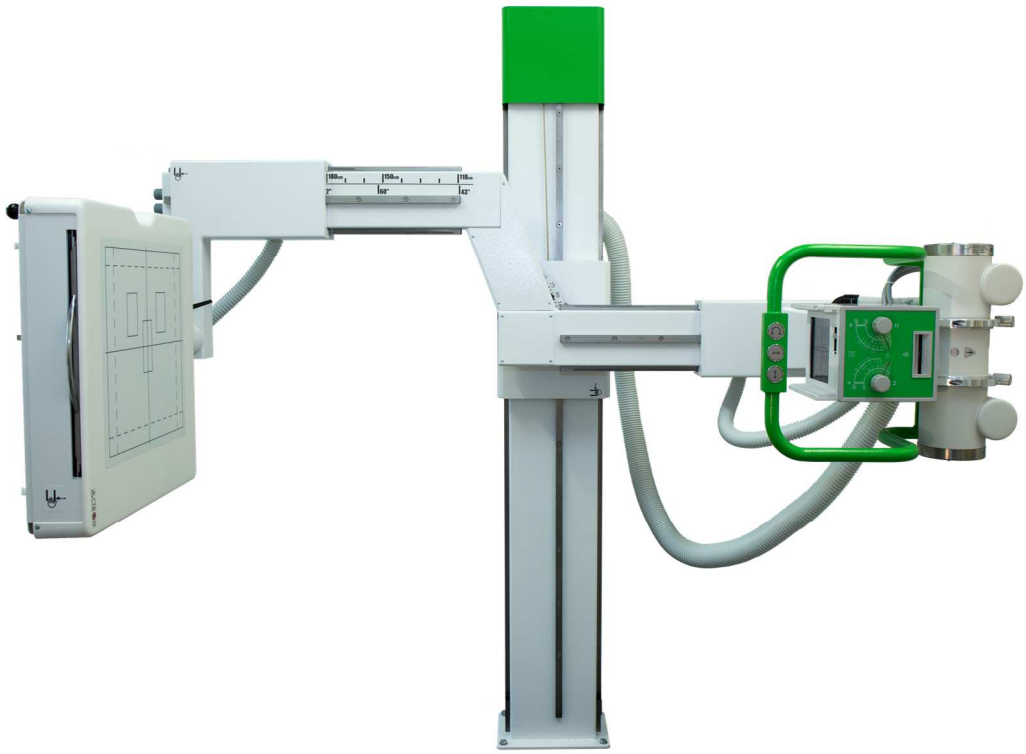
PEDS 600

Tube assembly and detector mounted at one single device

Model/ID: 7090-9-8xxx(L)

User Manual

Ident. Nr. 5090-0-0002



CE 0297

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These accompanying documents were created and distributed by the documentation department.
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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 Version

Revision	Date	List of revised pages	Comments
2.0	04/05/2016	all	Layout new, chapter 8 new

Mechanical–Electrical 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

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 kind of systems.
Those persons responsible for the planning and installation of this equipment must observe the national regulations.

To the User

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.
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.

Improvement Recommendations

Users of this Document are encouraged to report errors, omissions and improvement recommendations to **PROTEC GmbH & Co. KG.**

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 table 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 Intended use

The PROTEC PEDS 600 radiography system is intended for general radiologic X-ray exposures in the diagnostic human medicine. The use of the system is only for professional users who are trained in the operation of diagnostic X-ray equipment in accordance with the respective national regulations and who were instructed in the appropriate handling, use and operation as well as in the permitted connection with other medical devices, objects and accessories.

The PEDS 600 system is equal to a swivelling arm system and is used as a universal, horizontal X-ray workplace. It supports all exposure techniques in the areas orthopaedics, surgery and urology.

1.3 Intended user group

The radiographic system PEDS 600 is exclusively designated for use by professionals who are trained, in accordance with the corresponding national regulations, in the use of diagnostic X-Ray equipment and its proper (certified) use in connection with other medical products, objects and accessories.

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

1.4 Conformity

CE

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

The declaration of conformity is available directly from PROTEC:

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1.5 Produkt Description

1.5.1 Description

The PROTEX X-ray System PEDS 600 to be built up of following components:

- X-ray stand
- Optional DR-Bucky and RAPIXX DR-Flatpanel system
- Optional Bucky with cassette tray
- Optional 3-field ionisation chamber
- Optional Grid
- X-ray tube
- Collimator, rotatable with or without filter selection
- High frequency generator

Optional accessories

- CONAXX 2 Software
- Mobile movement patient table
- Compression Band
- Dose area product meter system

1.6 Labels

The company label (Figure1.6) find you at the back of the X-ray stand, on the floor.

Figure 1.6

2 Safety Instructions

2.7 General safety notice

Adjustments and calibrations that are described within the user manual must be made, with the aid of the technical description for PEDS 600, by the **PROTEC** customer service department or a PROTEC authorized service technician.

The operator(s) are required, prior to initial use of the product; to become acquainted with all control elements and their functionality.
All care and maintenance work should always be completed as suggested by the manufacturer.
The maintenance work must be recorded.

2.7.1 Requirement for operation

The PEDS 600 is a component of a complete X-Ray system. This product is to be outfitted and operated with a commercially available X-Ray tube and image acquisition unit, for which the high voltage, low voltage and ground will be supplied through direct connection to the X-Ray generator. All components within this system are required to fulfill the requirements of the MDD (Medical Device Directive 93/42/EEC) and contain the CE label.

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 PEDS 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 connecting ports with 230V 50/60 Hz.
The PEDS 600 is a ME Class I product.
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 power the connected X-Ray generator must be shut off.

A complete X-Ray system is only allowed to be taken into normal operation by customers when the **PROTEC** customer service department or PROTEC authorized service technician has successfully completed the installation and the system has been officially handed over to the customer.

It is important to ensure that all required registration activities are completed prior to initial use.
The national regulations regarding the approval of newly installed X-Ray Units as well as additional monitoring of the unit throughout its operational life by official testing organizations must be followed.
Additionally, it is absolutely necessary to follow the Maintenance specifications as set out in Chapter 5.

2.7.2 Operator

The PEDS 600 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.

Only properly trained and authorized personnel are allowed to work with the PEDS 600

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.

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 basis for orderly operation.

2.7.3 Explosion protection

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

2.7.4 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.

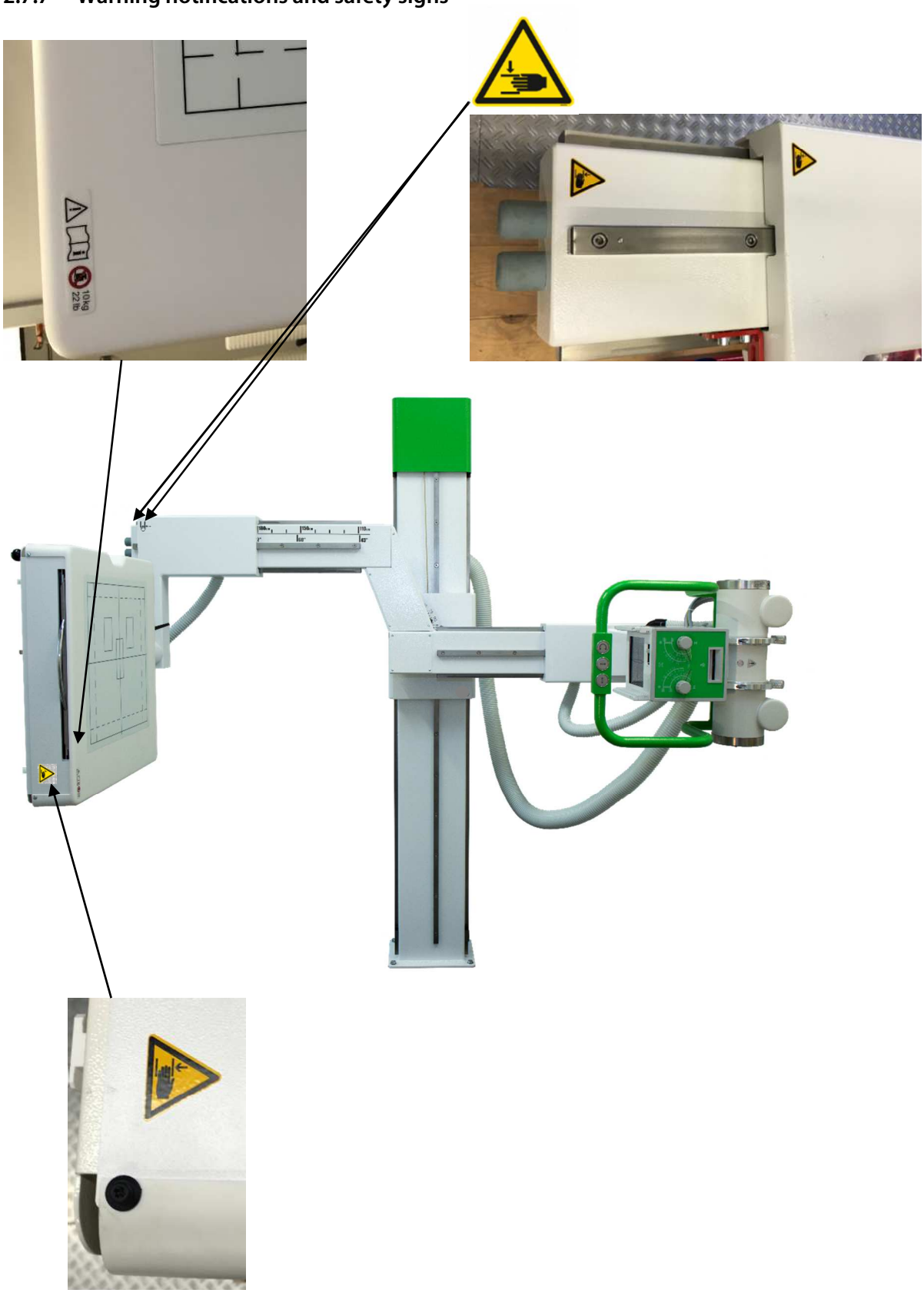
2.7.5 Ventilation

It is important to ensure that the air exchange of the X-Ray generator with the PEDS 600 is not hindered. The ambient air temperature is not allowed to exceed 40°C.

2.7.6 Interaction with external devices

Unwanted interaction with external devices is not known.

2.7.7 Warning notifications and safety signs



3 Control elements and device display

3.1 Rotating the cross arm

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.
Attention / URGENT:

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

3.2 Focus film distance (FFD) - button

This button releases the brake on the two horizontal carriages. The focus film distance is easy to set with this button
Attention / URGENT:

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

Do not run hard to the end stop!

3.3 Vertical travel

When you press this button, the brake on the vertical carriage is released so that it can move up and down the vertical axis.
Attention / URGENT:

- 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.

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

Safety warnings: mechanical loads
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 trapping fingers** either between parts of the machine and nearby objects, or when holding on to the support.

The machine has been designed so that the risk of damage or trapping fingers is reduced to a minimum. Nevertheless, any parts that may still pose a risk bear a caution label. In addition, when setting the machine, operating personnel must ensure that no one is holding on to the machine or standing between moving parts.
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

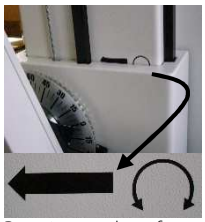
Urgent for every adjustment oft the FFD / Rotation / vertical travel

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

4.2 Setting technique

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!

4.2.1 Process of rotation



Rotation mark on front support

To avoid accidents, set the cross arm to the rotation position before beginning
the rotation procedure:

- X-ray table in standby position (outside the area of rotation)
- move the cross arm onto the rotation mark on the support
- set the focus film distance to 120cm

You can now rotate the cross arm to the required position.

4.2.2 Process of positioning with the Patient bench (table)

- Set the FFC to be at 1200mm.
- Move the stand into the marked vertical position (see the rotation indicator on the stand column).
- First conduct all movements related to rotation prior to manipulated (adjusting) the device further.
- Position the table, with patient on the tabletop, above the Bucky.
- Recommendation: It is generally good to leave a distance of 20 mm between the Bucky and the underside of the table.
- The patient must keep all extremities within the confines of the patient table top. (Pinching protection: warning signs on the x-ray tabletop).

4.3 Rotation the X-ray tube

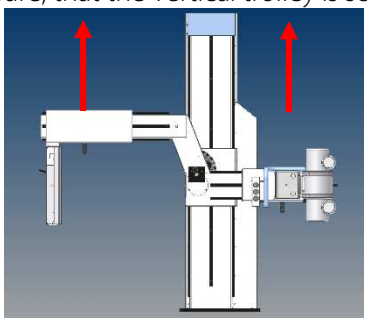
The tube can be tilted at an angle to take radiographs or rotated 90° to take X-rays of the foot on the floor.

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

4.4 Parking position

The vertical trolley is counterbalanced with a spring inside the column. The workload of the spring is different se spring is

If the system is not in permanent use (overnight, bank holiday, vacancy) make sure, that the vertical trolley is set in the parking position.



correct

wrong

4.5 Operation of the Bucky

Consult the individual User Manual for the corresponding Bucky (provided separately).

4.6 Operation of the Software

Consult the User Manual for the CONAXX 2 Software (provided separately).

4.7 Operation of the generator

Consult the operation manual for the corresponding PROVARIO HF generator (provided separately).

4.8 Operation of the mobile movement patient table

Consult the User Manual for the corresponding PROGNOST table (provided separately).

5 Safety and Maintenance

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 table with stand following initial installation.

5.2 Cleaning and disinfection

5.2.1 Cleaning

Caution:

Changes to material are possible

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

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

5.2.3 Allergy

The material selection ensued in all conscience. Today, there are no allergic reaction known with the selected material.

5.3 Check-up and maintenance

Maintenance and repair work may only be performed by qualified personnel. Any intervention by unqualified personnel could result in serious personal injury and/or damage to the machine.
Failure to respect the prescribed service or quality control intervals and any maintenance work or repairs performed by unauthorised personnel will nullify liability and render any guarantee claims void.

As the manufacturer, PROTEC is responsible for safety-related characteristics/ performance of the unit as long as the maintenance, repair and corresponding changes are undertaken by PROTEC or an

expressly from PROTEC authorized service and when components (related to the safety of the unit) are replaced, in the case of component failure, with original spare parts

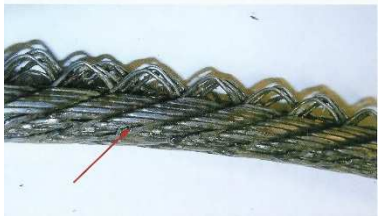
Only original spare parts are to be used in situations requiring component replacement

In the case that the required maintenance is not completed as intended, **PROTEC** is no longer responsible for damages/injury to the operator and/or third party, provided that the damage is the result of improper or missing maintenance.

Tiredness wire fractures
There is no more assurance: If on a length of 20 x rope diameter 10 wire fractures are.)

If, on examination, you discover that some of the cable wires are worn, the
cable must be replaced. Failure to respect this instruction could result in
serious personal injury and/or damage to the machine.

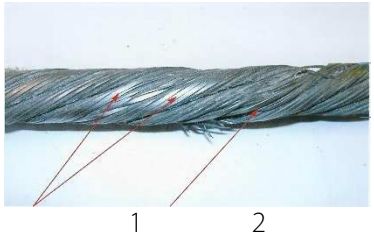
After normal use of 10 years, both cable must be replaced through original components performed by qualified personnel.



Wire fractures from mechanical damage

Wire fractures clusters

Wire fractures



1 2

If the rope diameter d is wears out more than 10 % or the structure changes are like constrictions, flattening and squeezed more than 15%

1. abrasion d ≥ 0.9 x d
2. structure changes d ≥ 0.85 x d

5.4 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.

- The usable life of electronic components as well as parts susceptible to wear and tear such as ball bearings, pull ropes, tension springs, rope pulleys, etc. , is extremely dependent upon the use of the system. These components can show signs of damage or can break prior to the lapse of 10 years which, although not relevant to the safety of the device, can require repair or replacement components.
- After 5 and 10 years of use, the manufacturer recommends an extensive overhaul of the device. In particular it is important to test the components relevant to safety such as pull ropes, falling break, tension springs and all suspension components for material fatigue or wear. Components susceptible to wear and tear are to be replaced only by original parts. The assessments of the technical maintenance personnel are held to be valid. The manufacturer will deny all liability claims related to omitted or neglected maintenance and/ or control of the components relevant to safety.
- The manufacturer is no longer accountable for the functional capability of the system after 15 years. Accountability is reserved for systems with proof of an extensive overhaul / maintenance actions within the last two years.

5.5 Liability

The exclusion of liability in the event of non-compliance with the pre-defined maintenance intervals and/ or a lack of qualification of the operator and service personnel (persons which are not trained or authorized by PROTEC) is hereby noted.

5.6 Guarantee

A 24 month full guarantee of the material and relevant corresponding components, for the entire contents of delivery, is granted from the delivery date (date the product leaves the factory).

The X-Ray tube is excluded from the guarantee

All repairs and replacement of components as a result of misuse and/ or incorrect operation are excluded from the guarantee.

Guarantee work can only be carried out by trained technical staff.

5.7 Disposal

The PEDS 600 does not contain toxic substances. All mechanical and plastic components are to be disposed of in accordance with the corresponding national guidelines. As users of electro- and electronic devices, you are responsible for utilizing the local collection system. In cases of doubt, contact PROTEC.

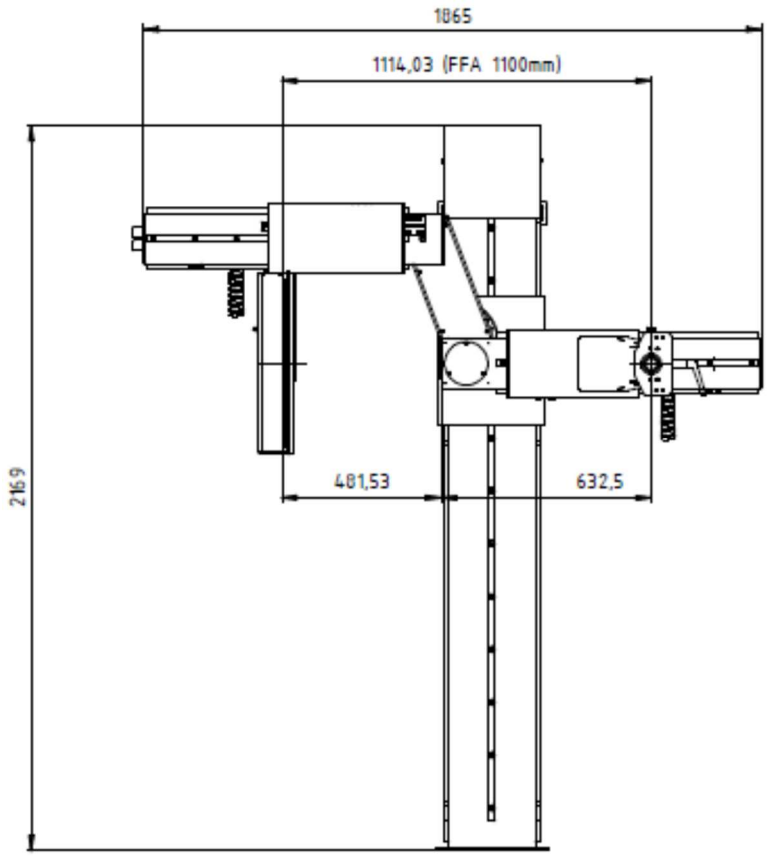
6 Electromagnetic compatibility (EMC) according to EN 60601-1-2

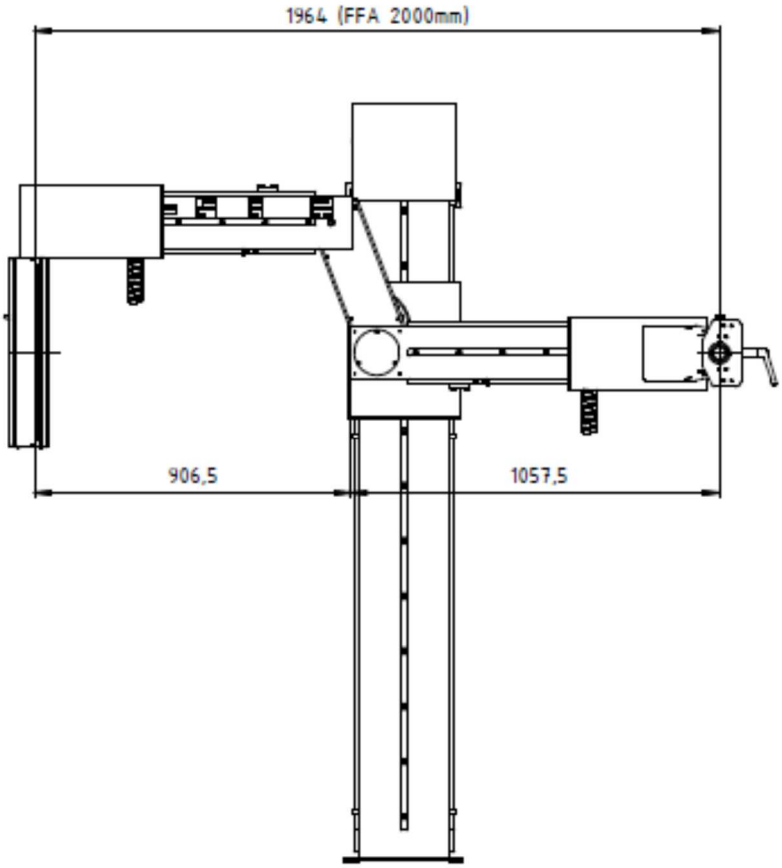
- As an electronic medical device the PEDS 600 is subject to special regulations in regards to precautionary measures related to EMC. The installation and initial operation of the device must be performed in accordance with the EMC relevant indications and /or suggestions located within the accompanying documents.
- Portable and/or mobile HF- communication units can have an influence upon electronic medical devices.
- The PROVARIO HF X-Ray generator integrated into the PEDS 600 radiography system emits electromagnetic waves during normal operation and can, as a result, disrupt and/or be disrupted by other external devices.
  For EMC guidelines and manufacturer declaration(s) according to EN 60601-1-2 see the separately provided operation manual for the corresponding PROVARIO HF X-Ray generator.

7 Technical Data

7.1 Dimension sheet stand views

Minimal room height for usage with a patient trolley 2.5meter.





7.2 Device attenuation factor

The universal stand will be delivered with different Bucky and table options/versions. The device attenuation factor must be ascertained during the acceptance inspection/test. The variable components such as X-Ray tubes, Collimator *(light field indicator),* etc. individually alter the attenuation factor. The determination of the attenuation factor is required to be carried out in accordance with the applicable technical regulations. In the event that the required values cannot be reached and/or adhered to, immediately report the problem to PROTEC.

7.3 Floor load bearing capacity

The universal stand is composed primarily from metal components. The multitude of metallic components has the corresponding effect upon the weight of the device. The weight of the PEDS 600, without additionally mounted components such as the X-Ray tube & Collimator, is equal to 280 kg. An additional weight of approximately 65 kg, as a result of all corresponding mounted equipment, should be added to the final weight for all load calculations.

Every technician is required to test/check, prior to every installation, the load bearing capacity of the floor. It is also important to take raised and or false floors into account. The surface area of the baseplate is equal to 0.076 m^2

7.4 Power supply

The PEDS 600 requires a power supply with an output equal to 24VAC with a nominal capacity of 175VA. The supply is required to be hooked to a source containing a tested/certified 4KV isolating transformer. The isolating transformer cannot break down under a load of 230V.

7.5 Environmental conditions

7.5.1 Environmental conditions during operation

Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 70% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

7.5.2 Environmental conditions during Transport and Storage

Ambient Temperature	- 15°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


Caution, Observe accompanying documents


Classification according to EN 60601-1 (Type B)


CE-Mark


User manual


Year of manufacture


Address of manufacture

Order number of product

Serial number of product


Electrical product. Disposal as domestic waste is prohibited


Caution; Important note


Attention: Crushing hazard from fingers and hands

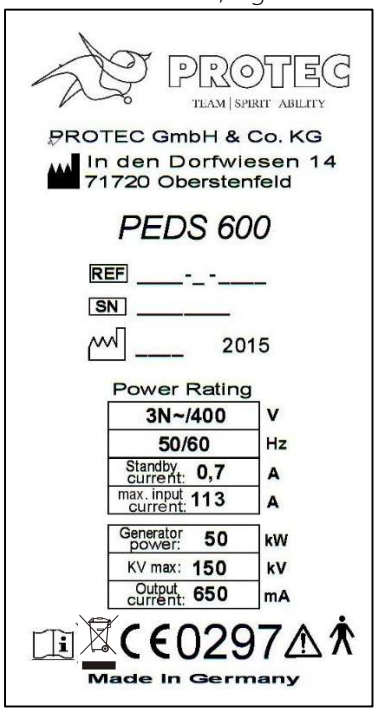

Do not exceed the maximum indicated weight

PEDS 600 Product name


Control elements PEDS 600 (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**)

8.2 Labels

Identification label; Figure with 50KW generator



8.3 Abbreviations

mm	Millimeter
cm	Centimeter
lb.	Pound
kg	Kilogram
Sec	Second
°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