PRS 500 F

Radiographic system

Model/ID: 7067-9-8070L
7087-9-8070L

User Manual

Ident. Nr. 5087-0-0002

CE 0297

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NOTE

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Table of contents

NOTE

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

Document Effectivity

Revision No.	Date	List of effective pages	Comments
3.0	12/05/2017	all	Original issue

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

WARING!

The component of the equipment described within this Document is part of a system for the intended generation of X-rays for medical diagnosis.
X-rays generate a potential risk for both patients and operators.
For this reason, the application of X-rays for a given medical purpose must aim at the minimization of radiation exposition to any persons. Those persons responsible for the application must have the specific knowledge according to legal requirements and regulations and must establish safe exposure procedures for these kinds of systems. Those persons responsible for the planning and installation of this equipment must observe the national regulations.

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 F, knowledge of which are required for efficient and effective use of the radiographic system.

Prior to working with the PRS 500 F, 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 F can be composed with the following components:

- Horizontal, height adjustable patient positioning table with floating table top and integrated column stand with control arm,
- Bucky or Grid entity*,
- Vertical wall stand*,
- X-ray Generator,
- X-ray tube assembly with housing*,
- Anti-scatter Grid*
- Collimator*

Optional components

- 3-field measuring chamber*,
- Dose area product meter system* and
- Different direct X-ray-systems (RAPIXX-Serial)
  (consisting of DR-detector*, Interface Box, and Software)

Optional Accessories

The PRS 500 F can be equipment or customized with the following accessories:

- Patient extending handle (ID: 7401-0-6810)*
- Compression band (ID: 7755-0-4001)*
- Mattress (ID: 7765-0-4001)*
- Short hand grip (ID: 7303-0-1100)*
- Short hand grip adjustable (ID: 7303-0-1150)*
- Long hand grip (ID: 7301-0-0610)*

* These components can also be used in a patient area.

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 F.
Contact information's of persons which are qualified to make installations are requestable at:

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1.2.2.1 Floor capacity

NOTE

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

The radiographic system **PRS 500 F has a weight of 630kg** (incl. UT 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
- Motor activated table top brake for effortless patient positioning
- A low (optimized) distance between the table top surface and the film (detector) surface
- Large adjustment range of the table top for position of the patient
- Reliable construction
- Lateral rails of the table top prepared to accept a number of table accessories
- Prepared for the installation of a Bucky with anti-scatter grid and 3-field measuring chamber intended for the use with automatic exposure control
- Extensive cassette program including Format 13 cm x 18 cm up to Format 35.6 cm x 43 cm
- Ceiling-free column stand intended for use within rooms with a ceiling height of at least 2.3 meters
- 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 25 cm up to 189 cm during horizontal beam projection
- Electromagnetic brakes for the longitudinal movement of the column stand, the vertical movements of the carrying arm as well as the rotational movements of the X-ray tube assembly around the axis of the carrying arm with integrated latching every 90°
- Integrated safety connector for automatically centering the X-ray tube assembly and the Bucky in the longitudinal direction
- Prepared for digital Buckys

1.3.2 Vertical wall stand

- Space saving with minimal footprint
- Wall – floor mounting of floor mounting
- cassette loading from the right or left side (specified at installation)
- Cassette sizes from 13 cm x 18 cm (5 x 7) to 35,6 cm x 43 cm (14 x 17)
- Prepared for digital Bucky's

1.4 Intended use

The general-purpose diagnostic radiographic 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 §23 of the German Radiological Ordinance (RöV), 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 luxations and ligament ruptures of the locomotor system.
- For the diagnosis of degenerative, inflammatory, traumatic and tumorous diseases and changes of the locomotor system.
- For diagnostic of malformations and malalignments of the skeletal system.
- For the diagnosis of thoracic and pulmonary symptoms (thorax exposures)
- For the diagnosis of sclerotherapy.
- For the diagnosis of inflammatory and expansive processes of the mucosa, cranial bones and paranasal extension.
- For the diagnosis of the abdomen (e.g. acute abdomen, plain abdominal radiography, urethrogram, cystogram).

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 1.5.1 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 F 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 intended use in connection with other medical devices, objects and accessories.
Suitable users could include the following: Radiologist, radiology assistants, radiology technicians, doctors and other medically trained personnel.

1.7 Conformity

CE 0297

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 radiographic 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 clothes.

CAUTION!

The manual contains every safety relevant information's 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's are on the delivered document-CD. Those information's count as additional information's 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 radiographic systems have to be fulfilled. The radiographic 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!

Class I ME device
To reduce the risk of electric shock, this unit is designated exclusively for connection to a supply network with protective earth.
The power for the components of radiographic system PRS 500 F 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 F with stand is am ME Class I product.
This device contains no on/off switch. The PRS 500 F 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 F from the power the connected X-ray generator must be shut off.

2.1.2 Operating of the radiographic system

When having troubles with operating the radiographic system PRS 500 F, 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 F 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 radiographic systems.

NOTE

Only properly trained and authorized personnel are allowed to word with the radiographic system PRS 500 F.

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 PRS 500 F. 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 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 PRS 500 F 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 radiographic 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 F 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 F 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.

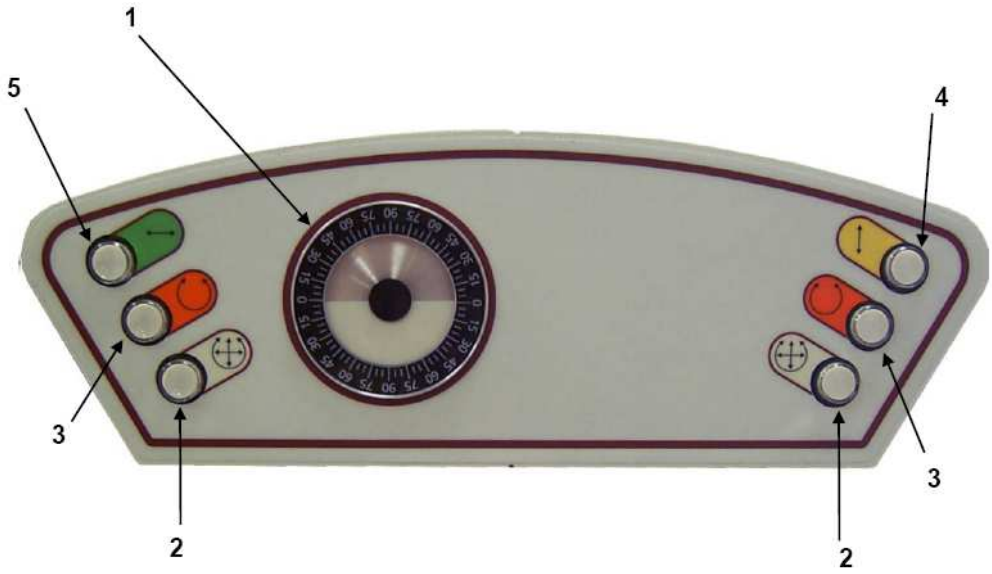
The PRS 500 F is intended for the usage in a professional environment of the medical service (e.g. clinic, surgery centers, physiology offices …)

3 Control elements and device displays

3.1 Control elements and device displays PROGNOST FS

Detailed information please find in the enclosed User Manual of the PROGNOST FS.

3.2 Control elements and device displays control handle



Pos. 1 -> Angle indicator, indicates angle of the X-ray tube assembly.
Pos. 2 -> Central brake release switch; when actuated, all movements are released.
Pos. 3 -> Angulation brake release switch; releases brake for movement of the X-ray tube assembly around horizontal support arm axis.
Pos. 4 -> Vertical brake release switch; release brake for vertical movement of the X-ray tube assembly.
Pos. 5 -> Longitudinal brake release switch; release brake for longitudinal movement of the tubestand.
The controls are operated from the front (operator side) of the tubestand. With pressure by the operator´s thumb on the control arm switches can easily release the electromagnetic brakes related to one or more of the movements to allow convenient and accurate positioning of the X-ray tube assembly.

3.3 Control elements and device displays collimator

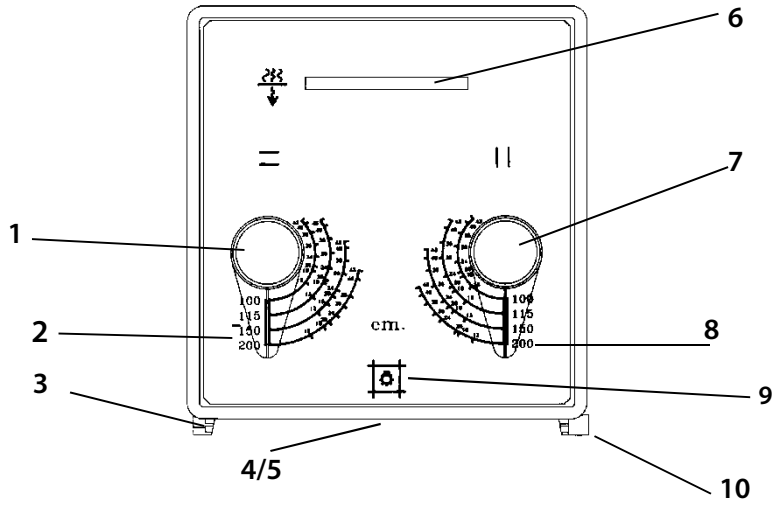


Figure collimator (Ralco 302), may differ depending on the system.

Pos. 1 -> Collimator adjustment control; allows for manual opening and closing of collimator shutters (transversely to table top).
Pos. 2 -> Scales; indicate the opening of collimator shutters (transversely to table top).
Pos. 3 ->Accessory rails (can be used for measuring phantoms).
Pos. 4 -> Light resp. X-ray field; corresponding to opening of collimator shutters.
Pos. 5 -> Light centering device; allows centering of the X-ray tube assembly with the bucky unit.
Pos. 6 –> Filter control for slection of additional filtration.
Pos. 7 -> Collimator adjustment control; allows for manual opening and closing of collimator shutter (longitudinally to table top).
Pos. 8 -> Scales; indicate the opening of collimator shutters (longitudinally to table top).
Pos. 9 -> Collimator light switch; turns on collimator light.
Pos. 10 -> Measuring tape.

Detailed information please find in the enclosed User Manual collimator.

3.4 Control elements and device displays of X-ray tube

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

3.5 Control elements and device displays of X-ray generator

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

3.6 Control elements of Bucky, Grid entity

Detailed information please find in the enclosed User Manual.

3.7 Control elements and device displays of vertical wall stand PROVERT

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

3.8 Control elements and device displays of RAPIXX system

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

3.9 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 tabletop

- Step on the brake release pedal bar.
- Move the tabletop into position for patients convenient getting on the tabletop.
- Release the brake release pedal bar.
- Assist the patient in getting on and lying down on the tabletop.
- Step on the brake release pedal bar and position the patient by moving the floating tabletop.

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

- Press the button 5 (Figure control arm) 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 (see item 4.1.1.1).
- 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 (FFD)

- Set the X-ray unit with a tape measure at the collimator or the display on the tube to the desired focus-film distance (FFD).
- Press the button 4 (Figure control arm) 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 9, 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 7, 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 FFD.
- Press the collimator light switch (button 9, 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 lightfield with the adjuster 1 and 7 (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 PROVERT

4.1.2.1 Adjustment of the X-ray unit to the mid of a cassette or Bucky/Grid entity of a X-ray table (vertical center beam)

- By pressing button 3 (figure control handle) the brake for the rotation of the Collimator will be released.
- Swing the X-ray unit to the wall stand.
- Set the Bucky, Grid entity on the vertical stand to the size of the patient.

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

- Release the longitudinal movement brake of the column by pressing button 5 (figure control handle) 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 button 4 (figure control handle) 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 4 (figure control handle).
- Release Button 4 (figure control handle) to activate the height-adjustable brake for the collimator.
- By using button 9 (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 2 and 8 (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 X-ray table PROGNOST FS

Detailed information please find in the enclosed User Manual of the PROGNOST FS.

4.3 Operation collimator

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

4.4 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 PROVARIO HF and CONAXX 2 User Manual chapter 5.3.

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

4.5 Operation X-ray generator

Detailed information please find in the enclosed User Manual of the PROVARIO HF:

4.6 Operation Bucky, Grid entity

Detailed information please find in the enclosed User Manual.

4.7 Operation vertical wall stand PROVERT

Detailed information please find in the enclosed User Manual PROVERT.

4.8 Operation RAPIXX system

Detailed information please find in the enclosed User Manual.

4.9 Operation Software

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

4.10 Function of the PRS 500 F

4.10.1 Switching On/Off the PRS 500 F

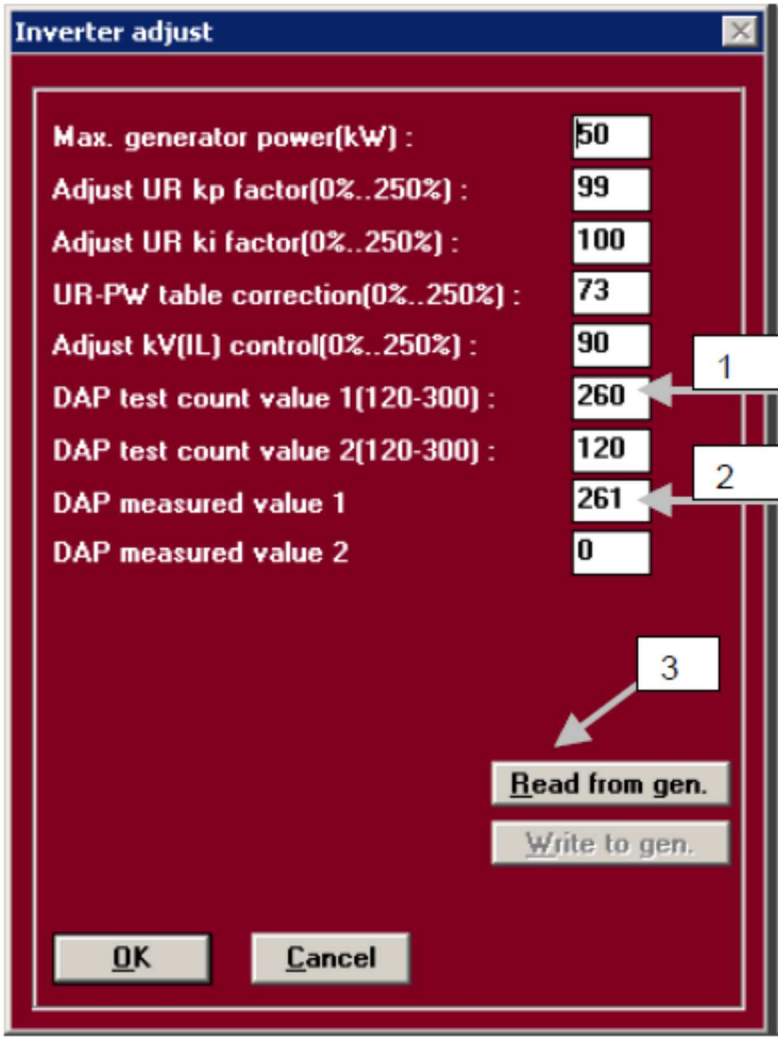
Switching on the PRS 500 F happens via the control panel of the Generator. The Generator supplies every system component with power.
On the Generator and the control panel will run a self-test when switching them on. After the self-test was successful the parameters will be displayed which can be saved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

	Switch on the X-ray generator	button POW1
	Switch of the X-ray generator	button POW2

4.10.2 Dosimetric Calibration (only PROVARIO HF)

The Generator is running a self –test, at switching on and changing the tube in a two tube operation, on the chosen area dose measuring chamber.
On this test every Vacutec area dose measuring chamber emits a determinated
number of test pulses, which are getting detected by the Generator, the Generator compares it with a deposited test value. At a deviation +/- 2% the error E018 „DAP-System“ gets displayed on the control panel which indicates a decalibrated measuring chamber.
The test value of the area dose measuring chamber, which can be found on the test protocol, has to be applied to the parameter 846 of the Generator or via the Service program into the field “DAP test count value x (120-300)” (1).

The current measured test value is displayed in the field “DAP measured value x”(2) after switching on the Generator. For this the function “read from gen”(3) has to be executed. Modest differences in the measures test value can be caused by air pressure fluctuations or wrong installed measure chambers.



This window can by opened in the Service program:
Menu -> Settings -> Setup kV Control…

Dosimetric Calibration Venus 50R, detailed information please find in the enclosed documentation of the generator.

4.11 Exposure automatic

If the PROS 500 E 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.

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 a radiographic system with RAPIXX implementation please see the attached RAPIXX manual, chapter 8.2 for detailed information's 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 radiographic system PRS 500 F or to the coating of the individual components.

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

Chrome components should be cleaned by being wiped down with a dry 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 PRS 500 F, including unit accessories, should undergo a wipe down disinfection using appropriate surface disinfection agents (e.g. Melsept* SF, 15 min. reaction time with a concentration of 2%). The information provided by the disinfectant manufacturer in regard to concentration and reaction time must be closely followed.

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

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

5.3 Check-up and maintenance

WARNING!

It's forbidden to make any checkup or maintenance services while the PRS 500 F is in use with a patient! Any checkup or maintenance services can only be done by people who got trained or authorized by PROTEC.

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

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

See User Manual off all integral components.

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

Required maintenance must be performed at 6-month intervals by PROTEC Service or specific authorized service provider to ensure the sage and reliable operation of the equipment.
In the event that scheduled maintenance is not performed, PROTEC GmbH & Co. KG will not be responsible for damages incurred by the user or third parties if such damages are the result of improper or omitted maintenance.
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.

Authorized technicians may only do service and maintenance work.

5.3.5 Product life time

The PRS 500 F 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 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)
Table top	Applied part
Cover – vertical wall stand	Applied part
Detector	Applied part
Housing parts PROGNOST F	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
Compression Band (**optional**)	Part, get handled like an application part
Mattress (**optional)**	Part, get handled like an application part

5.3.8 Disposal

The X-ray system PRS 500 F contains different plastics, oils and heavy metal. At disposal of exchange parts or the whole system the current regulations have to be observed. Please contact the service or a company specialized for disposing the components.

6 Electrical data

NOTE

The radiographic system is in need of the following power supply (see table „Power supply Generator).

Type generator	**PROVARIO HF 50**	**PROVARIO HF 60**	**PROVARIO HF 80**	**Venus 50R, 3 phase**	**Venus 50R, 1 phase**
Output Power	50kW	65kW	80kW	50kW	50kW
Power supply voltage	400V AC			380V AC/400V AC	220V AC
Phase	3PH-N-PE			3PH-N-PE	1phase
Power frequency	50/60 Hz			50/60Hz	50/60Hz
Electrical resistance per phase	0,3Ω	0,2Ω	0,12Ω	0,15 Ω/0,17 Ω	0,5Ω
Fuse	50A			63A	16A

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.

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

CAUTION!

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

CAUTION!

The X-ray generator integrated into the radiographic system PRS 500 F 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.

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

The radiographic system PRS 500 F 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.

Emissions test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	This radiographic system 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 radiographic system 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 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 radiographic system or shielding the location.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuation/ flicker Emission EN 61000-3-3	Complies	

The radiographic system 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.

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 radiographic system **r**equires continued operation during power mains interruptions, it is recommended that the radiographic system 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			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment - guidance**
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 than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol: 
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 radiographic system is used exceeds [field strength] V/m, observe the radiographic system to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the radiographic system 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 3 V/m.			

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 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.

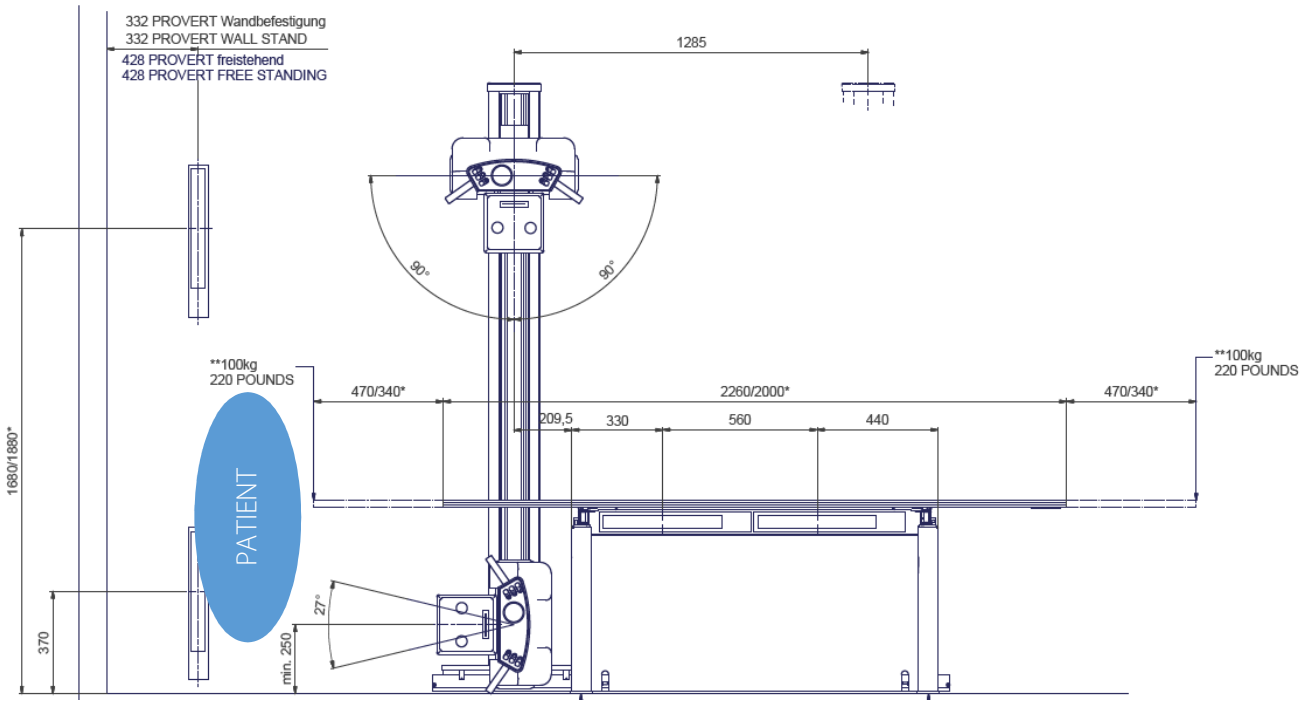
Note:

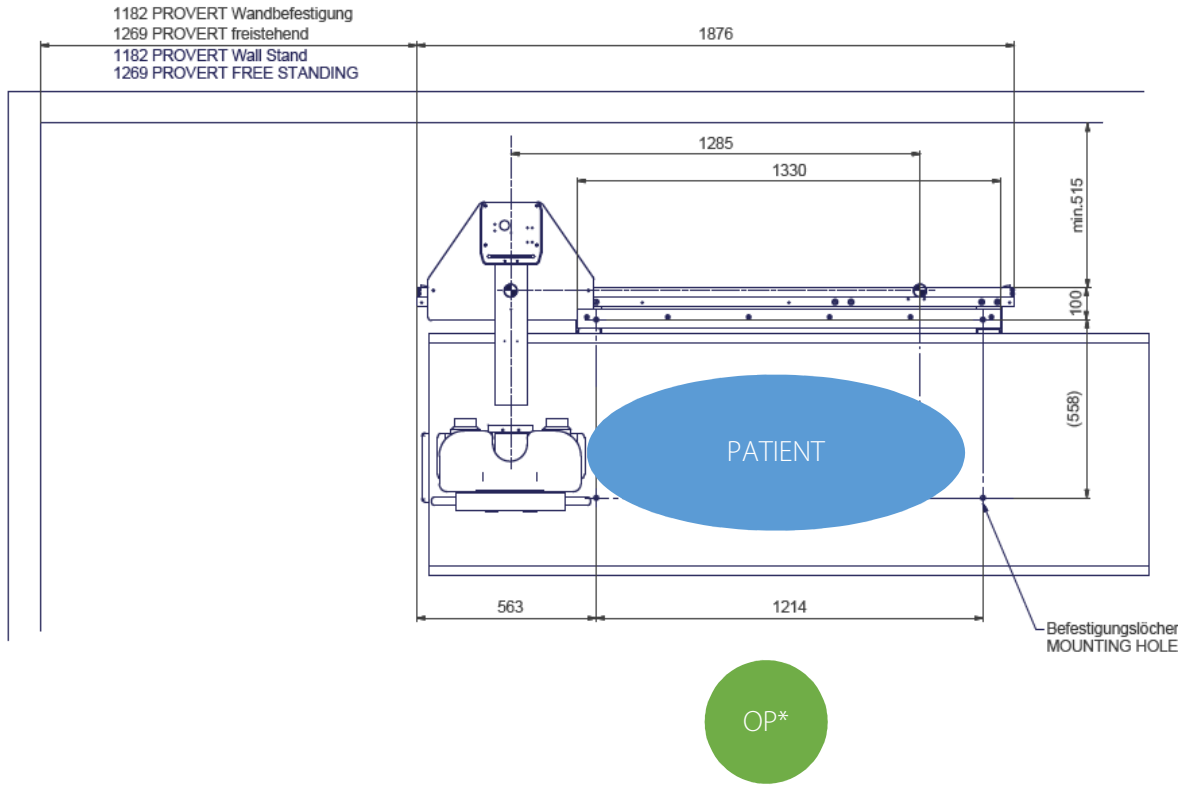
(1) at 80MHz and 800MHz, the separation distance for the higher frequency range applies

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

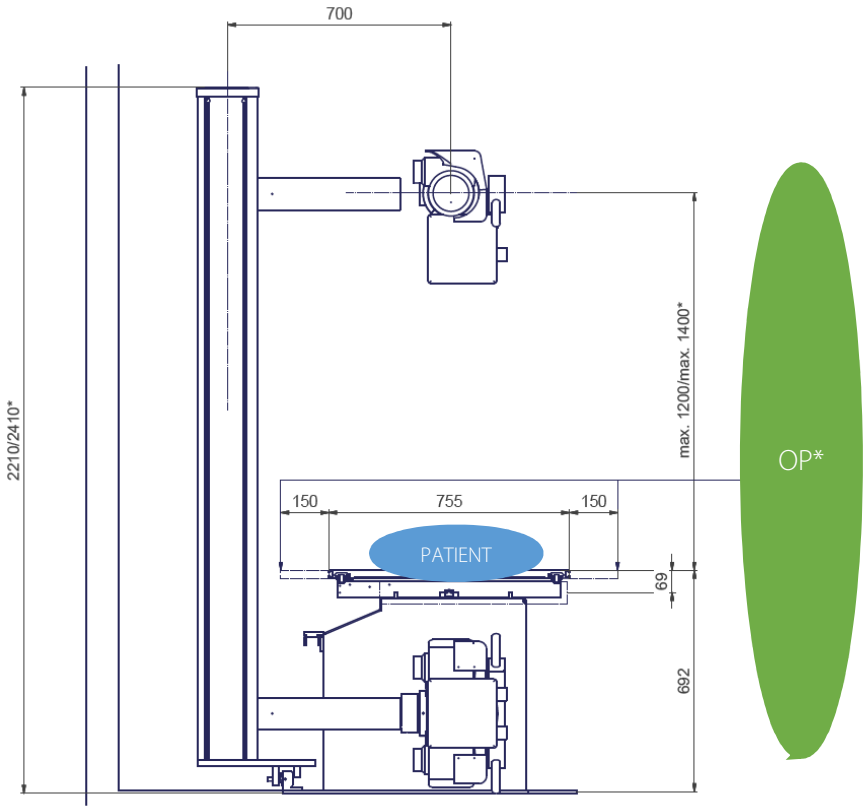
7 Technical Data

7.1 Dimensions





*OP – Operator



*OP -Operator

7.2 X-ray table PROGNOST FS

Table top dimension (L x B):	2260 mm x 755 mm, standard 2000 mm x 755 mm, optional 2000 mm x 655 mm, optional
Patient load, max	230 kg TP composite fiber 250 kg TP carbon fiber
Table top height:	692mm
Table top movement, transvers (from the mid-position):	± 150 mm
Table top movement longitudinal (from the mid-position):	± 470 mm (TP 2260mm) / ±340mm (TP 2000mm)

The brakes of the tabletop are used electro-mechanic.

Detailed information please find in the enclosed User Manual, Technical Description of the PROGNOST FS.

7.3 Bucky, Grid entity

Longitudinal travel:	560 mm
Min. distance Bucky center to table head end:	330 mm
Min. distance Bucky center to table foot end:	440 mm
Table top - film-distance:	67 mm

The Bucky, Grid entity and the measure chambers are connected to the generator.

Detailed information please find in the enclosed User Manual, Technical Description of the Bucky, Grid entity.

7.4 X-ray column

Focal spot vertical travel - horizontal X-ray beam:	250 - 1892 mm
Focal spot vertical – film distance:	max. 1276 mm
Focal spot vertical – table top distance :	max. 1200 mm
Angulaton X-ray tube assembly	
Around horizontal support arm:	± 120°
Around tube column (optional):	± 90°
Detents at:	- 90°, 0°, + 90°
Vertical travel supporting arm:	1642 mm
Tube stand longitudinal travel:	1285 mm
Tube stand longitudinal travel, FFD 3m with long rails:	1985 mm

Detailed information please find in the enclosed User Manual, Technical Description of the PROGNOST FS.

7.5 Vertical wall stand

Standard	
Column height:	2133 mm
Vertical shift film center:	1310 mm
Version long column	
Column height:	2333 mm
Vertical shift film center:	1510 mm

The Bucky, Grid entity and the measure chambers are connected to the generator.

Detailed information please find in the enclosed User Manual, Technical Description of the PROVERT.

7.6 Attenuation Equivalent

WARNING!

The radiographic system PRS 500 F can be delivered with different options on the Grid Entity/Bucky.
The attenuation factor must be determined at the final inspection at the customer. The variables like X-ray tube, Collimator etc. have influence to the factor. The attenuation value of the components can be read out of the accompanying documents of the component. The attenuation value has to be determined at the technical specifications. If the limits can't be kept please inform PROTEC immediately. If additional accessories are use it has a negative influence to the quality of the X-ray image.

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

The cover vertical wall stand is defined as application part.
The aluminium attenuation equivalent of the cover vertical wall stand is typically 0,4 and < 0,5 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 F 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

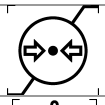
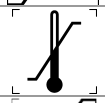
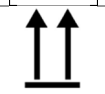
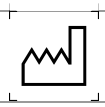
Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

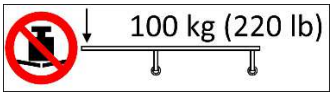
7.8.2 Environmental Conditions for Shipping and Storage

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

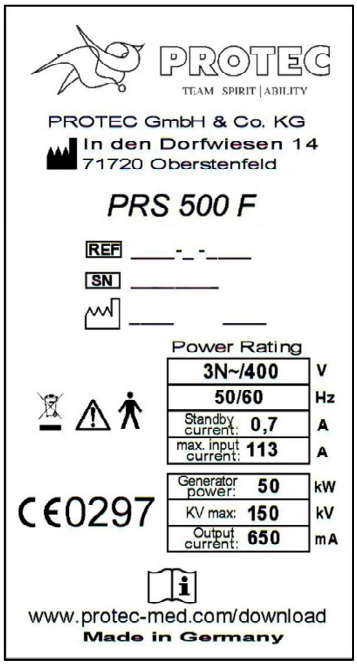
8 Description of symbols, labels and abbreviations

8.1 Symbols

	Limitation atmospheric pressure
	Limitation temperature
	Limitation humidity
	Keep dry
	Fragile, Handle with care
	This way up
	Attention, consult accompanying documents
	Refer to user manual
CE 0297	CE-Mark
	Manufacturer
Typ	Trade name
REF	Order number
SN	Serial number
	Date of manufacture
	Classification according to EN 60601-1 (Type B)
 www.protec-med.com/download	With this symbol we point out that Usage instructions of the corresponding product is on out Homepage
	Notes on disposal; WEEE , Waste of Electrical and Electronic Equipment
	Protective ground (Earth)
	Caution: pinch-/crushing hazard for hands and fingers

	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight

8.2 Identification label

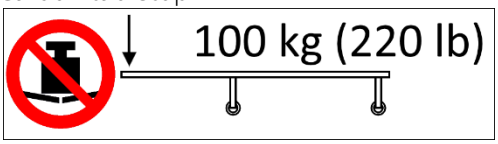


x Exemplary for PRS 500 F with X-ray generator 50 kW

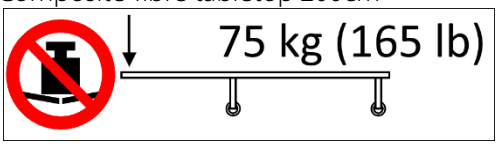
8.3 Labels

Labels on the side of the tabletop

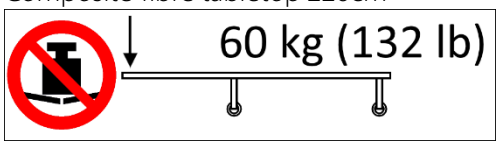
Carbon tabletop



Composite-fibre tabletop 200cm



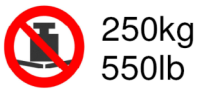
Composite-fibre tabletop 226cm



Labels on top of the tabletop

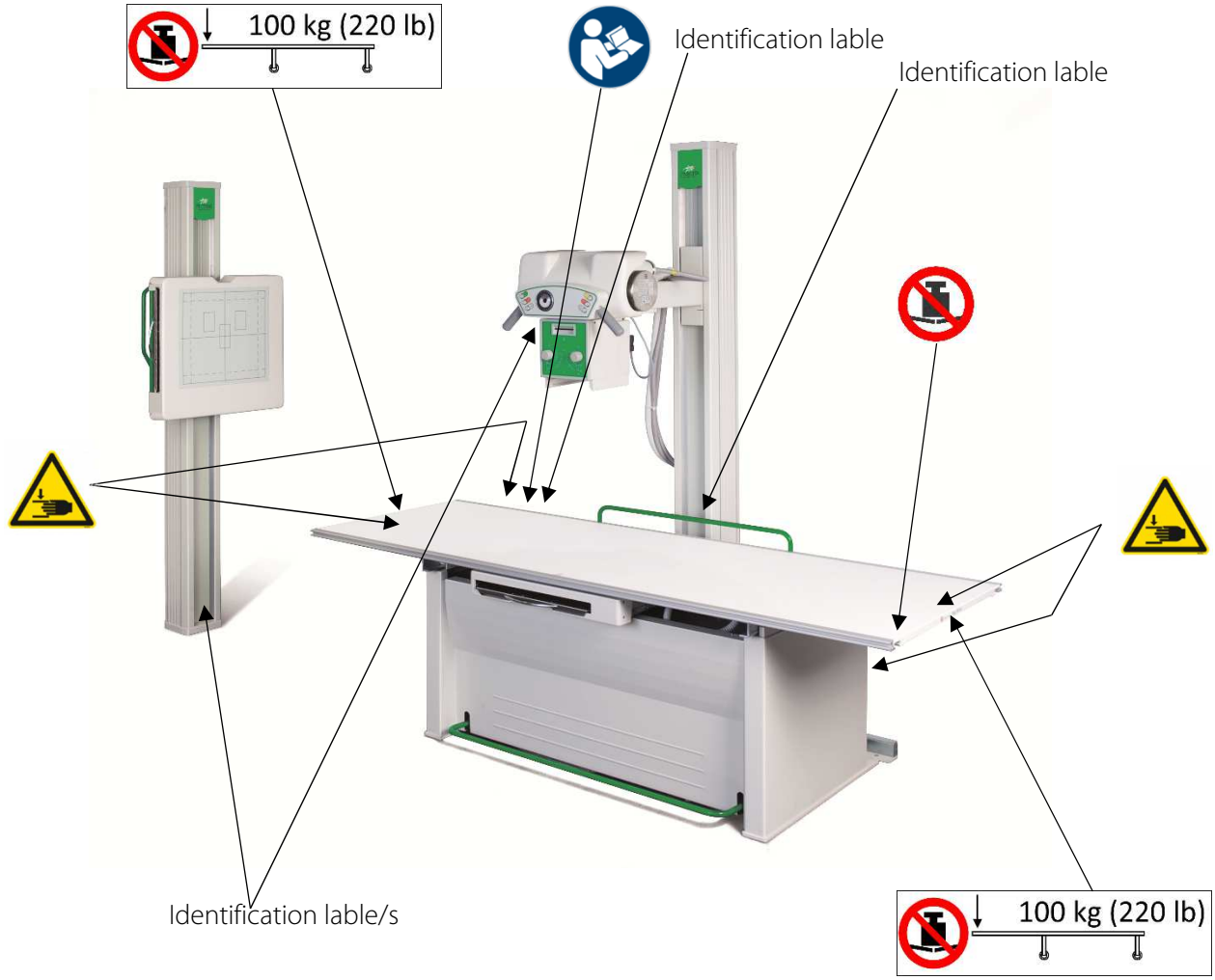
Caution: Possible pinch-/crushing hazard fort he hands and fingers while moving the tabletop, table and or X-ray tube assembly unit.

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



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

8.4 Position symbols and labels



8.5 Abbreviations

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