PROGNOST B

Mechanics for basic diagnostic X-ray systems

Model/ID: 7014-9-0001

User Manual

Ident. Nr. 5014-0-1002

Figure with X-ray components

CE

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NOTE

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NOTE

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

Document Effectivity

Revision No.	Date	List of effective pages	Comments
1.0	14/02/2018	n/a	First edition
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3.0	2020-11-25	Front page, Chap.1.2.1, Chap. 1.3.3, Chap.1.4	Product description revised

General Notes

WARNING!

No changes of the ME device!

Mechanical – Electric Warning

WARNING!

All of the movable assemblies and parts of this equipment should be operated with care and routinely inspected in accordance with the manufacturer's recommendations contained in the equipment Accompanying Documents.
Maintenance and service is only to be performed by Customers authorized by PROTEC GmbH & Co. KG.
Live electrical terminals are deadly.
Do not remove flexible high-tension cables from X-ray tube housing 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 this Document is directed to read and carefully review the instructions, warnings and cautions contained herein prior to beginning operation, installation or service activities.
While you may have previously operated equipment similar to that described in this Document, changes in design, manufacture or procedure may have occurred which significantly affect the present operation.
Although the product was subject to a risk analysis and the design corresponds to the current state of the art, residual risk will remain in clinical use. These are

displayed in the following user manual by application limitations, contraindications, warnings and precautions.
The installation and service of equipment described herein is to be performed by authorized, qualified **PROTEC GmbH & Co. KG** Customers.
Assemblers and other Customers not employed by nor directly affiliated with **PROTEC GmbH & Co. KG** technical services are directed to contact the local **PROTEC GmbH & Co. KG** office before attempting installation or service procedures.
For Installations and service procedures it is necessary to read the „technical description" of the product and to observe any containing point in it.

1 Product description

1.1 Introduction

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

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

1.2 Description

The stationary basic mechanism for X-ray system PROGNOST B is constituted of a fixed elevating patient positioning table with floating table top, a completely integrated tube column stand , a fixed double operating mode wall stand and an electronic cabinet (without X-Ray components).

The floating table op is fixed in height by a motor activated braking system in the vertical directions. Both the table top brakes and height adjustment of the table is controlled using an integrated foot switching unit.

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 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).

The wall column stand is designed as two layouts, which can be fixed in the each side of the table. It is prepared for the installation of a vertical sliding (manually and automatically movable) Bucky or Grid entity. The vertical movement of the Bucky or Grid entity is fixed by using an electromagnetic braking system.

The following axes are motorised to support the user in a good manner. 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. And also the source image distance (SID) between table and X-ray tube unit 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.
The system is also ideal for oblique examinations thanks to the automatic drive of the Bucky to the central ray position, both for X-ray table and for wall stand.

360° rotation of the entire X-ray tube stand for a maximum of application flexibility. Ideal for immobile patients who should be X-ray examined directly in sickbed without relocating the person.

1.2.1 Models

7014-9-0001 PROGNOST B Mechanics for basic diagnostic X-ray systems

1.2.2 Installation

See separate “Installation manual” PROGNOST B
Contact information’s of persons which are qualified to make installations are available on request at:

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1.2.2.1 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 PROGNOST B has a weight of 780kg (without Generator and X-ray components).

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 Variable height radiographic table

- Suit for different room, the chest column stand can be layout at each side of patient table.
- Automatic locking function for some specific desired SID.
- Remote operation for vertical movement of the chest column stand Bucky
- Variable table height (57,5 cm- 87,5 cm)
- Floating table top
- Table top colour – white
- Magnetic activated table top brake for effortless patient positioning
- A low (optimized) distance between the table top surface and the film (detector) surface
- Large adjustment range of the table top for position of the patient
- Reliable construction
- Lateral rails of the table top prepared to accept a number of table accessories
- Prepared for the installation of a Bucky with anti-scatter grid and 3-field measuring chamber intended for the use with automatic exposure control
- Extensive cassette and detector program including formats from 13 cm x 18 cm up to 43 cm x 43 cm
- Column stand intended for use within rooms with a ceiling height of at least 2.5 meters
- Maximum of application flexibility due to 360° rotatability of the entire X-ray tube stand
- Control elements within the control panel 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 35 cm up to 180 cm during horizontal beam projection
- Electromagnetic brakes for the longitudinal movement of the tube 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 with integrated latching every 90°as well as the vertical movements of the thorax Bucky

1.3.2 Vertical Bucky Wall Stand

- Space saving with minimal footprint
- Floor mounted wall stand
- cassette loading from the right or left side (specified at installation)
- Cassette/detector sizes from 13 cm x 18 cm (5 x 7) to 43 cm x 43 cm (17 x 17)

- Suitable for analogue and digital application

1.3.3 Product components

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

- A stationary, height-adjustable X-ray table with auxiliary drive,
- a rotatable X-ray tube column with floor fixation including control arm,
- a wall stand column,
- an EC box and
- a console

Table top version

Model ID	Material	L	W	Table top colour
	Composite	230 cm	80.5 cm	white

1.3.4 Compatible components (stand-alone products) and combination possibilities

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

- A Bucky or Grid entity
- A ionisation or solid-state measuring chamber
- An anti-scatter grid
- A collimator
- An X-Ray tube assembly (tube and housing)
- An X-Ray generator

1.4 Intended use

The Mechanics for basic diagnostic X-ray systems 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 Intended user group

PROGNOST B, as a part of a basic diagnostic X-ray system, is exclusively designated for use by professionals who are trained, in accordance with the corresponding national regulations, in the use of diagnostic X-Ray equipment and its proper (certified) use in connection with other medical products, objects and accessories.

Suitable users could include the following: Radiologist, radiology assistants, radiology technicians, surgeons, emergency surgeons, orthopedists and other medically trained personnel.

1.6 Conformity

CE

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

The declaration of conformity is available directly from PROTEC:

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

NOTE

Every operating elements are descript in the corresponding manual.

2.1 General safety notice

2.1.1 Requirements for operation

WARNING!

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 stationary basic mechanism for X-ray system PROGNOST B is designated to be exclusively supplied through a direct connection to the EC-box. The PROGNOST B stationary basic mechanism is a ME Class I product. The device contains no on/off switch. The PROGNOST B is directly connected to the EC-box and is switched on/off through the switching on and off of console. In order to disconnected the PROGNOST B from power the connected EC-box must be shut off.

2.1.2 Operating of the radiographic system

It is essential to make sure that, while the table top is being positioned, no person or object (chairs, tables, pushcarts, etc.) is in an obvious area that could be dangerous (table adjustment area)
Failure to pay attention can lead to bodily harm (crushing, pinching, bruising, etc.) and damage to the table and/ or external objects.

In the case of disrupted functionality, use of the product should be discontinued and the customer service department from **PROTEC** or a service technician authorized by **PROTEC** should be informed.

2.1.2.1 Operating type

The PROGNOST B is not designated for continuous operation.

2.1.3 Operating personnel

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

NOTE

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

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 Emergency stop switch

The PROGNOST B contain of five emergency stop switches, they are assembled on the front of table, upper of control panel, back of the wall column stand, front of EC-box and control panel, thus the following must be considered:

- Actuate the emergency stop switch immediately if the patient, operator and or device is in danger. The electrically driven actuators for the table top brake and the elevating columns for height adjustment well be disconnected from power resulting in immediate interruption of all table movements.
- Only when the hazard has been clearly identified and removed can the emergency stop switch be switched off and normal system function be resumed. In all other cases (e.g. error of the table control) the PROTEC customer service department or a PROTEC authorized service technician should be notified.

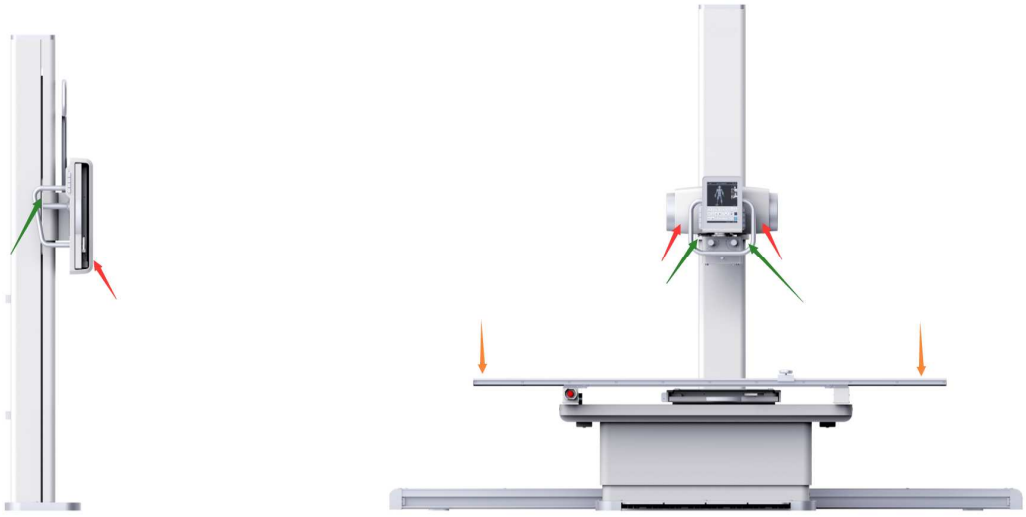
NOTE

The PROGNSOT B has a console with on and off switch. The radiographic table with stand and the wall columns stand will be switch on (off) directly through the switching on and off of the connected EC-box. In order to completely disconnect the PROGNOST B from power the connected EC-box must be switched off or disconnected from power.

2.1.5 Pinching and Collision Hazards

CAUTION!

Pinching of the fingers, hands and/or feet is possible within marked areas, in the following picture shown as green arrow.
Collision hazard for head within the marked areas, in the following picture shown as red arrow.
Please pay close attention and ensure that neither the patient nor the operating personnel find themselves in known areas of movement during movement of the PROGNOST B.



CAUTION!

Ensure that while using any product that can be lowered, raised or moved in different directions, neither yourself (operator), the patient nor 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.

2.1.6 Explosion protection

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

2.1.7 Radiation protection

X-Ray radiation can pose a hazard to patients and other people when the regulations regarding the operation of X-Ray systems are not followed.

For this reason, the basic principles of radiation protection are of the highest priority and must be followed without exception:

- **Distance from the radiation source**
  The dosage is reduced as a factor of the square of the distance from a (dot shaped) radiation source. Double the distance ¼ dose, triple the distance 1/9 dose
- **Keep the exposure time as short as possible**
  The dosage is directly correlated with the exposure time. A half exposure time results in a radiation dose half that of a full exposure. (This is especially pertinent with fluoroscopy, as X-Ray images have predetermined mAs)
- **Utilize shielding and protective clothing**
  The protective value grows exponentially with the thickness of the shielding. Two half-value layer thickness (HVL) weaken (homogeneous) radiation to ¼, 3 HVL to 1/8, und 10 HVL to less than 1/1000 of the original value.
- **Do not reach into the direct X-Ray beam**
  The dosage in a un-weakened-Ray beam is around 100 times larger than that in the scattered radiation.
- **Use personal dosage meters**
  In working with radiation (X-Rays), the use of personal dosage monitors is suggested.

The X-Ray images are principally triggered from behind a protective wall. For the creation of images near the reproductive organs use the maximum available protection (e.g. testicular shielding or lead covers)
People that must remain close to the patient are required to wear protective clothing (e.g. lead apron). This counts for maintenance and installation work as well.

2.1.8 Ventilation

It is important to ensure that the air exchange of the X-Ray generator within the PROGNOST B is not hindered. The ambient air temperature is not allowed to exceed 40°C.

2.1.9 Interaction with external devices

Unwanted interaction with external devices is not known.

2.1.10 Electromagnetic Environment and the influence of devices

CAUTION!

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

NOTE

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

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

3 Control elements and device displays

3.1 Footswitch

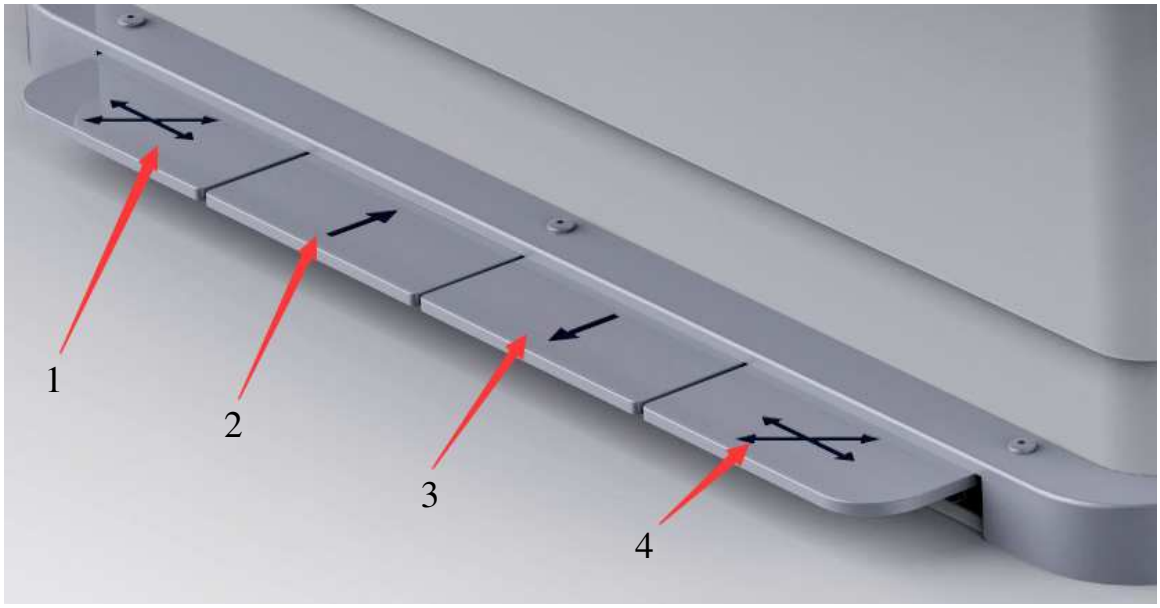


Figure 3- 1 (Footswitch-PROGNOST B)

Pos. 1 Release for table top brakes. The (floating) table top can move freely in all (horizontal) 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 horizontal directions

CAUTION!

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 in order to activate the function. As soon as the pedal is released the function/movement will immediately stop.

3.2 Components

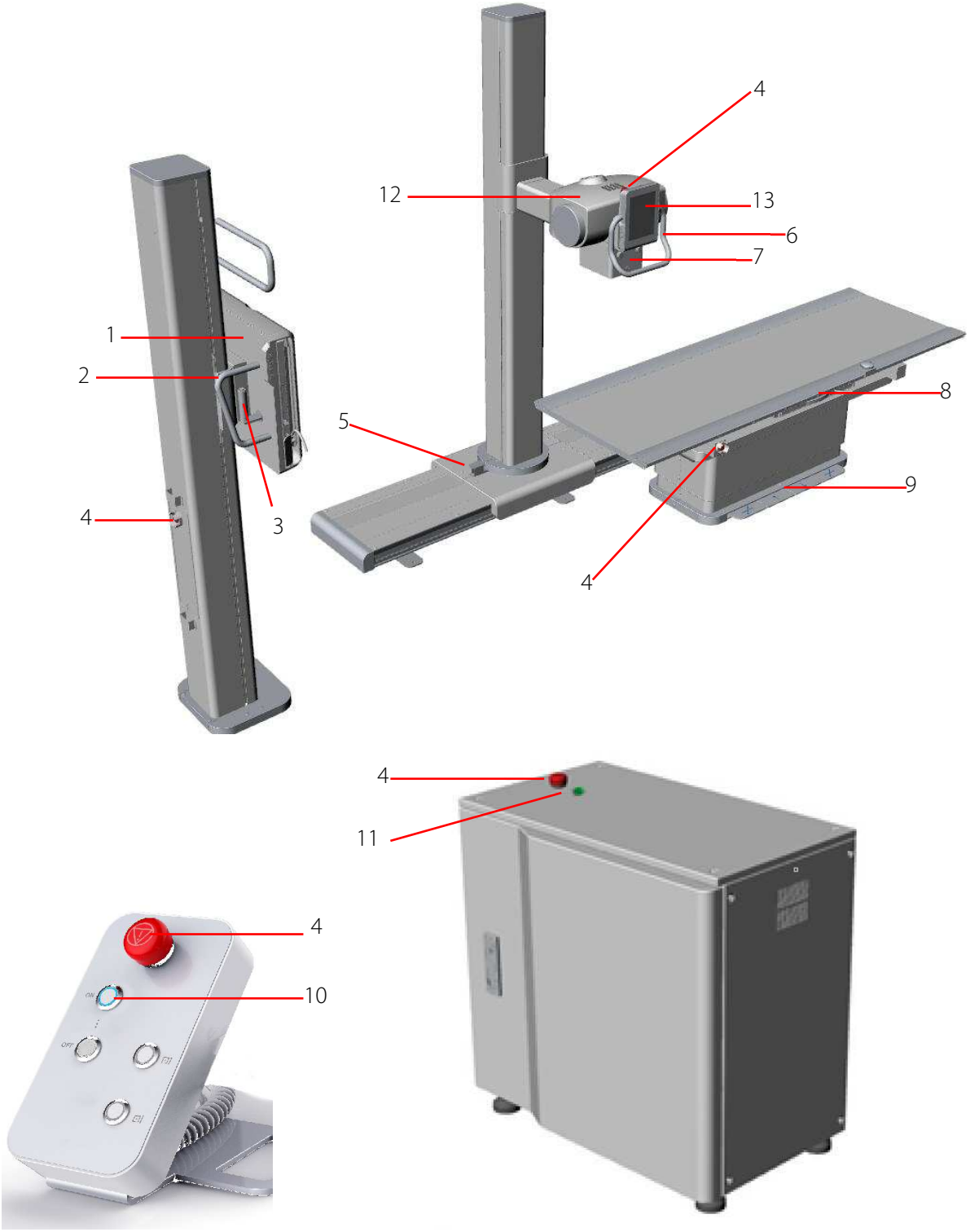


Figure 3-2

Pos.	Component
1	Cover of Bucky wall stand
2	Patient grips
3	Manual handle
4	Emergency stop switch
5	Pedal for column rotation
6	Control handle for operator

7	Collimator *
8	Under-table Bucky Wagon *
9	Footswitch
10	ON indicator
11	Signal-LED
12	Tube cover
13	Control panel

*Not included with delivery of the Standard PROGNOST B

3.3 Emergency stop switch and signal-LED

Actuation of the emergency stop switch (Figure 3-2; 4) results in the disconnection of the following components from the power supply

- Brakes within table top, tube column stand, wall column stand
- Elevating columns (table top height adjustment)
- Elevating motor wall stand Bucky
- Central control unit (PCB)

The emergency stop switch is unlatched from the actuated position through clockwise rotation of the switch.

The Signal – LED (Figure 3-2; 10) located inside of button on the console indicate whether the PROGNOST B is started up (blue).
The Signal – LED (Figure 3-2; 11) located on the top of EC-box indicate whether the EC-box is powered on (green) as the air switch on the side of EC-box is turned on.

CAUTION!

Even when the emergency stop switch has been activated, parts of the PROGNOST B can still be connected to power.

Only by switching off (or disconnection from) the EC-box is the PROGNOST B 100% disconnected from power.

3.4 Column stand

1. Turn Tube Column +/-180°
2. Tube Column Stand Rotation Base
3. Release pedal for Rotation of tube column stand
4. Control Panel (With Touch Screen)

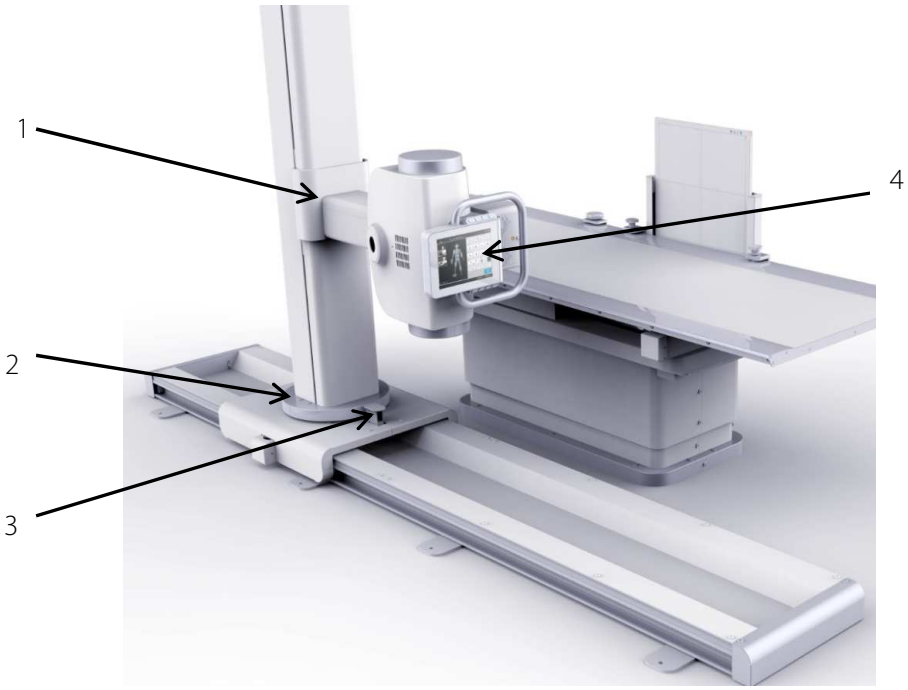


Figure 3- 3

3.5 Control panel (with touch screen)

Figure 3- 4

1. Brake release, motor activated for vertical upward movement of the Wall column stand Bucky
2. Brake release, motor activated for vertical downward movement of the Wall column stand Bucky
3. Brake release for longitudinal adjustment of the tube column stand
4. Brake release for rotation of the X-Ray tube assembly
5. Brake release, Motor activated for vertical upward movement of the X-Ray tube assembly
6. Brake release, Motor activated for vertical downward movement of the X-Ray tube assembly
7. Touch Screen for indicating SID, height of patient table, angle of tube, etc.
8. Control handle for operator

The unit is operated from the frontside (operators side) of the the tube column stand.
When gripped on the either side of handle (around the control panel) the electromagnetic brake or motor can be released or activated by actuating the corresponding button on the commandoarm with the thumb. Once released, the X-Ray tube assembly can be brought into the desired position.

4 Handling / Operation

4.1 Operation Tube assembly

The functions activated by pressing buttons around the touch screen.

Press the tube upward movement button [ ] or tube downward movement button [ ] and hold. The tube assembly will move up or down along the tube column automatically. Release the button to stop the movement. The tube assembly can be moved up or down at any angle. But when the system is in under-table autotracking mode, the two buttons are functionless and the height of the tube assembly adjusts to the height of the table.
In under-table positioning, the X-ray tube assembly will stop automatically when it reaches the default position like SID=1.0 m. And if you want to continue the movement of the X-ray tube assembly, you have to press again the button [ ] or [ ].
As the X-ray tube assembly is at 0°, the minimum safety distance between the X-ray tube and table top is 50 cm. The X-ray tube assembly will stop automatically when it reaches this limit distance and the message “reach min safety distance” will appear at the bottom of the touch screen. But when the tube assembly is rotated to ±90° or the tube column is moved beside the table, the safety distance is not valid anymore.

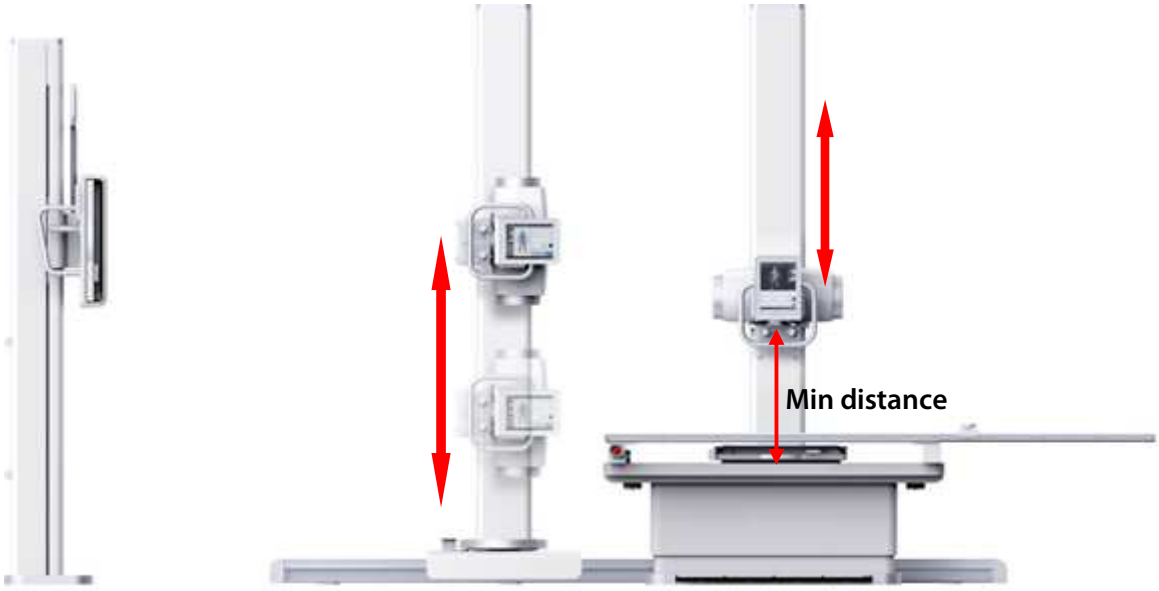


Figure 4-1-1

4.1.1 Rotation

The rotation of the tube assembly at the vertical plane (along the horizontal axis) is manual mode. Press the vertical rotation button [ ] or [ ] and hold, pull the handle to rotate the tube assembly along the horizontal axis by hand.
The tube may rotate at the vertical plane within the range of -180°~0°~+180°. The degree of rotation will display on the touch screen. The rotation detent is located at 0°, ±90° and 180°. Release the button to lock the rotation.

Figure 4-1-2

4.1 Radiography table

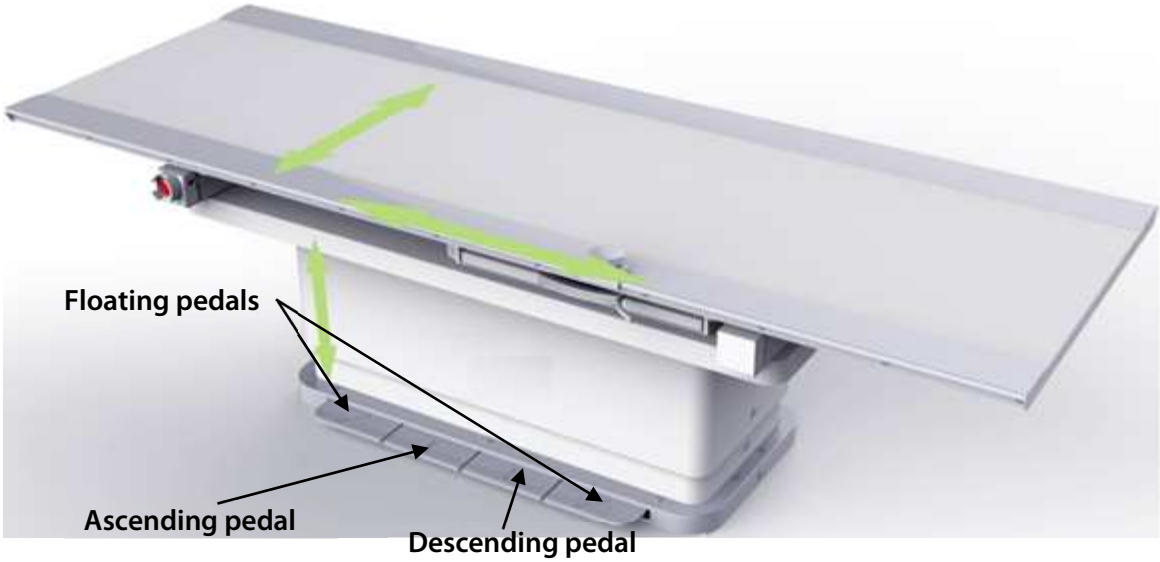


Figure 4-2

4.1.1 Adjustment

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

CAUTION!

The table is to be operated with the operator in a standing position, facing the front of the table. Operating the table while seated should be avoided, as it is possible for the operator's leg to become trapped between the table top and the foot pedal if the table top is in the foremost position. If the table must be operated from a sitting position, the table top must be pushed completely towards the back of the table.

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

4.1.2 Under-table exposures

- To ease the process of getting onto the table (for the patient), adjust the table height to an appropriate height as instruction in chapter 4.2.1.

CAUTION!

The PROGNOST B serves only as a support for the patient during the examination.

Patients are only allowed to get onto and off of the table under the supervision or with the help of those completing the examination. Failure to comply increasing the risk of injury. Offer help to the patient when getting onto and off of the table.

- Getting onto and off of the table (*see figure 4-1-2*)
  - Move the table top completely to one side (left or right)
  - Centre the table top as much as possible (front to back)
  - The patient should get onto the table in the middle of the table top.

Figure 4 - 1-2

- Allow the patient to lay down on the table top. When required (e.g. patient has open wounds)) cover the surface of the table top using appropriate towels or one time use health care towels.

CAUTION!

Crushing danger around the edges of the table top and pinching hazard above and below the table top!
When positioning the table top, horizontally, it is possible for extremities to become trapped between the table top and a fixed object (wall, column, X-Ray tube assembly). It is therefore necessary to check that neither the patient nor the operator find themselves within the area which the table top is being positioned. It is particularly important to ensure, for each patient that no extremity (arms, hands, fingers, feet) extend beyond the edges of the table top. Each patient should be correspondingly informed and told that once on the table top they are to remain still unless told to change position.

- Release the table top brakes and move the table top and patient into the exact position needed for the exposure. Fix the table top by releasing the corresponding foot pedal.

4.2 Tube column stand

4.2.1 Longitudinal movement

The longitudinal movement of the tube column stand is manual mode. Press the longitudinal movement button [] and hold to release the brakes, pull the handle to move the tube column stand (x-ray tube assembly) leftward or rightward along the ground rail by hand. Release the button to lock the movement. For the thorax exam, the tube column will halt automatically to indicate the 2 SIDs. Default values are set to 1.15 m and 1.5 m.

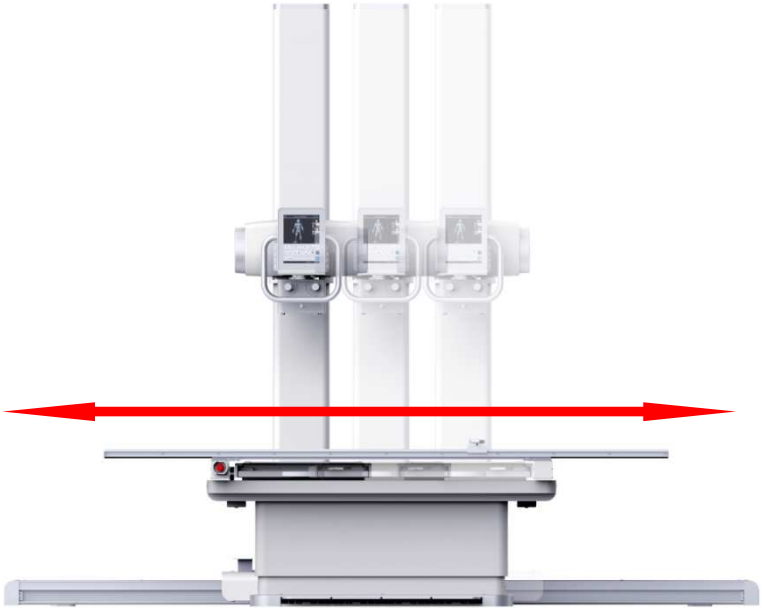


Figure 4-3-1

4.2.2 Rotation of tube column stand

Step the pedal on the base of the tube column stand to release the arrester, drag the handle of the control panel to rotate the tube column along vertical axis by hand. When the tube column reach 0°, ±90°and 180°, the arrester will work. Release the button to lock the arrester.

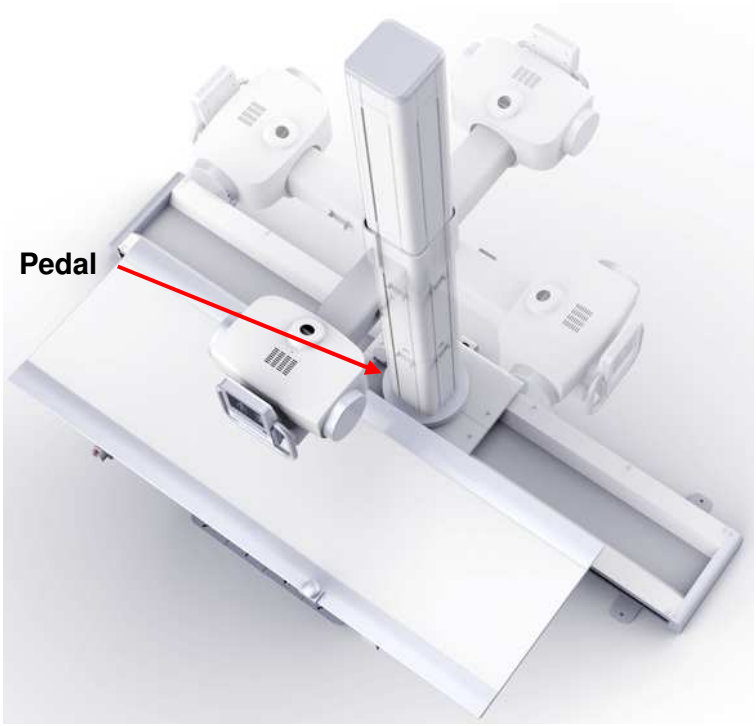
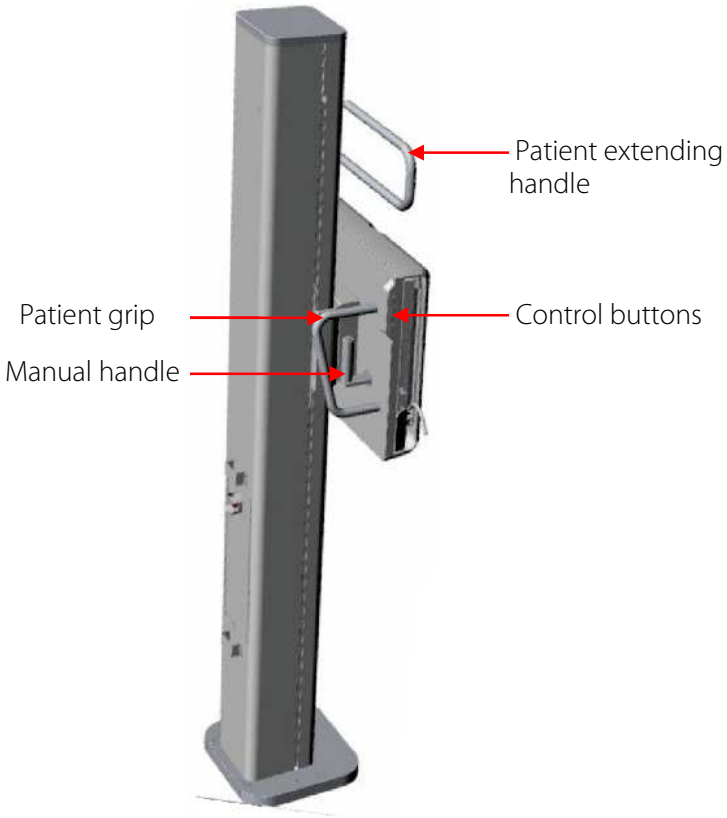


Figure 4-3-2

4.3 Wall column stand



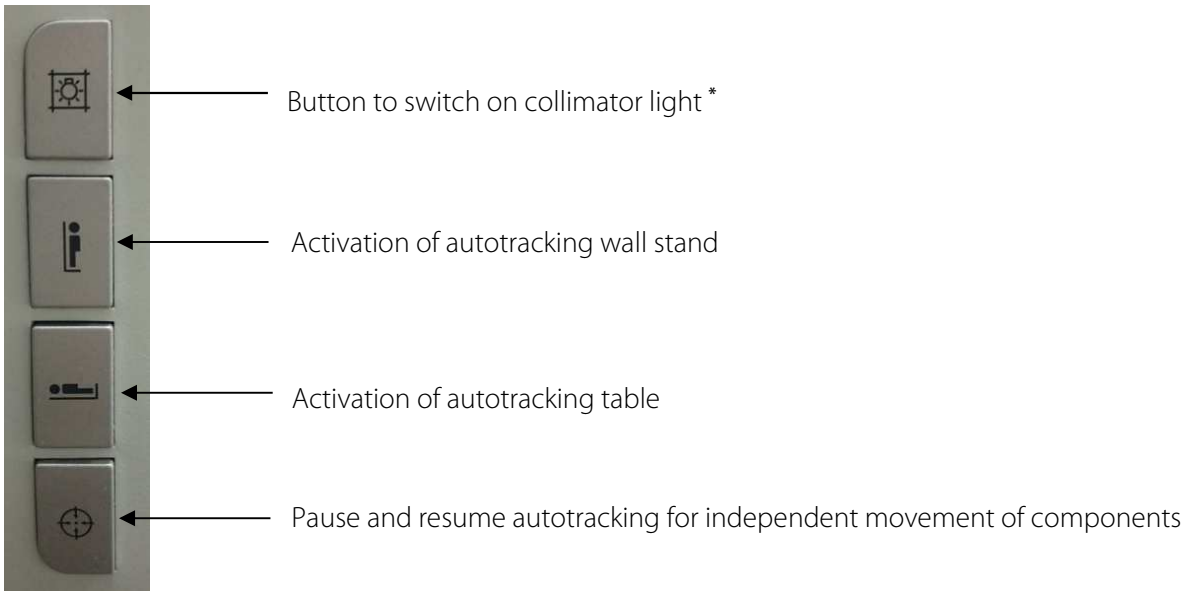


Figure 4-4

Press the collimator light button [], collimator light and laser line localizer turn on. The light turns off automatically after 30s.

[], [], [] The function of these buttons on the Bucky's lateral panel is the same like the buttons on the touch screen.

***the collimator itself is not included in the PROGNOST B and may vary depending on the system

4.3.1 Vertical movement of wall stand Bucky

- Automatic Mode

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

- Manual Mode
  Grab the manual handle and press the button on the top of grip to release the brake. Pull the handle to move the Bucky up and down by hand. Release the button to lock the movement.

Figure 4-4-1

4.3.2 Patient extending handle

The patient extending handle helps patient stability for exam in lateral position.
There is a slot for inserting the handle at one side of the Bucky at least. The handle can be inserted in this slot in 0° and 90° angle.

Figure 4-4-2

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 the patient extending handle, the bar may hit the head of the patient. To raise the Bucky for high patients, remove the patient extending handle to avoid collision into the ceiling. The patient extending handle is a non weight-bearing positioning aid only, and not a patient support bar.

4.4 Touch screen

The orientation of the display will automatically rotate according to the degree of tube assembly:

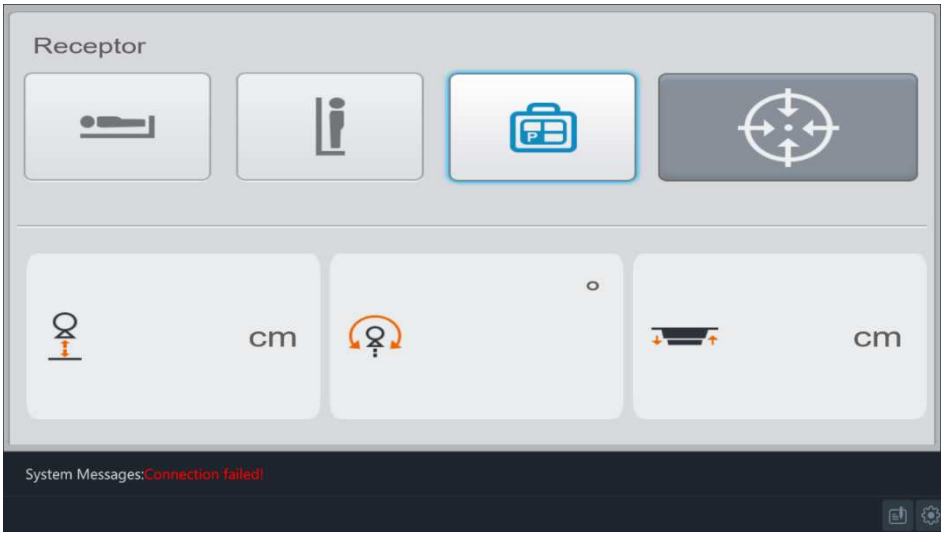


Figure 4-5

1) The colours of the icons on the touch screen are defined as follow:

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 patient table

2) Autotracking wall stand button: 

If the angle of the X-ray tube assembly is not ±90°, rotate it to ±90° position and move, if needed, the tube column in direction wall stand column until the icon  changes to black and can therefore be activated.

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 1.4 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 table button: 

If the angle of the X-ray tube assembly is not 0°, rotate it to 0° position. The system now recognises, that it is undertable position and the symbol is activatable.

Click this icon [] and following actions will be performed:
① The X-ray table will move up or down to the default height 650 mm above the floor
② The X-ray tube assembly moves automatically up or down to the default SID of 1 m (default setting of the source image distance)
③ The Bucky below the table top automatically moves horizontally to centre itself with the X-ray tube assembly. The position is reached and the autotracking is activated. If the tube assembly is not in the movement range of the undertable Bucky, the message “Out of the Tracking Range” appears on the touch screen. Then move the tube column with the tube assembly into this range.

4) Deactivating autotracking: 

Deactivates the autotracking. When the system in the autotracking status, click  to exit the autotracking. Then the movement of tube assembly or wall stand Bucky is relatively independent.

NOTE

With this button  you can immediately stop the autotracking movement

5) Pause autotracking: 

Pause and resume autotracking function for independent movement of wall stand Bucky, tube or table

NOTE

With this button  you can immediately stop the autotracking movement

6) Log file function: 

[]: Click this button to enter the logging interface. Information of mechanical motions can be checked.

NOTE

The log files are intended for technical service personnel

7) Configuration menu: 

[]: Click this button to enter the configuration interface. For detail instructions see service manual.

WARNING!

The configuration menu can only be operated by people who got trained or authorized by PROTEC.
Improper changing of settings can cause malfunctions or endanger patients, operators and third parties.

4.5 Autotracking

4.5.1 Wall stand autotracking

First, make sure the system is set to the position 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 centre itself to the wall stand Bucky.

Figure 4-6-1.a

Wall stand oblique autotracking

① Rotate the tube assembly to the desired angle;
② The tube assembly will move up or down automatically, to align tube focus with the wall stand Bucky.
If the rotation angle of tube assembly exceeds a preset degree, the oblique autotracking function will be null, a message will appear on the touch screen: "out of the tracking range".

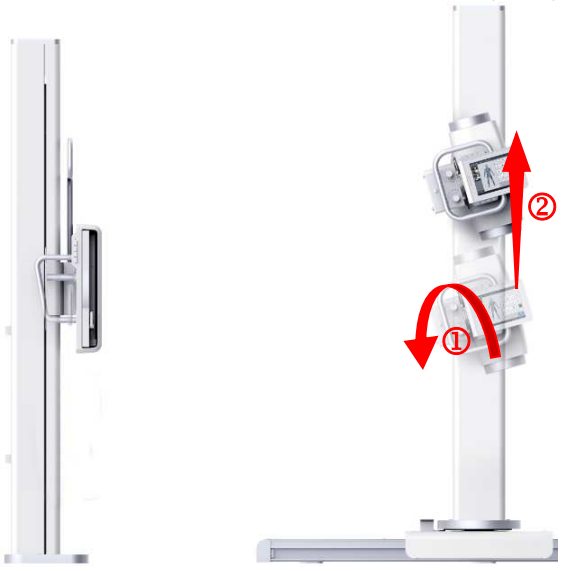


Figure 4-6-1.b

4.5.2 Table autotracking

At first, make sure the equipment reaches the under-table position.

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

If the under-table position autotracking function is activated, move the tube column stand horizontally along the ground rail at first, then the under-table Bucky will make the corresponding horizontal

motion automatically, to align the centre point of under-table Bucky with the X-ray tube focus. When the tube column moves out of the range of under-table Bucky travel, the autotracking function will pause until moving the tube column stand back inside this range, and the message will displayed on the touch screen "out of tracking range" .

Figure 4-6-2.a

Table oblique autotracking:

① Rotate the tube assembly to desired angle;
② The under-table Bucky will make horizontal motion automatically to level its centre at the X-ray centre.
If the rotation angle of tube assembly exceeds a preset degree, the oblique auto-tracking function will be null, a message will appear on the touch screen: "out of tracking range"

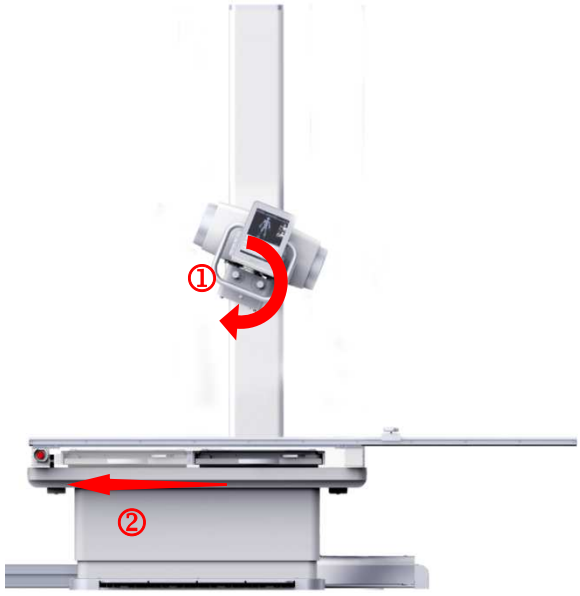


Figure 4-6-2.b

4.6 Remote operation

There are two control buttons on the control console for moving the wall stand Bucky. The user can achieve the upward or downward movement of the wall stand Bucky by pressing one of these two buttons in the operator room.
The function of these two buttons on the control console is the same like the corresponding buttons at the control panel.

Figure 4-7

Prior to positioning the patient, bring the X-ray unit into position for the required exposure.

4.7 Functions of the PROGNOST B

4.7.1 Switching n/off the PROGNOST B

Switching on the PROGNOST B has to be done by the following steps:

1. Switch on the desktop PC.
2. Switch on the EC-Box at the air switch on the side of the EC-Box. The light on the top of the EC-Box turns on.
3. Press the "on" button on the control console. All the brakes and motors will be powered on. The Touch-PC starts up. After a short time the display will show the mail screen to operate the PROGNOST B.

Now the system is ready to start the movements.

4.8 Prompt Messages in Touch Screen

CODE	PROMPT	MEANING	TREATMENT
3001	Out of the Tracking Range	In autotracking mode: X-ray tube assembly does not track wall stand Bucky or table Bucky does not track X-ray tube assembly, because the requested target position is out of the movement range.	1、Move the wall stand Bucky into the defined vertical movement scope or change the angle position of the X-ray tube. 2、Move the tube column into the defined horizontal movement scope or change the angle position of the X-ray tube.
3002	Reach Min Safety Distance	Most minimal SID between the X-ray tube assembly and the image receptor reached. X-ray tube cannot be moved downwards and the table cannot be move upwards anymore.	Move the X-ray tube upwards or move the table downwards.
3003	No Position Calibration for WS Bucky	No position calibration for wall stand Bucky	Chest stand Bucky position calibration is needed
3004	No Height Calibration for Tube	No height calibration for X-ray tube	X-ray height calibration is needed
3005	No position Calibration for Table Bucky	No position calibration for table Bucky	Table Bucky position calibration is needed
3006	No Height Calibration for Table	No height calibration for X-ray table	Lifting Table height calibration is needed
3007	No Angle Calibration for Tube	No angle calibration for X-ray tube	X-ray tube angle calibration is needed

5 Safety and Maintenance

WARNING!

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

5.1 Introduction

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

5.2 Cleaning and disinfection

NOTE

Caution
Changes to material are possible!

Prior to cleaning or disinfection, switch off the EC-box. As a result, the PROGNOST B will be disconnected from power and the danger of electric shock is eliminated.

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

5.2.1 Cleaning

The use of corrosive or abrasive cleaning agents as well as solvents is not allowed. These materials can cause damage to the outer surface of the unit or to the coating of the individual components.

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

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

5.2.2 Disinfection

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

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

All components within the 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 vapours be created through the use of the chosen disinfection agents, the unit can only be switched on when the gas/vapours have 100% disappeared.

5.3 Check-up and maintenance

WARNING!

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

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

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

5.3.2 Regular controls

5.3.2.1 Quality control measures completed by operator

Quality control activities for X-Ray units are to be undertaken in regular intervals according to the corresponding national guidelines.

- Check the surface of the table top for damage (dents, scratches, tears. . .)
- Check that the Collimator (X-Ray beam) is correctly centred.

5.3.2.2 Safety-related controls

In the interest of the safety of the patient, operator and external 3rd parties, the check /control activities related to maintaining the operational safety and /or functionality of the unit are required to be undertaken in regular **12 month** intervals by the **PROTEC** service department or a **PROTEC** authorized service provider.

All components within the PROGNOST B, which, through wear and tear, could present a hazard, are required to be checked, and when needed replaced, every 12 Months by the PROTEC service department or a PROTEC authorized service provider.

In the case that the required safety-related control activities and checks are not completed as intended, **PROTEC** is no longer responsible for damages/injury to the operator and/or third party provided that the damage is the result of improper or missing safety related controls.

5.3.3 Maintenance

NOTE

Only original spare parts are to be used in situations requiring component replacement Maintenance

Required maintenance must be performed at 12-month intervals by PROTEC Service or specific authorized service provider to ensure the reliable operation of the equipment.
In the event that scheduled maintenance is not performed, PROTEC GmbH & Co. KG will not be responsible for damages incurred by the user or third parties if such damages are the result of improper or omitted maintenance.
Prior to operation (creation of X-Ray images), the operator must ensure that all Safety related mechanisms, indicators and/or switches described within the user manual are fully functional and that the unit is overall operationally ready.
See Technical Description off the PROGNOST B.
Only original spare parts are to be used in situations requiring component replacement.

5.3.4 Warranty

NOTE

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

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

Only authorized technicians may do service and maintenance work.

5.3.5 Product life time

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

5.3.6 Further Information

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

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

Part	**Definition** (as applied part or parts which get handled like an applied part but not defined as an applied part)
Table top	Applied part
Cover – vertical wall stand	Applied part
Housing parts PROGNOST B	Part, get handled like an application part

5.3.8 Disposal

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

6 Electrical data

NOTE

The PROGNOST B needs the following power supply.

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

WARNING!

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

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

The PROGNOST B is consistent with the requirements for electromagnetic compatibility according to EN 60601-1-2, Limit class B
The EMC clause within guidline2004/ 108 EWG has been fulfilled by the PROGNOST B.

CAUTION!

The PROGNOST B is, as a medical electrical electric device, subject to particular precautionary measures in regard to EMC and is required to be installed and prepared for initial use as described within the accompanying documents.

CAUTION!

Mobile HF-Communication devices shouldn't be used closer than 30cm (12 Inch) to the marked parts and cables of the PROGNOST B. Disregarding this can cause a decrease in the performance features of the device.

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

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

The PROGNOST B is intended for use in the electromagnetic environment specified below. The customer or the user of the **Equipment** should assure that it is used in such an environment.		
Emissions test	**Compliance level**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for its internal function. Therefore, the RF emission is very low and unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	This **Equipment** is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the **Equipment** or shielding the location.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuation/ flicker emission EN 61000-3-3	Complies	

The **Equipment** is intended for use in the electromagnetic environment specified below. The customer or user of the **Equipment** should assure that it is used in an electromagnetic environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	EN 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output	EN 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	EN 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5 % U_T for 0,5 cycle (>95 % dip in U_T) 40 % U_T for 5 cycles (60 % dip in U_T) 70 % U_T for 25 cycles (30 % dip in U_T) <5 % U_T for 5 s (>95 % dip in U_T)	EN 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Equipment r**equires continued operation during power mains interruptions, it is recommended that the **Equipment** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	EN 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the alternating supply voltage prior to application of the test levels

The **Equipment** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Equipment** should assure that it is used in such an environment

Immunity Test	EN 60601-1-2 Test level	Compliance level	Electromagnetic Environment
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **Equipment,** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance** $d=1.2\times\sqrt{P}$ 80 MHz to 800MHz $d=2.3\times\sqrt{P}$ 800 MHz to 2.5GHz $d=1.2\times\sqrt{P}$ Where *P* is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less then the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF EN 61000-4-6	3 V 150 kHz to 80 MHz	3 V	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.

[a] Fields strengths from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters , an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the **Equipment** is used exceeds **[field strength]** V/m, observe the **Equipment** to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the **Equipment** or using a shielded location with a higher RF shielding effectiveness and filter attenuation

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

The **Equipment** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Equipment** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the **Equipment** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz $d=1.2\times\sqrt{P}$	**80MHz to 800MHz** $d=1.2\times\sqrt{P}$	**800MHz to 2.5GHz** $d=2.3\times\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

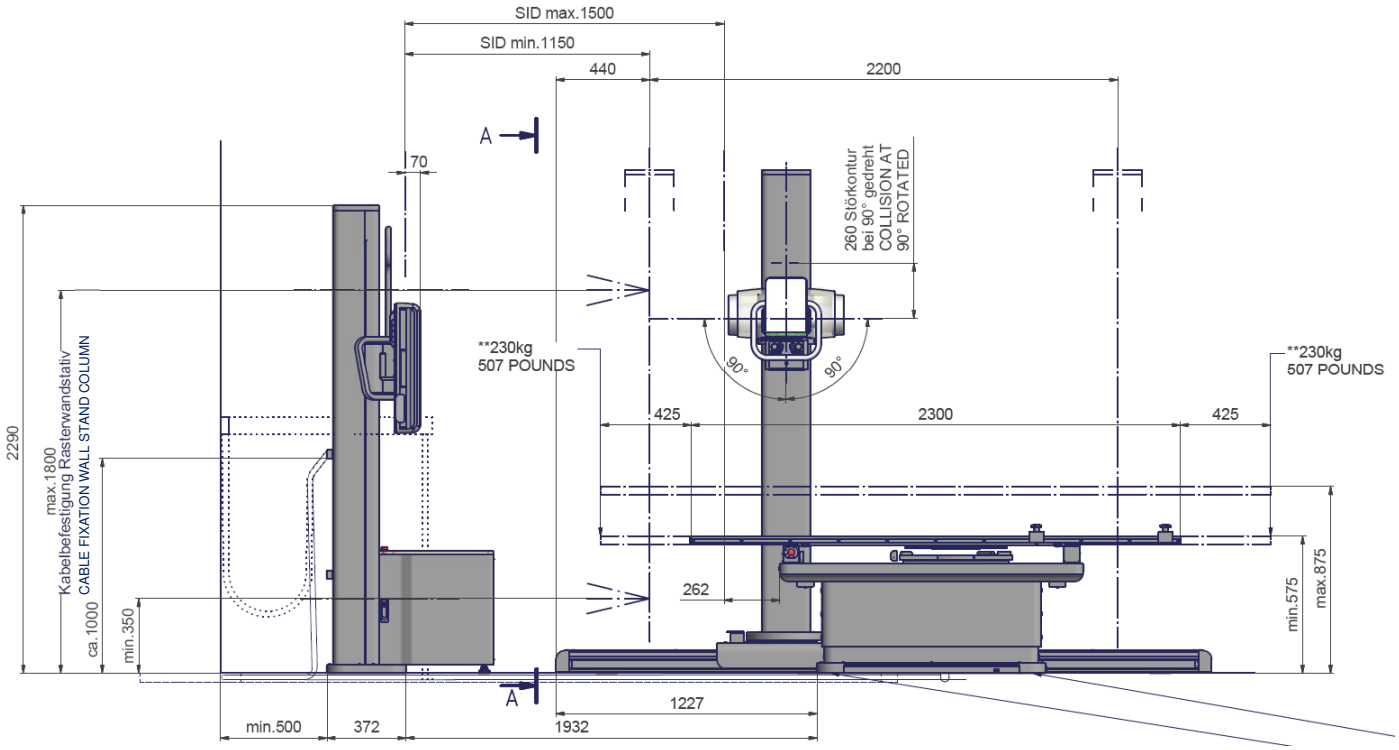
Note:

(1) at 80MHz and 800MHz, the separation distance for the higher frequency range applies

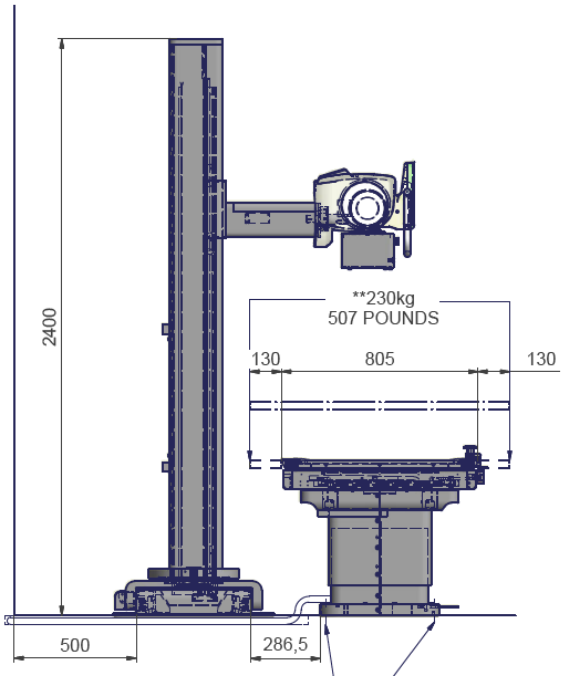
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

7 Technical Data

7.1 Dimensions



A-A (1/15)



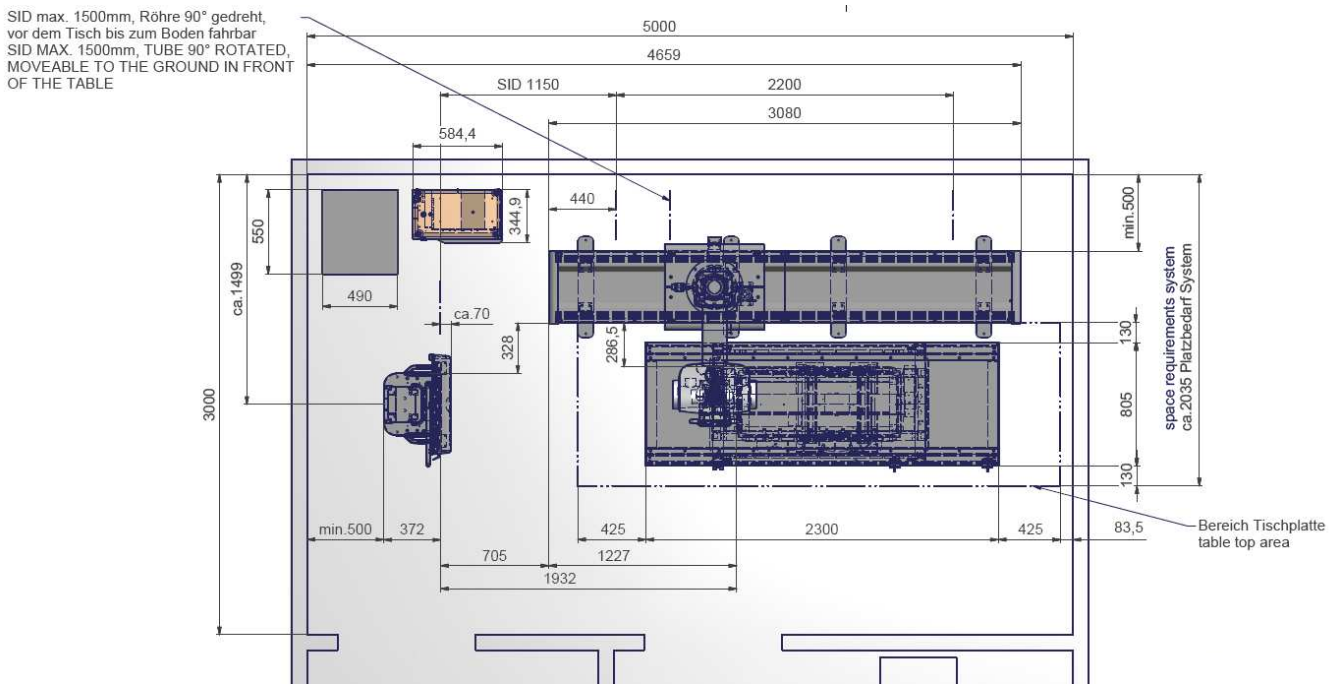


Table top dimensions (L x W):	230 cm x 80, 5 cm
Max. Patient weight (uniform load)	320 kg
Table height	575mm - 875 mm
Transverse movement of the table top (from the mid-position):	± 130 mm
Longitudinal movement of the table top (from the mid-position):	± 425 mm

The table top brakes are electromechanically released.

7.1.1 Under-table Bucky*

Longitudinal movement:	500 mm

7.1.2 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°
Latching at:	- 90°, 0°, + 90°, 180°
Vertical travel- carrying arm:	1450 mm
Longitudinal range of travel, column stand:	2200 mm

7.1.3 Wall column stand

Wall stand Bucky vertical travel range:	350 – 1800 mm
Longitudinal focus – tube distance (default):	min.115 mm

7.1.4 Complete Weight

Without patient	ca. 780 kg

7.2 Attenuation Equivalent

The table top is defined as application part.
The aluminium 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 (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 cover vertical wall stand is defined as application part.
The aluminium attenuation equivalent of the cover vertical wall stand 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 (HVLT) of 3.7 mm Al.

7.3 Electrical Data

7.3.1 Protection Art and Protection Class

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

7.3.2 Power connection

The PROGNOST B system must always be connected to an X-Ray generator.
The three internal power adapters must be hard wired to the EC-Box
The X-Ray generator is required to offer a minimum of a 230V connection which is fuse-protected by an internal 10 A circuit breaker.

PROGNOST B mains connection:
Voltage: 110-240 VAC, 0.6 kVA (50/60 Hz)

7.4 Environmental

7.4.1 Environmental conditions during operation

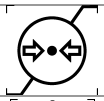
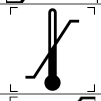
Ambient Temperature	+ 10°C to + 30°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

7.4.2 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

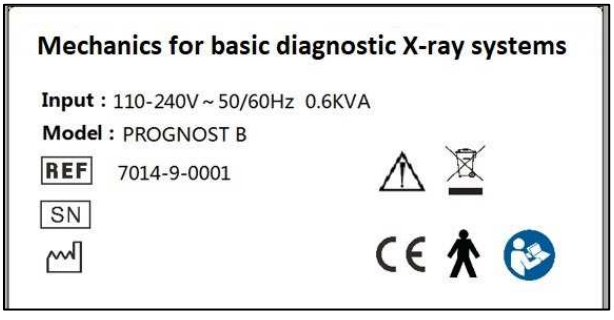
8 Description of symbols, labels and abbreviations

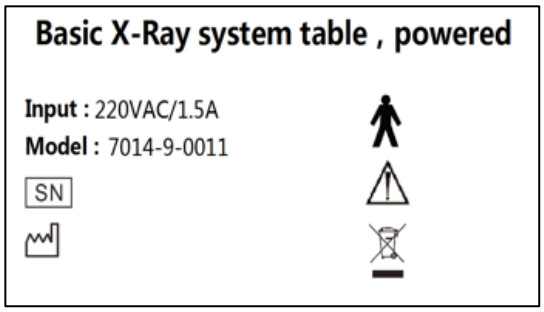
8.1 Symbols

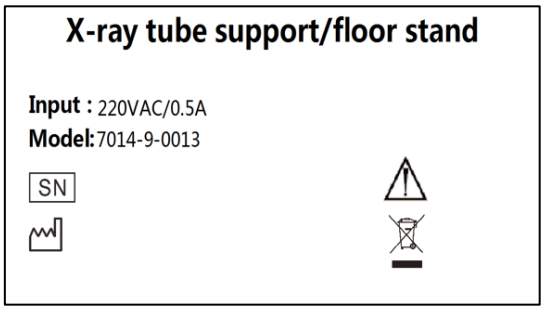
	Limitation atmospheric pressure
	Limitation temperature
	Limitation humidity
	Keep dry
	Fragile, Handle with care
	Do not stack
	Do not tilt
	Protect from light
	This way up
	Caution, note warning notice and safety instructions
	Refer to user manual
	CE-Mark
	Classification according to EN 60601-1 (Type B)
	Caution: Collision hazard for head (standing people prohibited)
	Caution: pinch-/crushing hazard for hands and fingers
	Caution
	Warning high voltage
	Do not exceed the maximum indicated weight

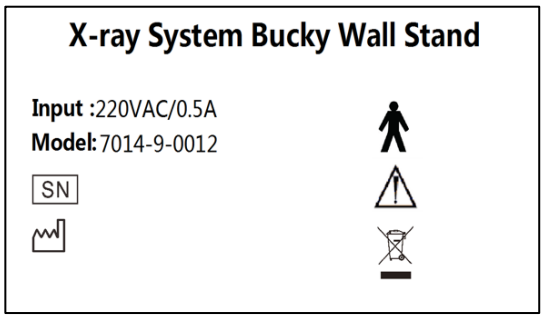
	Do not walk
	Do not stand on it
	Emergency OFF switch label
	Table height adjustment – table up
	Table height adjustment – table down
	Release table top brakes
	Manufacturer
	Date of manufacture
	Serial number
	Order number
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer or an authorized waste management company for information concerning the decommissioning of your equipment.

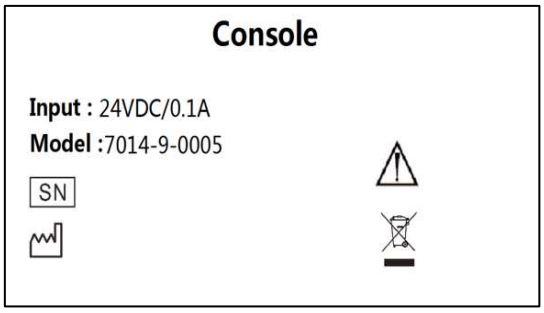
8.2 Identification label

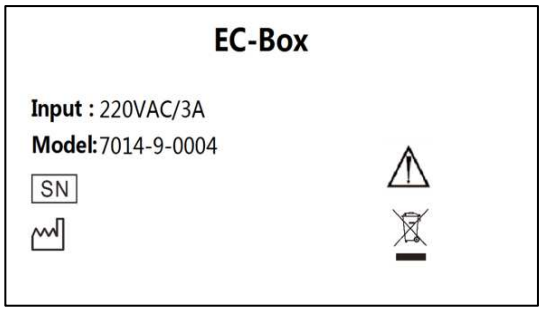






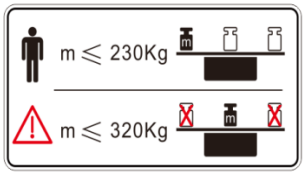






8.3 Labels

Labels on the side of the table top



Labels on sides of the tube column stand and wall column stand

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

Labels on left and right side of the tube assembly cover

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

Labels on the front of the wall stand Bucky housing

Maximum allowable weight

Labels on the floor rails

Do not step over the floor rails

Labels on the floor rails

Do not step on the floor rails

Labels on the table top

No putting your hand or fingers under the table top as the table top is moving

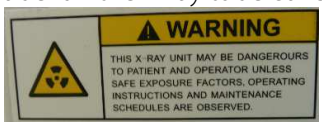
Label on the EC-Box

High voltage to be opened by authorized personnel only.

Label on the EC-Box and the cover X-ray column/floor rails

Non-professional authorized personnel cannot disassemble the housing

Label on the X-ray tube cover



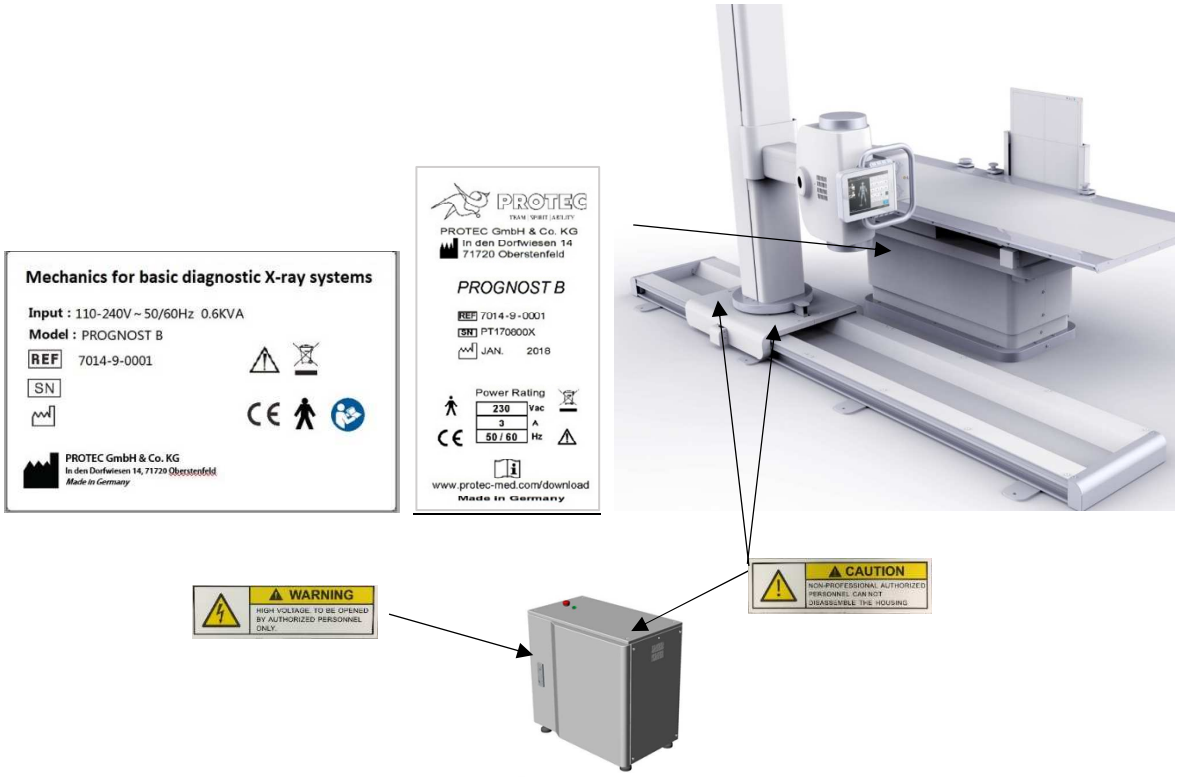
Warning X-rays

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

Company label

8.4 Position symbols and labels

The company label can be found on the side of the table near the bottom rear.


Mechanics for basic diagnostic X-ray systems
Input : 110-240V ~ 50/60Hz 0.6KVA
Model : PROGNOST B
REF 7014-9-0001
SN
PROTEC GmbH & Co. KG
In den Dorfwiesen 14, 71720 Oberstenfeld
Made in Germany
PROTEC
PROTEC GmbH & Co. KG
In den Dorfwiesen 14
71720 Oberstenfeld
PROGNOST B
REF 7014-9-0001
SN PT170600X
JAN. 2018
Power Rating
230 Vac
3 A
50 / 60 Hz
www.protec-med.com/download
Made in Germany
WARNING
HIGH VOLTAGE. TO BE OPENED BY AUTHORIZED PERSONNEL ONLY.
CAUTION
NON-PROFESSIONAL AUTHORIZED PERSONNEL CAN NOT DISASSEMBLE THE HOUSING


WARNING
CAUTION
m ≤ 230Kg
m ≤ 320Kg
WARNING:
No putting your hand or fingers under the tabletop as the tabletop is moving.
PROTEC
TEAM | SPIRIT | ABILITY

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