PROGNOST SH

Model/ID: 7040-5-XXXX

Instructions for Use

Ident. Nr. 5040-0-0002

Fig.: System illustration with optional PROVERT and X-ray tube assembly
Similar to figure

CE

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Content

NOTE

The information contained in this document conforms with 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 GmbH & Co. KG Technical Service Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
	16/06/2012		Original Issue
01	11/02/2015		New control handle

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 Equipment Description

1.1 Introduction

These „Instructions for Use“ describe the special features of the PROTEC floor mounted tube stand PROGNOST SH and provide operational instructions for its efficient and effective use.

It is suggested that you review the operating instructions, the safety notes and the controls described in these “Instructions for Use” before using the PROGNOST SH. Each control is described to make you familiar with its function.

1.2 Intended Purpose

The tube stand PROGNOST SH (horizontal movable) is mounted on floor rails with vertical movement of a support arm for the mounting of a X-ray tube unit, to be used in medical used room.

The PROGNOST SH must be operated by qualified users trained in the use of human diagnostic X-ray equipment in conformity with the respective national regulations. An introduction of the product is necessary for the user.

1.3 Declaration of Conformity

CE This product is in conformity to the requirements of the European Community Medical Device Directive 93/42/EEC from 06/14/1993.

You can get the declaration of conformity directly from:

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1.4 Functioning

1.4.1 Description

PROGNOST SH is prepared for the mounting of a X-ray tube unit.
The tube stand is guided on two floor-fixed rails on the floor.
The counterbalanced support arm is prepared for the mounting of the X-ray tube assembly (X-ray tube with collimator) and the control arm with the control elements.
All movements of the tube stand and the X-ray tube assembly are easy going and are arrested by electromagnetic brakes. Additionally, the X-ray tube assembly movement around its horizontal support arm axis has click-stops at 90°, e.g., for alignment with a bucky wall stand.

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

1.4.2 Features

- Ceiling independent tube stand suitable for rooms with minimum 2,30 m ceiling height.
- Wide range of applications
- Short installation time
- High reliability
- Control elements are arranged for easy access and operation on the control arm.
- Angle indicator ensures reproducible position of X-ray tube assembly (rotation around the support arm axis).
- Vertical travel range of focal spot from 25 cm up to 189 cm with horizontal X-ray beam
- Electromagnetic brakes for longitudinal travel of tube stand, vertical travel of X-ray tube assembly, and rotation of X-ray tube assembly around support arm axis, with additional 90° click-stops.
- Short wall distance allows an optimal utilization of room

1.5 Equipment Components

The **PROGNOST SH** tube stand can consist of the following elements:

- Tube stand
- Control arm
- Collimator with fixed or movable mounting *
- X-ray tube with trunnion ring *
- Turn Tube +/-90°*

1.6 Optional Components

The following optional components are available:

1.6.1 X-ray tube

X-ray tubes from different manufacturers with the respective trunnion rings and mountings can be used.

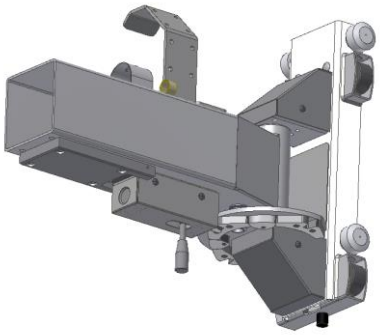
1.6.2 Collimator

Collimator with fixed or movable mounting for manual adjusting of cassette size.

1.7 Nameplate

The nameplate of the **PROGNOST SH** is located at the lower front side of the column.

1.8 Turn Tube +/-90°*



* optional

2 Controls

2.1 Tube stand

1. **1** Control arm (see fig. 2-1/1)
2. **2** Collimator (see fig. 2-1/2)

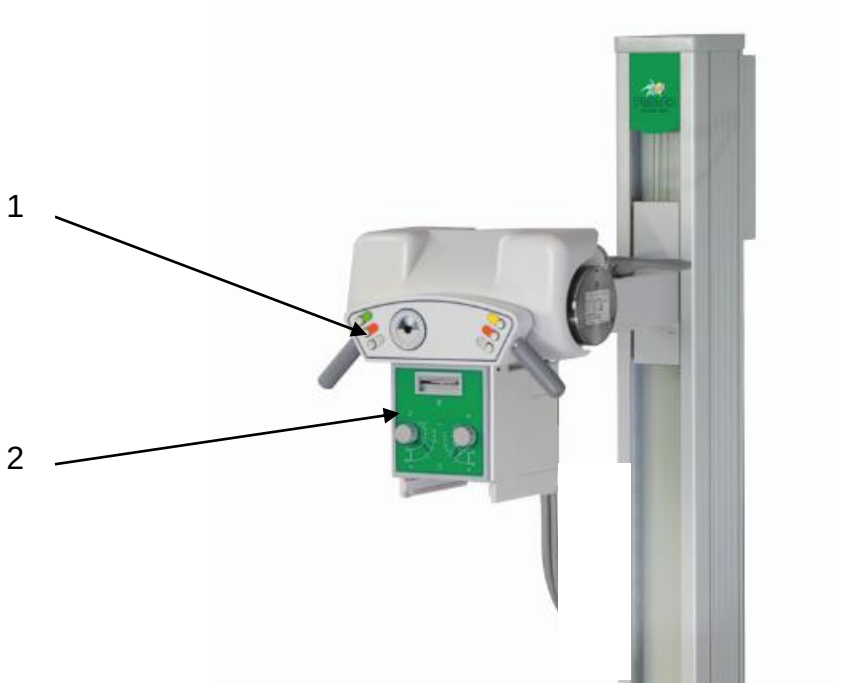


Figure 2-1
Similar to figure

2.2 Control arm

1 Angle indicator for adjustment of X-ray assembly.
2 Central brake release switch; when actuated, all movements are released.
3 Angualtion brake release switch; releases brake for movement of the X-ray tube assembly around horizontal support arm axis.
4 Vertical brake release switch; releases brake for vertical movement of the X-ray tube assembly.
5 Longitudinal brake release switch; releases brake for longitudinal movement of the tube stand.
6 X-ray tube cover.

Controls are operated from the front side (operator side) of the tube stand. With the handles grasped, pressure by the operators thumb on the control arm switches can easily release the electromagnetic brakes related to one or more of the movements to allow convenient and accurate positioning of the X-ray tube assembly.

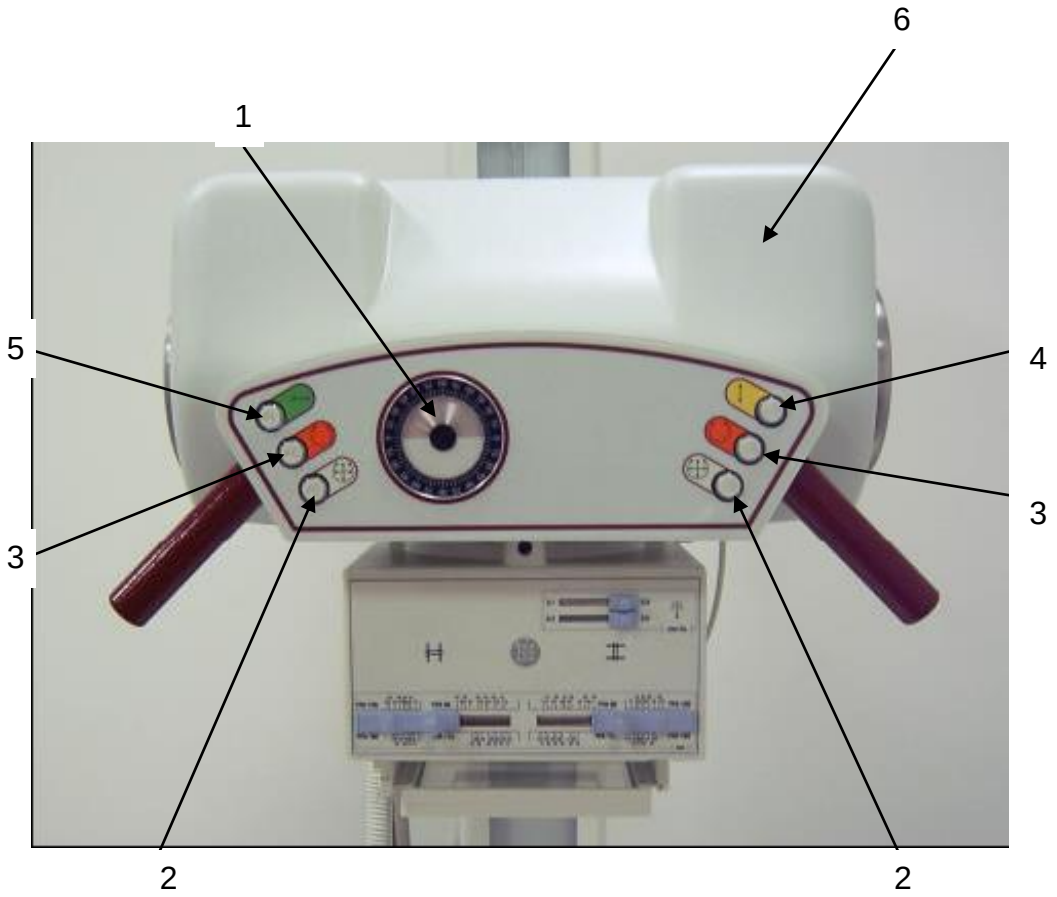


Figure 2-2
Similar to figure

2.3 Collimator * (e.g. PROTEC version)

1. **1** Collimator adjustment control; for manual opening and closing of collimator
2. shutters (transversely to tabletop).
3. **2** Scales; indicate the opening of collimator shutters (transversely to tabletop).
4. **3** Accessory rails (can be used for measuring phantoms).
5. **4** Light centering device; allows centering of the X-ray tube assembly with the
6. bucky unit.
7. **5** Light resp. X-ray field; corresponding to opening of collimator shutters
8. **6** Filter disc for selection of additional filtration of 0 mm Al, 1mm Al + 0,1 mm Cu,
9. 2 mm Al + 0,2 m Cu or 2 mm Al
10. **7** Collimator adjustment control; for manual opening and closing of collimator
11. shutters (longitudinally to tabletop).
12. **8** Scales; indicate the opening of collimator shutters (longitudinally to tabletop).
13. **9** Collimator light switch; turns on collimator light.
14. **10** Measuring tape.

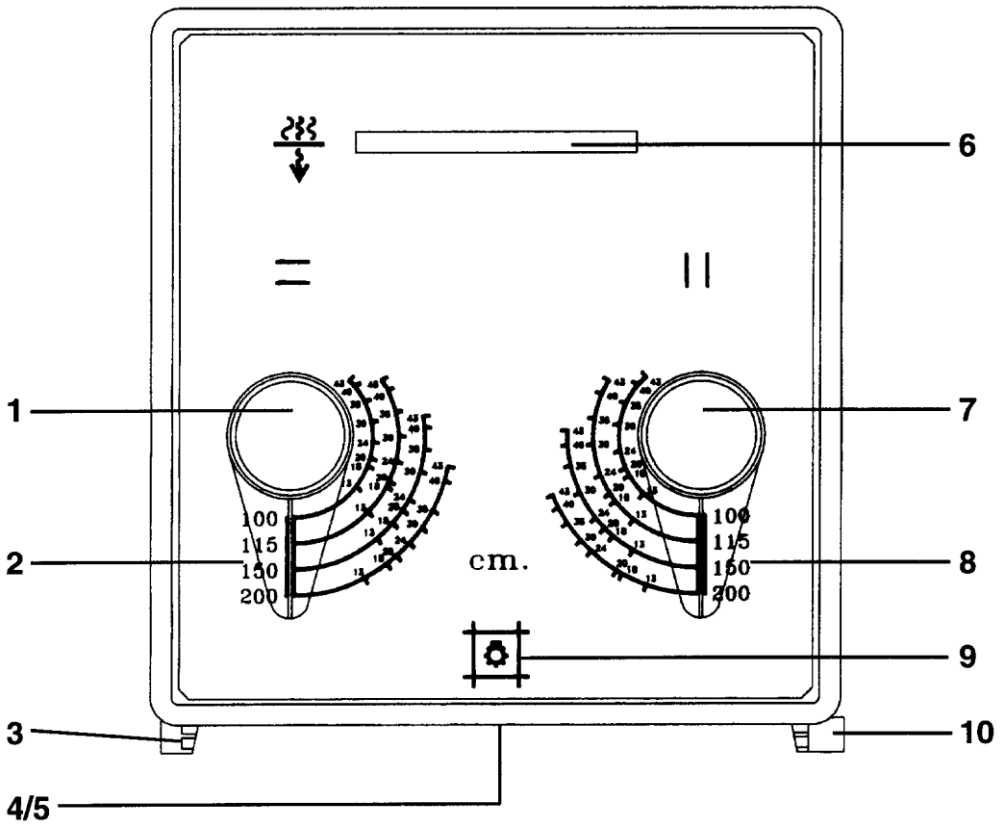


Figure 2-3 Collimator

* optinal

2.4 Turn Tube +/-90°*

1. Tube arm
2. Control lever
3. Arrester (3 pieces)

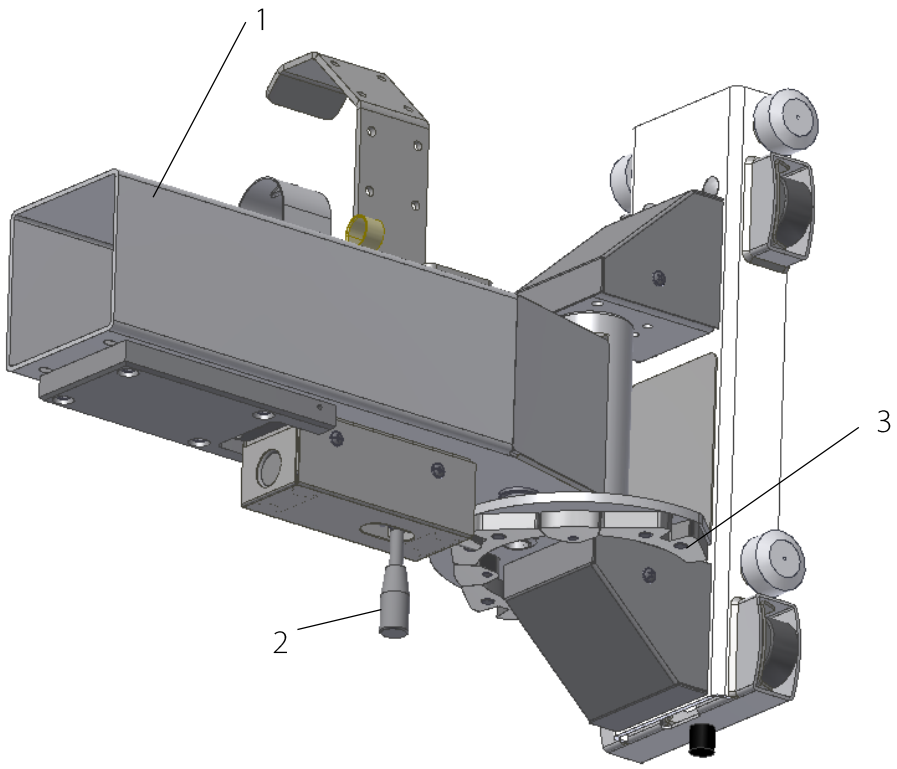


Figure 2-7

***** is not included with the PROGNOST SH and may vary depending on system

3 Operating Instructions

3.1 Safety Aspects

3.1.1 Requirements for Operation

The **PROGNOST SH** must to be completely installed and officially handed over to the customer before it can be used by the customer.
It has to be ensured that before operation all necessary announcements are done.
The national regulations concerning the release of new installed X-ray equipment and monitoring of the operating system must be met.
The maintenance has to be carried out according to instructions in chapter 4.

3.1.2 Users

The **PROGNOST SH** must be operated by qualified users trained in the use of human diagnostic X-ray equipment in conformity with the respective national regulations. A product introduction for the users is necessary.

3.1.3 Emergency OFF Switch

If an emergency OFF switch is provided by the owner, then the following shall be observed:
Activate the emergency OFF switch immediately in case of hazard to the patient, the operator or the unit. This disconnects the power supply from the entire system.
The emergency OFF switch may be reset only after the hazard has been positively identified and the problem is solved. Notify the **PROTEC** customer service department in all other cases (such as a malfunctioning of the unit).

3.1.4 Explosion Protection

This unit is not designed for operation in potentially explosive atmospheres.

3.1.5 Radiation Protection

X-rays represent a hazard to both patients and operator if the rules for the use of such systems are not observed. For this reason the principles of radiation protection must have the highest priority and they shall be observed at all times.

- **Maintaining distance from the radiation source**
  The dose declines with the square of the distance from a (point-like) radiation source, i.e. doubling the distance reduces the dose to one quarter, tripling the distance reduces the dose to one ninth, etc.

- **Keep exposure periods short**
  The dose rises linear to the exposure time, i.e. halving the exposure period will halve the dose (this is applicable particularly for fluoroscopy; when making X-ray films the current time product (mAs value) is prescribed in the most cases).

- **Use shielding and protective clothing**
  The protective factor rises exponentially with the thickness of the shielding. This means that two half-value layers will reduce (homogeneous) radiation to 1/4, three half-value layers to 1/8, and 10 half-value layers will reduce the radiation to less than 1/1000 of the original value.

- **Never reach into the direct X-ray beam**
  The dose in the direct, non-attenuated X-ray beam is some 100 times higher than the scattered radiation.

- **Personal dose meters**
  During work with x-ray use corresponding personal dose meters for measurement of the accumulated dose.

When taking X-rays near the reproductive organs, pay attention to using the best possible protection (testicle shielding cup or lead apron).
The operator shall always stand behind a shielding panel or partition when taking exposures.
Persons who must be near the patient during fluoroscopy shall wear protective clothing (a lead apron, for instance). The same applies for maintenance and repair work.

3.1.6 Interferences to other devices

There are no interferences to other devices known.
The system is in accordance with the requirements of DIN EN 60601.

3.2 Adjustment of X-ray assembly to center of cassette or bucky of bucky table (vertical X-ray beam)

- By pushing button (Fig. 2-2/5) release brake for vertical movement of tube stand.
- Grasp both handles of control arm
- Switch on collimator light
- Remove tube stand in direction vertical to center of cassette.

3.3 Adjustment of focal spot to film distance (FFD)

- Adjust X-ray tube assembly with measuring tape (Fig. 2-3/10) on collimator to the requested focal spot to film distance (FFD).
  Before this, release brake for height adjustment on the X-ray tube assembly by pressing the button (fig. 2-2/4).

3.4 Adjustment of light/X-ray field

- Press the collimator light switch (Figure 2-3, item 9,) to turn on the collimator light, and check the opening of the collimator shutters, relative to the used of the exposure medium size.
- Adjust collimator shutters to size of used cassette with collimator adjustment controls.(fig. 2-3/1 and fig. 2-3/7). Several FFD scales (Figure 2-3/2 and fig. 2-3/8) are provided to indicate the correct settings of the collimator adjustment controls. So the light beam and the X-ray field can be limited to the desired of the exposure medium size.

3.5 Operation Turn Tube +/-90°

For the purpose of this description, the tube arm ist arranged in the 0°-position in which the tube arm is positioned in line with the vertical carriage. The position of the X-Ray tube assembly, which is to be assembled at the end of the tube arm, is not important. The tube header can be pointed downwards to either side.

Warning!
When rotation of the swing arm takes place, the brakes both for the vertical adjustment and for the rotation of the X-Ray assembly should be fixed. Only lateral rotation of the tube arm should be possible!

3.5.1 Operation instructions

1. With one hand, pull the control lever in direction the X-Ray tube. The tube arm is now free to move (no longer fixed).
2. With the other hand, swing the tube arm into the new position (+/-90°)

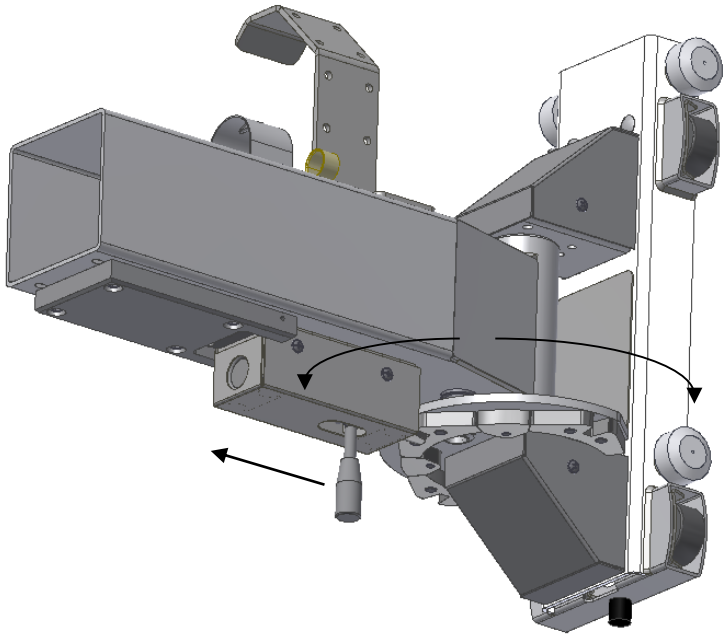


Figure 3-11-1

3. Release the control lever. The tube arm is fixes into the place through spring force.

Warning!
While rotating the swing arm, both hands should be contact with the tube arm and move along with it. Never reach into the access cover or into the area surrounding the latch-possible risk of injury!

4. For reasons of safety, ensure that the latching mechanism engaged and the swing arm is fixed.

Recommendation:

To reduce patient dose and to optimize image quality it should be superimposed to size of the object.

3.6 Exposure Preparation/Exposure Release

1. Select needed device at the X-ray generator control console.
2. Push the desired Anatomically Programmed Radiography (APR) switch or manually select the desired exposure factors. Start the exposure by pressing the switches for exposure preparation and exposure release.

3.7 Exposures with vertical Bucky Stand

- Adjust bucky on vertical bucky stand to desired examination region.
- By pressing the button (Fig. 2-2/3) release brake for rotation of X-ray tube assembly around support arm axis.
- Move X-ray tube unit towards vertical bucky unit.
- By pressing button (Fig. 2-2/5) release brake for the longitudinal movement of the stand and adjust X-ray tube assembly to the necessary focal spot to film distance (FFD) (only possible with version SH). Observe focus range of the bucky on bucky stand and adjust it with measuring tape on collimator (fig. 2-3/10).
- By pressing button (Fig. 2-3/9) switch on collimator light.
- By pressing button (Fig. 2-2/4) release brake for height adjustment of X-ray tube assembly.
- Adjust X-ray tube assembly to desired height and align it with light of collimator (fig. 2-3/4) towards bucky.
- Release button (Fig. 2-2/4) and fix brake for height adjustment of X-ray tube assembly.
- By pressing button (Fig. 2-3/9) switch on collimator light in order to check opening of collimator shutters to the used of the exposure medium size.
- Adjust collimator shutters to size of used exposure medium with collimator adjustment controls.(fig. 2-3/1 and fig. 2-3/7). Several FFD scales (Figure 2-3/2 and fig. 2-3/8) are provided to indicate the correct settings of the collimator adjustment controls. So the light beam and the X-ray field can be limited to the desired of the exposure medium size.

Recommendation:

To reduce patient dose and to optimize image quality it should be superimposed to size of the object.

- Select needed device at the X-ray generator control console (vertical bucky unit).
- Push the desired Anatomically Programmed Radiography (APR) switch or manually select the desired exposure factors. Start the exposure by pressing the switches for exposure preparation and exposure release.

4 Maintenance through the User

4.1 Introduction

This chapter provides a maintenance schedule to ensure proper and safe operation after installation. Any further adjustments or calibration not contained in these "Instructions for Use", is permitted only from **PROVOTEC** service or the expressly authorised service providers according to the applicable "Technical Description".

4.2 Safety Information

The user and the service Customers are reminded to observe all **CAUTIONS** and **WARNINGS** as they appear throughout the text of these "Instructions for Use". Failure to comply may result in serious or fatal bodily injury.
In the event of a malfunction, turn the equipment off and notify **PROTEC** service or the expressly authorised service providers.

4.3 Technical Safety Information

To protect the safety of patients, users, and third parties, it is absolutely essential that the equipment be subjected to tests by **PROTEC** service or by expressly authorised service providers in intervals of 6 months to ensure its reliable function and operational safety.

All parts of this equipment that could create a hazard through wear and tear must be checked, and if necessary, replaced by **PROTEC** service or by expressly authorised service providers in intervals of 6 months.

As the manufacturer, we are responsible for the technical safety aspects of the equipment if any maintenance, repairs and/or modifications are performed by our staff or by expressly authorised service providers. Likewise, if component parts that affect the safety of the equipment are replaced by original replacement parts in the event of a failure, we are responsible for the technical safety aspects of the equipment.

In the event that scheduled maintenance is not performed, **PROTEC** 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 the start of examination operations, the operator must ensure that all the equipment, which is listed in the Instructions for Use and which is relevant to safety, is functioning properly and that the product is ready for use. A visual check shall be made to insure that all displays and indicator lamps are functioning correctly.

4.4 Maintenance Schedule

4.4.1 User´s Maintenance Scheduler

Prior to cleaning or disinfecting, ensure that the system power is turned off, that the emergency OFF switch or safety switch is actuated, and that no liquids can penetrate into the equipment.

4.4.1.1 Cleaning

NOTE:

Do not use water for cleaning. Water causes short circuits in the electrical portion of the system, and corrosion in the mechanical components.

Do not use corrosives, solvents or abrasive cleaning materials.

Clean painted and plastic surfaces only with a cloth and common household cleaners and wipe surfaces with a clean, dry, lint-free cloth.

Clean chrome-plated parts by wiping with a clean, dry, lint-free cloth.

4.4.1.2 Disinfection

NOTE: For safety reasons, no spray disinfectants may be used.

All components, including accessories and connecting cables, may be disinfected only by wiping with a disinfectant solution. Please contact **PROTEC** if detailed information is needed concerning appropriate disinfection materials.

The equipment must be well covered with plastic sheets during room disinfection.

Recommendations and instructions regarding the use of disinfectants and methods of disinfection may be derived from the most recent rules and guidelines concerning disinfection and explosion safety.

4.4.2 User´s daily Maintenance prior to Operation

No daily maintenance check is required prior to operation.

4.4.3 User´s daily Maintenance during Operation

No daily maintenance check during operation is required.

4.4.4 Monthly Check

4.4.4.1 Quality Control

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, e.g., by monthly “Konstanzprüfung”

4.4.5 Maintenance

Required maintenance must be performed at 6-months intervals by PROTEC Service or a specifically authorised service provider to ensure the safe and reliable operation of the equipment.
In the event that scheduled maintenance is not performed, PROVOTEC will not be responsible for damages incurred by the user or third parties if such damages are the result of improper or omitted maintenance.

4.4.6 Duration of Life Time of the Product

The **PROTEC PROGNOST SH** is designed for a useful life of ten years, when used as intended and the regular maintenance schedule will be performed by the **PROTEC** service organisation or by expressly authorised service providers.

4.4.7 Disposal Remarks

The **PROGNOST SH** do not contain any toxicological materials.
All mechanical, electrical and plastic components have to be disposed according to local or national regulations.

5 Combination with other Equipment

- The stand PROGNOST SH is normally prepared for the use with Varian X-ray tubes. X-ray tubes of other manufacturers can also be adapted. Before combination with these X-ray tubes, please contact PROTEC GmbH & Co. KG for checking of compatibility.
- All components listed below optional components in chapter 1.
- Tube stand PROGNOST SH can be used with generators of the series ProVario.
- Combinations with a vertical bucky stand PROVERT, the mobile table PROGNOST XS or with the mobile table series PROGNOST XPx are possible.
- Combination with other units upon request and release prior to use from PROTEC

6 Technical Data

6.1 Tube stand

Focal spot vertical travel (horizontal X-ray beam):	250 to 1890 mm
Angulation of X-ray tube assembly around horizontal support arm axis:	± 120°
Detents	- 90°, 0°, + 90°
Longitudinal travel, tubestand	1280 mm

6.2 Total weight

Approx. 200 kg with X-ray tube assembly

6.3 Electrical Data

6.3.1 Safety Class

The device corresponds to the safety class I.

6.3.2 Voltage

21 VAC, 50/60 Hz, 2 A
Voltage for electromagnetic brakes of tube stand and collimator is provided by the Generator. Alternativ a power supplay transformer is available.

6.4 Environmental Conditions

6.4.1 Operating Environment

Temperature range:	+ 10 °C to + 40 °C
Relative humidity range:	30 % to 75 %
Atmospheric pressure range:	700 hPa to 1060 hPa

6.4.2 Transport and Stock Environment

Temperature range:	- 10 °C to + 70 °C
Relative humidity range:	10 % to 95 % (not condensing)
Atmospheric pressure range:	500 hPa to 1060 hPa

6.5 Standards

DIN EN 60601-1 (1996-03)	Medical electrical equipment, General requirements for safety
DIN EN 60601-1-2 (1994-09)	Medical electrical equipment, General requirements for safety, additional Standard Electromagnetic Compatibility
DIN EN 60601-2-32 (1995-11)	Medical electrical equipment, Part 2: Special Requirements for Safety of X-ray equipment

The CE-labeling of this product is in conformity to the requirements of the European Community Medical Device Directive 93/42/ECC according to Article 11 Appendix II.

7 Description of Symbols, Labels and Abbreviations

7.1 Symbols

Attention, consult accompanying documents

Protective earth

CE-marking

Classification according to EN 60601-1, Class 1 Equipment, Type B

7.2 Labels

Nameplate

7.3 Abbreviations

mm	millimeter
cm	centimeter
kg	kilogram
°C	Degree centigrade
hPa	Hektopascal
DIN	German Industrial Standard
EN	European Norm
CE	CE-marking