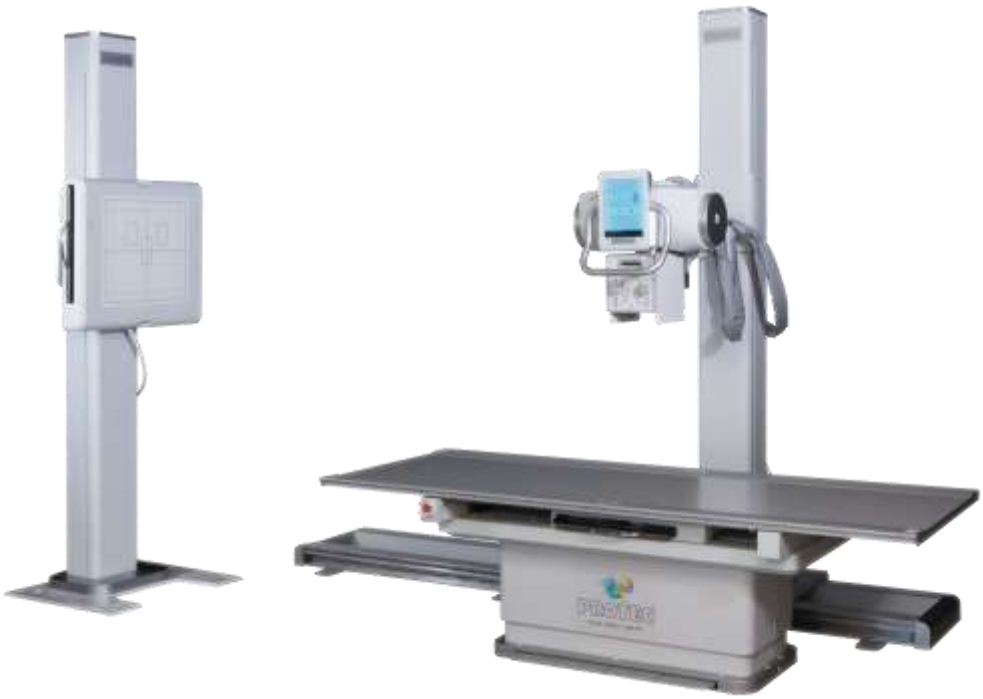
PROGNOST B

Diagnostic X-ray system mechanics

Model/ID: 7014-9-0001
Basic UDI-DI: 426050264X012ZG

Instructions for use

ID No. 5014-0-1002



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 Organisation.

Revision Status

Revision	Date	Updated pages	Comments	Author
1.0	14/02/2018	n/a	First edition	
2.0	15/08/2018	7, 8, 9 11, 15, 16, 17, 20, 23, 24, 26, 27, 28, 30, 31, 32, 40, 41, 42, 45	Editorial revision	
3.0	2020-11-25	Front page, Chap.1.2.1, Chap. 1.3.3, Chap.1.4	Product description revised	
4.0	2021-05-25	all	V3.0 transferred to new layout (MDR)	MB
6.0	2022-04-26	41, 42	Figure changed	ML

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 B.

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

1.2 Description

The diagnostic X-ray system mechanics PROGNOST B is constituted of a fixed elevating patient positioning table with floating table top, a floor-guided, ceiling-free tube column stand, a vertical Bucky wall stand and an electrical cabinet (EC-Box) (without X-ray components).

The floating table top is can be locked by a brake in longitudinal and transverse direction. The table top brakes and height adjustment of the table is controlled by using an integrated foot switching unit.
The table is prepared for the installation of a grid device (Bucky) or Grid Entity, that can be moved in the longitudinal direction by a motor, an anti-scatter grid and a measuring chamber intended for use with an automatic exposure control.

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 smooth and locked by electromagnetic brakes. The tube arm is prepared for the installation of an X-Ray tube assembly (X-Ray tube, collimator and control panel with integrated controls).
The 360° rotatability of the complete X-ray tube column ensures maximum application flexibility. Ideal for immobile patients who, for example, need to be X-rayed directly in the hospital bed without repositioning.

The vertical Bucky wall stand can be delivered in two versions. Either mounted on the left or right side of the table. The wall stand is prepared for the installation of a vertical sliding (manually and motorized movable) Bucky or Grid Entity. The vertical movement of the Bucky or Grid Entity is fixed by using an electromagnetic braking system.

There are also integrated functions like Autotracking and other safety options.

Autotracking functions:
The automatically Autotracking X-ray tube unit adjusts its position to the height of the wall stand Bucky. The Bucky inside the table automatically adjusts itself to the central beam direction of the X-ray tube unit. The source image distance (SID) between table and X-ray tube unit also adjusts itself automatically.
When performing an X-ray examination of the patient in standing position in front of the wall stand, the manual positioning of the tube and further adjustments by the user become redundant.
Ideally suited also for oblique exposures because the Bucky in the table automatically moves into the central beam or the X-ray tube unit automatically moves to the center of the Bucky of the wall stand.

1.2.1 Versions

PROGNOST B diagnostic X-ray system mechanics 7014-9-0001

Table top version:

Material	L	W	Table top color
Composite	230 cm	80.5 cm	white

Optional Components
- Bucky or Grid Entity
- Measuring chamber (Ionization or solid state)
- Anti-scatter grid
- Collimator
- X-Ray tube assembly (tube and housing)
- Generator

Optional Accessories
The PROGNOST B can be equipped with the following accessories:
- Ceiling bracket cabling 4m
- Wall bracket cabling 4m
- Wall bracket for console
- Patient extended handle
- Handle for table top
- Detector holder incl. 2 handles
- Mattress 225 cm x 70 cm x 2 cm

Accessories that can influence the EMC conditions
- Network cable (take note of the max. cable length in the system documents)
- Wi-Fi router (Only use devices approved by PROTEC)

1.2.2 Hardware and Network System Requirements

As a stand-alone product, the PROGNOST B has an integrated Touch Display, therefore it should be ensured that the country-specific requirements for data protection and IT security are met.

1.2.3 Installation

NOTE

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

For more information, please see separate "Installation manual PROGNOST B".
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 B is primarily made of metal pieces. This has a corresponding effect in the weight of the device.

The PROGNOST B has a weight of 780kg.

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 Height adjustable X-ray system table

- Suitable for different room layout, as Bucky wall stand can be placed on the left or right side of the patient table.
- Automatic locking function for some specific desired SID.
- Remote control for the vertical movement of the Bucky of the wall stand
- Variable table height (57,5 cm- 87,5 cm)
- Floating table top
- Table top color white
- Magnetic table top brake for effortless patient positioning
- A low optimized distance between the table top surface and the detector (film) surface
- Large adjustment range of the table top for positioning of the patient
- High reliability
- Lateral profile rails on the longitudinal side of the table top for attaching 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
- Variable cassette/detector sizes can be used. Formats from 13 cm x 18 cm (5″ x 7″) up to 43 cm x 43 cm (17″ x 17″), depending on analogue or digital use
- Ceiling-free tube column stand suitable for rooms with a ceiling height of at least 2.50 meters
- Maximum application flexibility due to 360° rotatability of the entire X-ray tube column
- Control elements within the control panel easy to reach and easy to activate
- Reproducible positioning of the X-Ray tube unit when rotating around the axis of the tube arm due to angle display
- Vertical travel range of the focus height from 35 cm up to 180 cm with horizontal beam path
- Electromagnetic brakes for the longitudinal movement of the tube column stand, the vertical movements of the tube arm and the rotational movements of the X-Ray tube assembly around the axis of the tube arm with additional 90° detents, as well as the vertical movements of the wall stand Bucky

1.3.2 Vertical Bucky Wall Stand

- Space saving with small footprint
- Floor mounted
- Cassette loading from the left or right side
- Variable cassette/detector sizes can be used. Formats from 13 cm x 18 cm (5″ x 7″) up to 43 cm x 43 cm (17″ x 17″), depending on analogue or digital use
- Suitable for a Bucky or Grid Entity (analogue and digital)

1.3.3 Product components

The PROGNOST B is a diagnostic X-ray system mechanics and consisting of the following essential system components:

- A stationary, height-adjustable X-ray system table,
- a rotatable X-ray tube column with floor rails including tube arm,
- a wall stand column,
- an EC-Box with console

1.4 Intended use

The X-ray system mechanics PROGNOST B 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 function to diagnose, treat and/or monitor medical conditions.

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 or contraindications can be shown for them.

1.9 Intended User Group

As a component of a diagnostic X-ray system, PROGNOST B 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, orthopedists 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 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 B 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 B 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 B 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 Requirements for operation

WARNING!

The PROGNOST B is a protection class I device (according to EN 60601-1).
To avoid the risk of an electric shock, this device may only be connected to a supply network with a protective earthing conductor.
The power supply for the PROGNOST B of the X-ray system is exclusively made by direct connection to the X-ray generator or the Power Box and is permanently connected there. The X-ray generator or the Power Box must have at least 2 connections for 230V 50/60Hz.
The X-ray generator of the X-ray system is connected to the supply network (see technical description of the X-ray generator).
To reduce the risk of electric shock, the system must be connected to a supply network with protective earthing.
The system does not have an on/off switch. It is switched on or off directly by switching on the X-ray generator or by the switch on the Power Box. In order to separate any electrical voltage from the X-ray system, the connected X-ray generator or the Power Box must be switched off.

2.1.2 Device Operation

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

2.1.2.1 Operating Type

The PROGNOST B is not designated for continuous operation.

2.1.3 Operating Personnel

NOTE

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

NOTE

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

2.1.4 Crushing and Collision Hazard

WARNING!

It must be ensured that when operating the moving parts of PROGNOST B, 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 B or other objects.

2.1.5 Explosion Protection

This PROGNOST B is not designated for use within areas with explosive hazards.

2.1.6 Interaction with Other Devices

Interactions with other devices are not known.

2.1.7 Electromagnetic Environment and Influencing 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 B 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 B and the other devices should be observed to ensure that they are working properly.

NOTE

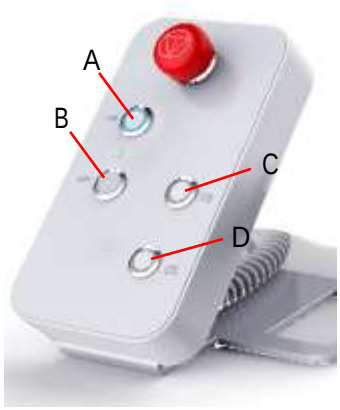
The properties of this device, determined by emissions, allow its use in industrial areas and in hospitals (CISPR 11, class A). When used in residential areas (for which class B is usually required by CISPR 11), this device may not provide adequate protection for radio services. The user may need to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

The PROGNOST B 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 B

Switching the PROGNOST B on and off is performed via a mini console (with EC-Box switched on).



A	Switch on PROGNOST B
B	Switch off PROGNOST B
C	Wall stand Bucky movement upwards
D	Wall stand Bucky movement downwards

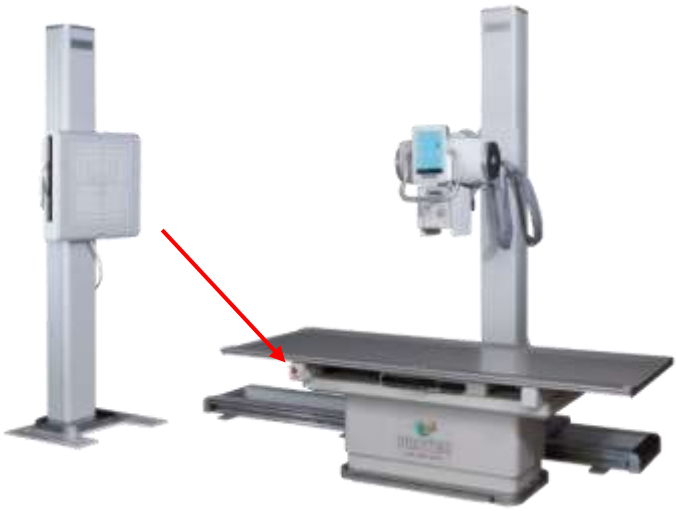
3.2 Emergency Stop Switches of the PROGNOST B

The PROGNOST B has the following emergency stop switches, which can be used to bring the device to an immediate standstill and disconnect it from the power supply.

The PROGNOST B has a total of five positions of the emergency stop switches (following figures with X-ray components).

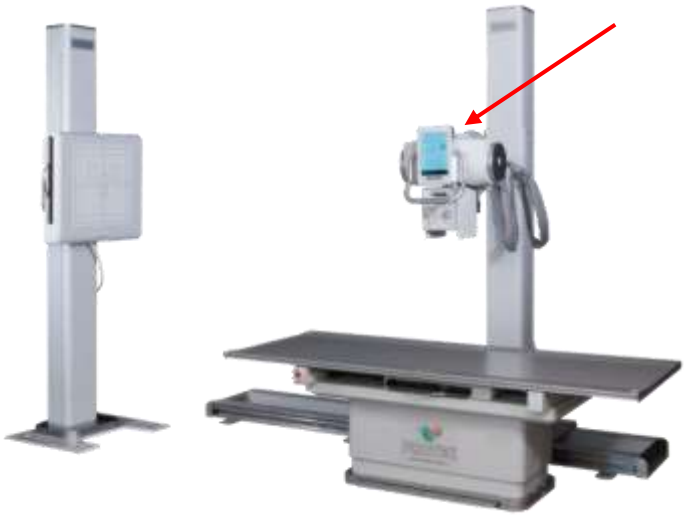
3.2.1 X-ray System Table Emergency Stop Switch

The emergency stop switch is located on the left side of the X-ray system table.



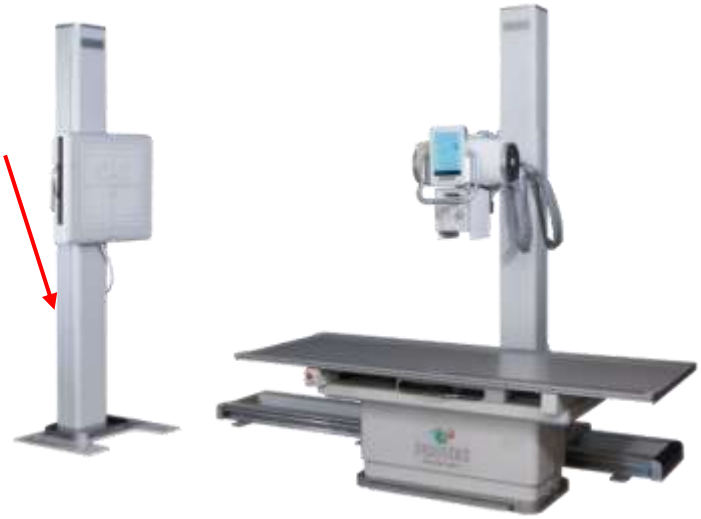
3.2.2 Tube Stand Emergency Stop Switch

The emergency stop switch is located behind the Touch PC, on top of the X-ray tube.



3.2.3 Wall Stand Emergency Stop Switch

The emergency stop switch is located on the backside of the wall stand.



3.2.4 EC-Box emergency stop switch

The emergency stop switch is located on top of the EC-Box.

3.2.5 Emergency Stop Switch Mini Console

The mini console is usually located in a shielded X-ray side room, which is intended for X-ray personnel. The emergency stop switch is located on top of the console.

CAUTION!

Even if the emergency stop switch has been activated, parts of the PROGNOST B may still be connected to the power.
Only by switching off (or disconnecting) the EC-Box, the PROGNOST B is completely disconnected from the power supply.

3.3 Control Elements and Display of PROGNOST B

3.3.1 Control Unit

1. Release brake, motor for vertical upward movement of the Bucky/Grid Entity in the wall stand activated
2. Release brake, motor for vertical downward movement of the Bucky/Grid Entity in the wall stand activated
3. Release brake for longitudinal movement of the X-ray tube column
4. Release brake for the rotation of the X-ray tube unit
5. Release brake, motor for vertical upward movement of the X-ray tube unit activated
6. Release brake, motor for vertical downward movement of the X-ray tube unit activated
7. Touchscreen for displaying the SID, height of the X-ray system table, angle of the X-ray tube etc.
8. Operating handle for the operator

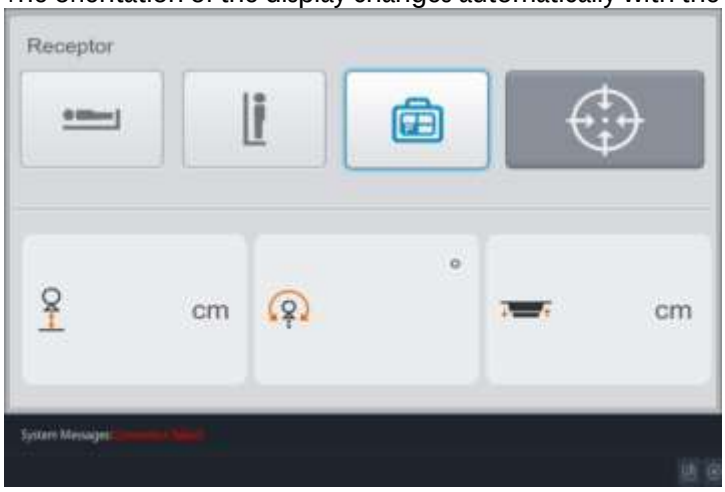
The operation is performed from the front (operator side) of the X-ray tube column.
By grasping the handle (around the control unit) with both hands, the electromagnetic brake or motor can be released or activated by pressing the corresponding button on the control unit with the thumb. Once released, the X-ray tube unit can be moved to the desired position.

3.3.2 Touchscreen

NOTE

Different symbols in the PROTEC CONAXX Touch2 software for stationary basic diagnostic X-ray systems (see "Instructions for use PRS 500 B")

The orientation of the display changes automatically with the rotation of the X-ray tube unit.



1) The colors of the icons on the touch screen are defined as follows:

Dark grey: The function of this icon is not activatable
Black: The function of this icon is usable but not activated
Blue: The function of this icon is activated
Positioning information: This area displays the SID value, the degree of tube assembly rotation and the height of the X-ray system table

2) Autotracking wall stand button: 

If the angle of the X-ray tube assembly is not ±90°, rotate the unit to this position and move the tube column, if needed, in direction wall stand. The symbol  must be pressed to activate Autotracking wall stand.

If the position of the wall stand Bucky is higher than the tube position, the tube assembly will automatically move upwards as soon as clicking on the symbol  . The tube assembly adjusts itself to the wall stand Bucky height and the Autotracking is activated.

If the height of the wall stand Bucky is lower than the tube height, the wall stand Bucky automatically adjusts to 1.40 m as soon as clicking on the symbol  . Following this, the tube assembly automatically adjusts itself to the height of the wall stand Bucky and the Autotracking is activated.

3) Autotracking X-ray system table button: 

If the angle of the X-ray tube assembly is not 0°, rotate the unit to this position. The system now recognizes that it is the under table position and the Autotracking table symbol is activatable.

Click this icon  and following actions will be performed:

1. The X-ray system table will move to the height of 650 mm (standard setting) above the floor
2. The X-ray tube assembly moves automatically to the default SID of 1 m (standard setting)
3. The Bucky below the table top automatically moves horizontally to center itself with the X-ray tube assembly. The position is reached and Autotracking is activated. If the tube assembly is not within the movement range of the under table Bucky, the message "Out of the Tracking Range" appears on the touch screen. Please move the X-ray tube unit into this range.

4) Deactivating Autotracking: 

When the system in the Autotracking mode, click  to exit the Autotracking. The movement of the X-ray tube assembly or wall stand Bucky can now be determined individually.

5) Pause Autotracking: 

Pause and resume Autotracking function for individual movement of wall stand Bucky, X-ray tube assembly or X-ray system table.

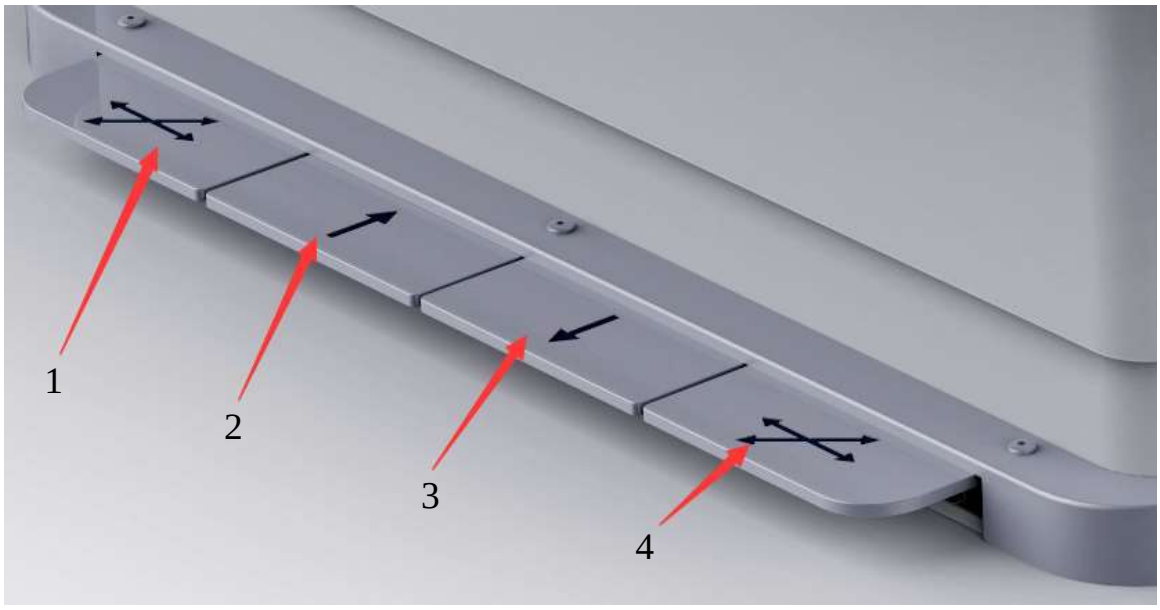
6) Configuration menu: 

Click this button  to enter the configuration interface. For detail instructions see "Technical Description PRS 500 B".

WARNING!

The configuration menu many only be operated by PROTEC trained or authorized personnel.
Improper changing of settings can lead to malfunctions or endanger patients, operators and third parties.

3.4 Footswitch



Pos. 1 Release for table top brakes. The (floating) table top can be moved in all directions
Pos. 2 Height adjustment. The table (table top) moves upwards.
Pos. 3 Height adjustment. The table (table top) moves downwards.
Pos. 4 Release for table top brakes. The floating table top can be moved in all directions

NOTE

All functions operated through activation of the foot switches can only be activated using the proper "stepping and holding" activation. The corresponding pedal must be stepped twice and held to activate the function. As soon as the pedal is released the function/movement will immediately stop.

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 B

4.2.1 Exposures on the X-ray system table

4.2.1.1 Positioning/descending of the patient on/from the table top

- Adjust the height of the tabletop so the patient can climb on it easily
- Positioning/descending of the patient:
    - Center the table top as much as possible to the back/front.
    - The patient should take place in the middle of the table top and stand at this position.

4.2.1.2 Setting the X-ray unit to the centre of Bucky or Grid Entity

- Move the tube column to a position in between the limits of the traveling range of the table Bucky. Press the button for Autotracking on the Touch display (see chapter 3.3.2 Touchscreen)
- The X-ray tube moves to the defined height, the table moves to the defined height and the Bucky travels to the position where centre beam is aligned to table Bucky centre. The SID is also set to the standard height and will not be changed.
- Now if you move the tube column the Bucky follows the tube position, as long both are in the limits of the Bucky travel. Otherwise, an error message appears on the Touch display: "Out of tracking range". If you move the tube back into the travel range the message disappears and the Bucky follows again.

4.2.1.3 Inserting a detector into the cassette tray

- A detector is inserted into the cassette tray of the Bucky, 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.
- Turn the latch for opening/closing the clamping device, for lateral fixation of the detector, counter clockwise.
- Open the clamps far enough to insert a detector of the desired size.
- Insert the detector, with its centreline aligned with the notch in the clamps or by engaging the cassette positioner in the size of the detector corresponding detent (13 cm, 18 cm, 24 cm, 30 cm, 35 cm, 40 cm or 43 cm), push the detector to the cassette positioner.
- Push the cassette clamps against the detector and rotate the latch into the locked position.
- Push the cassette tray fully into the Bucky, Grid Entity.

4.2.1.4 Adjusting the source to image-detector distance (SID)

- Set the X-ray unit with a tape measure at the collimator or the display on the Touch head to the desired source to image-detector distance (SID).
- *Manual mode:* You can adjust the SID by moving the tube column up or down by pressing the corresponding button on the tube head (see chapter 3.3.1 Control Unit).
- *Autotracking mode:* The SID is fixed in the system. You can only move the table height. The tube height will follow and the movement stops at the pre-defined SID.

4.2.1.5 Adjusting the light/X-ray field

- Press the collimator light switch to turn on the collimator light and view the opening of the collimator shutter in both axes relative to the detector size.
- Use the adjusters to set the collimator shutters to the size of the detector being used. The setting is made using the scale on the collimator for the corresponding focus-to-film distance (SID). This limits the light/beam field to the detector size used.

4.2.1.6 Exposure preparation / exposure release

- Set the desired organ program or exposure data either in the interface of the software (digital direct radiography) or on the control panel of the generator (analogue radiography). Check the exposure site (under table, on table) and X-ray parameters, set them if necessary and initiate the exposure by pressing operating elements for exposure preparation/exposure triggering.

4.2.1.7 On table exposure

- Place a detector to the desired position on the table top.
- Move the X-ray tube to the desired position and adjust the SID.
- Press the collimator light switch to turn on the collimator light and view the opening of the collimator shutter in both axes relative to the detector size.
- Place the object on the detector.
- Use the adjusters to set the collimator shutters to the size of the detector being used. The setting is made using the scale on the collimator for the corresponding focus-to-film distance (SID). This limits the light/beam field to the detector size used.
- At the X-ray generator operator console control panel, select the desired X-ray equipment (X-ray system table for on table exposure).
- Press the desired organ program or manually select the desired exposure factors. Start the exposure by pressing the switches for exposure preparation and exposure release.

4.2.1.8 Exposures with the lateral detector holder (optional)

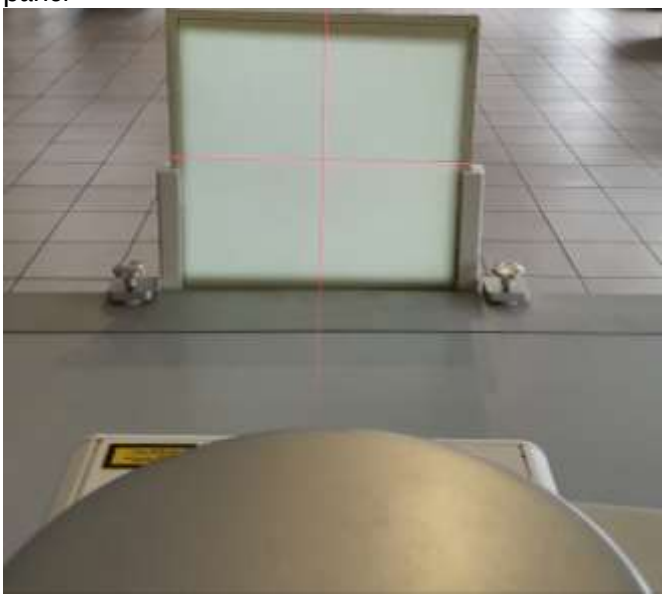
- 1. Step: Move the tube down beside the table

- 2. Step: Press the foot pedal on the tube column wagon to rotate the whole tube column to the left or right side

- 3. Step: Turn the tube head in direction of the lateral detector holder

- 4. Step: Push the tube column to the lateral detector holder

- 5. Step: Adjust the height of the tube arm or of the table that the light field is aligned to the panel



NOTE

Because of the protection functions of the PRS 500 B it is only possible to move the tube down beside the table to reach the panel height in the lateral detector holder. If the tube moves too high within the alignment it is not possible to move the tube back down.
In this case the whole tube column must be pushed beside the table and the tube must be moved down again.

4.2.2 Operation at vertical wall stand

4.2.2.1 Anti-collision sensor

The anti-collision sensor is an infrared sensor. It isn't sensitive to dark subjects, but very sensitive to bright surfaces. It is only suitable for detecting and anti-colliding with the table top. The distance between the sensor and the table top is measured internally by this sensor and a signal is released when the distance is shorter than the previous detecting distance adjustment.

4.2.2.2 Adjusting the X-ray unit to the centre of the Bucky/Grid Entity on the wall stand (horizontal central beam)

- By pressing the button for rotation on the tube head, the brake for the rotation will be released.
- Turn the X-ray unit to the wall stand.
- Set the Bucky/Grid Entity on the wall stand to the height for the patient.

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

NOTE

The display shows the correct SID only when making orthogonal exposures on table or on wall stand. If you make exposures beside the table top or oblique exposures the displayed value is not correct. A tape measure or similar is required to measure the SID for these exposures.

- Release the brake for the longitudinal movement of the column by pressing the button for horizontal brake. Set the required film focus distance (SID) which will be used for the exposure. The display shows the current SID distance.

4.2.2.4 Adjusting the light/X-ray field

- Press the button on the control unit to release the brake for adjusting the height of the X-ray tube unit (see chapter 3.3.1 Control Unit).
- Set the X-ray unit to the desired height and align the X-ray tube unit with the Bucky using the centering light of the light sensing device.

- Release the corresponding button to reactivate the brake for height adjustment of the X-ray tube unit.
- Press the collimator light switch to turn on the collimator light and view the opening of the collimator shutter in both axes relative to the detector size.
- Use the adjusters to set the collimator shutters to the size of the detector being used. The setting is made using the scale on the collimator for the corresponding focus-to-film distance (SID). This limits the light/beam field to the detector size used.

4.2.2.5 Exposure preparation/ exposure release

- Select the application device (wall stand) on the console of the generator.
- Set the desired organ program or the exposure data and initiate the exposure by pressing the operating elements for exposure preparation/exposure triggering.

4.3 Operation of the PROGNOST B

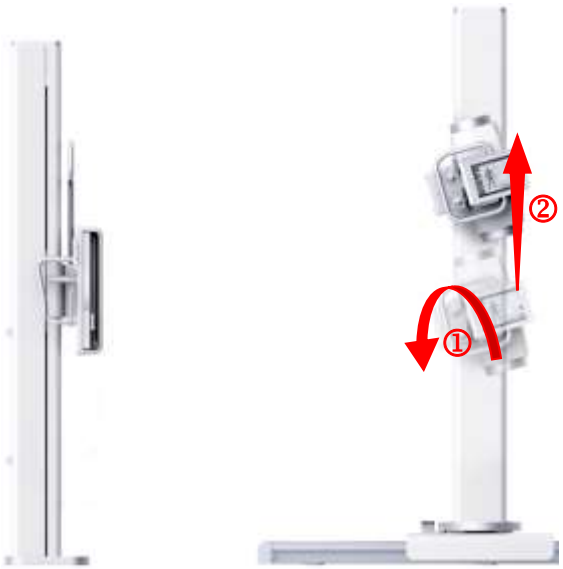
4.3.1 Autotracking

4.3.1.1 Autotracking Wall Stand

First, make sure the X-ray tube unit is turned to the Bucky wall stand.
If the Bucky wall stand Autotracking function is activated, the Bucky moves vertically up or down at first, and the tube assembly will follow automatically, to center itself to the wall stand Bucky.

4.3.1.2 Autotracking Wall Stand, oblique

1. Rotate the tube assembly to the desired angle. Autotracking of wall stand must be activated before changing the angle.
2. The X-ray tube assembly will move up or down automatically, to align tube focus with the wall stand Bucky.
   If the X-ray tube unit cannot follow the wall stand Bucky because of the angle or the tracking range, a message appears on the Touch Screen: "Out of tracking range".



4.3.1.3 X-ray System Table Autotracking

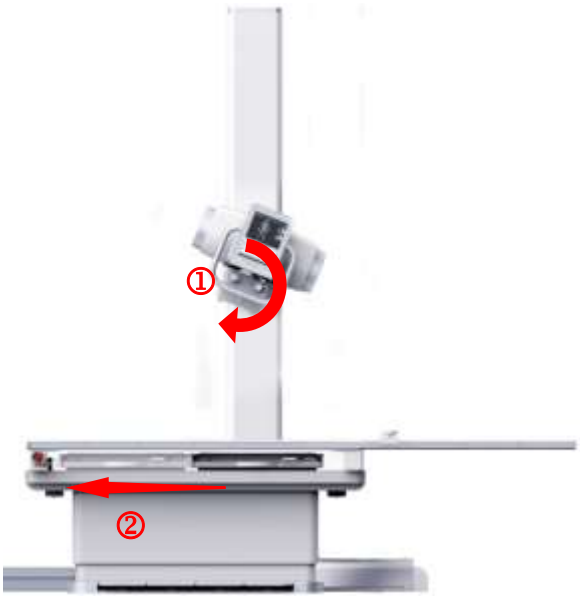
First, make sure the X-ray tube unit is turned to the table Bucky.

If the table Autotracking is activated, the SID between tube and receptor (detector or cassette) will always be automatically adjusted to the defined distance (default setting is 100 cm).

Move the tube column stand horizontally along the ground rail to the desired position at first. Subsequently, the under-table Bucky moves automatically in the horizontal direction according to the focus of the X-ray tube unit.
If the table Bucky cannot follow the X-ray tube unit because of the tracking range, a message appears on the Touch Screen: "Out of tracking range".

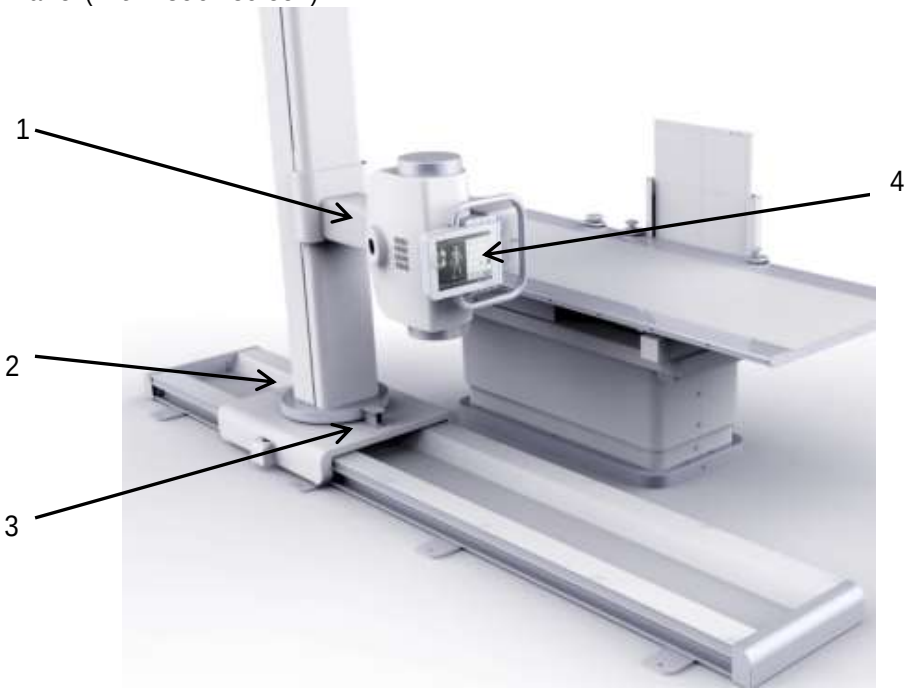
4.3.1.4 X-ray System Table Autotracking, oblique:

1. Rotate the tube assembly to the desired angle. Autotracking of table must be activated before changing the angle.
2. The table Bucky moves automatically in horizontal direction to center with the X-ray tube unit. If the X-ray tube unit cannot follow the table Bucky because of the angle or the tracking range, a message appears on the Touch Screen: "Out of tracking range".



4.3.2 Tube column stand

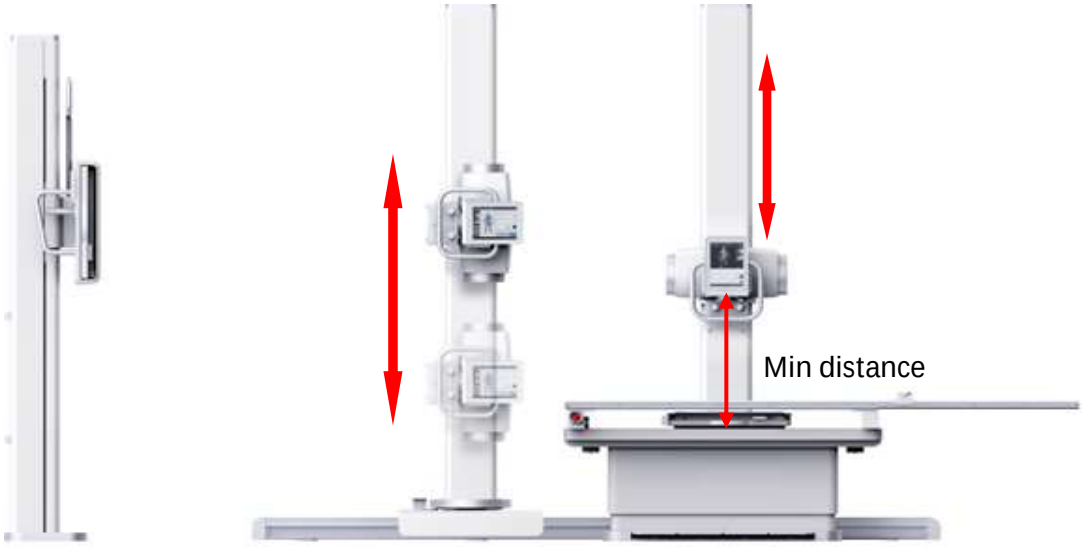
1. Rotation device Tube Column +/-180°
2. Rotation device Tube Column Stand
3. Pedal for the rotation of the Tube Column Stand
4. Control Panel (with Touch Screen)



Press and hold the tube upward movement button [ ] or tube downward movement button [ ]. The tube assembly will move up or down along the tube column automatically. Release the button to stop the movement. The X-ray tube assembly can be moved up or down at any angle.
If the system is in table Autotracking mode, the height of the tube assembly adjusts to the height of the table.

In Autotracking table mode, the X-ray tube assembly will stop automatically when it reaches the default position (e.g., SID=1.15m). If you want to continue the movement of the X-ray tube assembly, the button [ ] or [ ] must be pressed again.

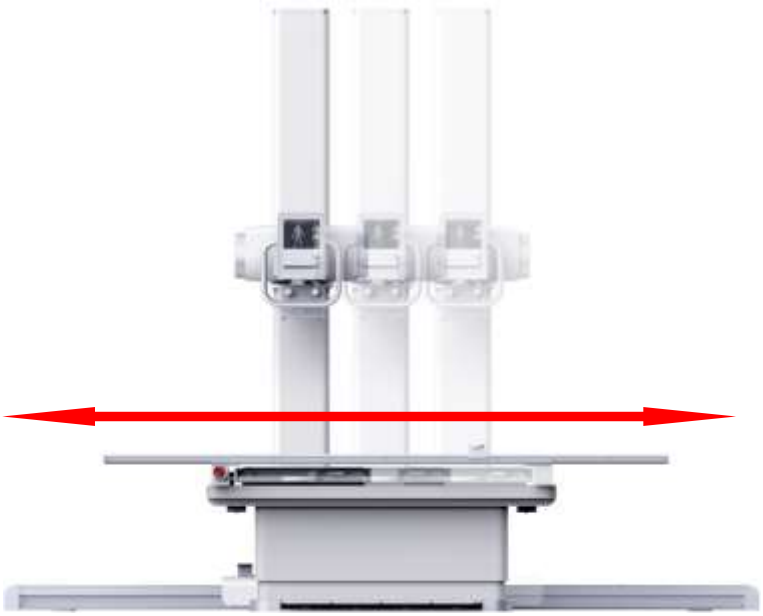
If the X-ray tube assembly is rotated to 0°, the minimum safety distance between the X-ray tube and the table top is 60 cm. The X-ray tube assembly will stop automatically when it reaches this limit distance and the message "reach minimum safety distance" will appear at the touch screen.
If the X-ray tube assembly is rotated to ±90° towards wall stand or moved beside the table, the safety distance is not valid anymore. The safety protection distance can be set in the calibration menu.



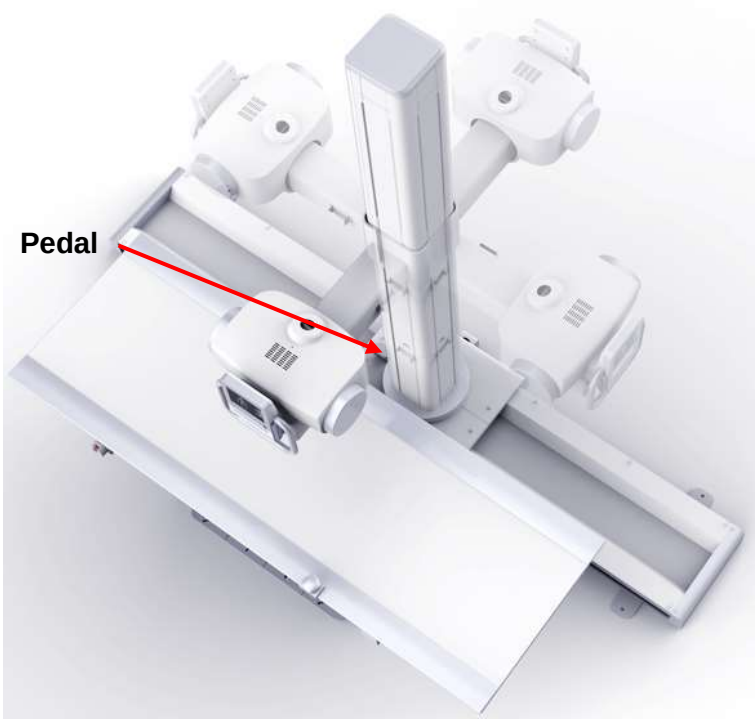
The rotation of the tube assembly at the vertical plane (along the horizontal axis) is operated manually.

Press and hold the rotation button [ ] or [ ] and pull the handle to rotate the tube assembly along the horizontal axis by hand.
The tube rotates within the range of -180°~0°~+180°. The angle of rotation is displayed on the touch screen. The rotation detent is located at 0°, ±90° and 180°. Release the button to lock the rotation.

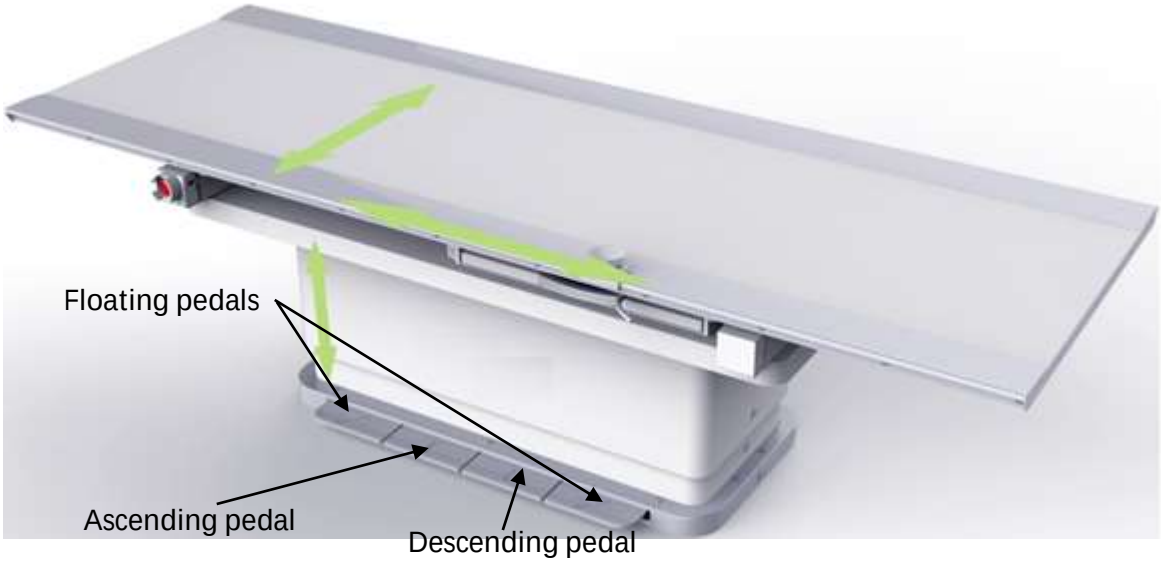
The longitudinal movement of the tube column stand is manually operated. Press and hold the longitudinal movement button [ ] to release the brakes and pull/push the handle to move the tube column stand leftward or rightward along the ground rail. Release the button to lock the movement.
For exposures on the wall stand Bucky, two stop position can be set in the calibration menu (default values are set to 1.15m and 1.5m).



Step the pedal on the base of the tube column stand to release the locking device. Pull the handle of the control panel to rotate the tube column along the vertical axis by hand. When the tube column stand reaches 0°, ±90° or 180°, the locking device engages itself.



4.3.3 X-ray System Table



Step and hold the ascending pedal [ ] or descending pedal [ ] two times (double click), the table top will move upward or downward automatically (driven by motor). Release the pedal to stop the movement. The height of the table top will be displayed on the touch screen. Once the table has reached the end position (upper or lower limit), the movement will automatically stop.

CAUTION!

The operator must face the table from the front during operation. Operating the table while sitting should be avoided, as it would be possible to trap the **user's** leg between the foot pedal and the table top. If the table must be operated from a sitting position, the table top should be in the rearmost position.

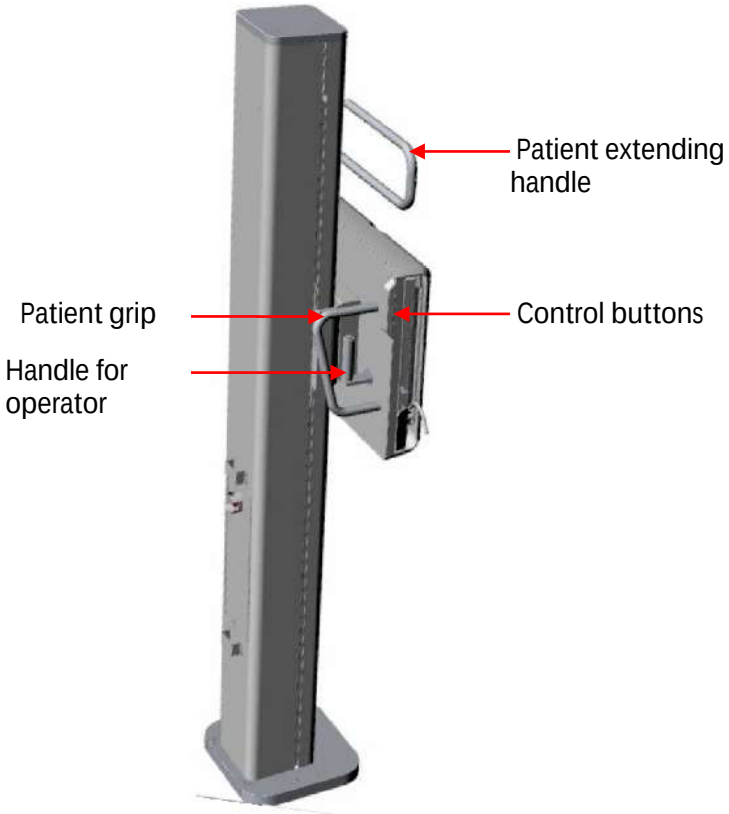
Step and hold one floating pedal [ ] two times (double click) to release all table top brakes. Move the floating table top horizontally or vertically by hand. Release the pedal to lock the table top.

CAUTION!

Crushing danger around the edges of the table top and pinching hazard below the table top!
While horizontal movement of the table top, it is possible for extremities to become trapped between the table top and a fixed object (wall, column, X-Ray tube assembly). It must therefore be checked that neither the patient nor the operator are in the area where the table top is moved. It is important to ensure that no extremities (arms, hands, fingers, feet) extend beyond the edges of the table top. Each patient should be appropriately informed to remain still on the table top unless asked to change position.

- Release the table top brakes and move the table top and patient to the position required for the exposure. Lock the table top by releasing the foot pedal.

4.3.4 Wall Stand



*The collimator is not included in the standard PROGNOST B.

The function of these buttons [ ], [ ], [ ] on the wall stand Bucky is the same as the buttons on the touch screen.

Automatic Mode

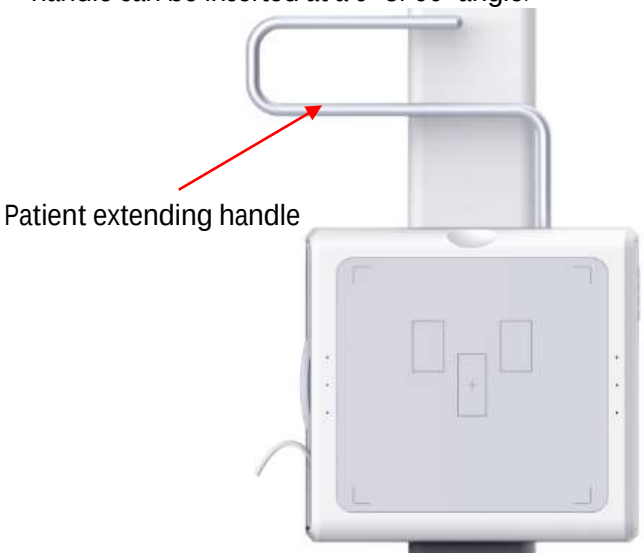
Press and hold the buttons for wall stand Bucky upward movement [ ] or wall stand Bucky downward movement [ ]. The wall stand Bucky will move automatically upward or downward along the wall stand column. Release the button to stop the movement.

Manual Mode

Grab the manual handle at the backside of the wall stand Bucky and press the button on the top, to release the brake. Pull the handle to move the Bucky up and down by hand. Release the button to lock the movement.

4.3.5 Patient extending handle

The patient extending handle helps the patient to remain still during exposures in lateral positions. On one side of the Bucky there is a slot for inserting the patient extending handle, into which the handle can be inserted at a 0° or 90° angle.



NOTE

When positioning the patient in front of the wall stand column, the operator should instruct the patient to use the patient extending handle.

WARNING!

If the Bucky is lowered with an inserted patient extending handle at a 90° angle, it could hit the patient on the head. If the Bucky height is adjusted for large patients, remove the patient extending handle to avoid collision with the ceiling. The patient extending handle is only suitable for weightless patient positioning and not as a handle for load support.

Move the X-ray unit to the required position before positioning the patient.

4.4 Function of the PROGNOST B

4.4.1 Switching the PROGNOST B on

The PROGNOST B is switched on via control panel of the EC-Box. All components are supplied with power via the EC-Box.

(1) Switch on the main switch of the X-ray room
(2) Switch on the operation PC if applicable.
(3) Switch on the EC-Box. The green light on top of the EC-Box lights up and shows the on-state.
(4) Press the "ON"-button (appr. 2 seconds) on the control console. The LED ring around the button lights up and shows the on-state of the system. The Touch-PC on the tube head starts up and the software will also start automatically.
(5) After the interface of the corresponding software is started, the PROGNOST B is ready for operation.

4.4.2 Switching the PROGNOST B off

CAUTION!

Before switching off the PROGNOST B, ensure that the tube head is turned to 0° to avoid accidently turning movements.

(1) Press the "OFF"-button (appr. 2 seconds) on the control console.
The LED ring around the button lights up and shows the turning off state of the system. After a few seconds the power of the electronic is turned off.

NOTE

To perform a regular shutdown of the Touch PC, it requires an operator PC with the appropriate CONAXX software as well as the compatible software on the Touch PC. If a component is not in operation or not available, no communication between both components can take place and the mechanics cannot be switched off regularly.

(2) Switch off the EC-Box.
(3) Exit the software of the operation PC if applicable.
(4) Switch off the main switch of the X-ray room.

NOTE

If the software on the Touch PC or operator PC is not compatible and/or one of the two has been terminated without switching off the mechanics in a regulated way beforehand, it is possible to perform a "hard shutdown".
The "OFF" button on the control console of the EC-Box must be pressed 5 seconds at least to cut the power supply to the system.

5 Safety and Maintenance

WARNING!

Caution, risk of electric shock!
Switch off the PROGNOST B before cleaning or disinfecting. This disconnects the PROGNOST B 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 B 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 B 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 cleaning of the PROGNOST B 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 B, 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.

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 B 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

- Check the ease of movement for the table top (horizontal) when the table top brakes are released.
- Check the table top brakes when they are fixed (table top should not be able to be moved)

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.

- Check the surface of the table top for damage (dents, scratches, cracks etc.)
- Check that the collimator and the radiation field is correctly centered

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 B, 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 B 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 B.

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)
Table top	Applied part
Cover / Wall stand	Applied part
Patient extended handle (Optional, mounted at the wall stand)	Part, considered as an applied part
Mattress (optional)	Part, considered as an applied part

5.4.8 Disposal Notes

The PROGNOST B 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 B requires the following power supply:

Voltage:	110-240 VAC, 0.6 KVA
Frequency:	50/60 Hz
Line resistance:	0.12 Ω

WARNING!

To avoid the risk of an electric shock, this device may only be connected to a supply network with a protective earth conductor.

6.1 Electromagnetic Compatibility (EMC) according to EN 60601-1-2

CAUTION!

As a medical electrical device, the PROGNOST B 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 in) to the marked parts and cables of the PROGNOST B. Failure to observe can lead to a reduction in the performance characteristics of the device.

6.1.1 **Guidelines and Manufacturer's Declaration** – Electromagnetic interference

The PROGNOST B 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.

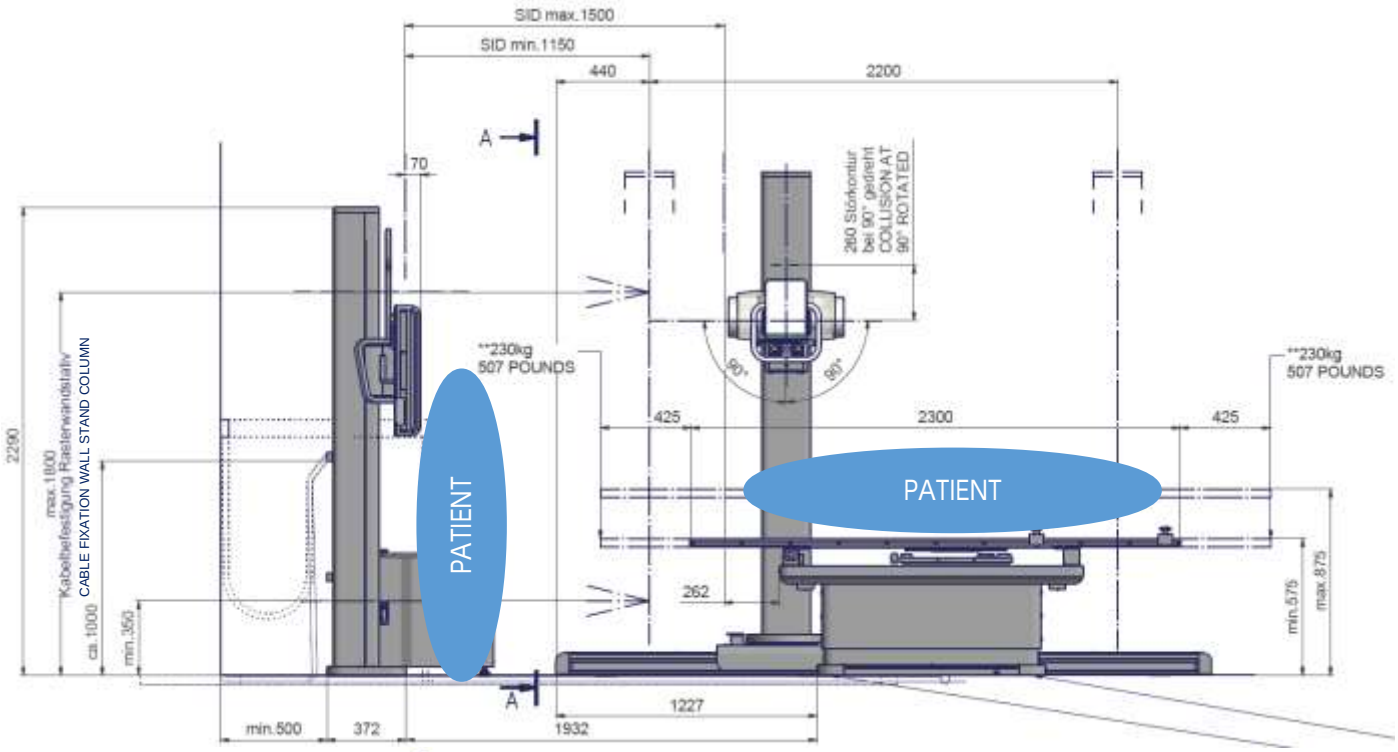
Measurement interference	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The X-ray component uses RF energy exclusively for its internal function. As a result, its RF emissions are very low and it is unlikely that nearby electronic devices will be influenced.
RF emissions CISPR 11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

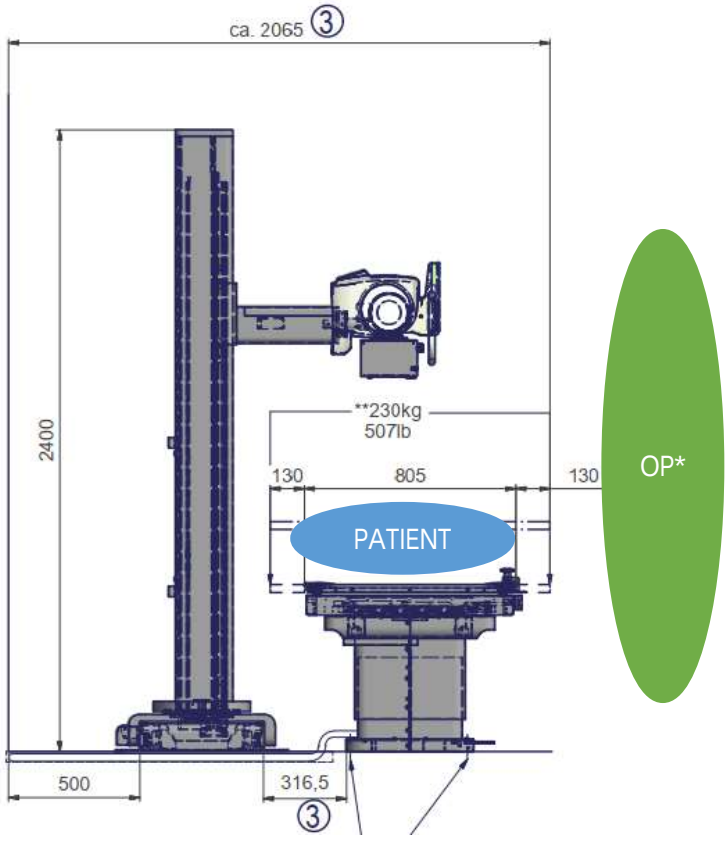
Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	Floors should be made 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

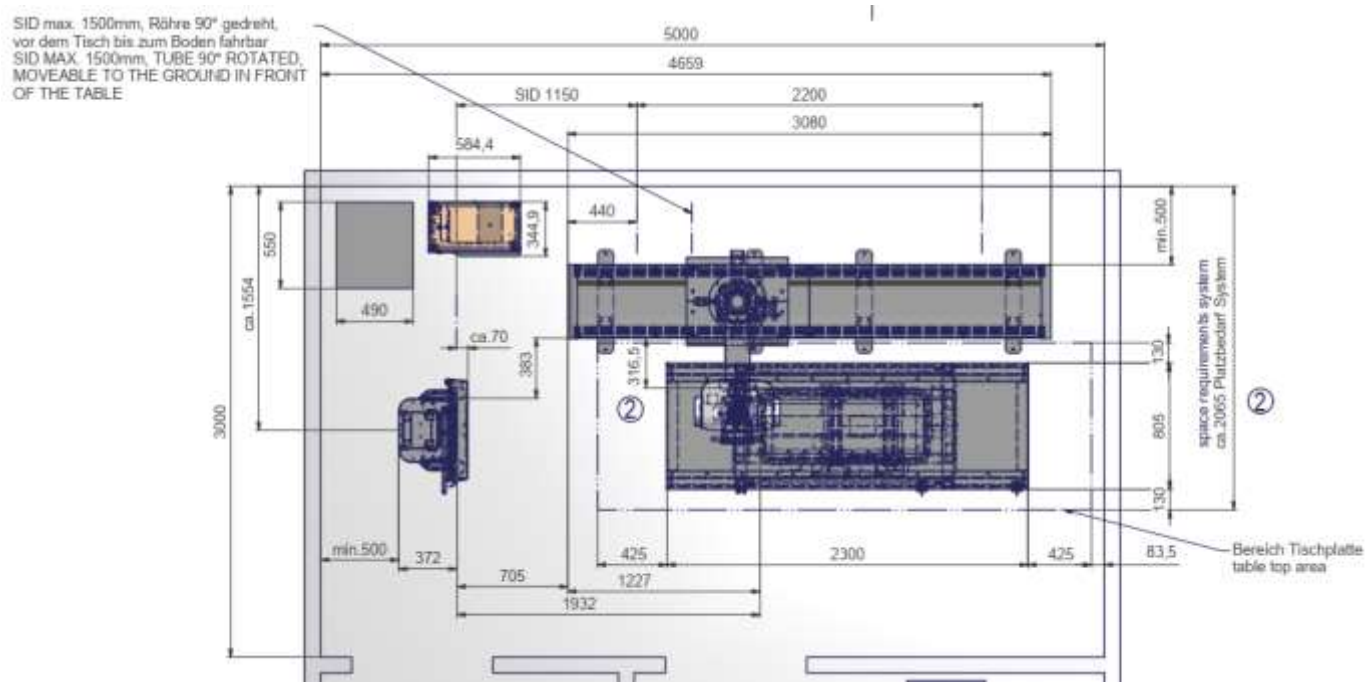
7 Technical Data

7.1 Dimensions





*OP - Operator



7.1.1 X-ray System Table

Table top dimensions (L x W):	230 cm x 80, 5 cm
Max. Patient weight (uniform load)	320 kg
Table height	575mm - 875 mm
Transverse movement of the table top (from the mid-position):	± 130 mm
Longitudinal movement of the table top (from the mid-position):	± 425 mm
Table Bucky Longitudinal movement:	500 mm

The table top brakes are electromechanically released.

7.1.2 Tube Column Stand

Vertical focus – range of travel (horizontal beam projection):	350 – 1800 mm
Vertical focus – Table distance (Standard):	max. 1225 mm
Rotation of the X-Ray tube assembly (around carrying arm axis):	± 180°
Detents at:	- 90°, 0°, + 90°, 180°
Vertical travel carrying arm:	1450 mm
Longitudinal range of travel column stand:	2200 mm

7.1.3 Wall Stand Column

Wall stand Bucky vertical travel range:	350 – 1800 mm

7.1.4 Weight

Without patient:	ca. 780 kg

7.2 Attenuation Equivalent

CAUTION!

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

The table top is defined as application part.
The aluminum attenuation equivalent of the table top is typically 1.25 < 1.3 Al mm for composite fibre, according to EN 60601-1-3. Tested at 100 kV with a first half-value layer thickness of 3,6 mm Al and typically 0,6 mm Al and < 0,8mm Al according 21CFR § 1020-30 (n) with 100 kV and a first half-value layer thickness of 3,6 mm Al.

The Bucky cover of the image receptor stand is defined as application part.
The aluminum attenuation equivalent of the wall stand Bucky cover is typically 0.95 and < 1 Al mm according to EN 60601-1-3. Tested at 100 kV with a first half-value layer thickness of 3.6 mm Al.

7.2.1 Protection Type and Protection Class

The PROGNOST B 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

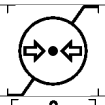
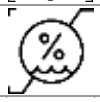
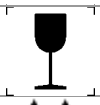
Ambient Temperature	+ 10°C to + 30°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

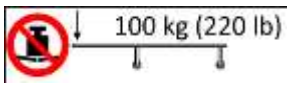
7.3.2 Environmental Conditions for Shipping and Storage

Ambient Temperature	- 10°C to + 40°C
Relative humidity	0% to 80% (non-condensing)
Atmospheric pressure	500 hPa to 1060hPa

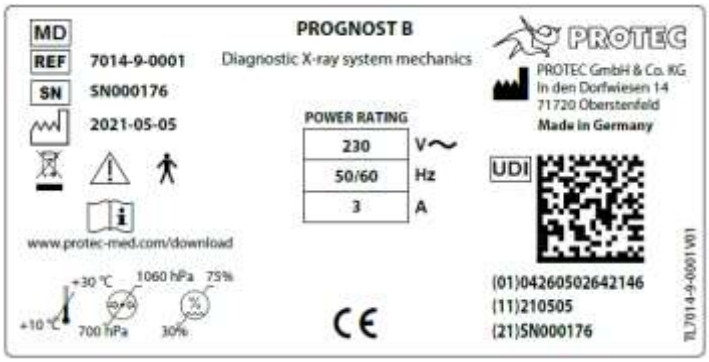
8 Description of Symbols, Labels and Abbreviations

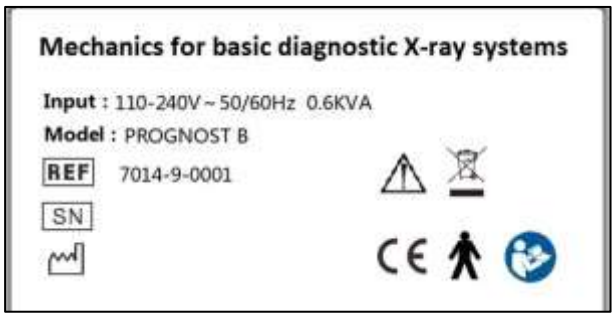
8.1 Symbols

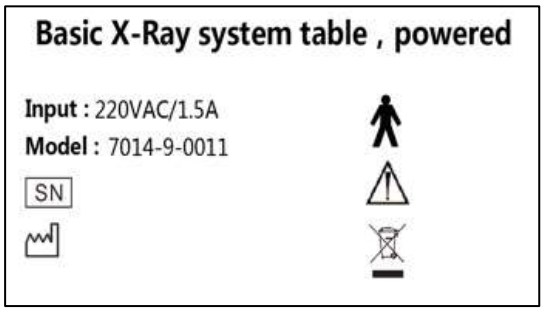
	Atmospheric pressure limit
	Temperature limit
	Humidity limit
	Keep dry
	Fragile, handle with care
	This way up
	Attention, observe accompanying documents
	Refer to Instructions for use
	CE marking
	Manufacturer
	Medical Device
	Order reference
	Serial number
	Unique Device Identification
	Production date
	Classification according to EN 60601-1 (type B applied part)
	Caution: pinch-/crushing hazard for hands and fingers
	Warning high voltage
 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.

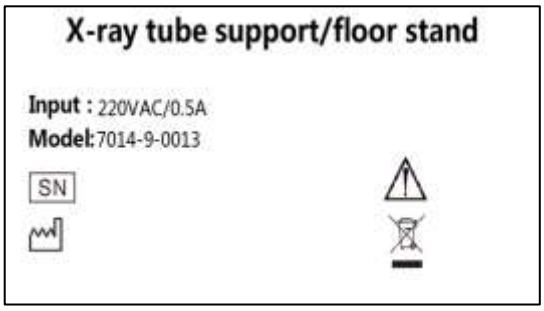
	Disposal instructions; WEEE (Waste of Electrical and Electronic Equipment) the decommissioning of your equipment.
	Protective earthing
	Climbing forbidden
	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight
	Do not walk
	Emergency stop switch label
	Table height adjustment – table up
	Table height adjustment – table down
	Release table top brakes

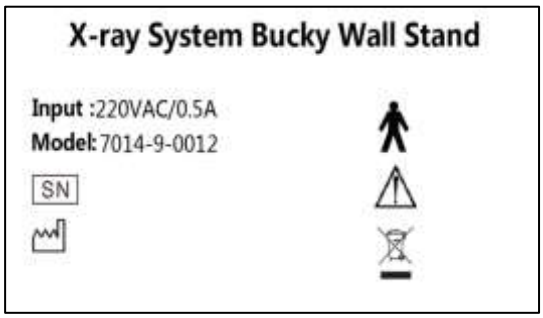
8.2 Type Label

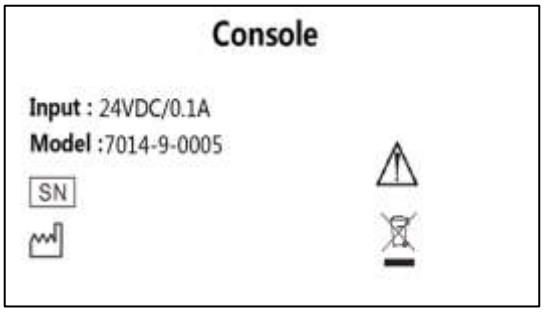


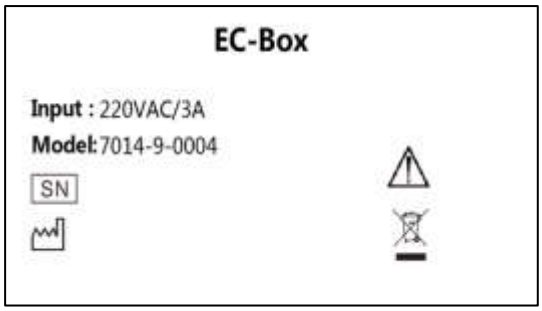






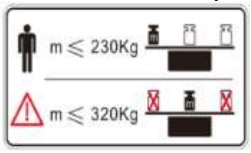






8.3 Labels

Label on the table top



Maximum allowed patient weight on the table top
Maximum permitted patient weight, tipping load

Labels on the side of the tabletop, tube column stand and wall column stand

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

Label on the X-ray tube cover, left and right side

Caution: Possible collision hazard for head and other body part while moving the Tube assembly or tube column stand.

Label on the front of Thorax Bucky housing

Maximum allowable weight

Label on the floor rails

Don´t step over the floor rails

Label on the floor rails

Don´t climb on the floor rails

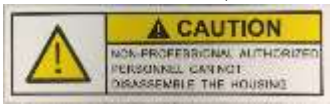
Label on the tabletop

No putting your hand or fingers under the tabletop as the tabletop is moving

Label on the EC-Box

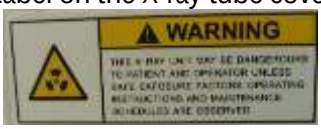
High voltage to be opened by authorized personnel only.

Label on the EC-Box, tube column and wall stand



Non-professional authorized personnel cannot disassemble the housing

Label on the X-ray tube cover



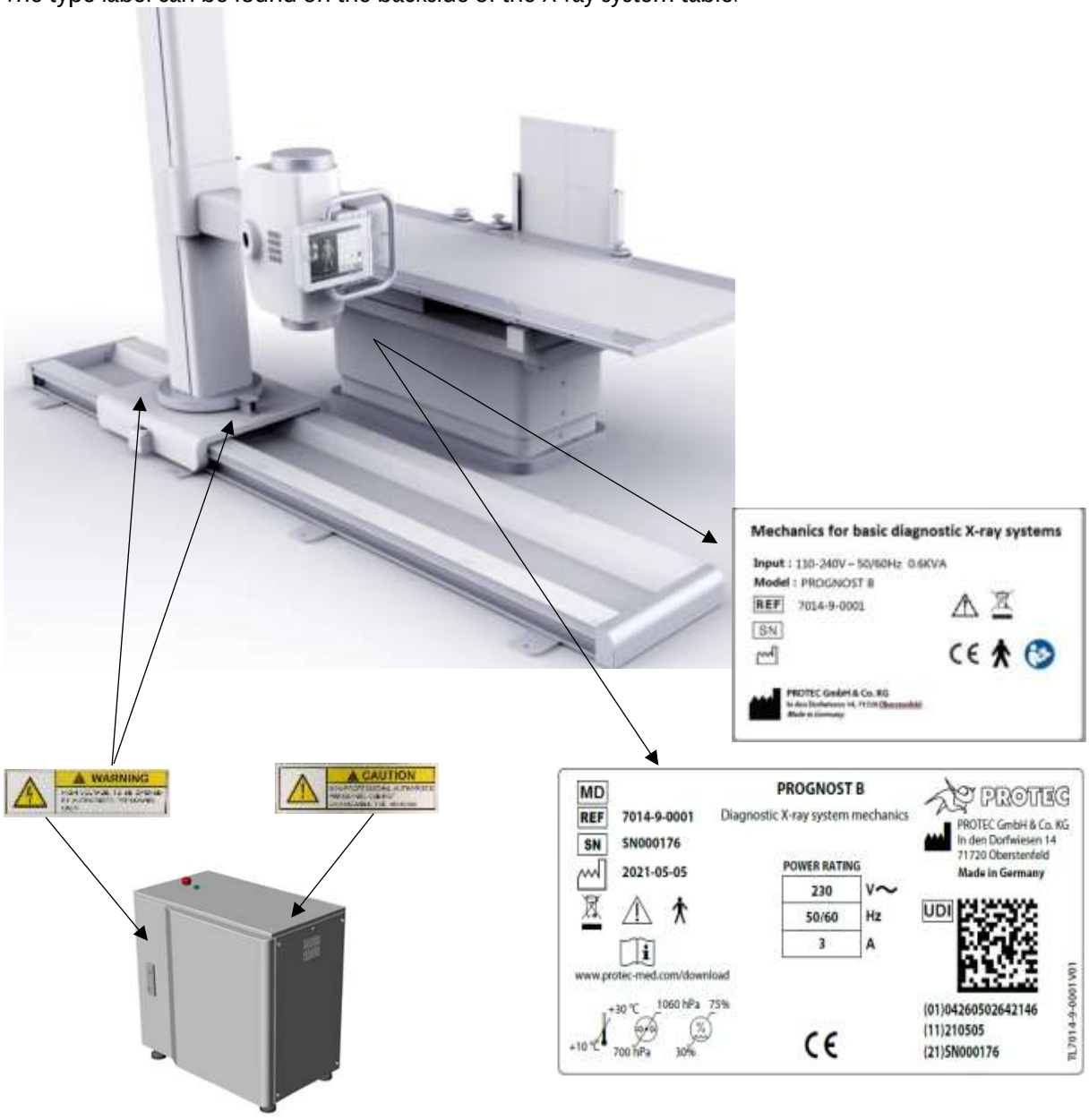
Warning X-ray radiation

Label on the front plate of the X-ray system table

Manufacturer Label

8.4 Positions of the Signs and Labels

The type label can be found on the backside of the X-ray system table.



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