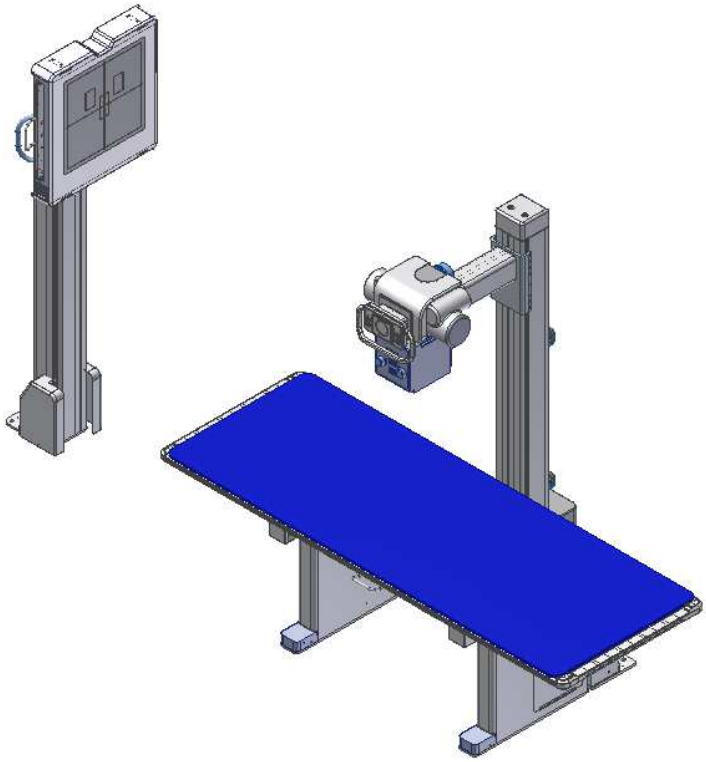
PRS 500 C

Basic diagnostic X-ray system

Model/ID: 7073-9-8050

Instructions for use

Ident. No. 5073-0-3002



CE 0297

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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	2020-11-12	all	Original issue
2.0	2021-02-17	7, 23	Radiation Warning, Power Box
3.0	2021-02-25	Front Page, 10, 14, 18, 21, 24, 30, 34	Product picture, Warning mattress, mattress at characteristic table added, symbols and labels, cleaning, mattress added to technical data table
4.0	2021-03-11	9, 10, 25, 26, 27, 28, 31, 32, 33, 34, 35	X-ray mattress description, compatible components, note X-ray mattress at characteristic table, Cleaning, disinfection, Life time, Applied part, symbols and labels, chapter power supply connection, X-ray mattress changed at technical data table, note attenuation equivalent

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.

Radiation Warning

WARNING!

The product documented in these accompanying documents is part of a system for the intended generation of X-rays for medical diagnostics. X-rays are ionizing radiation that can cause damage to living organisms (e.g. cancer or mutations).
X-rays represent a potential risk for patients and employees. Therefore, the aim is to minimize radiation exposure for both groups of people when using radiation and with a given medical problem.
The group of people responsible for the application must have the necessary specialist knowledge in accordance with the ordinances and guidelines and apply the procedures for the safe operation of such systems. The national regulations must also be observed during planning and installation. The X-rays are created in the X-ray tube by strong braking of previously accelerated electrons, which emit energy in the form of electromagnetic waves. The intensity depends on the set parameters voltage (kV), current (mA) and time (s) on the X-ray generator. The X-rays are only emitted at a radiation exit window of the tube and are limited by the fixed collimator directly below.
The X-ray components used by PROTEC are only devices for the human medical diagnostic area, which can be set up to a maximum of 150 kV. Further information can be found in the technical data in the instructions for use for the generators, X-ray tubes and collimators.

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.

NOTE

The usage of the product in combination with accessories which aren't authorized by PROTEC is forbidden.

1 Product description

1.1 Introduction

This user manual describes the special features and operational aspects of the PRS 500 C, knowledge of which are required for efficient and effective use of the radiographic system.

Prior to working with the basic diagnostic X-ray system PRS 500 C, it is required that the user read the safety notes as well as the chapter regarding operation.

1.2 Description

1.2.1 Equipment components

The PRS 500 C can be equipment or customized with the following components:

- Stationary patient positioning table with floating table top (incl. X-ray mattress)
  The basic diagnostic X-ray system PRS 500 C integrates a on the radiographic table fixed biocompatible X-ray mattress. This mattress is specially designed for X-ray imaging diagnostics. The mattress can be removed for cleaning.
- Floor railed X-ray system tube support, floor stand with control arm,
- Bucky unit,
- Vertical Bucky Wall stand,
- X-ray Generator VENUS-, CMP- or RFX series,
- X-ray tube assembly with housing,
- Anti-scatter grid
- Collimator

Optional components

- Measuring chamber (ionisation or solid state)
- Dose area product meter system
- Different direct X-ray-systems (RAPIXX-series)
  (consisting of DR-detector, Interface Box, and Software)

Optional Accessories

The PRS 500 C can be equipped or customized with the following accessories:

- Patient extending handle

Accessories which can influence the EMC-Condition

- Network cable (note the max. length in the documents)
- RAPIXX Data-Cable (note the max. length in the documents)
- WLAN-Router (only use devices that has an authorization by PROTEC)

1.2.2 Installation

See separate "Installation manual" PRS 500 C.
Contact information of persons which are qualified to make installations are requestable 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 X-ray system PRS 500 C has a weight of 665 kg (incl. Generator).

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

1.3 Product specific characteristics

1.3.1 Radiographic table

- Floating table top
- Table top colour – white
- Electromagnetic table top brake for effortless patient positioning
- A low (optimized) distance between the table top surface and the film (detector) surface
- Large adjustment range of the table top for position of the patient
- Reliable construction
- Prepared for the installation of a Bucky with anti-scatter grid and 3-field measuring chamber intended for the use with automatic exposure control
- Useable for variable cassette/detector sizes. Formats from 13 cm x 18 cm (5" x 7") to 43 cm x 43 cm (17" x 17"), depending on analogue or digital use.
- X-ray Mattress (attached on the radiographic table, 2190 mm x 800 mm x 15 mm, provides a convenient and comfortable patient positioning on the X-ray table)

1.3.2 Floor railed X-ray system tube support

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

1.3.3 Vertical Bucky Wall Stand

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

1.4 Intended use

The general-purpose diagnostic X-ray systems of the PRS 500-series are intended for various routine applications in planar X-ray imaging in human medicine.
They are stationary systems that can be used both for analogue and digital imaging.

NOTE

At the acceptance test a 25mm Aluminium / 99,5% purity can be used as a phantom for a patient equivalent.

The acceptance test has to be made in accordance to the local laws and directives. Only Special trained People are allowed to do this.

1.5 Indication and Contraindication

1.5.1 Indications

Justification of medical exposures
According to §83 of the German radiation protection law (StrlSchG), an X-ray examination is only justified if the patients benefit from x-ray diagnostics outweighs the radiation risk. The examination method, means the conventional X-ray with the PRS 500 system, must be suitable to answer the diagnostic question and no other more suitable alternative method is available.
Accordingly, it is also described by the International Atomic Energy Agency (IAEA) in the document *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards* (Requirement 37: Justification of medical exposures). It also refers to the need to consider national or international guidelines for the justification of a medical exposure.

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

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

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

1.5.2 Contra indications

There are no absolute contraindications for conventional X-rays.
But it is not allowed to make any exposures on humans when they are not medically indicated (see *Justification of medical exposures,* chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** Indication).
For pregnant women and children it is important to consider if the exposure is really necessary. It should be avoided if possible.

1.6 Intended user group

The radiographic system PRS 500 C is exclusively designated for use by professional who are trained, in accordance with the corresponding national regulations, in the use of diagnostic X-Ry 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, doctors and other medically trained personnel.

1.7 Conformity

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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.

NOTE

For the digital system implementation the manuals of CONAXX and RAPIXX have to be read and the containing safety note have to be observed.

NOTE

The commissioning of the X-ray system can only be done if all safety notes and user securities have been met. The user securities can be: door contact, marked area, dosimeter, safety clothings …

CAUTION!

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

NOTE

Every operating element is marked on the operating console and on the swivel arm or wall column, there are further descriptions for the symbols in the corresponding manual. The lawfully requirements for building regulations for X-ray systems have to be fulfilled. The X-ray system has to be checked according to the local law and also accepted by the responsible office.

CAUTION!

If the wrong SID is in use for exposures, personal injuries for the patient can be the result. The inverse square law takes place here. Halving the distance will cause a 4 time higher radiation dose.

WARNING!

It's not allowed to make any medical not indicated exposures on people. At pregnancy or children the question is if the exposure is really necessary. If possible it's better to abandon it.

2.1 General safety notice

2.1.1 Requirements for operation

WARNING!

Protection Class I ME equipment (according to EN 60601-1).
To reduce the risk of electric shock, this unit is designated exclusively for connection to a supply network with protective earth.
The power for the components of radiographic system PRS 500 C is designated to be exclusively supplied through a direct connection to the available X-Ray generator. The X-Ray generator is required to offer a minimum of two connection ports with 230V 50/60Hz.
The X-ray Generator of the System is directly connected to the power supply (see technical description of the Generator)
The radiographic system PRS 500 C with stand is a Class I ME product (according to EN 60601-1).
This device contains no on/off switch. The PRS 500 C is directly connected to the X-Ray generator and is switched on/off through the switching on and off of the generator itself. In order to disconnect the PRS 500 C from the power the connected X-Ray generator must be shut off.

WARNING!

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

2.1.2 Operating of the radiographic system

When having troubles with operating the X-ray system PRS 500 C, immediately call the Service of PROTEC or an authorized service and stop the using of the system.

2.1.3 Operating personnel

The radiographic system PRS 500 C with stand should only be operated by personnel who are trained in accordance with the corresponding national regulations in the use and operation of diagnostic X-Ray systems.

NOTE

Only properly trained and authorized personnel are allowed to word with the radiographic system.

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

NOTE

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

2.1.4 Pinching and Collision Hazards

CAUTION!

Ensure that while using any product that can be lowered, raised or moved in different directions, neither yourself (operator), the patient or any third party finds themselves in a hazardous position (area of movement). Remove all objects (e.g. chairs, pushcarts) from known collision areas.
Be aware that careless or improper adjustment of the radiographic system (movement of column, detector Bucky, Vertical Bucky wall stand and table top) can lead to damage of the X-Ray components, unusable X-Ray images and injury to the patient. Failure to pay attention can lead to damage of the radiographic system as well as external objects.

2.1.5 Explosion protection

These radiographic system is not designated for use within areas with explosive hazards.

2.1.6 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.

2.1.7 Ventilation

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

2.1.8 Interaction with external devices

Unwanted interaction with external devices is not known.

2.1.9 Electromagnetic Environment and the influence of devices

CAUTION!

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

CAUTION!

The usage of PRS 500 C straight next to other devices or stacked devices should be avoided, since it can cause an improper operating mode. If there is no other possibility than this the PRS 500 C and other devices should be studied to make sure they work proper.

NOTE

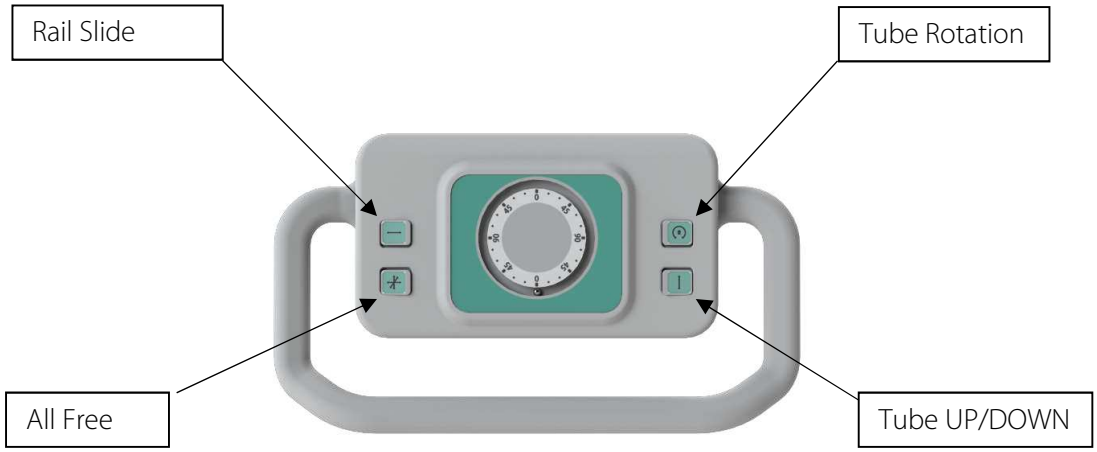
The characteristics of this device, as determined by emissions, allow its use in the industrial sector and in animal clinics (CISPR, Class A). When used in residential areas (for which Class B is usually required by CISPR 11), this unit may not provide adequate protection for radio services. The user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

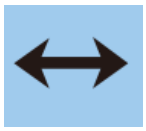
The PRS 500 C is intended for the usage in a professional environment of the medical service (e.g. clinic, surgery centers, physiology offices …)

3 Control elements and device displays

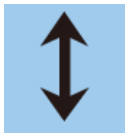
3.1 Control elements and device display of Basic X-ray system

3.1.1 Floor railed X-ray system tube support



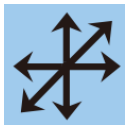


Rail Slide
When operator wants to move the tube stand at desired position horizontally, it can be moved manually while holding this button.



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

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

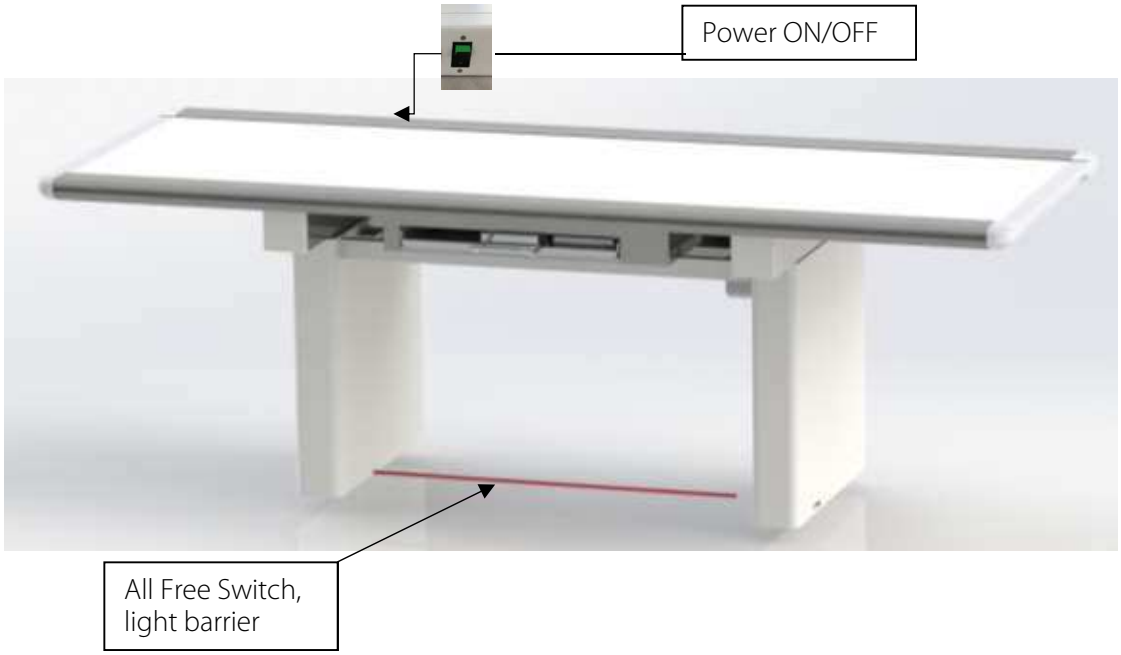


All Free Zone
It will allow to move the tube horizontally on the rail and up/down except the tube rotation.

3.1.2 Radiographic table

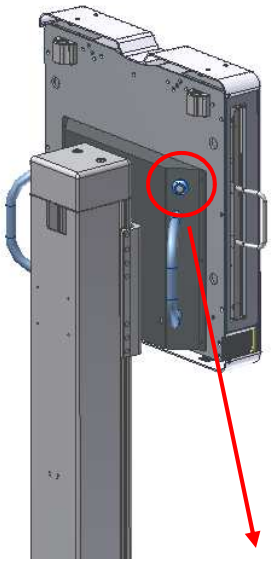
WARNING!

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



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

3.1.3 Vertical Bucky Wall Stand



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

3.2 Control elements and device displays collimator

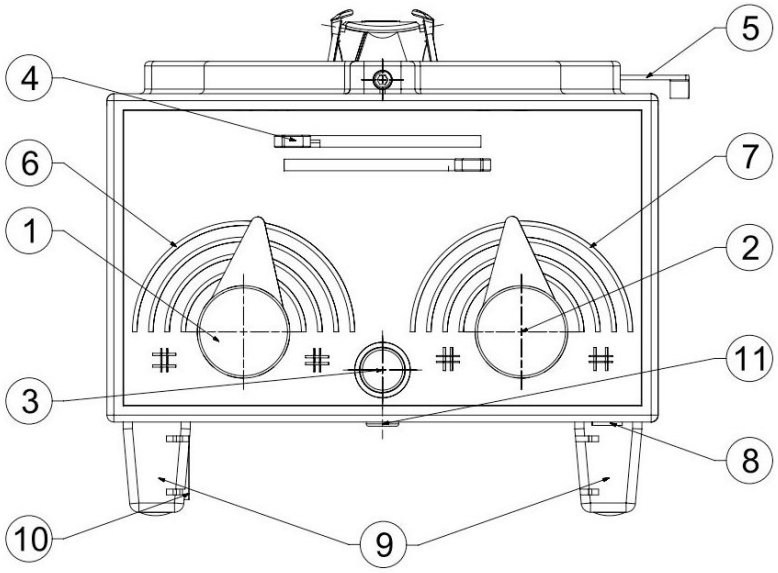


Figure collimator ML03

Pos. 1 -> Knobs for height format collimation (Rotating counterclockwise to open the collimator, rotating clockwise closes the collimator).
Pos. 2 ->Knobs for width format collimation (Rotating clockwise to open the collimator, rotating counterclockwise closes the collimator).
Pos. 3 ->Switching the radiation field and line light (laser) localizer lighting on. The lighting is switched off automatically by a timer.
Pos. 4 ->Slides for setting the pre-filtration(optional)
Pos. 5 ->Detent lever for ±45° rotation of the collimator about the vertical axis. The collimator only stops in the 0° position.
Pos. 6 ->Format height scales.
Pos. 7 ->Format width scales.
Pos. 8 ->Tape measure for SID measurement. Read off the measurement on the bottom edge of the collimator. (optional).
Pos. 9 ->Two accessory rails.
Pos. 10 ->Locking spring to fix accessories in the rails.
Pos. 11 ->Slide for laser light.

Detailed information please find in the enclosed User Manual collimator.

3.3 Control elements and device displays of X-ray tube

Detailed information please find in the enclosed User Manual of the X-ray tube.

3.4 Control elements and device displays of X-ray generator

Detailed information please find in the enclosed User Manual of the X-ray generator.

3.5 Control elements of Bucky, Grid entity

n/a.

3.6 Control elements and device displays of RAPIXX system

Detailed information please find in the enclosed User Manual of the RAPIXX system.

3.7 Control elements and device displays of CONAXX 2

Detailed information please find in the enclosed User Manual of the CONAXX 2.

4 Handling / Operation

4.1 Operation with the radiographic system

4.1.1 Operation at the X-ray table

4.1.1.1 Position of patients on the table top

WARNING!

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

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

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

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

4.1.1.3 Inserting a cassette into the cassette tray

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

4.1.1.4 Adjusting the focus-film distance (SID)

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

4.1.1.5 Adjusting the light resp. X-ray field

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

4.1.1.6 Exposure preparation / exposure release

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

4.1.1.7 Overtable exposures

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

4.1.2 Operation at vertical wall stand

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

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

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

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

4.1.2.3 Adjustment of the light-/ radiation field

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

4.1.2.4 Exposure preparation/ release

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

4.2 Operation collimator

Detailed information please find in the enclosed User Manual of the collimator.

4.3 Operation X-ray Tube

NOTE

The X-Ray tube needs to be warmed-up daily in order to extend the life of the tube and prevent tube arcs (Especially when the X-Ray tube was not used for a long period). The seasoning procedure shall be done upon turning on the generator for the first time.
Follow X-Ray tube manufacturer´s recommended seasoning procedure.
If X-Ray tube manufacturer´s seasoning is not available, then use the following procedure:
Set Generator: Large focal spot, 200mA, 40mAs
Take 8 exposures starting at 50 kV and increment the kV steps of 10 kV up to 120 kV (Exposure every 30 seconds, otherwise tube may arc).
See User Manual of the generator and CONAXX 2 User Manual 5.3.

Detailed information please find in the enclosed User Manual of the X-ray tube.

4.4 Operation X-ray generator

Detailed information please find in the enclosed User Manual of the generator.

4.5 Operation Bucky, Grid entity

Detailed information please find in the enclosed User Manual.

4.6 Operation RAPIXX system

Detailed information please find in the enclosed User Manual.

4.7 Operation Software

Detailed information please find in the enclosed installation- and User Manual CONAXX 2.

4.8 Switching On/Off the PRS 500 C

Switching on the PRS 500 C happens via the control panel of the Generator. The Generator supplies every system component with power.
On the Generator and the control panel will run a self-test when switching them on. After the self-test was successful the parameters will be displayed which can be saved under Organ-number #0.
When an Error gets displayed please see the manual PROVARIO Chapter 7.

	Switch on the x-Ray generator
	Switch of the x-Ray generator

NOTE

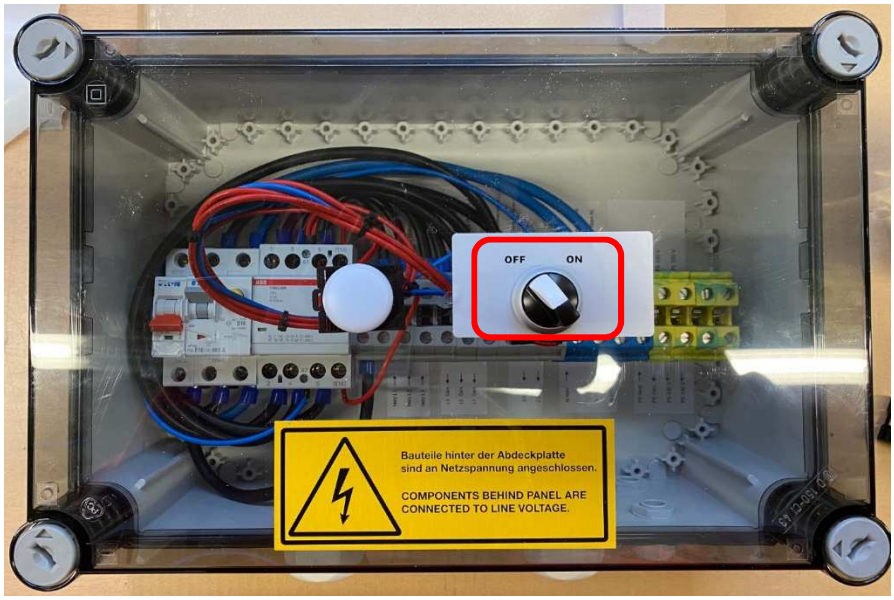
The Mechanics for basic diagnostic X-ray systems must be switched on!

4.8.1 Power Box

NOTE

→ The power box is only used with certain generators (e.g. Venus-series).
See "5021-0-0004 Technical Description" for a detailed description of the power box.

This power box ensures that the generator can be operated without a 230V connection and that the required 230V voltage for the components (power supply for the X-ray system and charging options for the DR panel) is separately fused and made available.
With the ON/OFF switch you could the power line of Generator and 230V components switched off and on (see picture).



4.8.2 Dosimetric Calibration VENUS, CMP, RFX generators

Detailed information please find in the enclosed documentation of the generator.

4.9 Exposure automatic

If the PRS 500 C is operated with an exposure automatic the functionality can be checked like this: Place a Phantom or any other weakening object in the radiation way. Choose a measuring chamber and expose. If this happens properly the measured value will be displayed. If something is not running properly an Error message will be shown. Repeat this procedure for every measuring chamber.

The quickest exposure time of the Generator is 2ms.

5 Safety and Maintenance

WARNING!

Caution electrocution hazard!
Prior to cleaning or disinfection, switch of the X-Ray generator. As a result, the radiographic system will be disconnected from power and the danger of electric shock is eliminated.

5.1 Introduction

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

5.2 Cleaning and disinfection

NOTE

Caution

Changes to material are possible!

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

NOTE

At an X-ray system with RAPIXX implementation please see the attached RAPIXX manual, chapter 8.2 for detailed information for cleaning and disinfections.

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.

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

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

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

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

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

5.3 Check-up and maintenance

WARNING!

It's forbidden to make any check-up or maintenance services while the **PRS 500 C** 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) by the user

See User Manual off all integral components.
Only original spare parts are to be used in situations requiring component replacement.

5.3.2 Regular controls by the user

See User Manual off all integral components.

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

The required maintenance must be carried out by PROTEC technical service or an authorized service provider to ensure the safe and reliable functionality of the system. The maintenance intervals depend on the frequency of use. The necessary specifications can be found in the corresponding Technical Description in Chapter 3.
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 system and off all integral components.
Only original spare parts are to be used in situations requiring component replacement.

5.3.4 Warranty

NOTE

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

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

PROTEC service department of PROTEC authorized technicians may only do service and maintenance work.

5.3.5 Product life time

The PRS 500 C 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.
Individual parts, components of the PRS 500 C may have a shorter product life time or should be replaced at shorter intervals for safety reasons. These parts, components and their required measures can be found in the maintenance checklist of the PRS 500 C Technical Description.

5.3.6 Further Information

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

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

Part	**Definition** (as applied part or parts which get handled like an application part but not defined as applied part)
X-ray mattress	Applied part
Cover – vertical wall stand	Applied part
Housing pars PROGNSOT C	Part, get handled like an application part
Optional accessory	
Patient extending handle (optional; mounted at the vertical wall stand)	Part, get handled like an application part
Detector	Applied part

5.3.8 Disposal

The X-ray system PRS 500 C 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

6.1 Connection

NOTE

The PRS 500 C is in need of the following power supply (see table „Power supply Generator).

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

It is intended that the central power supply of the PRS 500 C is always be connected to an supplied X-ray generator or power box using a hard-wired connection. Select a connection that consider the electrical specifications of the PRS 500 C like in the table above.
There is a central power supply connection on the radiographic table to which the X-ray floor stand and the vertical X-ray system image receptor stand are also connected.

Type generator	**VENUS 50R, 3 phase**	**VENUS 50R, 1 phase**	**VENUS 32R, 3 phase**	**VENUS 32R, 1 phase**
Output Power	50kW	50kW	32kW	32kW
Power supply voltage	380V AC/400V AC	220V AC	380V AC / 400V AC	220V AC/230V AC
Phase	3PH-N-PE	1phase	3PH-N-PE	1phase
Power frequency	50/60Hz	50/60Hz	50/60 Hz	50/60 Hz
Electrical resistance per phase	0,15 Ω/0,17 Ω	0,5Ω	0,27 Ω/0,29 Ω	0,5Ω
Fuse	63A	16A	63A	16A

List (Power supply generator)

Type generator	**CMP 200 DR 50**	**CMP 200 DR 60**	**CMP 200 DR 80**
Output Power	50kW	65kW	80kW
Power supply voltage	400/480 V AC only		
Phase	3PH-N-PE		
Power frequency	50/60 Hz		
Electrical resistance per phase	0,17Ω/0,24 Ω	0,13Ω/0,19Ω	0,10 Ω/0,15Ω
Fuse	60A/480V		

List (Power supply generator)

Type generator	**RFX 50**	**RFX 60**	**RFX 80**
Output Power	55kW	65kW	80kW
Power supply voltage	380V/400V/440V/480V		
Phase	3PH-PE (N not needed)		
Power frequency	50/60 Hz		
Electrical resistance per phase	0,15Ω 0,17Ω 0,20Ω 0,24Ω	0,15Ω 0,17Ω 0,20Ω 0,24Ω	0,10Ω 0,11Ω 0,14Ω 0,16Ω
Fuse	50A/480V		

List (Power supply generator)

WARNING!

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

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

CAUTION!

The radiographic system PRS 500 C 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 PRS 500 C. Disregarding this can cause a decrease in the performance features of the device.

CAUTION!

The X-Ray generator integrated into the radiographic system PRS 500C sends out electromagnetic waves during operation, which could cause interference with other devices.

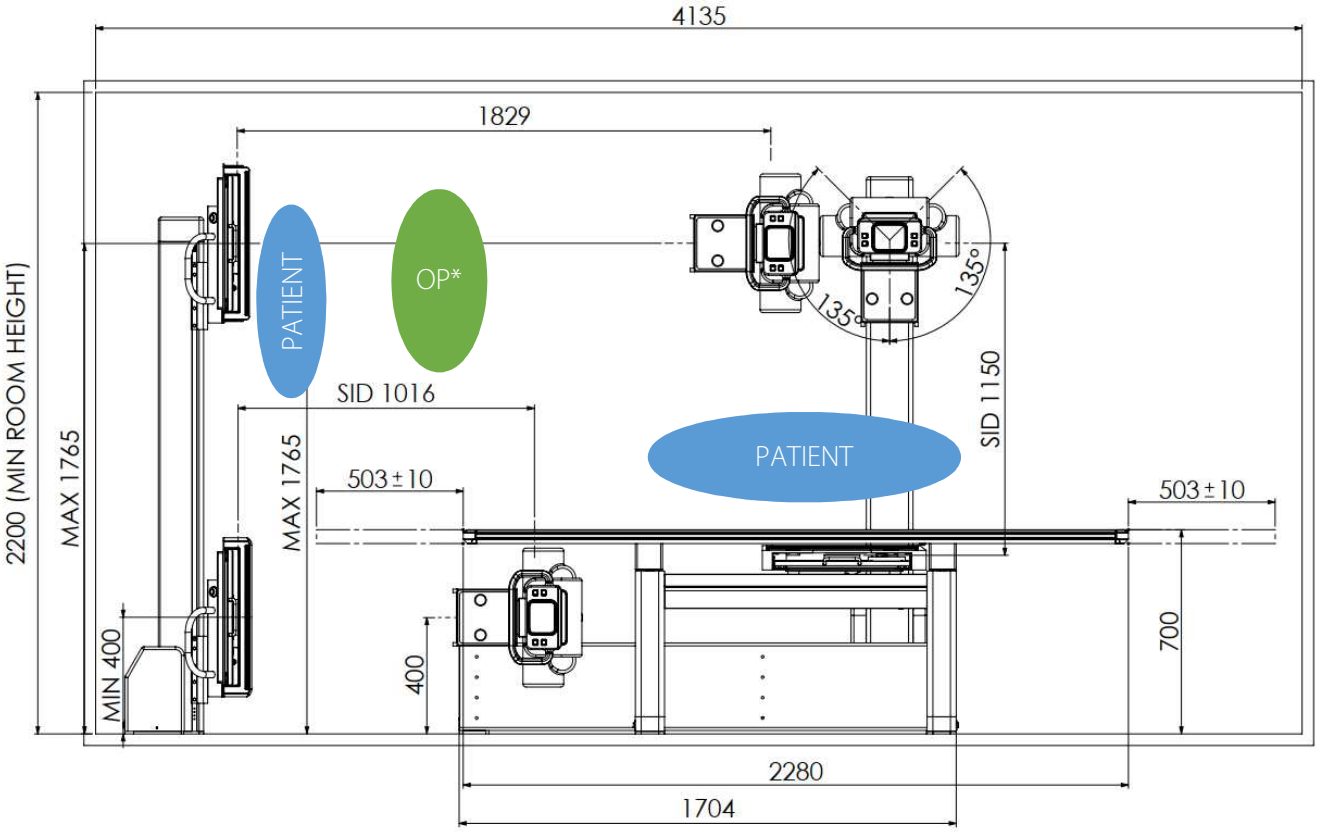
For EMC guidelines and manufacturers declaration for the generator according to EN 60601-1-2, see the separate User Manual for the corresponding generator.

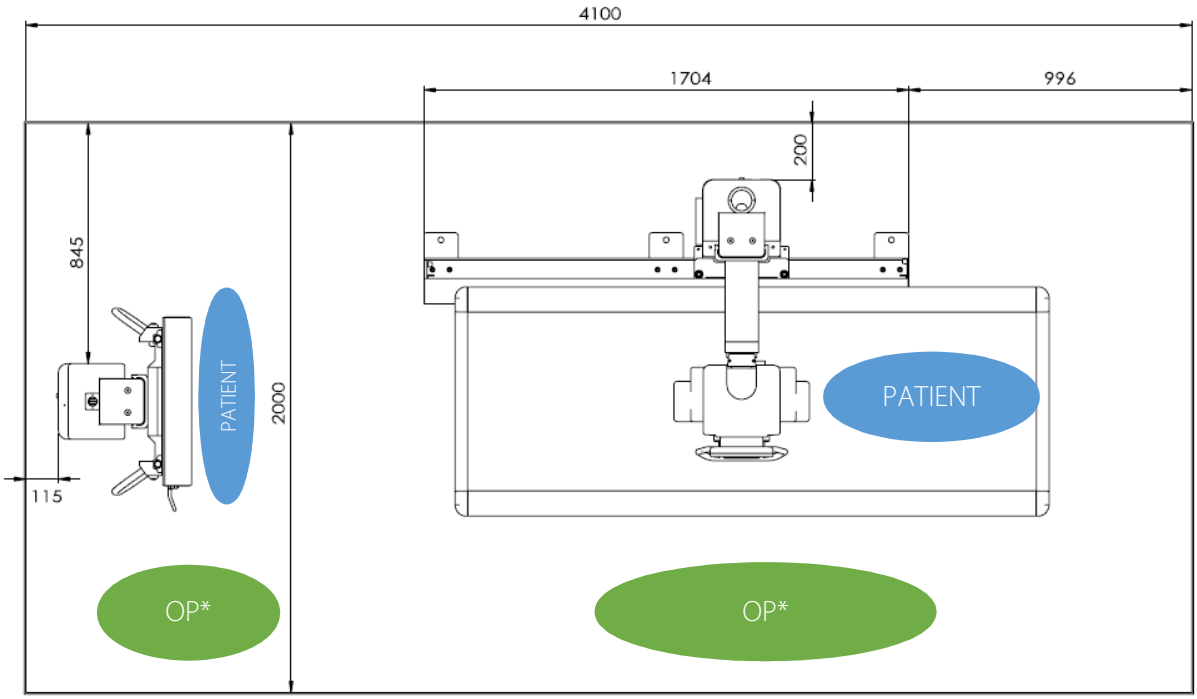
6.2.1 Guidelines and Manufacturers declaration – electromagnetic interference (non-life supporting device)

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

7 Technical Data

7.1 Dimensions





7.2 X-ray system table

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

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

7.2.1 X-ray mattress

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

Velcro ® fastening, cleanable, biocompatible

7.3 Bucky unit

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

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

7.4 X-ray stem tube support, floor stand

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

7.5 Vertical X-ray system image receptor stand

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

7.6 Attenuation Equivalent

WARNING!

The X-ray system PRS 500 C can be delivered with different options on the Grid device. The attenuation factor must be determined at the final inspection at the customer. The variables like X-ray tube, Collimator etc. have influence to the factor. The attenuation value of the components can be read out of the accompanying documents of the component. The attenuation value has to be determined at the technical specifications. If the limits can't be kept please inform PROTEC immediately. If additional storage aids (e.g. wedges, pillows) are placed in the beam path it can influence the incoming dose at the image receiver and thus also the image quality of the radiography. The more radiation impermeable the object, the stronger the effect.

The aluminium attenuation equivalent of the table top is typically 1.1 < 1.2 Al mm for composite fibre, according to EN 60601-1-3. Tested at 100 kV with a first half-value layer thickness (HVLT) of 3, 7 mm Al and typically 0.6 mm Al und <0,8mm Al according 21CFR § 1020-30 (n) with 100 kV and a first half-value layer thickness (HVLT) of 2,7mm Al.

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

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

7.6.1 Protection Art and Protection Class

The PRS 500 C is consistent with a protection class 1 device and contains applicable parts Type B (according to EN 60601-1).Environmental conditions.

7.7 Automatic cutoff dose

7.7.1 Analogue System

The automatic cutoff dose is 2,5µGy.

7.7.2 Digital System

The automatic cutoff dose depends on the detector.
For RAPIXX systems, see Installation- & User manual of the corresponding RAPIXX system (Chapter 3.2; 3.3)

7.8 Environmental

7.8.1 Environmental conditions during operation

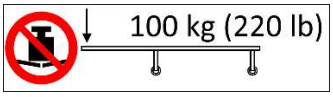
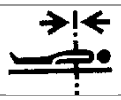
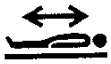
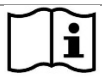
Ambient Temperature	+ 5°C to ~ 30°C
Relative humidity	10% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

7.8.2 Environmental Conditions for Shipping and Storage

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

8 Description of symbols, labels and abbreviations

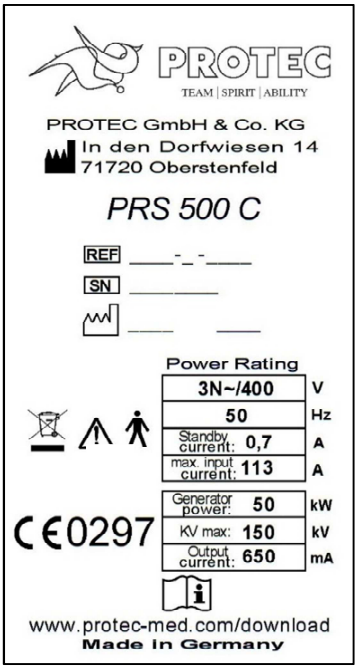
8.1 Symbols

	Keep dry
	Fragile, Handle with care
	This way up
	Caution, note warning notice and safety instructions
	Refer to user manual
CE 0297	CE-Mark
	Classification according to EN 60601-1 (Type B)
	Caution: pinch-/crushing hazard for hands and fingers
	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight
	Table top movements for exposure
	Longitudinal movement of the table top
	Transverse movement of the table top
	The positioning and support of a patient on the X-ray system table must not be carried out without this X-ray mattress!
 www.protec-med.com/download	With this symbol we point out that Usage instructions of the corresponding product is on out Homepage

8.1.1 Generator; Tube; collimator and optional accessories

For additional information see the Technical Description and User Manual for the corresponding components.

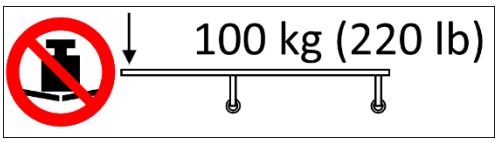
8.2 Identification label



Exemplary for PRS 500 C with X-ray generator 50 kW

8.3 Labels

Labels on the side of the table top



Labels on top of the table top

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

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

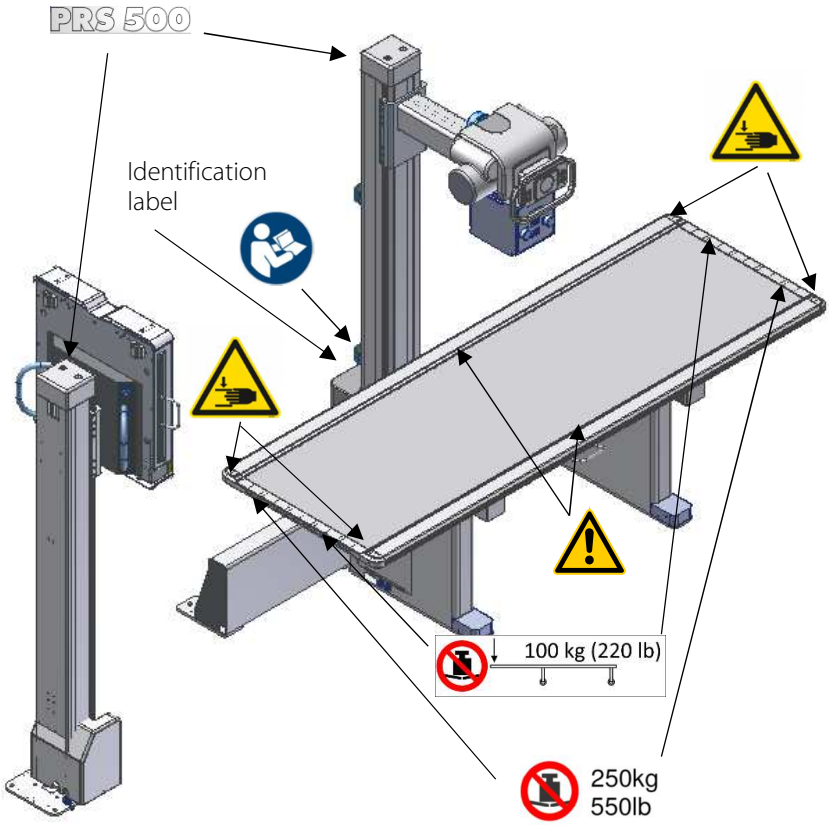
Labels on the X-ray system tube support, floor stand and column X-ray system image receptor stand

Product label

Label on the X-ray mattress

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

8.4 Position symbols and labels



Label of the X-ray mattress

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

8.5 Abbreviations

mm	Millimetre
cm	Centimetre
lb.	Pound
kg	Kilogram
°C	Degree -Celsius
hPa	Hectopascal
DIN	German Industry Standard
EN	European Standard
CE	CE-Mark
Hz	Hertz
ED	Duty cycle
A	Ampere
SN	Serial number