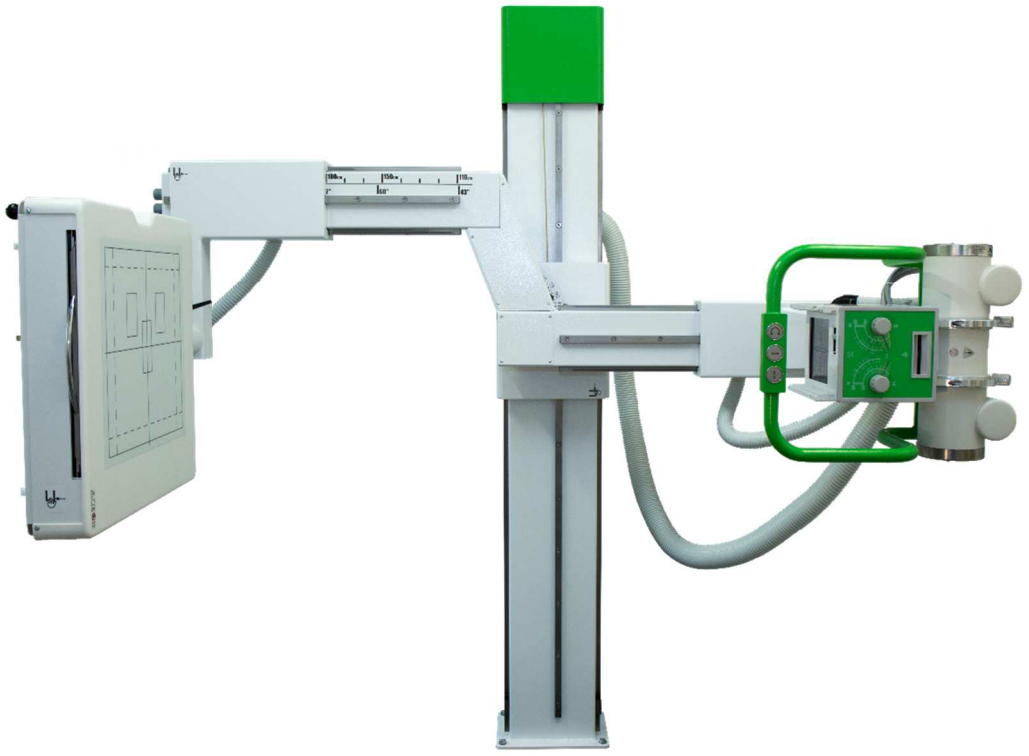
PEDS 600

Basic diagnostic X-ray system

Model/ID: 7090-9-8xxxL

User Manual

Ident. Nr. 5090-0-0002



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	2018-11-16	all	new layout, replaced V2.0

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.

The system causes different ionising radiation. The purpose is to create characteristic X-ray radiation. The intensity depends on the adjusted values of voltage, current and time. The radiation comes orthogonal out of the X-ray tube and is limited by the collimator.

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 PEDS 600, knowledge of which are required for efficient and effective use of the radiographic system.

Prior to working with the PEDS 600, 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 PEDS 600 can be equipment or customized with the following components:

- Horizontal, height adjustable patient positioning table with floating tabletop and integrated column stand with control arm,
- Bucky with cassette tray or detector- grid unit
- X-Ray Generator
- X-Ray tube assembly with housing* and
- Collimator*

Optional components

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

Optional Accessories

The PEDS 600 can be equipment or customized with the following accessories:

- CONAXX 2 software
- Mobile movement patient table*
- Compression band*
- Dose area product meter system

* 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" PEDS 600
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 PEDS 600 has a weight of 300kg (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

Due to its compact design, the system is ideally suited for orthopaedics, surgery and traumatology, where a small space is of the essence.

- Wide range of applications
- High reliability
- The floor-wall mounting ensure a secure stand
- A freestanding version is also available as an option.
- 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 analog or digital use

1.4 Intended use

The general-purpose diagnostic X-ray systems PEDS 600 is intended for various routine applications in planar X-ray imaging in human medicine.
It is a stationary system 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 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**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 PEDS 600 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

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 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 PES 600 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 PEDS 600 with stand is a Class I ME product (according to EN 60601-1).
This device contains no on/off switch. The PEDS 600 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 PEDS 600 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 X-ray system PEDS 600, 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 PEDS 600 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.

2.1.5 Explosion protection

These radiographic system PEDS 600 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 PEDS 600 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 PEDS 600 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 PEDS 600 is intended for the usage in a professional environment of the medical service (e.g. clinic, surgery centers, physiology offices …)

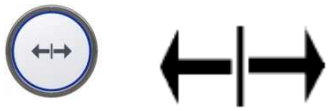
3 Control elements and device displays

3.1 Operating elements on the swivel arm

3.1.1 Button Rotation

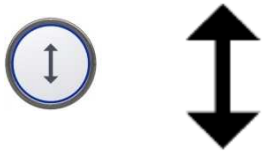
This button releases the cross arm brake, allowing the cross arm to rotate. The rotation dial displays the degree of rotation in relation to the initial horizontal position.
The brake snaps in safely every 5°. When moving the cross arm to another angular position, the rotation movement needs to be slowed down and stopped before releasing the button. Otherwise, the brake unit could be mechanically damaged.

3.1.2 Button SID



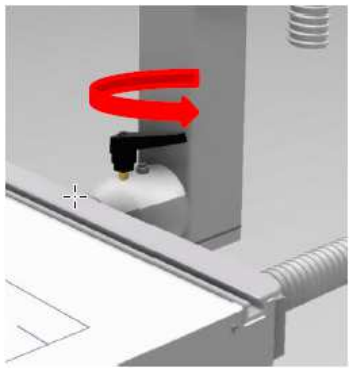
This button releases the brake on the two transverse carriages. The SID (Source Image Distance) can be easily set while pressing the button.
When adjusting the distance, the movement must be stopped before the button is released. A hard drive into the end stops should also be avoided. Otherwise mechanical damage can occur in both cases.

3.1.3 Button Vertical Movement



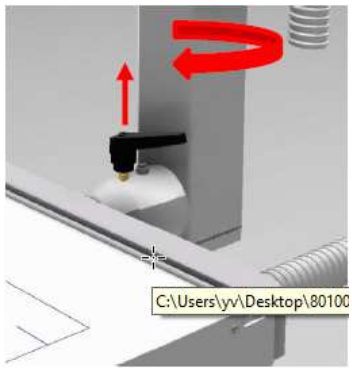
Pressing this button releases the brake of the vertical carriage. The vertical carriage can be moved up and down by hand while pressing the button.
It is absolutely necessary to stop the driving movement before releasing the button. Otherwise this will cause mechanical damage

3.1.4 Clamping lever



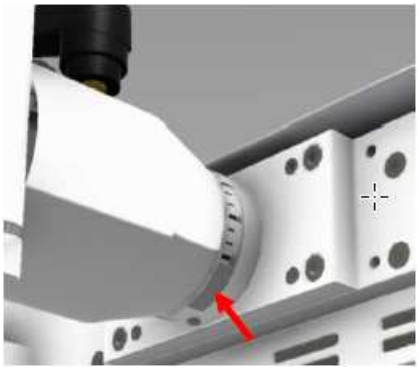
A slight rotation of the clamping lever releases the rotation movement of the imaging support or X-ray tube.

In case the lever is in an unfavourable position, the lever can be brought into a better position.



By lifting (pulling) the lever the serration is released and the lever can be put into the most favourable locking or unlocking position. When “letting go” the lever, it will catch again.

3.1.5 Angle indication ring



The rotation movements of the arm gives you the possibility to set an angle for oblique projections or even to rotate by 90° in order to perform e. g. a radiography of the foot on the floor.

The values on the rotation gauge are indicative points. The 0° initial position has to be set by using the collimator light beam and the Bucky marking.

3.2 Control elements and device displays collimator

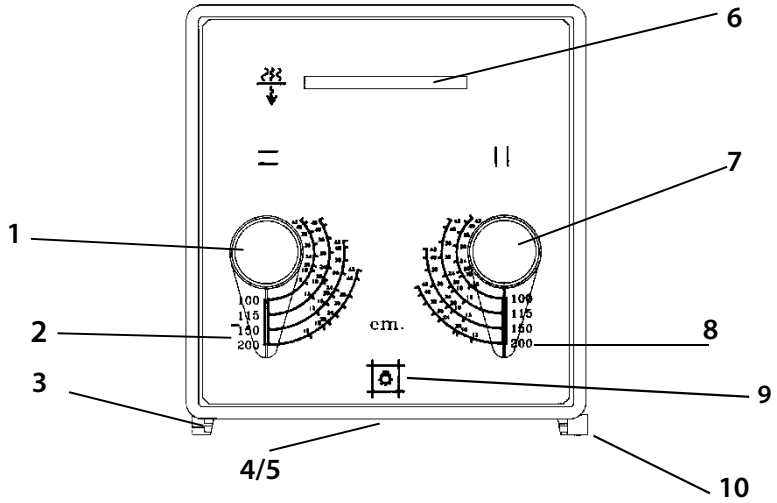


Figure collimator, may differ depending on the system.

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 selection 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.

3.3 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

Detailed information please find in the enclosed User Manual.

3.6 Control elements and device displays of RAPIXX system

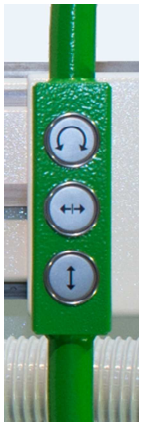
Detailed information please find in the enclosed User Manual of the RAPIXX system.

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 Operate the stand



The universal support is used to set the position of the X-ray source (X-ray tube) and the X-raying unit (flat panel detector in the docking station), or to set them in another position such as the floor, wall or table, as required.
There are three different axes. Pressing a button releases an electromagnetic brake lock in each axis. These buttons are located on the cross arm control unit. Control arm with control unit. Control buttons for positioning the support

The mechanical brake units are unfixed by an electromagnet which is controlled by one button on each command arm. The brake remains released as long as the button is pressed. As soon as the button is released, the brake locks again. The electromagnets are only designed for short-term operation. If they remain switched on too long, this can lead to malfunctions or defects of the magnets. The button for the respective travel movement must not be pressed for more than 40 seconds within 5 minutes.

NOTE

Important for tripod settings

- Push the button
- Positioning SID / Rotation / Vertical travel
- Brake gently the movement
- Release the button
- Softly engage the brake

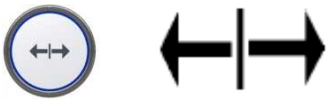
A hard impact on th end stops must be avoided

4.1.1 Button Rotation

This button releases the cross arm brake, allowing the cross arm to rotate. The rotation dial displays the degree of rotation in relation to the initial horizontal position.
The brake snaps in safely every 5°. When moving the cross arm to another angular position, the rotation movement needs to be slowed down and stopped before releasing the button. Otherwise, the brake unit could be mechanically damaged.
IMPORTANT:

- Push the button
- Rotate the cross arm
- Brake gently the rotating movement and stop
- Release the button
- Softly engage the brake

4.1.2 Button SID



This button releases the brake on the two transverse carriages. The SID (Source Image Distance) can be easily set while pressing the button.
When adjusting the distance, the movement must be stopped before the button is released. A hard drive into the end stops should also be avoided. Otherwise mechanical damage can occur in both cases.
IMPORTANT:

- Push the button
- Adjust the distance
- Brake gently the distance movement and stop
- Release the button
- Allow brake to engage by slight displacement

Do not drive hard into the end stops!

4.1.3 Button Vertical Movement

Pressing this button releases the brake of the vertical carriage. The vertical carriage can be moved up and down by hand while pressing the button.
It is absolutely necessary to stop the driving movement before releasing the button. Otherwise this will cause mechanical damage.
IMPORTANT:

- Push the button
- Adjust the vertical position
- Brake gently the movement and stop
- Release the button

The movement needs to be stopped before releasing the button. Otherwise, the brake unit could be mechanically damaged.

ATTENTION!

When positioning the tube and docking station, mechanical parts are set in motion. Due to their large size, these parts generate a considerable mechanical force. Failure to move these parts carefully or to follow the instructions may lead to the following:

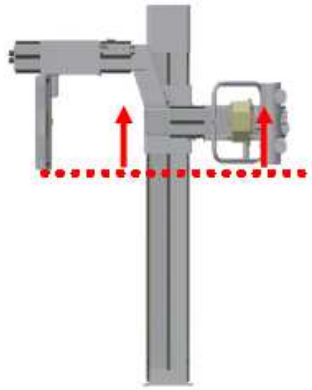
- **Danger of damage: machine parts and objects near the machine (including the floor, covers or X-ray table) may be seriously damaged. Patients and operating personnel may also risk injury.**
- **Danger of jamming or crushing on the one hand between parts of the device and the environment, on the other hand when holding on to certain points of the tripod. The risk of injury - in particular the pinching or squeezing of fingers - is practically eliminated by suitable design precautions. Where this is not possible, a warning sign is attached. In addition, the operator must ensure that nobody holds on to the designated points or is within the range of the moving parts during the positioning process. In principle, as many pre-setting as possible must be made before positioning the patient to be examined, so that only fine adjustments on the tripod are necessary if necessary. Rotation is only allowed in the rotation position.**

4.1.4 Rotation the X-ray tube

The tube can be tilted at an angle to take radiographs or rotated 90° to take X-rays of the foot on the floor.

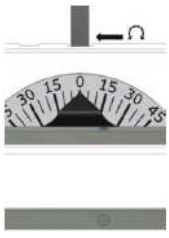
The values on the rotation dial indicate the brake points. Set the 0° initial position using the collimator and docking station mark.

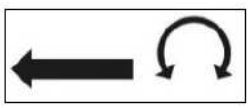
4.1.5 Parking position



The vertical carriage with the transversal arm is kept in balance by a spring inside the wall column. If the carriage is fixed at the highest position, the spring is only under light stress. If, however, the vertical carriage is fixed at the lowest position, the spring is under maximum stress.
In case the device is not used for a longer period (e.g. during the night or during holidays, vacation etc.) and in order to extend the life cycle of the tension spring, it is recommended to drive the vertical carriage to a parking position which lies at least at the height of the rotation mark or above.

4.1.6 Rotation marking transversal arm





Marking aid for rotating movement
With low ceilings it is not possible to rotate the transversal arm without a risk of collision with floor or ceiling. It can therefore be helpful to use a marker for the rotation position which can be placed on the wall column. When rotating the transversal arm in this position it is important to do this with the smallest FFD set. The reference line is the upper edge of the vertical carriage. The edge must be moved towards the center of the arrow.

4.1.7 Setting technique

NOTE

As a general rule, it is important to make as many adjustments to the machine as possible before positioning the patient on it. In that way, once the patient is in position, you will only need to make slight adjustments. Only rotate parts when the machine is in the rotation position.

4.1.7.1 Procedure for patient positioning without mobile X-ray table

1. Set the SID to e.g. 1200 mm.
2. Set vertical carriage to rotation mark.
3. Perform rotational movement.
4. Set vertical carriage to the required height (watch out for ceiling or floor collision risk).
5. Guide the patient into the room and position him according to the usual setting technique.

4.1.7.2 Procedure for patient positioning with mobile X-ray table

1. Set the SID to e.g. 1200 mm.
2. Set vertical carriage to the marked height (see rotation mark on stand column).
3. Perform all rotational movements first and then any other operation.
4. Guide the patient into the room and place him on the mobile X-ray table.
5. Move the mobile table with the lying patient above the Bucky.
6. Recommendation: Keep a general free space of 20 mm between Bucky and table.
7. During all movements with the mobile table, it is essential that the patient keeps all extremities on the mobile support at all times (pinching hazard).

4.2 Operation of the collimator

Consult the User Manual for the collimator (provided separately).

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 PROVARIO HF 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 cap. 5.3….

Detailed information please find in the enclosed user manual of the X-ray tube (provided separately).

4.4 Operation of the generator

Detailed information please find in the enclosed user manual of the X-ray generator (provided separately).

4.5 Operation of the Bucky

Detailed information please find in the enclosed user manual of the Bucky/Grid entity (provided separately).

4.6 Operation of the RAPIXX system

Detailed information please find in the enclosed user manual of the RAPIXX DR system (provided separately).

4.7 Operation of the software

Detailed information please find in the enclosed user manual of CONAXX 2 (provided separately)

4.8 Function of the PEDS 600

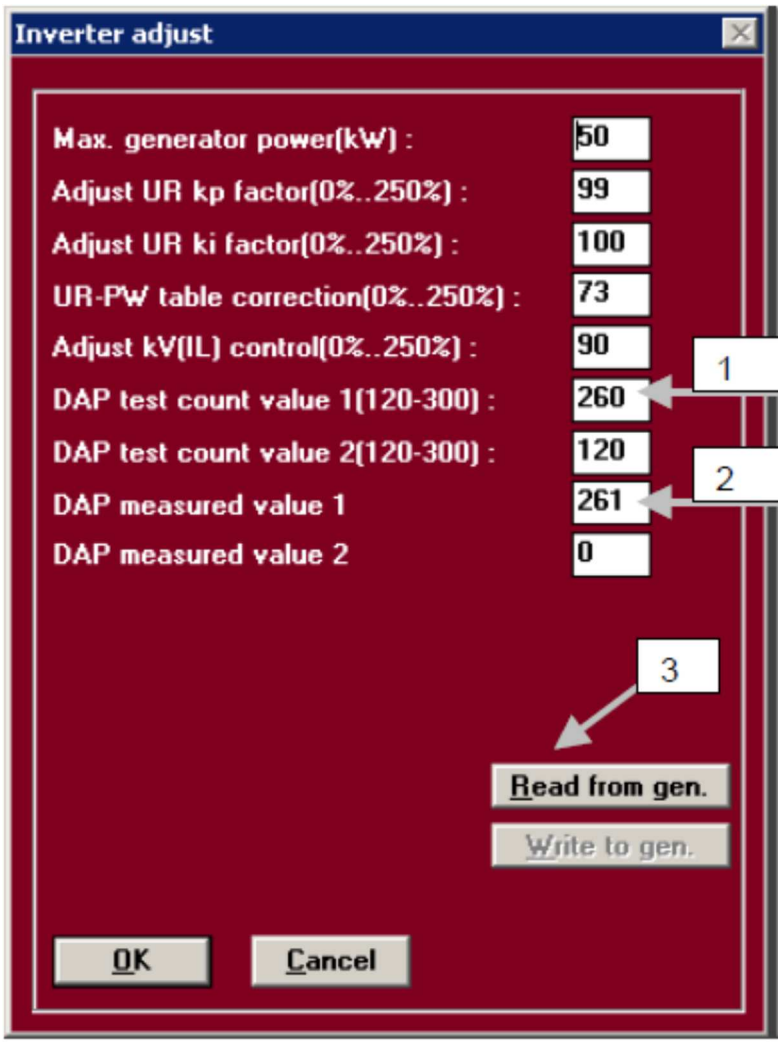
4.8.1 Switching On/Off the PEDS 600

Switching on the PEDS 600 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 of the generator.

	Switch on the x-Ray generator	button POW1
	Switch of the x-Ray generator	button POW2

4.8.2 Dosimetric Calibration

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…

4.9 Exposure automatic

If the PEDS 600 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 a 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 cleaning of the X-ray imaging system PEDS 600 is very easy due to the high quality surface coating. This is usually only done with a dry cloth. No caustic, solvent or abrasive cleaning agents may be used which could damage the device surfaces or the lacquer.

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 PEDS 600, 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.

NOTE

- After each use, the contact surfaces of the tripod, Bucky and X-ray tube (as well as other parts of the X-ray unit in contact with the patient) must be cleaned and disinfected.
- Disinfect all contaminated contact surfaces with common surface disinfectants. It may only be disinfected with a cloth moistened with disinfectant solution.
- Alcohol-free and aldehyde-free disinfection wipes are primarily suitable for this purpose. (e.g. Bode Mikrobac® Tissues).
- It should be noted that agents with a very high alcohol content must generally not be used to disinfect the Bucky front panel. Treating the front panel with such agents can cause material damage.
- Under no circumstances should any parts or components be poured over or sprayed with the disinfectant solution. This could lead to short circuits in the electrical and electronic components.

5.3 Check-up and maintenance

WARNING!

It's forbidden to make any check-up or maintenance services while the PEDS 600 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 Regular controls

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.

NOTE

The traction rope must be replaced every 3 years.

The counting starts with the first installation (corresponds approx. to the delivery date).

The traction rope is subject to very different wear due to the up and down movements of the vertical carriage.

The manufacturer prescribes that the traction rope (connecting wire rope between traction spring and vertical wagon) must be replaced every 3 years by trained service personnel and replaced by original components.

The rope change must be documented (protocol in the Appendix of the service manual).

5.3.2 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.

5.3.3 Product life time

The PEDS 600 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.
Wear parts like ball bearings, telescopic slides, spring-loaded pressing elements etc. strongly depend on the utilization of the installation. Before the limit of 10 years, they may show defects or damages which, however, are not safety-relevant but which may require a repair or the supply of spare parts.
The traction rope must be replaced every 3 years with original components.

5.3.4 Further Information

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

5.3.5 Liability

NOTE

We hereby expressly point out that PROTEC excludes any liability under the following points:

- Non-compliance with maintenance intervals
- Operation by untrained personnel
- Service and maintenance work by personnel not trained or authorized by PROTEC

5.3.6 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)
Cover Buckyframe	Applied part

5.3.7 Disposal

The X-ray system PEDS 600 contains different plastics, oils and heavy metal (counterweight). At disposal of exchange parts or the whole system the current regulations have to be observed. Please contact your contractual partner or the service company, or a company specialized for disposing the components.

6 Electrical data

NOTE

The X-ray 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**
Output Power	50kW	65kW	80kW
Power supply voltage	400V AC		
Phase	3PH+N		
Power frequency	50/60 Hz		
Electrical resistance per phase	0,3Ω	0,2Ω	0,12Ω
Fuse	50A inert		

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 PEDS 600 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 PEDS 600. Disregarding this can cause a decrease in the performance features of the device.

CAUTION!

The X-Ray generator integrated into the radiographic system PEDS 600 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 PEDS 600 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 PEDS 600 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

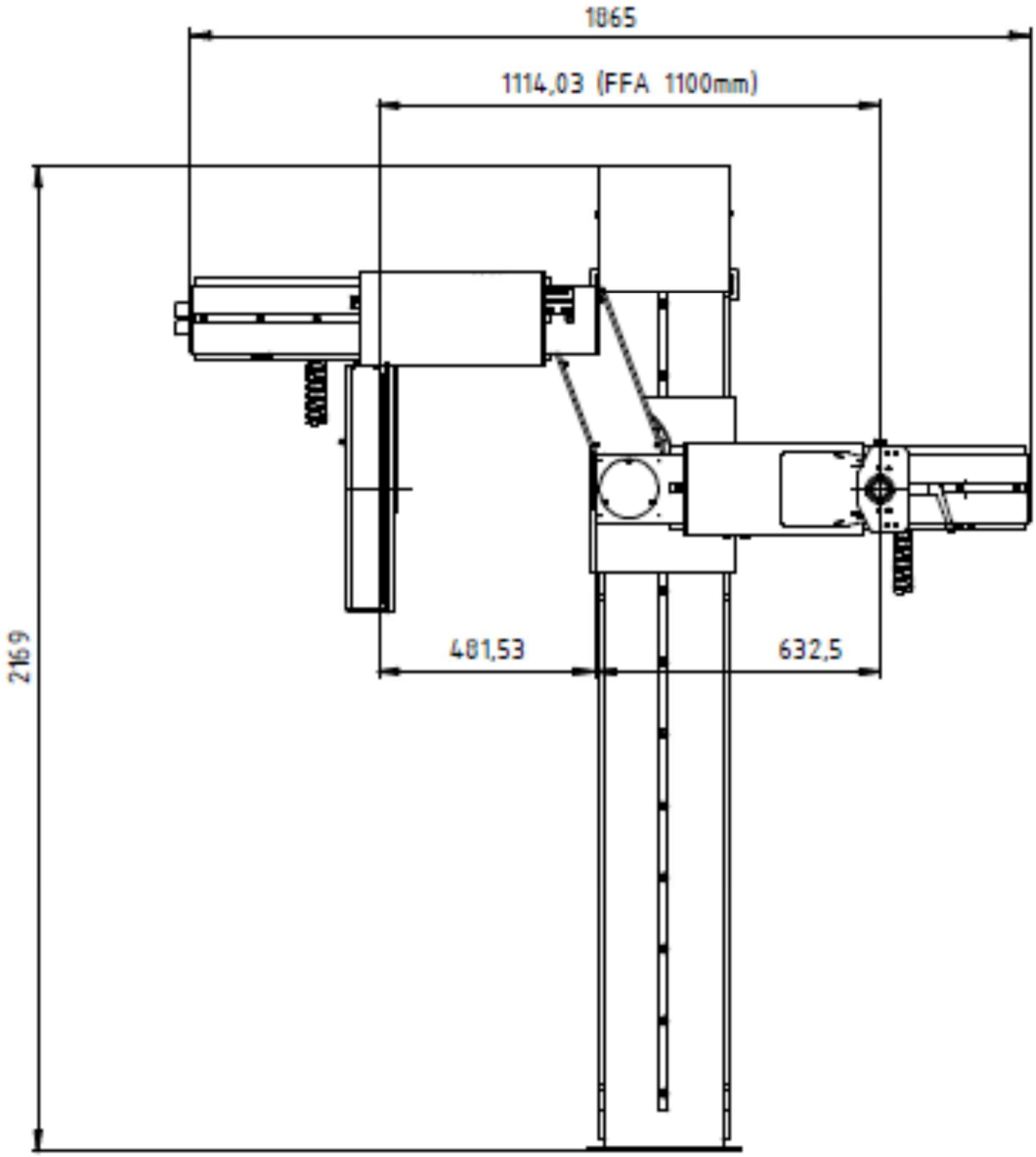
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

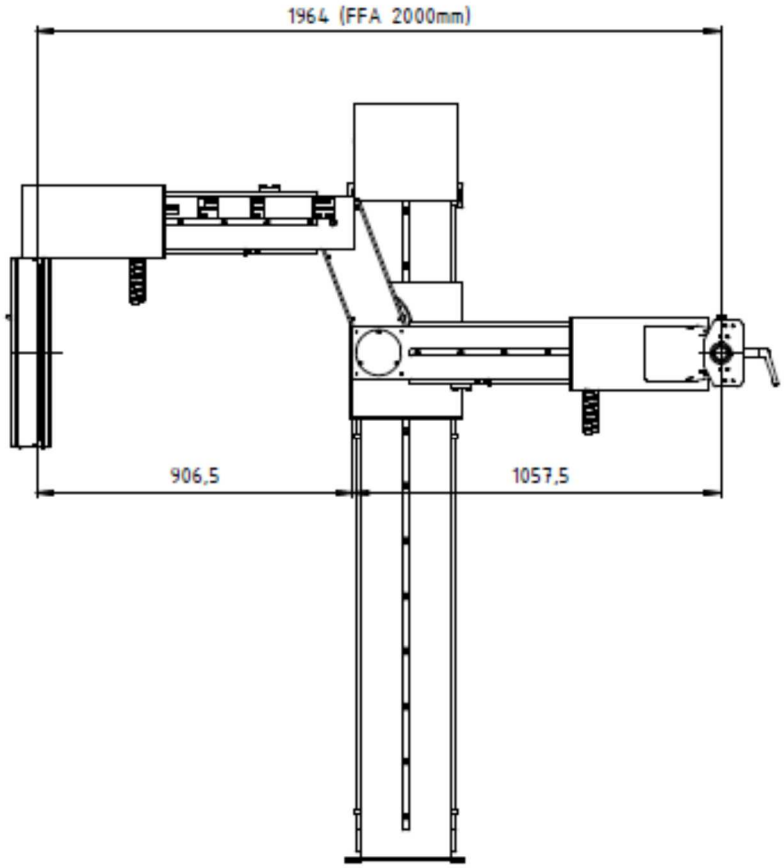
7 Technical Data

SID range	1,1 m to 2 m
Max. detector area	430 mm x 430 mm
Rotation range of tube assembly	± 90°
Rotation range of U-arm	+135° / -30°
Min. room height	2300 mm
Weight (without third-party components)	ca. 300kg
Colour	RAL 9002
Electrical specifications	24 VAC / 5A / 50Hz / 160VA
Protection class	IP 20

7.1 Dimensions

Minimal room height for usage with a X-ray table from PROTEC is 2.5meter.





7.2 Attenuation Equivalent

WARNING!

The X-ray system PEDS 600 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 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.

7.2.1 Protection Art and Protection Class

The x-ray system PEDS 600 is consistent with a protection class 1 device and contains applicable parts Type B (according to EN 60601-1).Environmental conditions.

7.3 Automatic cutoff dose

7.3.1 Analogue System

The automatic cutoff dose is 2,5µGy.

7.3.2 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)

7.4 Environmental

7.4.1 Environmental conditions for operation and storage

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

7.4.2 Environmental Conditions for transport

Ambient Temperature	- 25°C to + 70°C
Relative humidity	5% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa

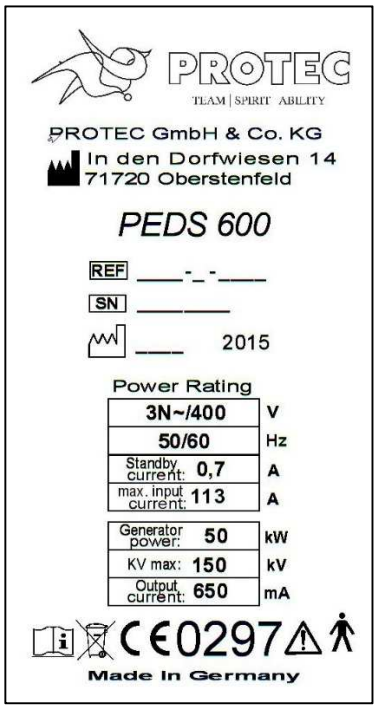
8 Description of symbols, labels and abbreviations

8.1 Symbols

	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
PEDS 600	Product label

	Operating element PEDS 600 Vertical movement Film-focus distance SID Rotation

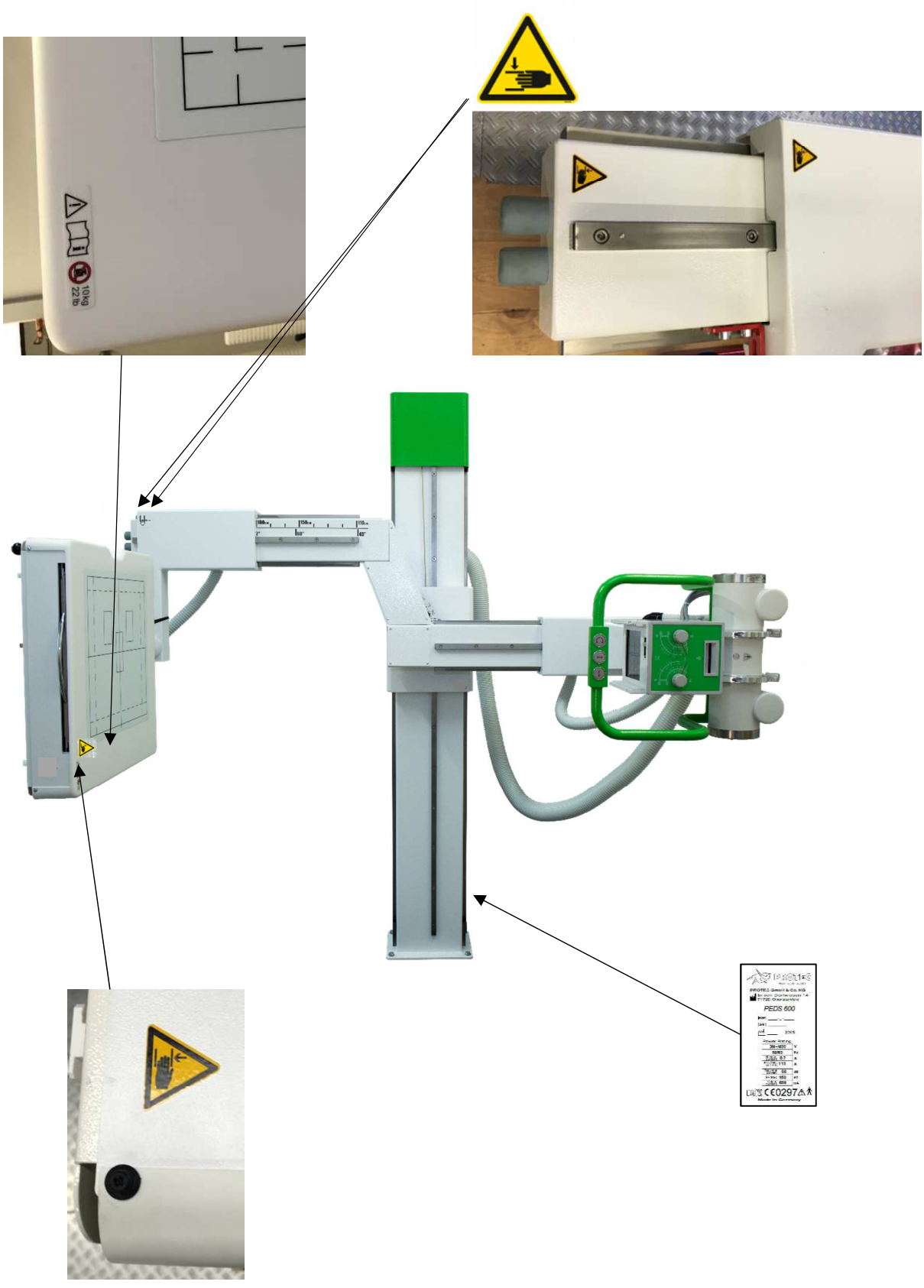
8.2 Identification label



8.3 Labels

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

8.4 Position symbols and labels



8.5 Abbreviations

mm	Millimetres
cm	Centimetres
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