- Patients for admission. 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 clamping on and below the table top!
When the table top is moved horizontally, extremities can be trapped between a table edge and a fixed obstacle (wall, column, X-ray equipment).
Therefore: When using the PROGNOST E, make sure that neither the patient nor the personnel are in the direction of movement. In particular, make sure that no extremities of the patient protrude over the edge of a table. This must be taken into account with every patient and the patient must also be informed that all body parts on the table top should remain unmoved.

4.2 Function of the PROGNOST E

4.2.1 Switching On/Off the PROGNOST E

The PROGNOST E starts automatically when the system is switched on and is not started separately. The PROGNOST E switches off automatically when the system is switched off and is not switched off separately.

5 Safety and Maintenance

WARNING!

Caution Electrocution hazard!
Disconnect the power supply.
If the component is to be supplied via X-ray system or generator, then switch off the whole X-ray system.

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 radiographic system following initial installation.

5.2 Cleaning and disinfection

NOTE

Caution

Changes to material are possible!

Pay attention that, during cleaning and/ or disinfection, no fluids find their way into the main housing of the radiographic table. This reduces the risk of short circuits and corrosion.

5.2.1 Cleaning

Cleaning of the PROGNOST E is very easy due to its high-quality surface coating. As a rule, this can be done with a dry cloth.
The use of corrosive or abrasive cleaning agents as well as solvents is not allowed. These materials can cause damage to the outer surface of the unit or to the coating of the individual components.

Clean the outer surfaces of the unit and all painted components using a damp towel and a mild – light alkaline cleaning agent (e.g. RBS* Neutral T). Dry the components off following cleaning.

Chrome components should be cleaned by being wiped down with a dry wool cloth.

5.2.2 Disinfection

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

For reasons related to safety, the use of spray disinfection is not allowed. The mist from such disinfection dispenser systems can find its way into the unit, resulting in short circuiting and/ or corrosive build up.

All components within the x-ray system table PROGNOST E, including unit accessories, should undergo a wipe down disinfection using appropriate surface disinfection agents (e.g. Melsept* SF, 15 min. reaction time with a concentration of 2%). The information provided by the disinfectant manufacturer in regard to concentration and reaction time must be closely followed.

No disinfection agent, which is classified as flammable, can be utilized.

Should explosive gas and / or vapors be created through the use of the chosen disinfection agents, the unit can only be switched on when the gas/vapors have 100% dispersed.

5.3 Check-up and maintenance

WARNING!

It's forbidden to make any checkup or maintenance services while the PROGNOST E is in use with a patient! Any checkup or maintenance services can only be done by people who got trained or authorized by PROTEC.

5.3.1 Daily Controls (prior to or during the unit operation)

Prior to operation (creation of X-Ray images), the operator must ensure that all Safety related mechanisms, indicators and/or switches described within the user manual are fully functional and that the unit is overall operationally ready.

- Check that the table top moves smoothly when the table top brake is released.
- Check the table top brake if it is not released.
- Check the height of the table top. In the case of a visible difference in height, a zero adjustment must be carried out in accordance with Chapter 3.2.3.

5.3.2 Regular controls

Quality assurance measures for X-ray equipment must be carried out at regular intervals in accordance with national regulations, e.g. by means of a monthly constancy test.

- Check the surface of the table tops for damage or cracks.

5.3.3 Maintenance

Required maintenance must be performed at 6-month intervals by PROTEC Service or specific authorized service provider to ensure the sage, and reliable operation of the equipment.
In the event that scheduled maintenance is not performed, PROTEC GmbH & Co. KG will not be responsible for damages incurred by the user or third parties if such damages are the result of improper or omitted maintenance.
See Technical Description off the system and off all integral components.
Only original spare parts are to be used in situations requiring component replacement.

5.3.4 Warranty

NOTE

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

All repairs and replacement of components because of misuse and/or incorrect operation are excluded from the warranty.

Only authorized technicians may do service and maintenance work.

5.3.5 Product life time

The PROGNOST E has an expected product life of 10 years when used in accordance with the product specifications/ limitations and provided that maintenance through the PROTEC service department or a **PROTEC** authorized service provider has be completed. After reaching the life span the further usage of the device happens on own risk.

5.3.6 Further Information

Further information to the chapters and for a safe usage, transport or storage are in the technical description of the PROGNOST E.

5.3.7 Applied Parts and parts which get handled like an application part

Part	**Definition** (as applied part or parts which get handled like an application part but not defined as applied part)
Table top	Application part
Table housing	Component can come into contact with the patient - No application part
Foot switch	Component can come into contact with the patient - No application part

5.3.8 Disposal

The X-ray system table PROGNOST E contains different plastics and metals. At disposal of exchange parts or the whole system the current regulations have to be observed. Please contact your contractual partner or the service company, or a company specialized for disposing the components.

6 Electrical data

NOTE

The X-ray system table PROGNOST E is in need of the following power supply (see table „Power supply Generator").

Power supply voltage	230 V AC
Input current	2,7 A
Power frequency	50/60 Hz

Table (Power supply generator)

It is provided to always connect the x-ray system table PROGNOST E to an X-ray generator.

WARNING!

To lower the risk of an electrical shock, the device can only be run on a power supply with a protective conductor.

6.1 Electromagnetic Compatibility (EMC) after EN 60601-1-2

CAUTION!

The X-ray system table PROGNOST E is, as a medical electrical equipment, subject to particular precautionary measures in regard to EMC and is required to be installed and prepared for initial use as described within the accompanying documents.

CAUTION!

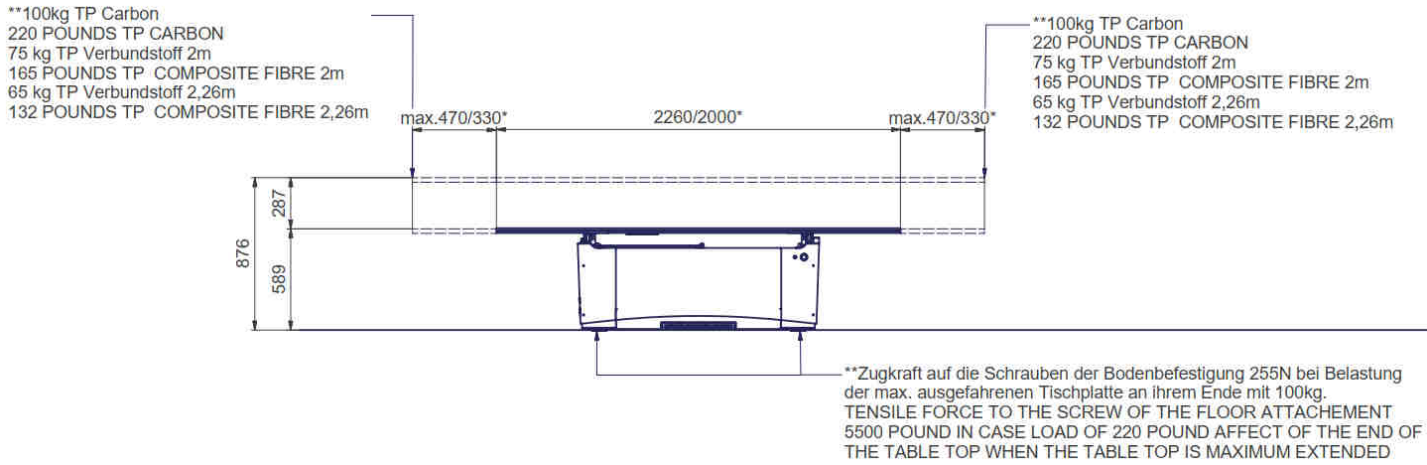
Mobile HF-Communication devices (radios) (including their accessories such as antenna cables and external antennas) shouldn't be used closer than 30cm (12 Inch) to the marked parts and cables of the PROGNOST E. Disregarding this can cause a decrease in the performance features of the device.

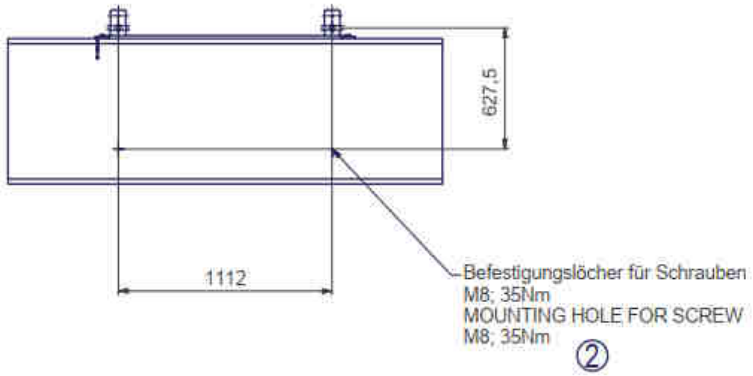
6.1.1 Guidelines and Manufacturers declaration – electromagnetic interference (non-life supporting device)

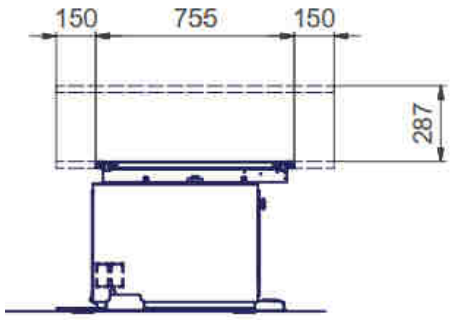
The X-ray system table is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the radiographic system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the X-ray system table.

7 Technical Data

7.1 Dimensions







7.1.1 Movement and dimension

Table top dimensions (L x W):	226 cm x 75.5 cm or 200 cm x 75,5 cm
Max. Patient weight (line load)	230 kg (standard) 250 kg (High speed)
Table height:	589mm - 876 mm (standard)

Table top transverse displacement (from the centre position):	± 150 mm
Longitudinal displacement of the table top (from the centre position):	± 330 mm (200 cm table top)
Longitudinal displacement of the table top (from the centre position):	± 470 mm (226 cm table top)

The brakes of the table top are actuated electromechanically.

7.1.2 Total weight

The maximum total weight of the PROGNOST E without Bucky is 196 kg.

7.2 Attenuation Equivalent

WARNING!

The X-ray system table PROGNOST E can be delivered with different options on the Grid Entity/Bucky.
The attenuation factor must be determined at the final inspection at the customer. The variables like X-ray tube, Collimator etc. have influence to the factor. The attenuation value of the components can be read out of the accompanying documents of the component. The attenuation value has to be determined at the technical specifications. If the limits can't be kept please inform PROTEC immediately. If additional accessories are use it has a negative influence to the quality of the X-ray image.

The aluminium attenuation equivalent of the table top is typically 0, 7 < 0, 8 Al mm for carbon / 0, 85 mm Al for composite fibre, according to EN 60601-1-3. Tested at 100 kV with a first half-value layer thickness (HVLT) of 3, 7 mm Al and typically 0, 6 mm Al und <0,8mm Al according 21CFR § 1020-30 (n) with 100 kV and a first half-value layer thickness (HVLT) of 2,7mm Al.

7.3 Protection Art and Protection Class

The PROGNOST E is consistent with a protection class 1 device and contains Applied Parts of type B (according to EN 60601-1).

7.4 Environmental

7.4.1 Environmental conditions during operation

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

7.4.2 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

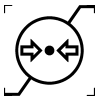
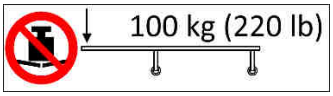
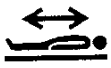
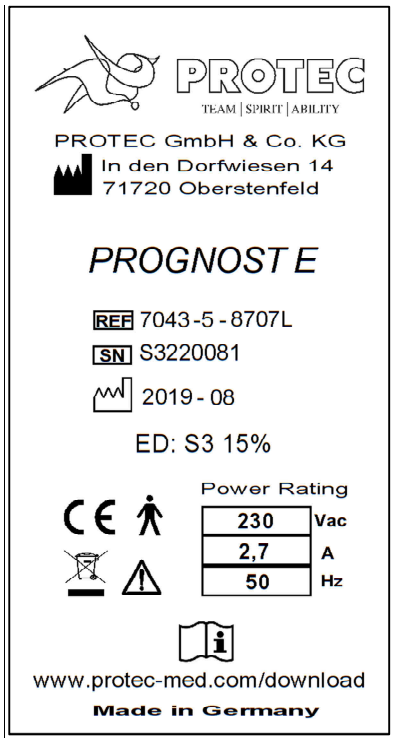
	Limitation atmospheric pressure
	Limitation temperature
	Limitation humidity
	Keep dry
	Fragile, Handle with care
	This way up
	Attention, consult accompanying documents
	Refer to user manual
	CE-Mark
	Classification according to EN 60601-1 (Applied Part Type B)
	Caution: pinch-/crushing hazard for hands and fingers
	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight
	Table top movement for exposure
	Longitudinal movement of the table top
	Transverse movement of the table top

	Table height adjustment – table up
	Table height adjustment – table down
	Release table top brakes
	Manufacturer
Typ	Trade name
	Order number
	Serial number
	Date of manufacture
 www.protec-med.com/download	With this symbol we point out that Usage instructions of the corresponding product is on out Homepage
	Notes on disposal; WEEE , Waste of Electrical and Electronic Equipment
	Protective ground (Earth)

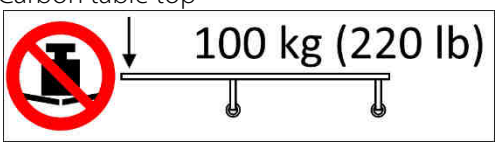
8.2 Identification label



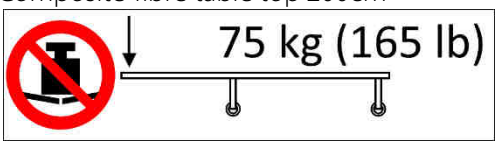
8.3 Labels

Labels on the side of the table top

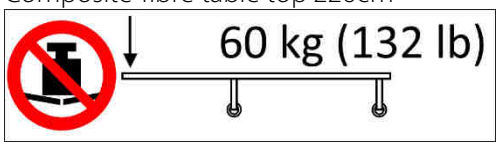
Carbon table top



Composite-fibre table top 200cm



Composite-fibre table top 226cm



Labels on top of the table top

Caution: Possible pinch-/crushing hazard fort he hands and fingers while moving the table top, table and or X-Ray tube assembly unit.

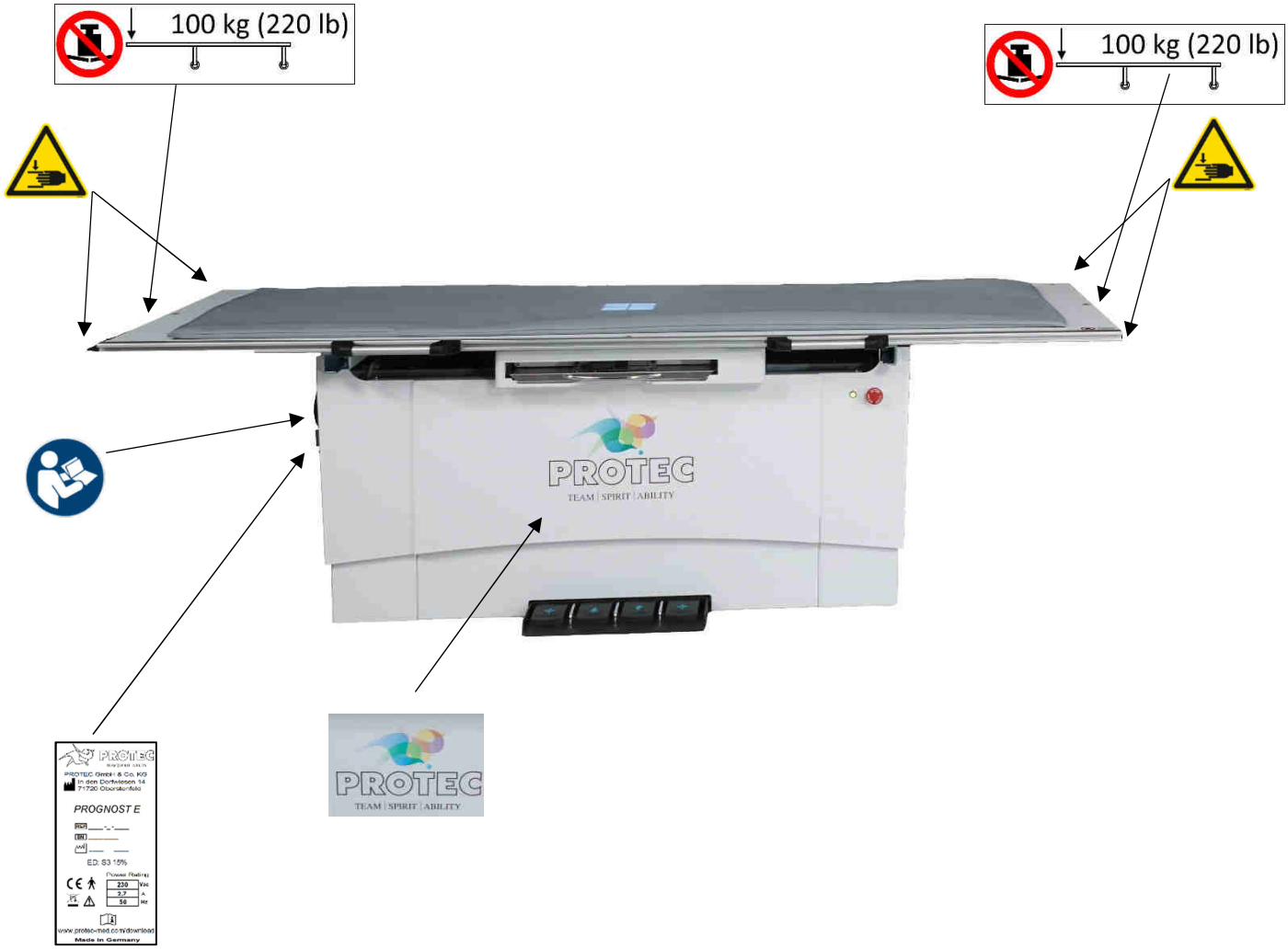
Maximum allowable Patient weight (distributed load) for the table top (Composite-fibre table top).

Maximum allowable Patient weight (distributed load) for the table top (Carbon table top).

Labels on the table front

Company label

8.4 Position symbols and labels



8.5 Abbreviations

mm	Millimeter
cm	Centimeter
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