PROVERT

X-ray system image receptor stand

Model/ID: 7401-5-8000L

Instructions for use

Ident. Nr. 5401-0-8002

CE

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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
1.0	2019-05-14	all	Newly created. Replace document 5401-0-0002_Rev07
2.0	2019-08-07	Page 8, 26 chap. 1 chap. 6.1.1 chap. 8.1 chap. 8.2	Changed weight Intenden use and GMDN terms actualized revised EMC tables removed Symbols added Identification label updated
3.0	2020-08-11	Front page, Cap. 5.3.3	Maintenance updated

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.

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.

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.

1 Product description

1.1 Introduction

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

Prior to working with the PROVERT, it is required that the user reads the Safety Notes as well as the chapter regarding operation.

1.2 Description

The counterbalanced Bucky holder is easily movable and permits simple, exact positioning. An electromagnetic brake serves to securely maintain the selected position.
The X-ray system image receptor stand is designed for radiography of standing and seated patients.

1.2.1 Models

X-ray system image receptor stand without Bucky left load	7401-0-8110
X-ray system image receptor stand without Bucky right load	7401-0-8111

Device components

The PROVERT consists of the following components:

- Column
- Vertical carriage and covers
- Counterweight
- Deflection head with magnetic brake (wall)
- Bucky holder with cover hood
- Baseplate with wall mounting
- Rope breakage indicator

Product variants

- Baseplate for self-supporting installation
- Patient extending handle
- Extension of the wall mounting

Accessories

- Patient extending handle (ID: 7401-0-6810)
- Compression band (ID: 7755-0-4001)
- Adaption compression band (ID: 7755-0-4401)

Compatible components (stand-alone products) and possible combinations

Those components are not included in the delivery of PROVERT but it is possible to combine them with the PROVERT.

- Bucky or Grid entity of the PROTEC series
- 3-field measurement chamber of the PROTEC series
- Anti-scatter grid of the PROTEC series

Accessory that can influence the EMC-conditions

- Network cable (note the max. cable length in the documents of components)

1.2.2 Installation

See separate "Installation manual" PROVERT.
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 image receptor stand PROVERT is primarily made of metal pieces. This has a main role in the weight of the device.

The X-ray system image receptor stand PROVERT has a weight of 168 kg (without Bucky).

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 characteristic

- Cassette sizes from 13 x 18 cm (5 x 7 in) to 43 x 43 cm (17 x 17 in)
- Prepared for mounting of bucky's with digital panels
- Space saving with minimal footprint
- Wall-floor mounting or floor mounting
- Cassette loading from the right or left side (specified at installation)

1.4 Intended use

The stand PROVERT is an electrically powered component of a diagnostic X-ray system intended to mount, support and facilitate positioning of an image receptor assembly (Bucky) [not included].
Intended user group
The PROVERT is exclusively designated for use by professional 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.

1.5 Indication and Contraindication

1.5.1 Indication

The X-ray system component PROVERT, considered as a single component, has no indication and no contraindication. Since this X-ray system component is intended for connection with other X-ray system components, the indication and contraindication of an entire X-ray system are considered.

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).

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.

1.5.2 Contraindication

- 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
- For pregnant women and children it is important to consider if the exposure is really necessary. It should be avoided if possible.

1.6 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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Internet: www.protec-med.com

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 not described within the user manual must be made, with the aid of the technical description for the device, 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

The commissioning of the PROVERT 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, etc.

CAUTION!

The manual contains every safety relevant information for the commissioning of the PROVERT. 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 elements are descript in the corresponding manual.

2.1 General safety notice

2.1.1 Requirements for operation

WARNING!

Protection 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.
In case for use with a X-ray generator:
The power for the PROVERT 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.
This device contains no on/off switch. The PROVERT 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 PROVERT from the power the connected X-Ray generator must be shut off.

2.1.2 Operating of the radiographic system

In case of functional disturbances, e.g. due to electromagnetic interference, the PROVERT shall no longer be used and the customer service department of PROTEC or a service company authorized by PROTEC should be informed.
The rope breakage indicator is an indicator for a rope breakage that has occurred. This is indicated by pushing a red-painted plate out of the column head. If this rope breakage indicator is visible, the PROVERT shall also not to be used anymore and the customer service department of PROTEC or a service company authorized by PROTEC should be informed.

2.1.3 Operating personnel

The PROVERT 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 PROVERT.

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.
Failure to observe this can lead to physical injury (crushing, bruising etc.) or damage to the device as well as objects.

2.1.5 Explosion protection

The PROVERT is not designated for use within areas with explosive hazards.

2.1.6 Interaction with external devices

Unwanted interaction with external devices is not known.

2.1.7 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!

Avoid using this device directly next to other devices or with other devices in stacked form, as this could result in incorrect operation. If it is still necessary to use it in the manner described above, this unit and the other equipment should be observed to ensure that they are operating properly.

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 PROVERT is intended for use in a professional environment of the medical service (e.g. clinic, surgery centres, physiology offices …)

3 Control elements and device displays

3.1 X-ray system image receptor stand, vertical carriage and the Bucky holder

1 Brake release for vertical movement of the Bucky
2 Switch on light field indicator of collimator (this function can only be realized in connection with the X-ray system tube support, floor stand)
3 Rope breakage indicator

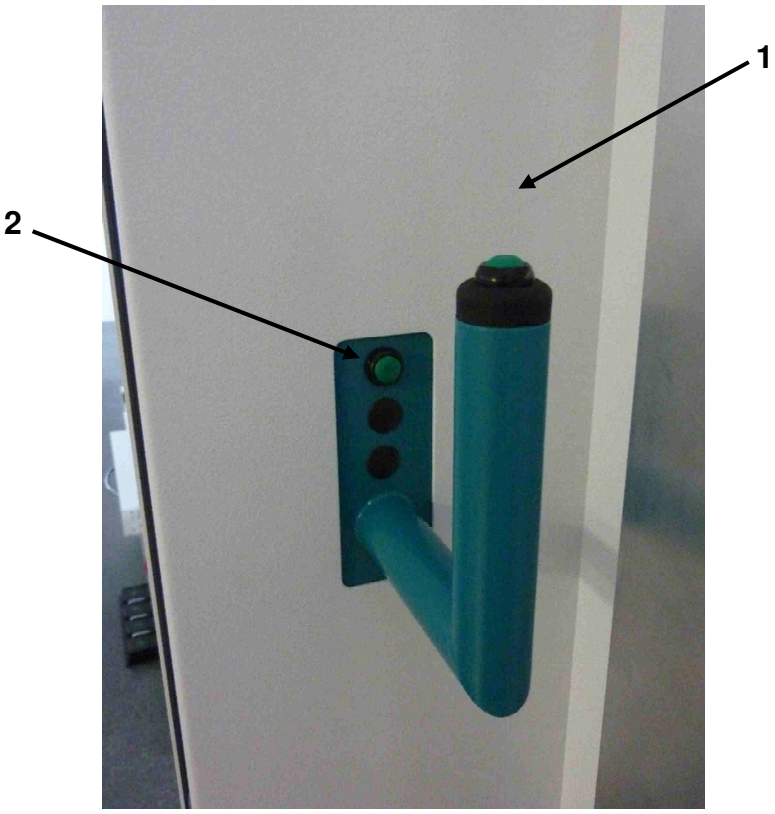


Figure 3-1

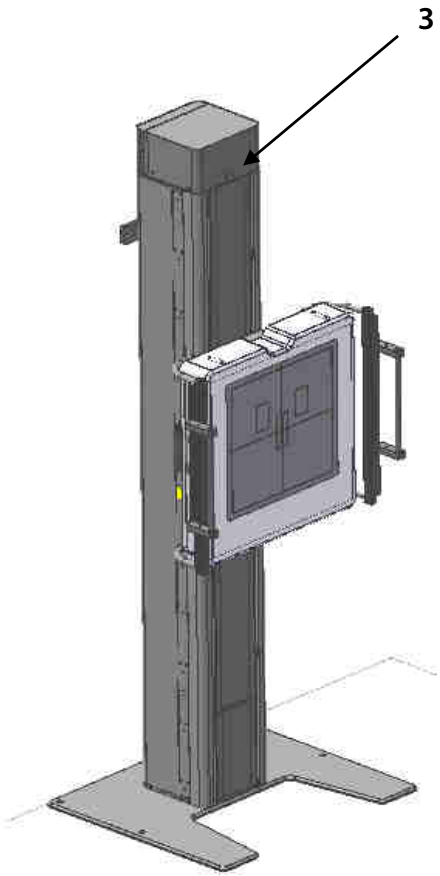


Abbildung 3-2

4 Handling / Operation

4.1 Operation PROVERT

Grab the handle at the back of vertical carriage and push the button (Figure 3-1/ 1) to release the brake in order to move the vertical carriage.
To turn on the light field indicator of the collimator at the X-ray system tube support, floor stand, push the button (Figure 3-1/ 2) on the back of the vertical carriage.

Option patient grip holder (Figure 4-1/ 1)
Insert the patient extending handle from above into the patient extending holder.
Lift the patient extending handle to turn the handle in steps of 90° to the left or the right side. By lowering the grip holder, turning is not possible anymore.
The picture below shows the patient extending handle perpendicular to the Bucky cover hood.

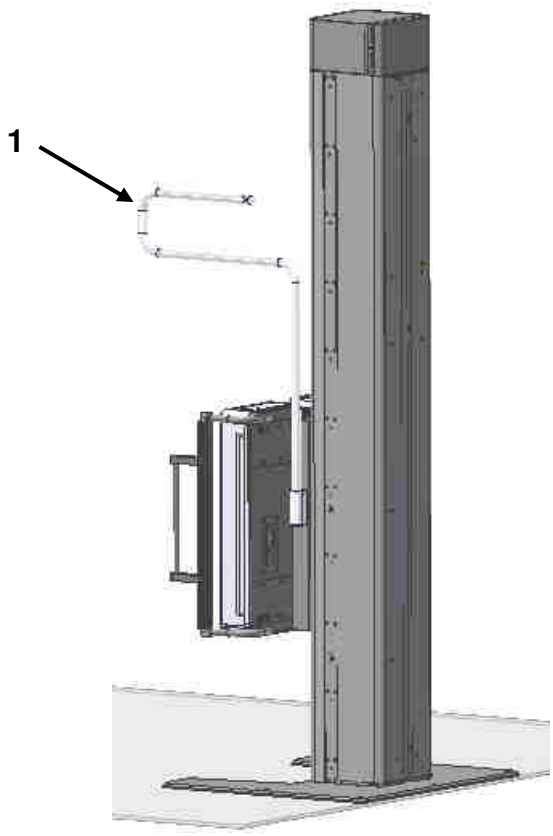


Figure 4-1

Option compression band with adaption compression band wall

The adaption for the compression band PROVERT consists of:

1 rails with holder

The compression band mounting kit consists of:

2 fixed roller
3 rotating roller with locking

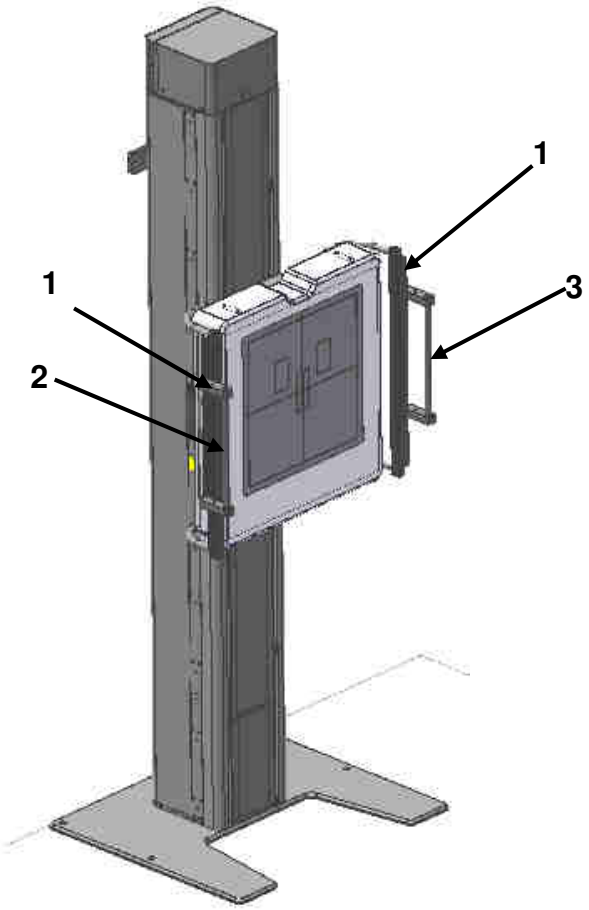


Figure 4-2

Installation of the compression band:
Step 1: Insert the stretching roller with locking into the support rail on the right side of the vertical carriage and fix it with the click wheel (Figure 4-2).

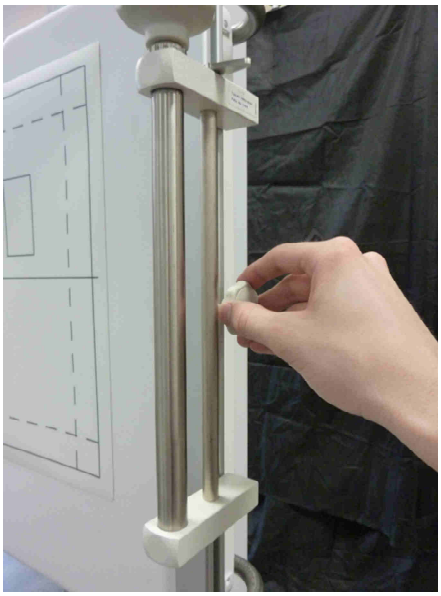


Figure 4-3

Step 2: Insert the fixed stretching roller into the support rail on the left side and fix it at the same height. Insert the compression band and pull it around the stretching roller (Figure 4-4).

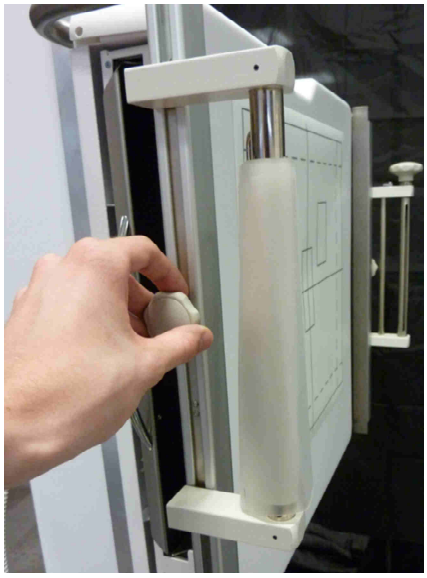


Figure 4-4

Step 3: Apply the compression band around the patient at the height of the reception area and insert it at the rotating stretching roller (Figure 4-5).

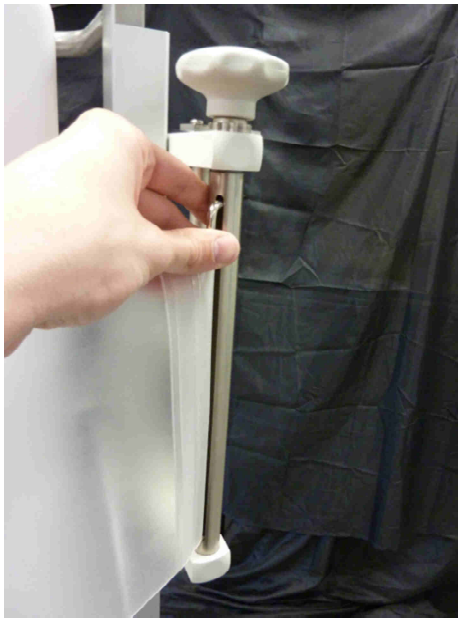


Figure 4-5

Step 4: Hold the band and turn the hand wheel to fasten the compression band (Figure 4-6).

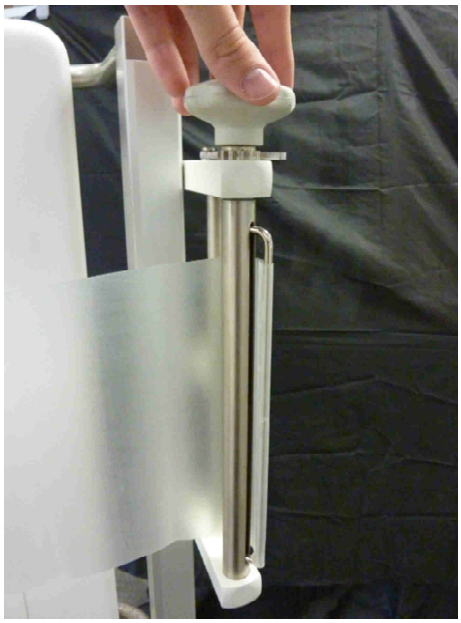


Figure 4-6

Step 5: To release the compression band, turn the hand wheel further and tilt the locking level forwards (Figure 4-7). Unscrew the hand wheel and remove the compression band in reversed chronology.

Figure 4-7

5 Safety and Maintenance

WARNING!

Caution Electrocution hazard!
Disconnect the power supply.
If the component is to be supplied via X-ray system or generator, then switch off the whole X-ray system.

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 Bucky cover. This reduces the risk of short circuits and corrosion.

5.2.1 Cleaning

Cleaning of the PROVERT is very easy due to its high-quality surface coating. As a rule, this can be done with a dry cloth.
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 woollen 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 PROVERT, including unit accessories, should undergo a wipe down disinfection using appropriate surface disinfection agents (e.g. Melsept* SF, 15 min. reaction time with a concentration of 2%). The information provided by the disinfectant manufacturer in regard to concentration and reaction time must be closely followed.

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

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

5.3 Check-up and maintenance

WARNING!

It's forbidden to make any check-up or maintenance services while the **PROVERT** is in use with a patient! Any check-up or maintenance services can only be done by people who got trained or authorized by PROTEC.

5.3.1 Daily controls (prior to or during the unit operation) by the user

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 device is overall operationally ready.

5.3.2 Regular controls by the user

X-ray equipment should be quality-controlled at regular intervals, at least monthly, or as required by applicable regulations to determine that the image quality remains in accordance to national regulations.

5.3.3 Maintenance

The required maintenance must be carried out by PROTEC technical service or an authorized service provider to ensure the safe and reliable functionality of the PROVERT. The maintenance intervals depend on the frequency of use. The necessary specifications can be found in the corresponding Technical Description in Chapter 3.
In the event that scheduled maintenance is not performed, PROTEC GmbH & Co. KG will not be responsible for damages incurred by the user or third parties if such damages are the result of improper or omitted maintenance.
Prior to operation (creation of X-Ray images), the operator must ensure that all safety related mechanisms, indicators and/or switches described within the user manual are fully functional and that the unit is overall operationally ready.
See Technical Description off the PROVERT and off all integral components.
Only original spare parts are to be used in situations requiring component replacement.

5.3.4 Warranty

NOTE

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

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

Only authorized technicians may do service and maintenance work.

5.3.5 Product life time

The PROVERT has an expected product life of 10 years when used in accordance with the product specifications/ limitations and provided that maintenance through the PROTEC service department or a PROTEC authorized service provider has be completed. After reaching the life span the further usage of the device happens on own risk.

5.3.6 Further Information

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

5.3.7 APPLIED PARTS and parts that can come into contact with PATIENT

The following table lists the parts that defined as applied part or parts that can come into contact with patient, but not defined as applied part.

Part	**Definition** (as APPLIED PART or parts that can come into contact with PATIENT, but not defined as APPLIED PART)
Bucky cover hood	applied part
Column assembly	part can come into contact with patient – not an applied part

5.3.8 Disposal

The PROVERT contains different plastics and metals. 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 PROGNOST SH is in need of the following power supply (see table „Power supply Generator).

Power supply	24 Vdc
Input current	10 A

The power supply for the electromagnetic brakes of the X-ray system image receptor stand is provided by a power supply with a power of 500W. This is mounted on the X-ray column. The power adapter comes with 230V; 6A 2,5A; connected directly to the generator and delivers 24Vdc, 20.83A.

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 PROVERT is, as a medical electrical equipment, 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!

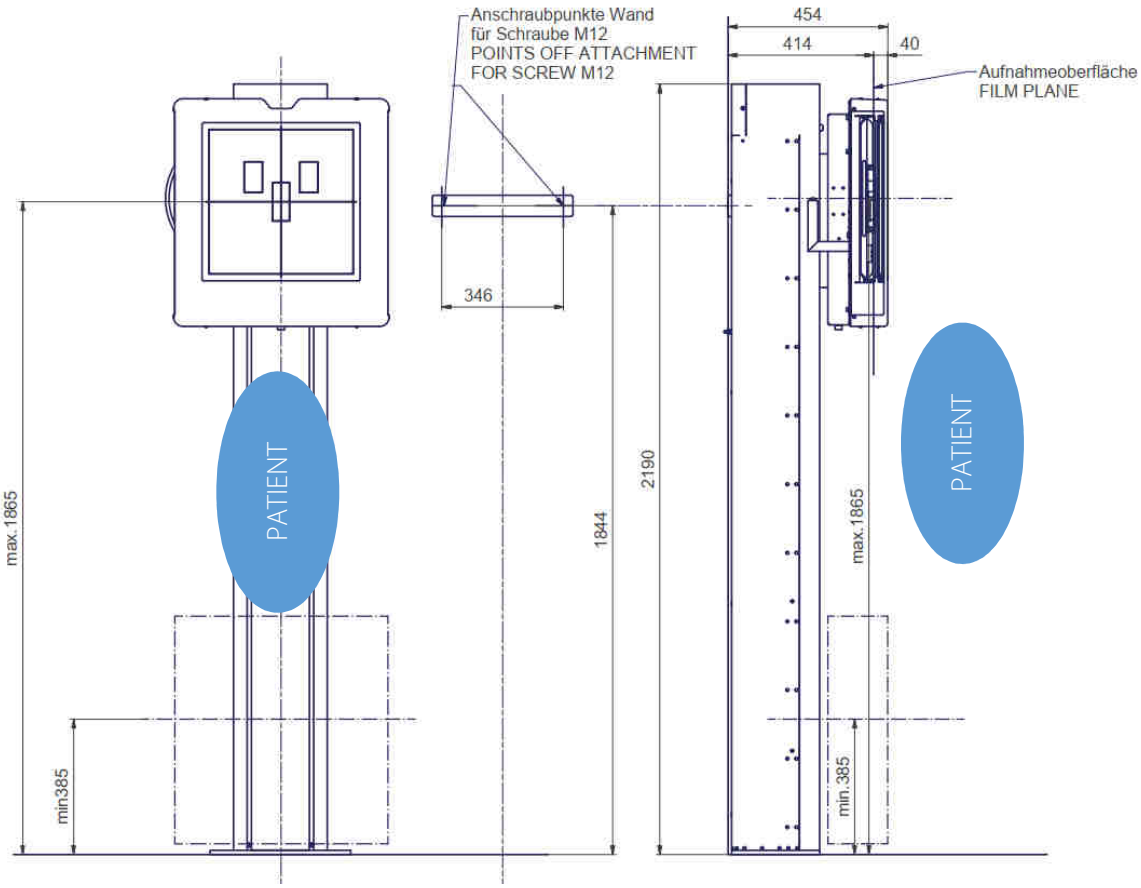
Mobile HF-Communication devices (radios) (including their accessories such as antenna cable and external antennas) should not be used closer than 30cm (12 Inch) to the marked parts and cables of the PROVERT. Disregarding this can cause a decrease in the performance features of the device.

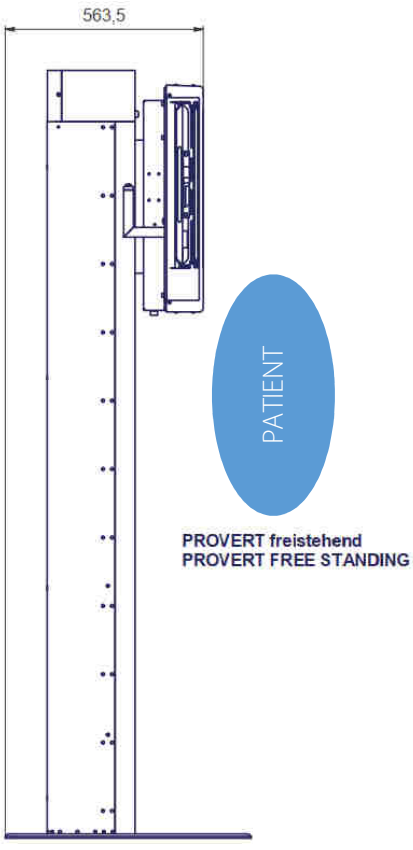
6.1.1 Guidelines and Manufacturers declaration – electromagnetic interference (non-life supporting device)

The X-ray system image receptor stand PROVERT 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 X-ray system image receptor stand.

7 Technical Data

7.1 Dimensions





7.1.1 Travel range

Vertical shift film center	385-1865 mm

7.1.2 Total weight

The maximum total weight of the PROVERT without accessories amounts 168 kg (without Bucky).

7.2 Attenuation Equivalent

WARNING!

The X-ray system image receptor stand PROVERT 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 **t**he accompanying **documents** of **t**he 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 **t**he quality of **t**he X-ray image.

The aluminium attenuation equivalent of the Bucky cover hood 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 PROVERT is consistent with a protection class 1 device and contains applicable parts Type B (according to EN 60601-1.

7.3 Environmental conditions

7.3.1 Environmental conditions during operation

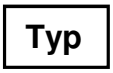
Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa

7.3.2 Environmental Conditions for Shipping and Storage

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

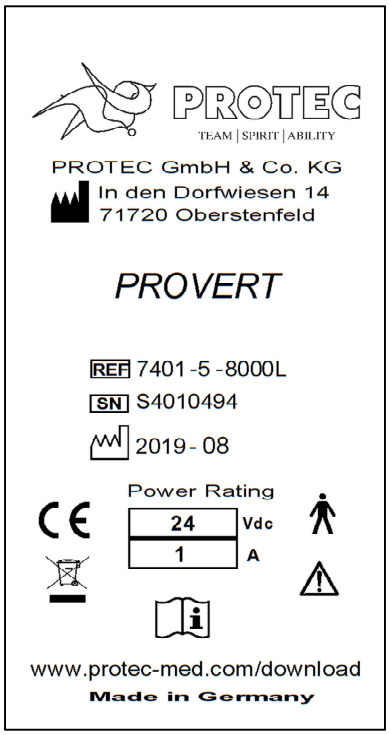
8 Description of symbols, labels and abbreviations

8.1 Symbols

	Limitation atmospheric pressure
	Limitation temperature
	Limitation humidity
	Keep dry
	Fragile, Handle with care
	This way up
	Refer to User manual
	Caution: pinch-/ crushing hazard of feet
	CE-Mark
	Classification according to EN 60601-1 (Applied Part Type B)
	Manufacturer
	Trade name
	Order number
	Serial number
	Date of manufacture
 www.protec-med.com/download	With this symbol we point out that Usage instructions of the corresponding product is on our homepage
	Note on disposal; WEEE, Waste of Electrical and Electronic Equipment

	Protective ground (Earth)

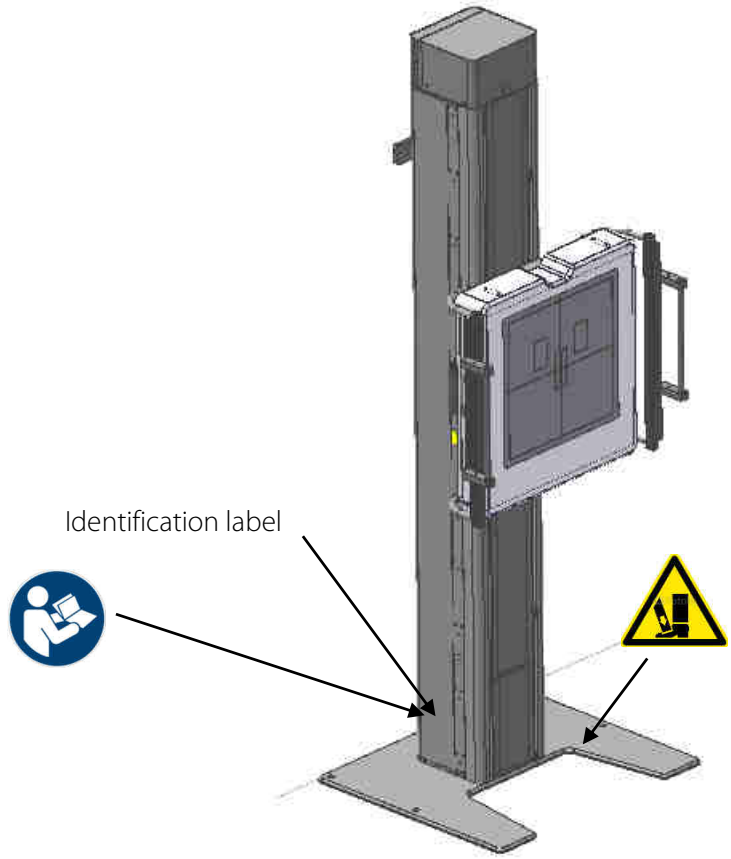
8.2 Identification label



8.3 Labels

Labels on the X-ray system image receptor stand	
	Refer to instruction manual/booklet.
	Caution: Possible pinch-/crushing hazard of feet while moving the Bucky holder

8.4 Position symbols and labels



8.5 Abbreviations

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