

PEDS 600 System

Stationary basic diagnostic X-ray system

Model/ID: 7095-9-8011
Basis UDI-DI: 426050264X021ZH

System instructions for use shortform

Ident. Nr. 5095-0-0002



Responsible for putting devices together
to this system to Article 22 of
Regulation (EU) 2017/745:

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**NOTE**

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

Revision Status

Revision	Date	Updated pages	Comment	Author
1.0	2019-12-17	all	Original issue	ML
2.0	2020-04-07	Title page, 7, 9, 10	New control unit	ML
3.0	2021-07-20	Title page, 5, 6,	change to article 22	ML
4.0	2022-06-23	11	Handling with detector loading	MB

Radiation Warning**WARNING!**

The system described in this document is for intended generation of X-rays for medical diagnostics-

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 person.

Those persons responsible for the application must have the specific knowledge according to legal requirements and regulations and must establish safe exposure procedure for these kinds of systems. The responsible persons for planning and installation of this equipment must observe the national regulations.

1 Product Description

1.1 Introduction

This Instructions for use shortform summarize the most important information for efficient and effective operation of the PEDS 600 system.



NOTE

Before you work with the PEDS 600 System, it is imperative that you read the applicable instructions for the system components with detailed safety and handling instructions. These documents are in charge and valid in their current version.

1.2 Intended Use

The general-purpose diagnostic X-ray systems PEDS 600 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.

1.3 Clinical Benefit

The clinical benefit of using diagnostic X-ray systems in human medicine is the generation of conventional two-dimensional X-ray images for creation or specification of findings as a basis for treatment decisions.

1.4 Patient target group

The intended patient group includes all people for whom a justifying indication for a medical X-ray has been given by a physician with the necessary expertise in radiation protection.

There are no general or fundamental restrictions on the patient group regarding age, gender, origin and patient condition.

1.5 Medical conditions to be diagnosed

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).

1.5.1 Indications

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 PEDS 600 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.



NOTE

Even if, according to the justifying indication, the benefit predominates the radiation risk, it must not be disregarded that there are residual risks due to ionising radiation and that undesirable side effects may occur. Ionising radiation (X-radiation) can damage the genome and, in the long term, lead to cancer and mutations and thus damage the human body.

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,). 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 mobile 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 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 Declaration according to Article 22

The Declaration according to Article 22 of Regulation (EU) 2017/745 is available on request from PROTEC:

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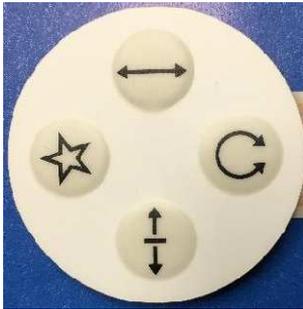
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2 Control Elements and Device Displays

2.1 Operating elements on the PEDS 600 swivel arm system



The controls are arranged in the middle of the control bracket.

The control buttons are used to control the driving axes, as in chapter 2.1.1, 2.1.2 and 2.1.3.

The control button with the star symbol has no function in the standard version.

2.1.1 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.

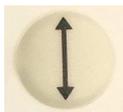
2.1.2 Button SID



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.

2.1.3 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.

2.2 Control elements and displays of the collimator

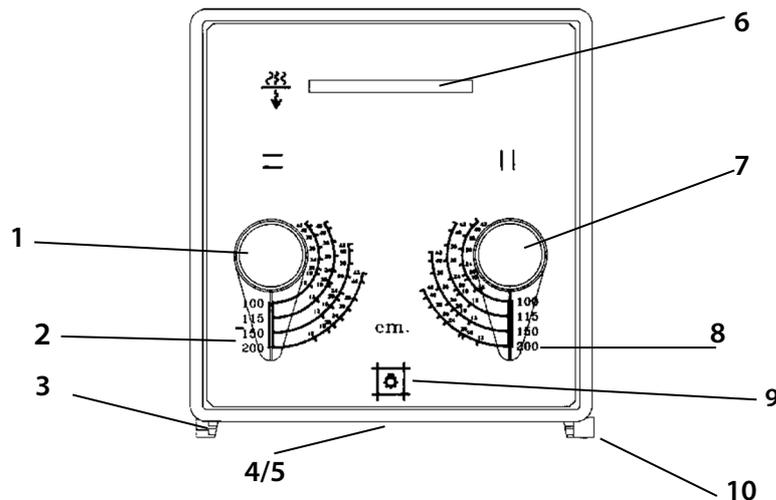


Figure collimator may differ depending on the system.

Pos. 1 -> Collimator adjustment control; allows for manual opening and closing of collimator shutters (transversely to tabletop).

Pos. 2 -> Scales; indicate the opening of collimator shutters (transversely to tabletop).

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 centring device; allows centring 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 tabletop).

Pos. 8 -> Scales; indicate the opening of collimator shutters (longitudinally to tabletop).

Pos. 9 -> Collimator light switch; turns on collimator light.

Pos. 10 -> Measuring tape.

Detailed information please find in the enclosed User Manual collimator.

2.3 Control elements and device displays of the X-ray tube

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

2.4 Control elements and device displays of the X-ray generator

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

2.5 Control elements of Bucky, Grid Entity

Detailed information please find in the enclosed User Manual.

2.6 Control elements and device displays of the RAPIXX DR system

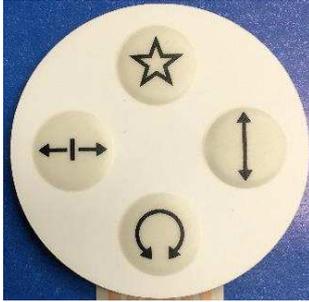
Detailed information please find in the enclosed User Manual of the RAPIXX DR system.

2.7 Control elements and device displays of CONAXX 2

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

3 Handling / Operation

3.1 Swivelling arm system



The universal support is used to set the position of the X-ray source (X-ray tube) and the image receptor (film cassette/flat panel detector) in the Bucky or any other position such as the floor, patient table, etc. 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.

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.



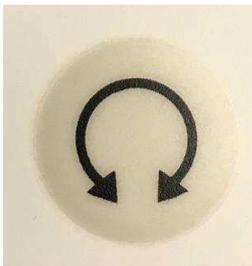
NOTE

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 the end stops must be avoided

3.1.1 Button Rotation



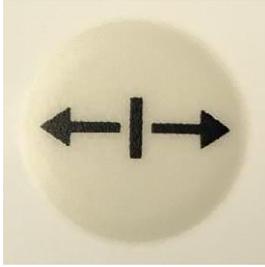
This button releases the cross arm brake, allowing the cross arm to rotate. The rotation dial displays the degree of rotation in relation to the initial horizontal position.

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.

IMPORTANT:

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

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.

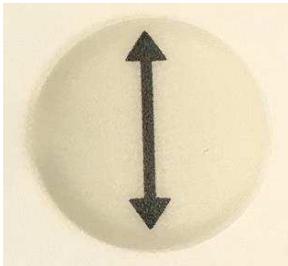
When adjusting the distance, the movement must be stopped before the button is released. A hard drive into the end stops should also be avoided. Otherwise, mechanical damage can occur in both cases.

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!

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.

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.**

For detailed information of the swivel arm system, please refer to the enclosed user manual of the swivel arm system.

3.2 Detector loading (optional)



NOTE

The detector must always be inserted at 0° while using the detector charging function.

To ensure the connection of the detector to the charging plug and thus the function of the detector loading, the detector must always be inserted at 0° position of the swivel arm.

3.3 Operation of the collimator

For detailed information of the collimator, please refer to the enclosed user manual of the collimator.

3.4 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 cap. 5.3

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

3.5 Operation of the generator

For detailed information of the generator, please refer to the enclosed user manual of the collimator.

3.6 Operation of the Bucky, Grid Entity

For detailed information of the Bucky, please refer to the enclosed user manual of the Bucky.

3.7 Operation of the RAPIXX DR system

For detailed information of the RAPIXX DR system, please refer to the enclosed user manual of the RAPIXX DR system.

3.8 Operation of the CONAXX2 software

For detailed information of the CONAXX2 software, please refer to the enclosed user manual of CONAXX2.

3.9 Switching on-off the PEDS 600 system

Switching on the PEDS 600 system happens via the control panel or the console of the generator. The generator supplies every system component with power.

When an Error appears please refer to the manual of the generator.

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