

PROGNOST SH

X-ray system tube support, floor stand

Model/ID: 7040-5-XX00L

Instructions for use

Ident. Nr. 5040-0-8002



PROGNOST SH in analogue base configuration



X-ray components (X-ray tube, collimator, X-ray generator) are not included in the PROGNOST SH.





NOTE

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**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	2019-05-14	all	Newly created. Replace document 5040-0-0002_Rev01
2.0	2019-08-02	Cap. 1.2.1, 1.2.2.1, 2.1.2, 6.1.1, 7.1.2, 8.1, 8.2	changed content, changed weight, Adaption of the intended use and GMDN term throughout the document EMC-tables removed Added symbols Identification label updated
3.0	2020-06-17	Cap. 1.2, 3.2, 3.2, 4.1, 7.1	Telescopic arm added
4.0	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 PROGNOST SH, knowledge of which are required for efficient and effective use of the radiographic system.

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

1.2 Description

The X-ray tube support, floor stand PROGNOST SH is guided by two floor-fixed rails to allow smooth horizontal movements. For special applications it is also possible to fix the X-ray tube support, floor stand directly to the floor.

The support arm is prepared for the installation of an X-ray tube assembly (X-ray tube with collimator) and the control unit with the user interface.

The horizontal movement of the tube stand and the vertical and rotational movement of the X-ray tube assembly are locked by electromagnetic brakes. Additionally, the rotation of the X-ray tube assembly around the horizontal support arm axis has pre-defined stops at 90°, e.g., for proper alignment with a Bucky wall stand. All movements are driven manually.

The control elements on the control arm of the tube stand and on the collimator are easily accessible from the front.

1.2.1 Models

PROGNOST SH 6AS; Angle display 8 button	7040-5-8000
PROGNOST SH 6T; TOUCH 6 button	7040-5-9000
PROGNOST SH 8AS; Angle display 8 button	7040-5-8500
PROGNOST SH 8T; TOUCH 8 button	7040-5-9500

Device components

The PROGNOST SH consists of the following components:

- X-ray tube support, floor stand
- vertical carriage and coversdeflection head with magnetic brake
- Universal X-ray tube support
- Control unit with inclinometer
- Tube arm and rotary brake with angle adjustment
- Floor rail
- Floor trolley
- Counterweights
- Rope breakage indicator

Product variants

- Operating unit with Touch-Display
- Base plate for wall installation
- Base plate for free-standing floor installation
- Telescopic function tube arm (+230mm)

Accessories

- Floor rail extension short (ID: 0061-0-7500)

Compatible components (stand-alone products) and possible combinations

The below mentioned components/products are not included with the standard delivery of PROGNOST SH but nevertheless can be combined with the PROGNOST SH tube stand.

- Collimator
- X-ray tube assembly
- X-ray generator

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 of PROGNOST SH.

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 PROGNOST SH is primarily made of metal pieces. This has a main role in the weight of the device.

The PROGNOST SH has a weight of max. 385 kg.

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

- Ceiling independent tube stand suitable for rooms with minimum 2,30 m ceiling height
- Wide range of application
- Short Installation time
- High reliability
- Short wall distance allows an optimal utilization of available space
- Control elements are arranged for easy access and operation on the control arm
- Angle indicator (inclinometer) ensures reproducible position of X-ray tube assembly (rotation around the support arm axis)
- Electromagnetic brakes for horizontal travel of the tube stand, vertical travel of the X-ray tube assembly, and rotation of the X-ray tube assembly around the support arm axis, with additional 90° click-stops

1.4 Intended use

The floor stand PROGNOST SH is a hardware assembly with its related electronic controls. As a component of a stationary basic diagnostic X-ray system PROGNOST SH is intended to mount, support and facilitate positioning of the X-ray tube assembly during a variety of routine planar procedures requiring a diagnostic X-ray system in human medicine.

1.5 Indication and Contraindication

1.5.1 Indication

The X-ray system component PROGNOST SH, 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 Intended user group

The PROGNOST SH is exclusively designated for use by professional users who are trained to operate diagnostic X-ray equipment in accordance with the corresponding national regulations and who were instructed in the proper (certified) use, application and operation as well as in the permissible connection with other medical devices, objects and accessories.

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

1.7 Conformity



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**

Contains information that are relevant to the usage.

xxx

**CAUTION!**

Contains information that can cause damage to properties at non conformity.

xxx

**WARNING!**

Contains information that can cause personal injuries at nonconformity.

xxx

**WARNING!**

Warning of radioactive substances or ionising rays. Contains information that can cause personal injuries at non conformity.

xxx

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 PROGNOST SH 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 PROGNOST SH. 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 a use with a X-ray generator:

The power for the PROGNOST SH 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 PROGNOST SH is a Class I ME product (according to EN 60601-1).

This device contains no on/off switch. The PROGNOST SH 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 PROGNOST SH from the power the connected X-ray generator must be shut off.

2.1.2 Operation of the device

In case of functional disturbances, e.g. due to electromagnetic interference, the PROGNOST SH 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 PROGNOST SH 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 PROGNOST SH 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 PROGNOST SH.

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 PROGNOST SH is not designated for use within areas with explosive hazards.

2.1.6 Interaction with external devices

Unwanted interaction with external devices are 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 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 PROGNOST SH 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 tube support, floor stand

- 1 Indication of rope rupture
- 2 Operating unit with Touch-Display
- 3 Keypad
- 4 Operating unit with inclinometer
- 5 Handle

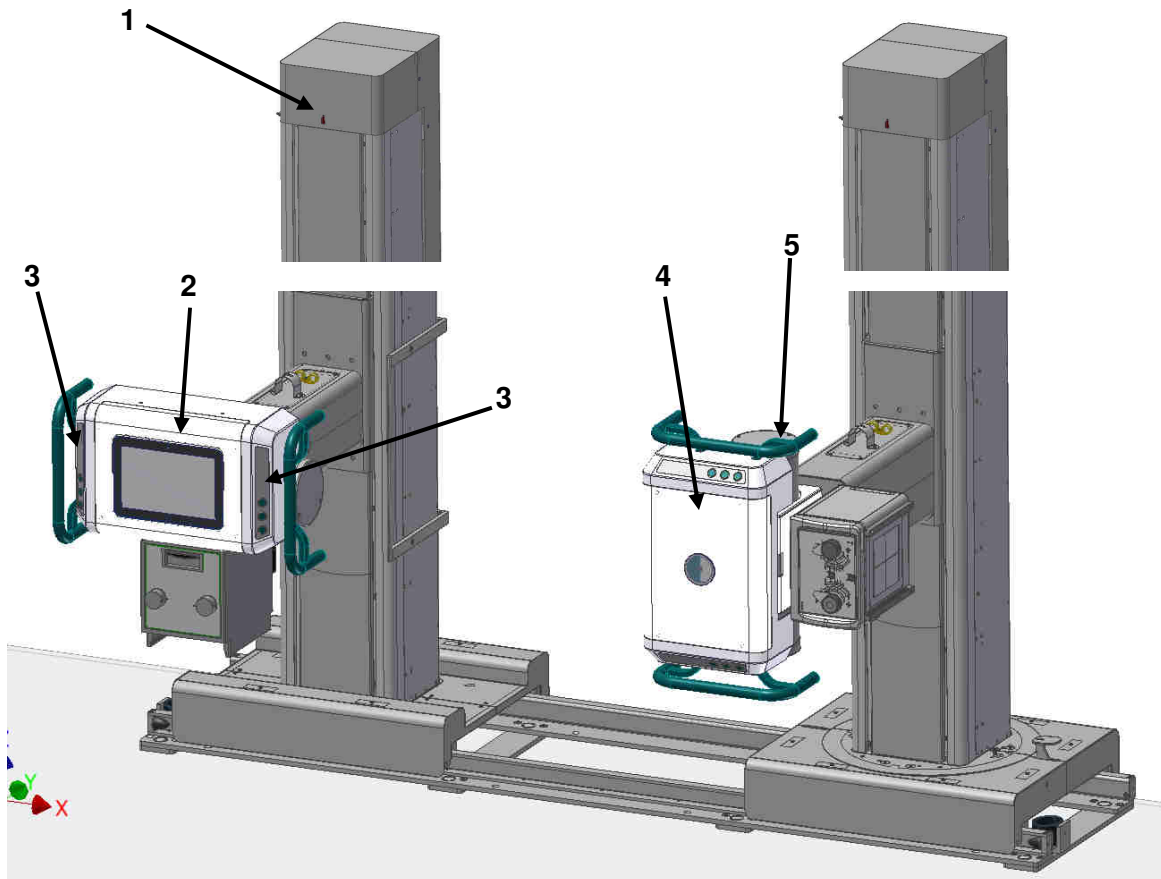


Figure 3-1

3.2 Command arm

3.2.1 PROGNOST SH

- 1 Angle indicator for adjusting the X-ray assembly
- 2 Brake release for horizontal movement of the X-ray floor stand
- 3 Brake release for rotational movement of the X-ray unit around the horizontal support arm axis
- 4 Brake release for vertical movement of X-ray tube arm and horizontal movement of X-ray floor stand
- 5 Brake release for vertical movement of X-ray tube arm and horizontal movement of X-ray floor stand
- 6 Brake release for movement of X-ray tube assembly around the horizontal support arm axis
- 7 Brake release for vertical movement of X-ray tube arm
- 8 Option: Brake release for transversal movement of X-ray tube arm (+230mm)
- 9 Option: Status-LED orange (if LED is on: X-ray tube arm is not engaged)

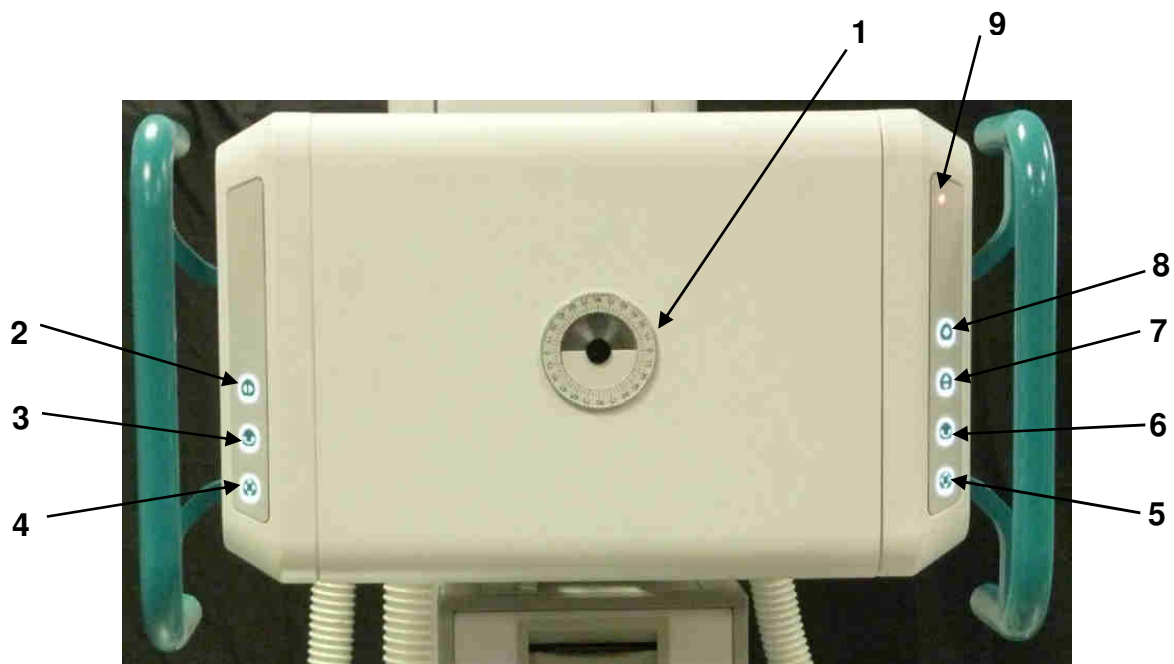


Figure 3-2

3.2.2 PROGNOST SH TOUCH

- 1 Touchdisplay of X-ray tube assembly
- 2 Brake release for horizontal movement of X-ray floor stand
- 3 Brake release for movement of X-ray tube assembly around the horizontal support arm axis
- 4 Brake release for vertical movement of X-ray tube arm and horizontal movement of X-ray floor stand
- 5 Brake release for vertical movement of X-ray tube arm and horizontal movement of X-ray floor stand
- 6 Brake release for movement of X-ray tube assembly around the horizontal support arm axis
- 7 Brake release for vertical movement of X-ray tube arm
- 8 Option: Brake release for transversal movement of X-ray tube arm (+230mm)
- 9 Option: Status-LED orange (if LED is on: X-ray tube arm is not engaged)

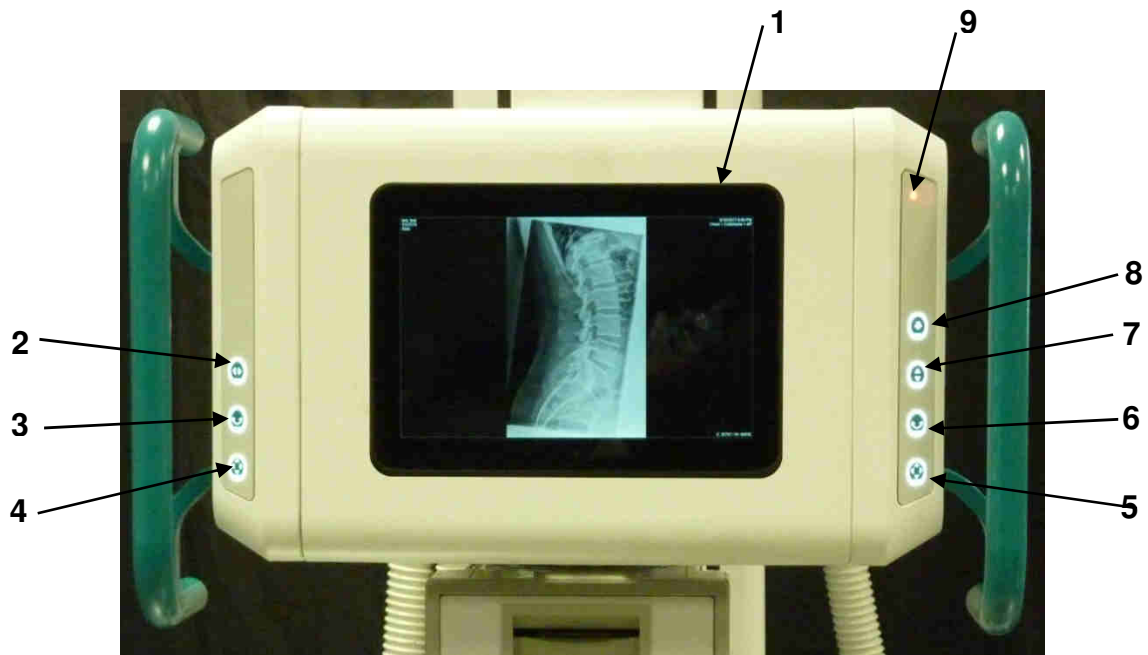







Figure 3-3

Controls are operated from the front side (operator side) of the X-ray tube assembly. With the handles grasped, the electromagnetic brakes can easily be released by pressing the respective button related to one or more movements to allow convenient and accurate positioning of the X-ray tube assembly.

4 Handling / Operation

4.1 Operation PROGNOST SH

Grab both handles of the X-ray tube assembly and push the button for the desired movement. The respective brakes are released and it is possible to move the X-ray tube assembly in the desired position.

	Horizontal movement of the X-ray tube stand
	Vertical movement of the X-ray tube assembly
	Rotation of the X-ray tube assembly
	Horizontal movement of the X-ray tube stand and vertical movement of the X-ray tube assembly
	Transversal movement of the X-ray tube assembly (option)

4.2 Function of the PROGNOST SH

4.2.1 Switching On/Off the PROGNOST SH

PROGNOST SH starts automatically by switching on the X-ray system. PROGNOST SH. The PROGNOST SH turns off automatically by switching off the X-ray system.

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 main housing of the control unit. This reduces the risk of short circuits and corrosion.

5.2.1 Cleaning

Cleaning of the PROGNOST SH 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 PROGNOST SH, 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 PROGNOST SH 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 PROGNOST SH. 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 PROGNOST SH 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 PROGNOST SH 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.

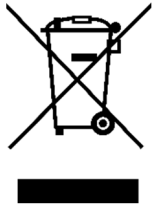
5.3.6 Further Information

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

5.3.7 Applied Parts and parts which get handled like an application part

The patient does not come in contact with PROGNOST SH while utilization. It is not necessary to define applied parts.

5.3.8 Disposal



The PROGNOST SH 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	230 Vac
Power frequency	50 - 60 Hz
Input current	2,5 – 6 A

The power supply for the electromagnetic brakes of the X-ray tube support, floor stand and the X-ray unit 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 PROGNOST SH 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!

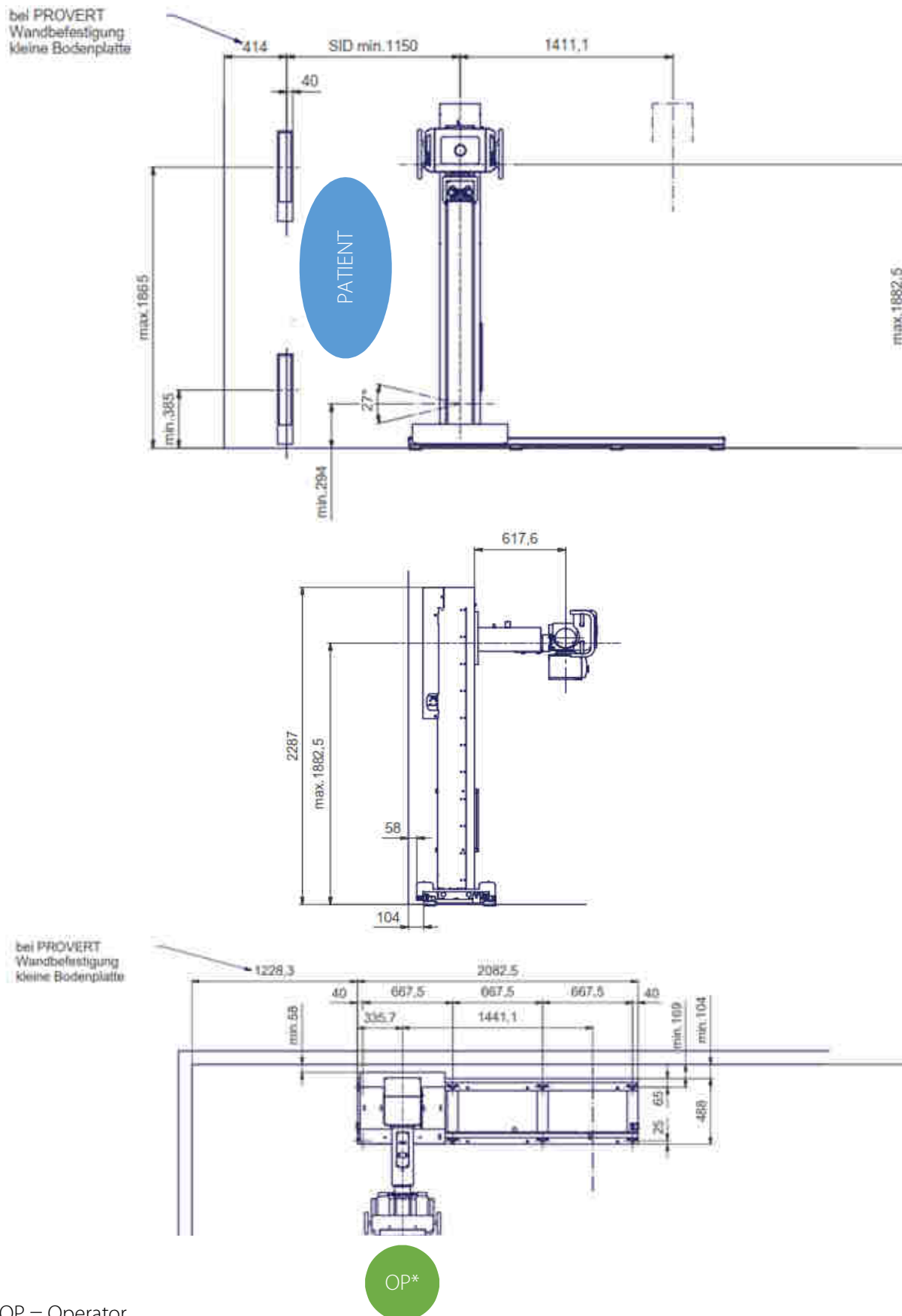
Mobile HF-Communication devices (radios) (including their accessories such as antenna cables and external antennas) should not be used closer than 30cm (12 Inch) to the marked parts and cables of the PROGNOST SH. Disregarding this can cause a decrease in the performance features of the device.

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

The X-ray system tube support, floor stand PROGNOST SH is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X-ray system tube support, floor stand can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the X-ray system tube support, floor stand.

7 Technical Data

7.1 Dimensions



*OP = Operator

7.1.1 Travel range

Angulation X-ray tube assembly around horizontal support arm	+/- 180°
Detents X-ray tube assembly around horizontal support arm	-90°; 0°; +90°, 180°
X-ray tube support, floor stand longitudinal travel:	1411 mm
X-ray tube support, floor stand longitudinal travel, with short floor rail extension	2078,5 mm
Focal spot vertical travel @horizontal X-ray beam:	294 -1882,5 mm
Floor-focal distance	max. 1882,5 mm
Extension telescopic X-ray arm	+230mm

7.1.2 Total weight

The maximum total weight of PROGNOST SH with floor rail and X-ray tube assembly amounts 385 kg.

7.2 Protection Art and Protection Class

The PROGNOST SH is consistent with a protection class 1 (according to EN 60601-1).

7.3 Environmental conditions**7.3.1 Environmental conditions during operation**



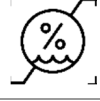

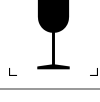



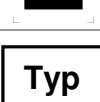

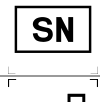
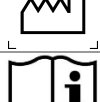



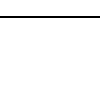

Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa








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 1060hPa

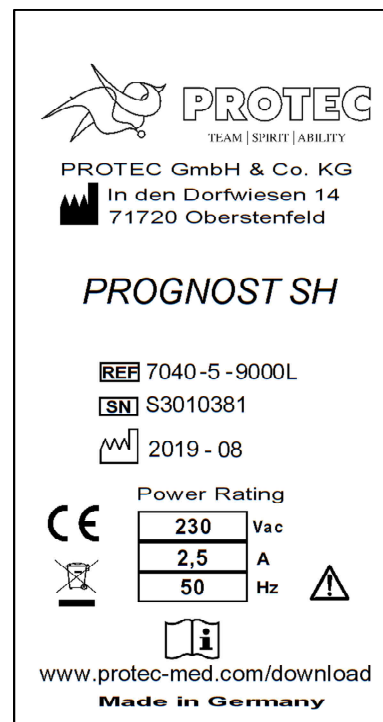
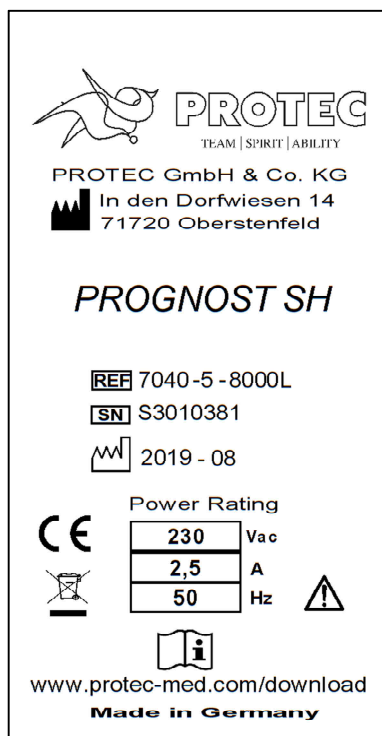
8 Description of symbols, labels and abbreviations

8.1 Symbols





	Limitation atmospheric pressure
	Limitation temperature
	Limitation humidity
	Keep dry
	Fragile, Handle with care
	This way up
	Refer to instruction manual/booklet.
	CE-Mark
	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)
	Caution: pinch-/crushing hazard for hands and fingers

	Caution: pinch-/ crushing hazard of feet
	No stepping on surface
	Attention: Electrostatic sensitive devices
	Horizontal movement of the X-ray tube stand
	Vertical movement of the X-ray tube arm
	Rotation of the X-ray tube assembly
	Horizontal movement of the X-ray tube stand and vertical movement of the X-ray tube assembly

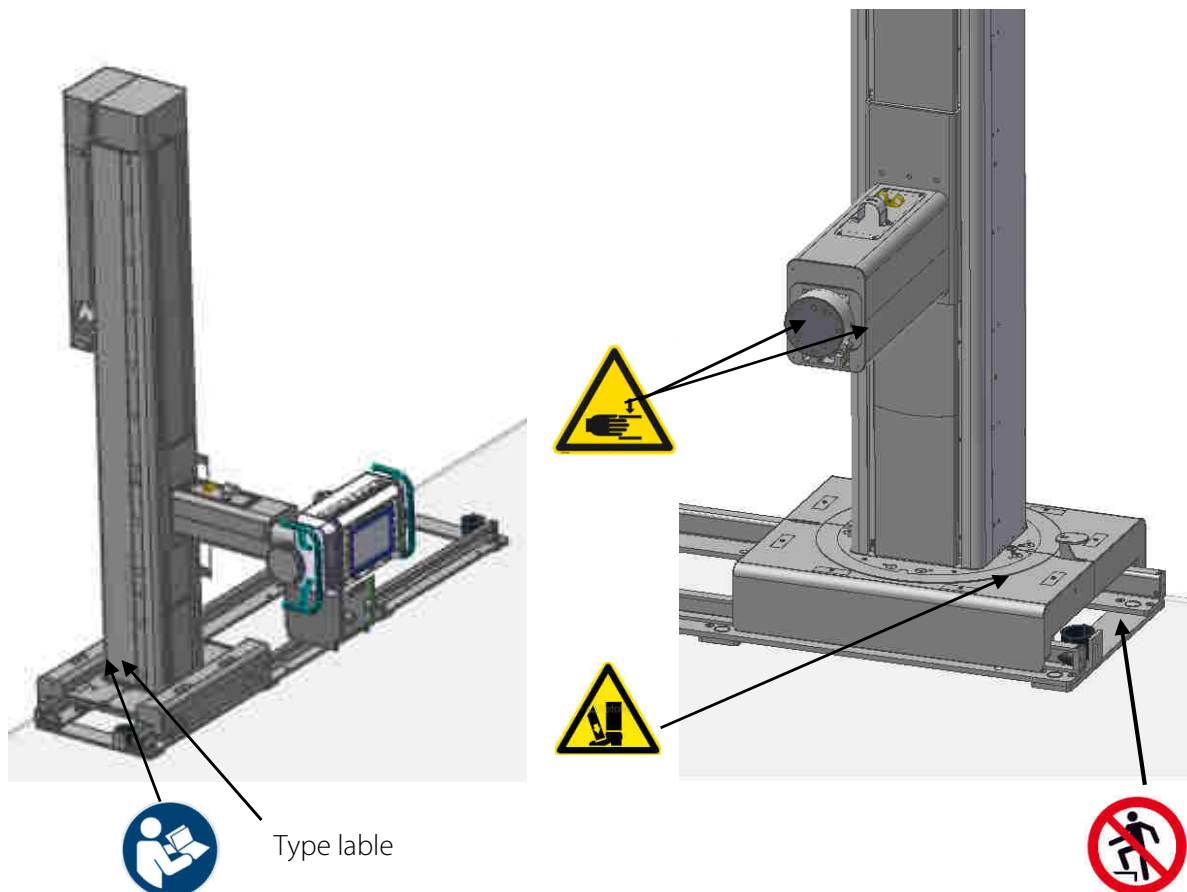
8.2 Identification label



8.3 Labels

Labels on the X-ray system tube support, floor stand	
	Caution: Possible pinch-/crushing hazard for the hands and fingers while moving the X-ray tube assembly unit.
	Refer to instruction manual/booklet.
	Caution: Possible pinch-/crushing hazard of feet while moving the X-ray tube support, floor stand and the X-ray tube assembly unit.
	Prohibition: No stepping on the floor rails.

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
Vac	Volt (AC voltage)
Vdc	Volt (DC voltage)
Inch	Inches