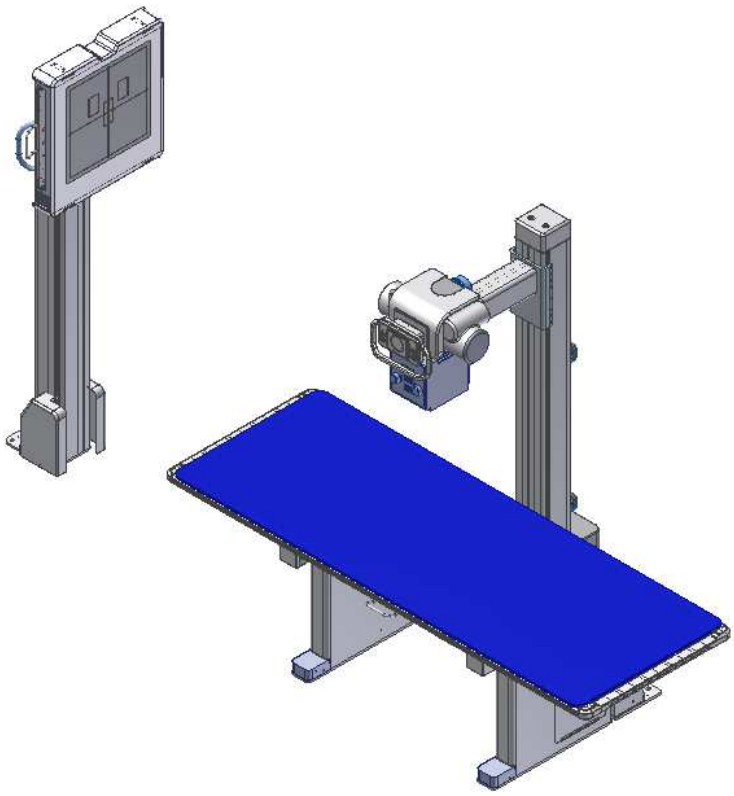
PROGNOST C

Diagnostic X-ray system mechanics

Model/ID: 7073-9-000X
Basis-UDI-DI: 426050264X013ZJ

Instructions for use

Ident. No. 5073-0-0002



CE

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NOTE

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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	Author
1.0	2020-11-26	all	Original issue	
2.0	2021-02-25	Front Page, 7, 11, 14, 15, 18, 23, 27	Product picture, Warning mattress, Compatible components, mattress at characteristic table added, symbols and labels, cleaning, mattress added to technical data table	
3.0	2021-03-11	7, 8, 18, 19, 20, 21, 23, 24, 25, 26, 27	X-ray mattress description, compatible components, note X-ray mattress at characteristic table, cleaning, disinfection, lifetime, applied parts, symbols and labels, chapter power supply connection, X-ray mattress changed at technical data table, note attenuation equivalent	
4.0	2021-05-26	all	V3.0 transferred to 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 – 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 usage of the product in combination with accessories not authorized by PROTEC is forbidden.

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 Product description

1.1 Introduction

This user manual describes the special features and operational aspects of the PROGNOST C, knowledge of which are required for efficient and effective use of the radiographic system.

Prior to working with the X-ray systems mechanics PROGNOST C, it is required that the user read the safety notes as well as the chapter regarding operation.

1.2 Description

The mechanics for basic diagnostic X-ray systems PROGNOST C is constituted of a fixed elevating patient positioning table with floating table top (incl. X-ray mattress), a completely integrated tube column stand, a fixed double operating mode wall stand and an electronic cabinet (without X-Ray components).

The floating table top can be locked in a longitudinal and transverse direction using an electromagnetic brake. The brake is controlled by a light barrier.

The table is prepared for the installation of a longitudinally sliding Bucky or Grid entity, an anti-scatter grid and a measuring chamber intended for use with an automatic exposure control.

The mechanics for basic diagnostic X-ray systems PROGNOST C integrates a on the radiographic table fixed biocompatible x-ray mattress. This mattress is specially designed for X-ray imaging diagnostics. The X-ray mattress can be removed for cleaning.

The tube column stand is guided by one rail, which is fixed on the ground behind the table. All movements of the column stand are well guided and therefor smooth. The movements of the column stand (horizontal and rotational) and desired positions are fixed using an electromagnetic braking system. The carrying arm is prepared for the installation of an X-Ray tube assembly (X-Ray tube, collimator and control panel with integrated controls).

1.2.1 Models

PROGNOST C	7073-9-0001 Wall stand left
PROGNOST C	7073-9-0002 Wall stand right

Optional Accessories

The PROGNOST C can be equipped or customized with the following accessories:

- Patient extending handle

Compatible components (stand-alone products) and possible combinations

The below mentioned components/products are not included with the standard delivery of PROGNOST C but nevertheless can be combined with the PROGNOST C.

- Collimator
- X-ray tube assembly
- X-ray generator
- Measuring Chamber
- Dose area product meter system
- Anti-scatter grid
- Different direct X-ray-systems (RAPIXX-series)
  (consisting of DR-detector, Interface Box, and Software)

1.2.2 Hardware and Network System Requirements

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

1.2.3 Installation

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

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1.2.3.1 Floor capacity

NOTE

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

The X-ray system PROGNOST C has a weight of 545kg.

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

1.3.1 Radiographic table

- Floating table top
- Table top colour – white
- Electromagnetic 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
- Prepared for the installation of a Bucky with anti-scatter grid and 3-field measuring chamber intended for the use with automatic exposure control
- Useable for variable cassette/detector sizes. Formats from 13 cm x 18 cm (5" x 7") to 43 cm x 43 cm (17" x 17"), depending on analogue or digital use.
- X-ray mattress (attached on the radiographic table, biocompatible, 2190 mm x 800 mm x 15 mm, provides a convenient and comfortable patient positioning on the X-ray table)

1.3.2 Floor railed X-ray system tube support

- Ceiling-free column stand intended for use within rooms with a ceiling height of at least 2.20 meters
- Wide range of application
- Small wall distance allows good space utilization
- Control elements within the command arm well placed and easy to activate
- Reproducible positioning of the X-ray tube assembly (positions resulting from rotation around the axis of the carrying arm) through angle indicator
- Vertical range of travel of the focus height from 40.0 cm up to 176.5 cm during horizontal beam projection
- Electromagnetic brakes for the longitudinal movement of the column stand, the vertical movements of the carrying arm, the rotational movements of the X-ray tube assembly around the axis of the carrying arm +/-135°.
- Integrated safety connector for automatically centring the X-ray tube assembly and the Bucky in the longitudinal direction.

1.3.3 Vertical Bucky Wall Stand

- Space saving with minimal footprint
- Wall – floor mounting of floor mounting
- cassette loading from the right or left side (specified at installation)
- Useable for variable cassette/detector sizes. Formats from 13 cm x 18 cm (5″ x 7″) to 43 cm x 43 cm (17″ x 17″), depending on analogue or digital use.

1.4 Intended Use

The X-ray system mechanics PROGNOST C is designated as a component to be used for the assembly of a diagnostic X-ray system 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 mechanics.

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 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 Medical Conditions to be diagnosed

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

1.8 Indications and Contraindications

As standalone products, X-ray system mechanics 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 Operator Group

As a component of a diagnostic X-ray system, PROGNOST C 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

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This product complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 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 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 described within the user manual must be made, with the aid of The technical description for the system, 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.

CAUTION!

The instructions for use contain all the information relevant to safety in order to generally put the PROGNOST C 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

Every operating elements are described 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 radiographic system PROGNOST C is designated to be exclusively supplied through a direct connection to the available X-Ray generator.
The PROGNOST C is a ME Class I 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.

WARNING!

The positioning and support of a patient on the X-ray system table must not be carried out without an X-ray mattress!

2.1.2 Operating of the radiographic system

When having troubles with operating of the PROGNOST C, immediately call the Service of PROTEC or an authorized service and stop the using of the PROGNOST C.

2.1.3 Operating personnel

The PROGNOST C 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 word with the PROGNOST C.

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.
Be aware that careless or improper adjustment of the radiographic system (movement of column, detector Bucky, Vertical Bucky wall stand and table top) can lead to damage of the X-Ray components, unusable X-Ray images and injury to the patient. Failure to pay attention can lead to damage of the radiographic system as well as external objects.

2.1.5 Explosion protection

These PROGNOST C 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 use of other accessories, other converters and other cables than those specified by PROTEC or provided in the documentation of the component manufacturer can result in increased electromagnetic interference or reduced electromagnetic immunity of the device and lead to defective operation.

CAUTION!

The use of the PROGNOST C 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 C and the other devices should be observed to ensure that they are working properly.

NOTE

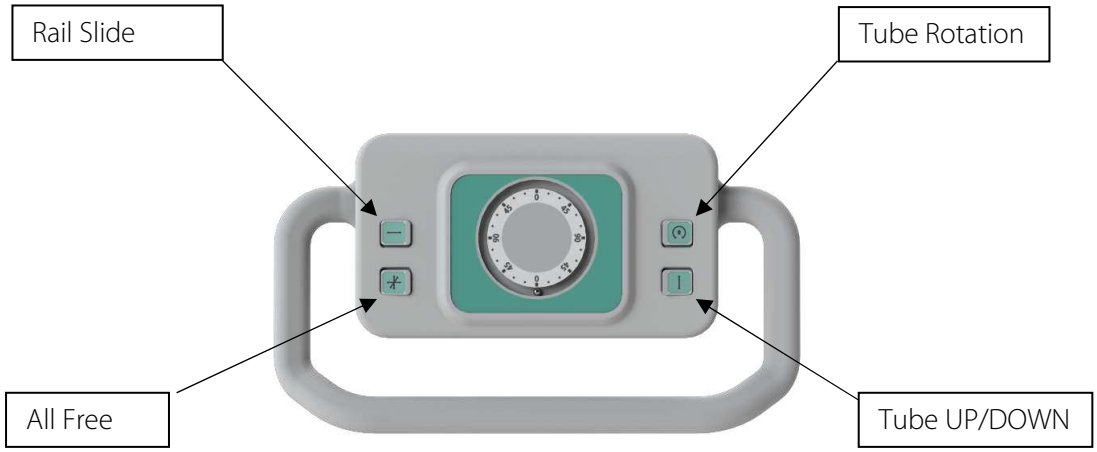
The properties of this device, determined by emissions, allow its use in industrial areas and in hospitals (CISPR 11, class A). When used in residential areas (for which class B is usually required by CISPR 11), this device may not provide adequate protection for radio services. The user may need to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

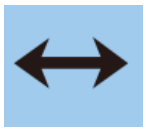
The PROGNOST C is intended for use in an environment in professional health care facilities (e.g., clinics, surgery centres, physiology practices ...)

3 Control elements and device displays

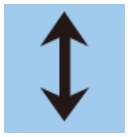
3.1 Control elements and device display of Basic X-ray system

3.1.1 Floor railed X-ray system tube support



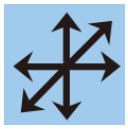


Rail Slide
When operator wants to move the tube stand at desired position horizontally, it can be moved manually while holding this button.



UP/DOWN
When operator wants to move the tube arm vertically at desired position, it can be moved manually while holding this button.

Tube Rotation
When operator wants to rotate the tube, it can be rotated manually while holding this button.

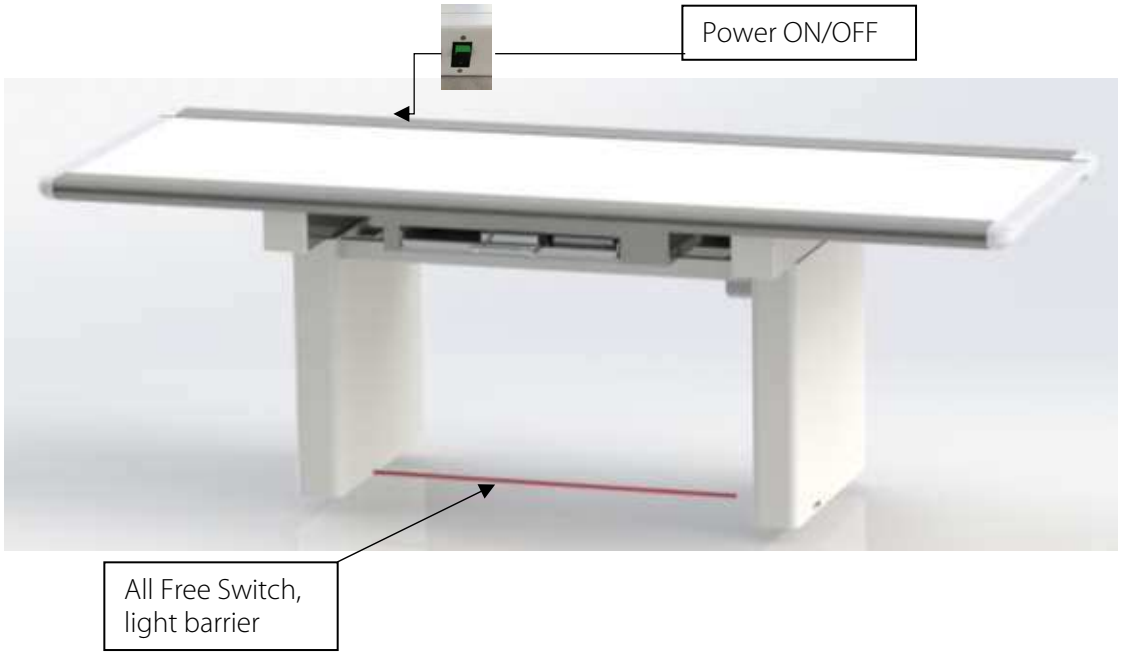


All Free Zone
It will allow to move the tube horizontally on the rail and up/down except the tube rotation.

3.1.2 Radiographic table

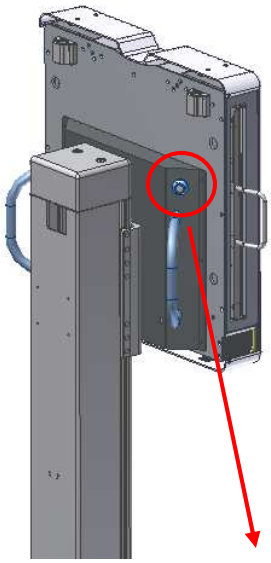
WARNING!

The positioning and support of a patient on the X-ray system table must not be carried out without an X-ray mattress!



The red line in the figure is the "ALL-FREE" switch. By bringing a foot or any object in this area, the "ALL-FREE" switch will be activated. With the switch checked, it is available to move the table top in any direction.

3.1.3 Vertical Bucky Wall Stand



For vertical movement of Bucky, it is available to move either up or down the Bucky manually while holding the UP/DOWN button as the figure
Detailed information please find in the enclosed User Manual of the PROGNOST C.

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).

4.2 Operation of the PROGNOST C

4.2.1 Releasing the table top brake (positioning the table top)

By actuating the light barrier with the foot, the brakes of the table top are released, whereby the table top can be moved floating by hand.

CAUTION!

The corner 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.

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

4.2.2 Positioning the image receptor from the wall stand

By pressing the release button on the wall stand, the brakes for the Grid device are released, the Grid device can be moved by hand.

4.2.3 Exposures with Mechanics for basic diagnostic X-ray systems

4.2.3.1 Position of patients on the table top

WARNING!

The positioning and support of a patient on the X-ray system table must not be carried out without an X-ray mattress!

- Move the table to a position in which the patient can climb onto the table surface as easily as possible.
- Center the table top as much as possible (back/front).
- The patient should take place in the middle of the table top and also leave at this position.

4.2.3.2 Setting the X-ray unit on the mid moving Bucky, Grid entity

- Press the button “Rail Slide” off the brake for the longitudinal motion of the tube stand.
- The handles on both sides of the control arm include.
- Moving the X-ray unit in the longitudinal direction of the Bucky table so unit the moving grid snaps into the safety coupling.

4.2.3.3 Inserting a cassette into the cassette tray

- A film cassette may be placed into the cassette tray, when the X-ray tube assembly is positioned.
- Pull out the cassette tray by its handle from the Bucky unit until it hits the forward stop.
- The cassette clamps center the cassette transversely within the cassette tray. Rotate its latch counter clockwise to unlock it.
- Open the cassette clamps far enough to insert a cassette of the desired size.
- At table Bucky insert the cassette, with its transverse centerline aligned with the notch in the cassette clamps or by engaging the cassette positioner in the size of the cassette corresponding detent (13 cm, 18 cm, 24 cm, 30 cm, 35 cm, 40 cm or 43 cm), push the cartridge to the cassette positioner.

- Push the cassette clamps against the cassette, and rotate the latch into the locked position.
- Push the cassette tray fully into the Bucky unit.

4.2.3.4 Adjusting the focus-film distance (SID)

- Set the X-ray unit with a tape measure at the collimator or the display on the tube to the desired focus-film distance (SID).
- Press the button "Tube UP/DOWN" off the brake to adjust the height of the X-ray unit.

4.2.3.5 Adjusting the light resp. X-ray field

- Press the collimator light switch (button 3, figure collimator) to turn on the collimator light, and view the opening of the collimator shutter in both axes relative to the cassette size scales.
- Several FFD scale (adjuster 1 and 2, figure collimator) are provided to indicate the correct settings of the collimator adjustment controls for the collimator shutters for several cassette sizes so that the light beam and the X-ray filed can be limited to the desired cassette size in both axes. Adjust cassette size as required using the collimator adjustment controls. Reduce shutter openings to objects size for better image quality.

4.2.3.6 Exposure preparation / exposure release

- At the X-ray generator operator console control panel, select the desire X-ray equipment (Bucky table with Bucky unit) by selecting the corresponding X-ray equipment/exposure technique switch.
- Press the desired Anatomically Programmed Radiography (APR) switch or manually select the desired exposure factors. Start the exposure by pressing the switches for exposure preparation/exposure release.

4.2.3.7 Overtable exposures

- Place a cassette to the desired position on the table top.
- Move X-ray tube to the desired position and adjust SID.
- Press the collimator light switch (button 3, figure collimator) to turn on the collimator light, and view the opening of the collimator shutters in both axes relatives to the cassette and object size.
- Place object on cassette.
- Adjust the light field with the adjuster 1 and 2 (figure Collimator) onto the size of the used cassette. So the radiation field will be limited to the size of the cassette.
- At the X-ray generator operator console control panel, select the desired X-ray equipment (Bucky table without Bucky unit) by selecting the corresponding X-ray equipment/exposure technique switch.
- Press the desired Anatomically Programmed Radiography (APR) witch or manually select the desired exposure factors. Start the exposure by pressing the switches for exposure preparation and exposure release.

4.2.4 Operation at vertical wall stand

4.2.4.1 Adjustment of the X-ray unit to the mid of a cassette or Bucky/Grid entity of aX-ray system image receptor stand (vertical center beam)

- By pressing button "Tube Rotation" the brake for the rotation of the Collimator will be released.
- Swing the X-ray unit to the X-ray system image receptor stand.
- Set the Bucky, Grid entity on the vertical stand to the size of the patient, see figure vertical Bucky Wall Stand.

4.2.4.2 Adjustment of the source to image-receptor distance (SID)

- Release the longitudinal movement brake of the column by pressing button "Rail Slide" and adjust the source to image-receptor distance (SID) which will be used for the exposure. Notice the focus area of the scanning unit, Bucky and Grid entity. Those settings have to be done with the measuring tape inside the collimator or with the markings on the upper guidance of the column.

4.2.4.3 Adjustment of the light-/ radiation field

- By using the button "Tube UP/DOWN" the button of the brake for adjusting the height will be released.

- Set the collimator to the requested height and align it to the Bucky by using the light-beam localizer "Tube UP/DOWN".
- Release Button "Tube UP/DOWN" to activate the height-adjustable brake for the collimator.
- By using button 3 (figure Collimator) the light-beam will be activated to control the vent of the collimator to the used cassette.
- With the adjuster 1 and 7 (figure Collimator) set the lamellas of the Collimator to the size of the used cassette. The settings will be done on the scale 6 and 7 (figure Collimator) to the according cassette source to image-receptor distance (SID). So the light-/ radiation field is limited to the according cassette.

4.2.4.4 Exposure preparation/ release

- Select the used device on the console of the generator (vertical-grid recording device).
- Select the requested organ program or the requested exposure details, and start the exposure by using the control element for exposure preparation/ release.

4.3 Function of the PROGNOST C

4.3.1 Switching On/Off the PROGNOST C

NOTE

The Mechanics for basic diagnostic X-ray systems must be switched on!

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

5 Safety and Maintenance

WARNING!

Caution, risk of electric shock!
Turn off the PROGNOST C before cleaning or disinfecting. This disconnects the PROGNOST C from the power source and avoids the risk of electric shock.

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 C 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 C 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., torn cable, 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!

WARNING!

Make sure that no liquid enters the interior of the housing during cleaning and disinfection in order to prevent electrical short circuits and/or corrosion.

5.3.1 Cleaning

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.

The X-ray mattress is equipped with a Velcro ® system. To make cleaning easier, the mattress can be removed to clean the areas underneath and the mattress itself. After cleaning, the X-ray mattress must be reattached to the X-ray system table. Make sure that it is positioned correctly.
The X-ray mattress can be cleaned moist. Use warm water and a mild cleaning agent. If necessary, wipe the product with a damp cloth and let it dry thoroughly. Don't use any abrasive or bleaching agents and sharp-edged objects for cleaning.

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 woolen cloth

5.3.2 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 radiographic system, 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.

The resistant material of the X-ray mattress can be treated with a commercially available wipe disinfectant. Check the compatibility beforehand and if necessary use the instructions for the disinfectant. We recommend aldehyde- and alcohol-free agents such as Trionic®, Mikrobac® tissues, Mikrobac® forte, Bacillol® 30 foam or Bacillol® 30 tissues.

WARNING!

No highly flammable disinfectants may be used! For safety reasons, spray disinfection must not be carried out, as the spray mist could penetrate the device and cause short circuits or corrosion.
If disinfectants are used that can form explosive gas mixtures, the device may only be switched on again when the gas mixtures have evaporated!

5.4 Inspection and maintenance

WARNING!

No maintenance or repair work may be performed while the PROGNOST C 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 investigation Operation

- Check that the table top moves smoothly when the table top brake is released.
- Check the table top brakes when they are activated (table top should not be able to move)

5.4.2 Regular Monitoring

5.4.2.1 Quality control by the user

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

- Check the surface of the X-ray mattress for damages (scratches, cracks, etc.)
- Check the movement of the components (table top, X-ray column, wall stand)

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 for damage to the user or third parties, if damage results from inadequate or not carried out maintenance.

Before starting the operation, the user must ensure that all the equipment concerning safety, listed in the instructions for use, are functional and that the device is ready for use.
See the technical description of the device.
Wear parts are to be replaced with original components.
In the event that the scheduled maintenance is not carried out, PROTEC GmbH & Co. KG assumes no liability whatsoever for damage to the user and third parties if and to the extent that damage results from inadequate or non-performed maintenance.
Prior to test operation, the user must satisfy himself that all devices 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 system.
Wear parts are only to be replaced with original parts.

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 C is designed for a service life of 7 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.

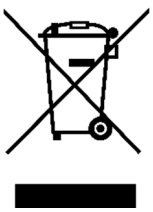
5.4.6 Further Information

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

5.4.7 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)
X-ray mattress	Applied part
Cover – vertical wall stand	Applied part
Housing pars PROGNOST C	Part, get handled like an application part
Optional accessory	
Patient extending handle (optional; mounted at the vertical wall stand)	Part, get handled like an application part

5.4.8 Disposal



The PROGNOST C contains various plastics and heavy metal. When disposing exchange and spare parts, or if necessary, the entire system, 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 Electrical data

6.1 Connection

NOTE

The PROGNOST C is in need of the following power supply

Power supply	220-240 Vac
Power frequency	50-60 Hz
Input current	2,5 A

It is intended that the central power supply of the PROGNOST C is always be connected to an supplied X-ray generator or power box using a hard-wired connection. Select a connection that consider the electrical specifications of the PROGNOST C like in the table above.
There is a central power supply connection on the radiographic table to which the X-ray floor stand and the vertical X-ray system image receptor stand are also connected.

WARNING!

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

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

CAUTION!

As a medical electrical device, the PROGNOST C is subject to special precautionary measures regarding EMC and must be installed and commissioned in accordance with the EMC information contained in the accompanying documents.

CAUTION!

Portable RF communication devices (radio devices) should not be used closer than 30 cm (12 inches) to the marked parts and cables of the PROGNOST C. Failure to observe can lead to a reduction in the performance characteristics of the device.

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

The PROGNOST C is intended for use in the electromagnetic environment specified below. The customer or the Operator of the radiographic system should assure that it is used in such an environment.

Measurement interference	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The X-ray component uses RF energy exclusively for its internal function. As a result, its RF emissions are very low and it is unlikely that nearby electronic devices will be influenced.

RF emissions CISPR 11	Class A	The device is suitable for use in facilities other than residential areas and those that are directly connected to the public supply network, which also supplies buildings that are used for residential purposes, provided the following warning is observed: **Warning**: This device is intended for use by medical professionals only. This is a class A device according to CISPR 11. This device can cause radio interference in residential areas, in which case it must be necessary to take appropriate remedial measures such as new alignment, rearrangement or shielding of the device or filtering of the connection to the location.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	compliant	

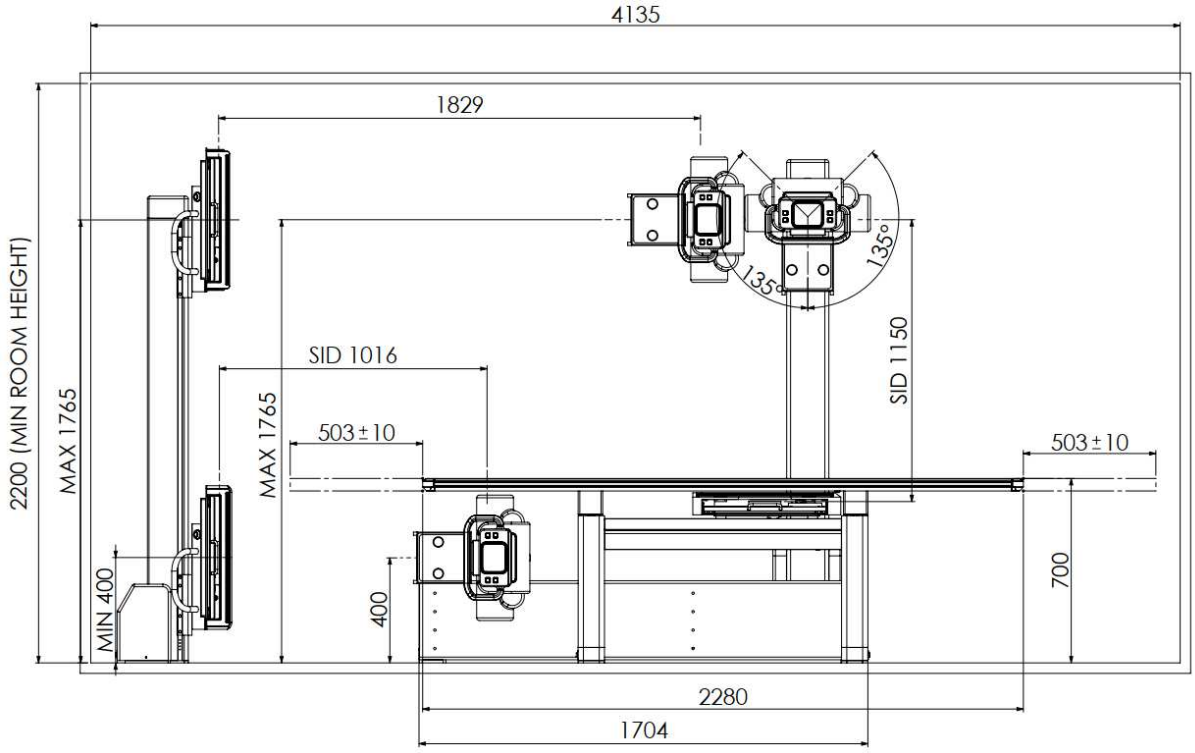
Immunity Test	**EN 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbance variables / burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges EN 61000-4-5	± 0,5 kV ± 1 kV ± 2 kV	± 0,5 kV ± 1 kV ± 2 kV	The quality of the supply voltage should be that of a typical commercial or hospital environment.
Magnetic field at the supply frequency (50/60 Hz) EN 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Magnetic fields at the mains frequency should correspond to the typical values found in a business and hospital environment.
Voltage dips, short interruptions and fluctuations in the supply voltage EN 61000-4-11	<5 % UT (>95 % dip in UT) for ½ cycle <5 % UT (>95 % dip in UT) for 1 cycle 70 % UT (30 % dip in UT) for 25/30 cycles <5 % UT (>95 % dip in UT) for 5/6s	<5 % UT (>95 % dip in UT) for ½ cycle <5 % UT (>95 % dip in UT) for 1 cycle 70 % UT (30 % dip in UT) for 25/30 cycles <5 % UT (>95 % dip in UT) for 5/6s	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the device demands continued operation even if there are interruptions in the energy supply, it is recommended that the device be fed from an uninterruptible power supply or battery.
Conducted disturbances induced by RF fields EN 61000-4-6	3 V/m 1 kHz 80% AM 150 kHz bis 80 MHz	3 V/m	

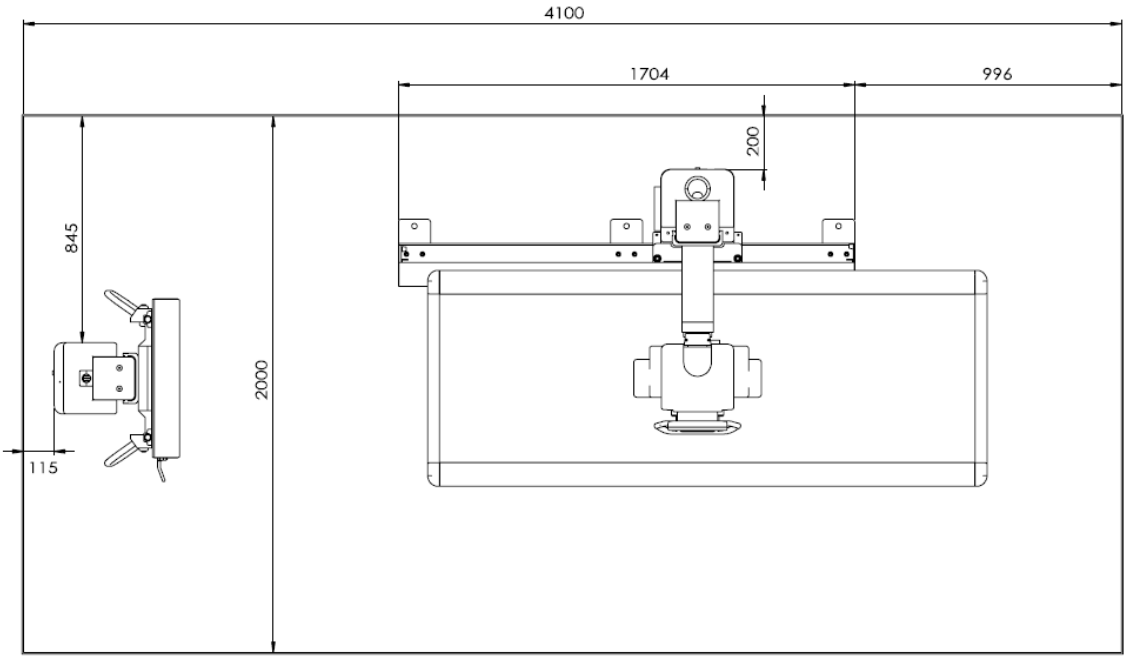
Radiated RF disturbances EN 61000-4-3	3 V/m 1kHz 80% AM 80 MHz to 2.7 GHz	3 V/m	See table below
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.			

Test Frequency in MHz	**Frequency Band in MHz**	**Service in MHz**	**Modulation**	**Immunity Testing Level in V/m**
385	380 - 390	TETRA 400	Pulse modulation: 18 Hz	27
450	430 – 470	GMRS 460, FRS 480	FM ±5 kHz Deviation 1 kHz Sine	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation: 217 Hz	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation: 18 Hz	28
1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation: 217 Hz	28
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation: 217 Hz	28
5240 5500 5785	5100 - 5800	WLAN, 802.11 a/n	Pulse modulation: 217 Hz	9

7 Technical Data

7.1 Dimensions





7.2 X-ray system table

Table top dimension (L x B):	2280 mm x 800 mm, standard
Safe patient weight, max	200 kg
Safe working load (without X-ray mattress), max	250 kg
Table top height:	700 mm
Table top movement, transvers (from the mid-position):	± 100 mm
Table top movement longitudinal (from the mid-position):	± 500 mm

The brakes of the table top are used electro-mechanic.

7.2.1 X-ray mattress

Length	2190 mm
Width	800 mm
Height	15 mm
Patient load, max	200 kg

Velcro ® fastening, cleanable, biocompatible

7.3 Bucky unit

Longitudinal travel:	580 mm
Table top - film-distance:	75 mm

The Bucky unit and the measure chambers are connected to the generator.

7.4 X-ray system tube support, floor stand

Focal spot vertical travel - horizontal X-ray beam:	400 mm – 1765 mm
Focal spot vertical – film distance:	max. 1150 mm
Focal spot vertical – table top distance:	max. 1075 mm
Rotation X-ray tube assembly around horizontal support arm:	± 135°
Tube stand longitudinal travel:	1265 mm

7.5 Vertical X-ray system image receptor stand

Column height:	1870 mm
Vertical shift film center:	400mm - 1765mm

7.6 Attenuation Equivalent

WARNING!

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

The aluminium attenuation equivalent of the table top is typically 1.1 < 1.2 Al mm 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.

The X-ray mattress is defined as an applied part.
The attenuation equivalent of the X-ray mattress is typically 0.5 mm Al to EN 6061-1-3 at 100 kV with a first half-value layer thickness of 3.7 mm Al.

The cover vertical wall stand is defined as application part.
The aluminium attenuation equivalent of the cover vertical wall stand is typically 0.5 and < 0.6 Al mm according to EN 60601-1-3. Tested at 100 kV with a first half-value layer thickness (HVLT) of 3.7 mm Al.

7.6.1 Protection Art and Protection Class

The PROGNOST C is consistent with a protection class 1 device and contains applicable parts Type B (according to EN 60601-1).

7.7 Environmental

7.7.1 Environmental conditions during operation

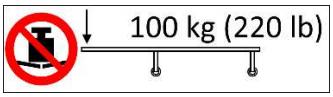
Ambient Temperature	+ 5°C to ~ 30°C
Relative humidity	10% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

7.7.2 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

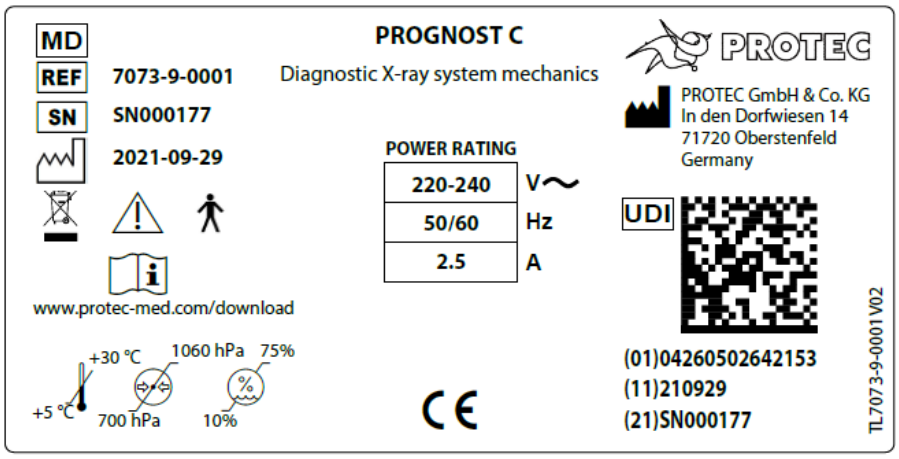
8 Description of symbols, labels and abbreviations

8.1 Symbols

	Air 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
	Classification according to EN 60601-1 (type B applied part)
	Caution: pinch-/crushing hazard for hands and fingers
	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight
	Manufacturer
MD	Medical Device
REF	Order reference
SN	Serial number
UDI	Unique Device Identification

	Production date
 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.
	Disposal instructions; WEEE (Waste of Electrical and Electronic Equipment)
	Protective earthing

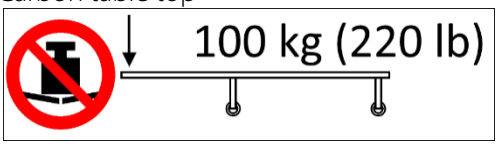
8.2 Type label



8.3 Labels

Labels on the side of the table top

Carbon table top



Labels on top of the table top

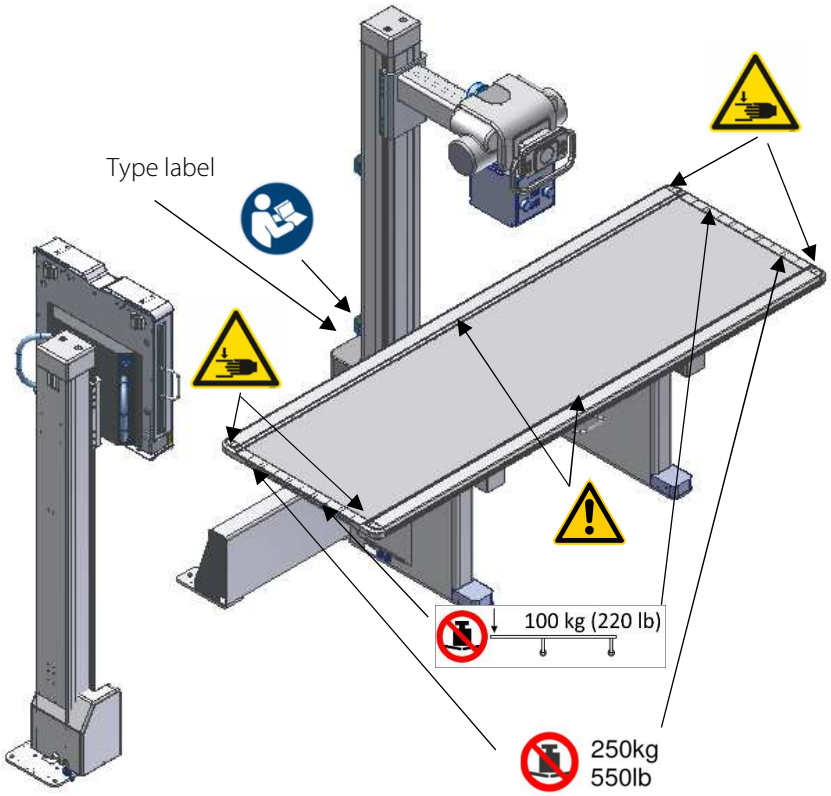
Caution: Possible pinch-/crushing hazard fort he hands and fingers while moving the table top, table and or X-Ray tube assembly unit.

Maximum safe working load radiographic table (without X-ray mattress)

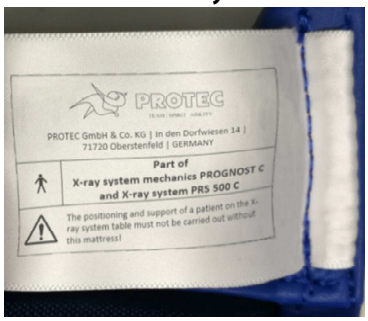
Label on the X-ray mattress

The X-ray mattress is identified as a component of the PRS 500 C. The positioning and support of a patient on the X-ray system table must not be carried out without this mattress!

8.4 Position symbols and labels



Label of the X-ray mattress



The label is located on the underside of the X-ray mattress.

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