Prognost FS

Model/ID: 7042-5-XXXX

Instructions for Use

Ident. Nr. 5042-0-0002

CE

PROTEC GmbH, In den Dorfwiesen 14,
71720 Oberstenfeld, Germany

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Content

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 GmbH Technical Service Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
01	17/07/2013		3m rails, Standard changed
02	17/12/2013	6-1	250kg patient weight

03	15/10/2014		Turn Tube new; figures updated;
04	03/12/2014		Turn Tube updated

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** .

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 kinds 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** Customers. Assemblers and other Customers not employed by nor directly affiliated with **PROTEC GmbH** technical services are directed to contact the local **PROTEC GmbH** 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 .**

1 Equipment Description

1.1 Description

This “Instructions for Use” describes the features of the **PROTEC** universal horizontal bucky table **Prognost FS** and provides 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 this “Instructions for Use” before using the **Prognost FS**. Each control is described to acquaint you with its function.

1.2 Intended Purpose

The Prognost FS is a modern, horizontal X-ray bucky table for a wide range of X-ray examinations for diagnostic human medicine use.
The Prognost is determined for fixed installation in medical rooms.
The Prognost FS 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/EWG from 06/14/1993.

You can get the declaration of conformity directly from

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1.4 Function

1.4.1 Description

The Prognost FS is prepared for the installation of a under table X-ray generator.

The Prognost FS consists of a bucky table with integrated tubestand.
The bucky table is prepared for the installation of a longitudinally displaceable running manually scanning device with electronic drive for an anti-scatter grid and 3-field measuring chamber for use with automatic exposure control.

The floating, flat tabletop of the bucky table is locked in place in the longitudinal and transverse directions by highly effective, foot-operated mechanical brakes.
Movement in both directions can be easily released by means of a conveniently placed brake release pedal bar. The easy floating movement of the tabletop and its wide range of displacement ensure convenient patient positioning. A long handgrip at the rear edge of the tabletop facilitates the patients getting on and off the bucky table.

The tubestand moves in two rails, which are integrally mounted, to the bucky table.
The counterbalanced horizontal support arm is prepared for mounting the X-ray tube assembly (X-ray tube and collimator) and control arm with the control elements. All movements of the tubestand and X-ray tube assembly are virtually effortless and are arrested by electromagnetic brakes. In addition, the X-ray tube assembly movement around its horizontal support arm axis has click-stops at 90° for alignment with a bucky wall stand etc.
All control elements on the control arm of the tubestand, collimator, and bucky table are easily accessible from the front of the bucky table.

All control elements on the control arm of the tubestand, collimator, and bucky table are easily accessible from the front of the bucky table.

1.4.2 Features

- Prepared for installation of an under table X-ray generator
- Wide range of applications.
- Short installation time due to the integrated tubestand
- High reliability
- Short wall distance allows efficient use of space.
- Table height of 70 cm provides convenient patient access.
- Floating, flat tabletop of carbon fiber combines high radio transparency with high rigidity.
- Tabletop color is pure white.
- Long handgrip at the rear edge of the tabletop is standard.
- Short tabletop-to-film distance
- Wide range of tabletop displacement for convenient patient positioning.
- Clearly marked tabletop centerline for transverse tabletop movement.
- Convenient low-profile lateral tabletop accessory rails for accessory attachment.
- Prepared for installation of a manual or automatic cassette loading bucky unit with bucky grid and 3-field measuring chamber for operation with Automatic Exposure Control (AEC).

- Capability can be expanded through the installation of a bucky unit with manual or automatic cassette loading and cassette size sensing for automatic collimation of the cassette sizes. This option requires an automatic collimator.
- Safety coupling for automatic centering of X-ray tube assembly to bucky unit.
- Extensive cassette program with nominal film sizes from 13 x 18 cm up to 35,6 x 43 cm.
- Ceiling independent tubestand suitable for rooms with minimum 2.30 m ceiling height.
- Control elements are arranged for easy access and operation on the control arm.
- Angle indicator ensures reproducible angulation positions 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 the X-ray beam horizontal.
- Electromagnetic brakes for longitudinal travel of tubestand, vertical travel of X-ray tube assembly, and rotation of X-ray tube assembly around support arm axis, with additional 90° click-stops.

1.5 Equipment Components

The Prognost FS can run the following equipment components:

- Horizontal bucky table with floating, flat tabletop and integrated tubestand
- electronically controlled bucky unit with cassette tray and adaptation parts *
- 3-field measuring chamber with mounting parts *
- collimator *
- control arm
- collimator with fixed or swivel subpanel *
- X-ray tube with hood clamp *
- Turn Tube +/- 90°*

* not included with the Prognost FS

1.6 Optional Equipment

The following accessories are available to expand the operational capabilities of the Prognost FS.

1.6.1 Bucky unit

All bucky units of **PROTEC** can be installed in the bucky table. Installation of bucky`s other manufacturers on request.
The bucky table is prepared for installation of manual or automatic cassette loading bucky units with bucky grid and 3-field measuring chamber for operation with Automatic Exposure Control (AEC).
Capability can be expanded through the installation of a bucky unit with manual or automatic cassette loading and cassette size sensing for automatic collimation of the cassette sizes. This option requires an automatic collimator.
Maximum bucky unit travel is 560 mm.
The bucky unit controls the bucky grid operation electronically and ensures bucky grid line-free radiographs. The exposure is timed to occur at maximum bucky grid velocity.

1.6.2 3-Field measuring chamber

A 3-field measuring chamber permits the automatic exposure control with an Automatic Exposure Control (AEC) system.

1.6.3 X-ray

You can X-ray source from different manufacturers with the appropriate hood clips and adjustment parts are used.

1.6.4 Collimator

Collimator with a fixed or rotating low subpanel for manual cassette format setting or automatically adjusting motor in conjunction with a running grating device with cassette format scanning.

1.6.5 Compression device

The compression device fits to the tabletop accessories rails. The transparent compression band can be used to compress or immobilize the body part under examination. The compression device is self-locking.

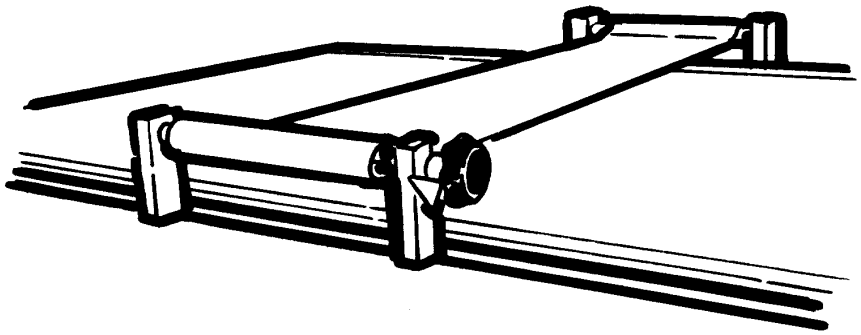


Figure 1-1

1.6.6 Tübinger positioning device

The Tübinger positioning device can be installed on the end of the tabletop for exposures of the patella.

1.6.7 Urological Accessoriers

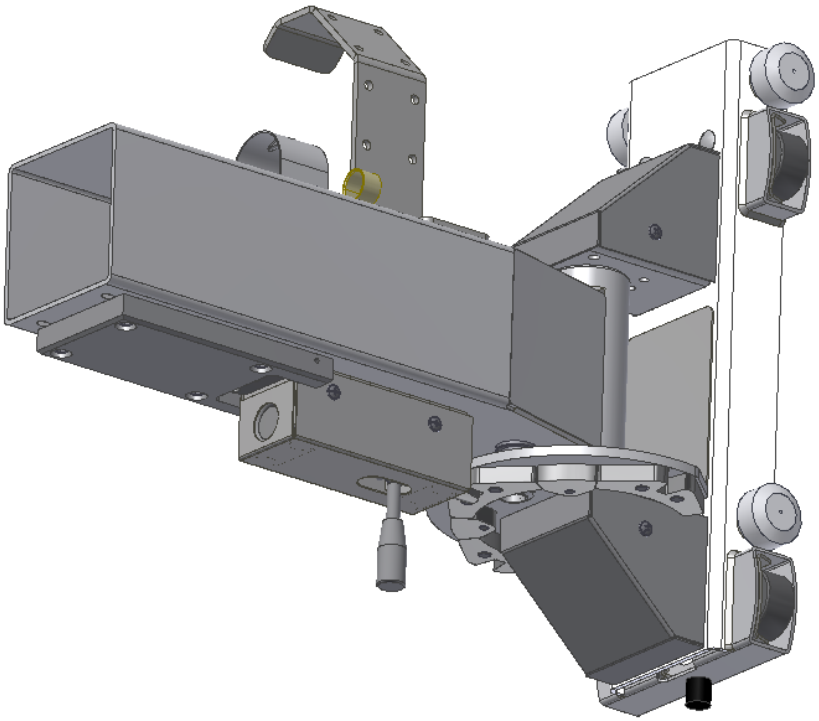
Urological accessories such as leg supports, positioning wedge, run-off basin, etc. are available on request.

1.6.8 Guide Rails for 3m Film Focus Distance (FFD)

Extended ground guide rails that allow for a three meter Film Focus Distance (FFD)

The ground guide rail extension can be implemented in both the left handed (Provert wall stand to the left of the table) and right handed (Provert wall stand to the right of the table) configurations.

1.6.9 Turn Tube +/-90°



1.7 Nameplate

The nameplate is located at the lower rear side at the right frame of the bucky table

2 Controls and Indicators

2.1 Brake release pedal bar and hand grip

The long handgrip (Figure 2-1/2) facilitates the patients getting on and off the bucky table.
Release the tabletop brakes by stepping on the foot-operated brake release pedal bar (Figure 2-1/4) to position the floating tabletop (Figure 2-1) manually.

The tabletop movement from the center position is as follows:

transverse direction ± 150 mm,
longitudinal direction ± 470 mm.

Caution:

Bring the tabletop (Figure 2-1) into the forward position before getting on or off the patient!

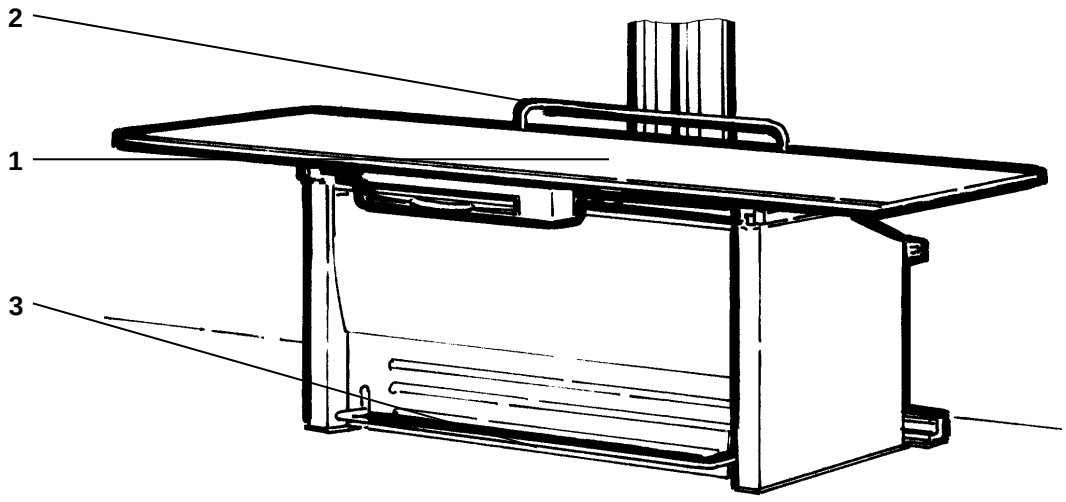


Figure 2-1

1. Tabletop
2. Hand grip
3. Brake bar

2.2 Bucky unit*

The bucky unit consists of a cassette tray (Figure 2-1/2). The cassette tray positions the cassette in the bucky unit.
Pull out the cassette tray (Figure 2-1/2) by its handle (Figure 2-3/2) from the bucky unit until it hits the forward stop. Two cassette clamps (Figure 2-2/2) center the cassette transversely within the cassette tray. Insert the cassette, with its transverse centerline aligned with the notch in the cassette clamps (Figure 2-2/2). Use the handle (Figure 2-3/2) to push the cassette tray (Figure 2-1/2) fully into the bucky unit. Maximum bucky unit travel is 560 mm.

* not included with the Prognost FS

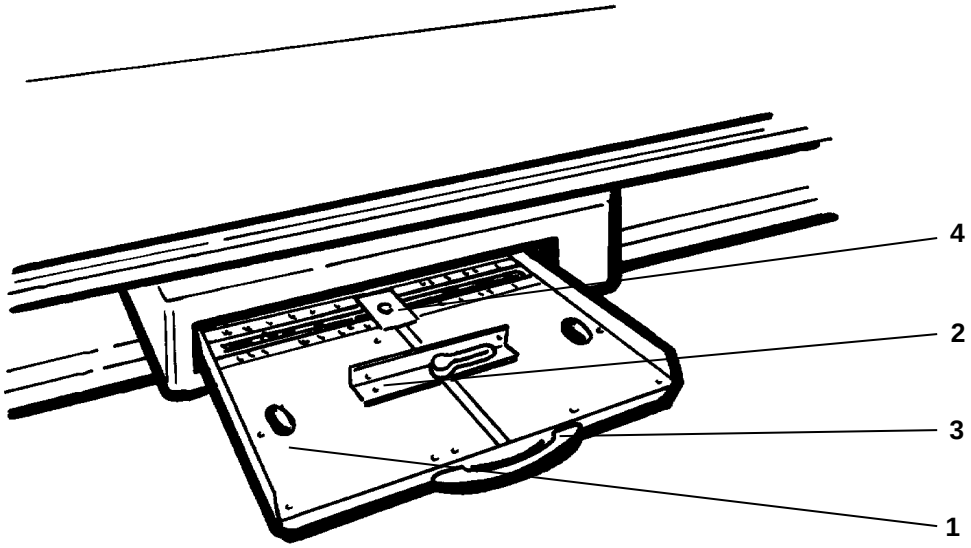


Figure 2-2

2.3 Safety coupling

The tubestand are centered focus coupled with the moving grid unit by a safety coupling. Thus, the assignment of X-ray unit and moving grid unit at shifting the X-ray unit in table longitudinally receive. Upon displacement of the tubestand on the range of movement of the moving grid unit also speaks the safety coupling immediately and separates the run from the tubestand tripod. Is the tubestand again moved to the range of movement of the running latch means which automatically connects the safety coupling stand with the moving grid unit.

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Caution:

Make absolutely sure that the safety coupling is fully engaged, otherwise the focus of the X-ray source does not coincide with the center of the film.

2.4 Tubestand

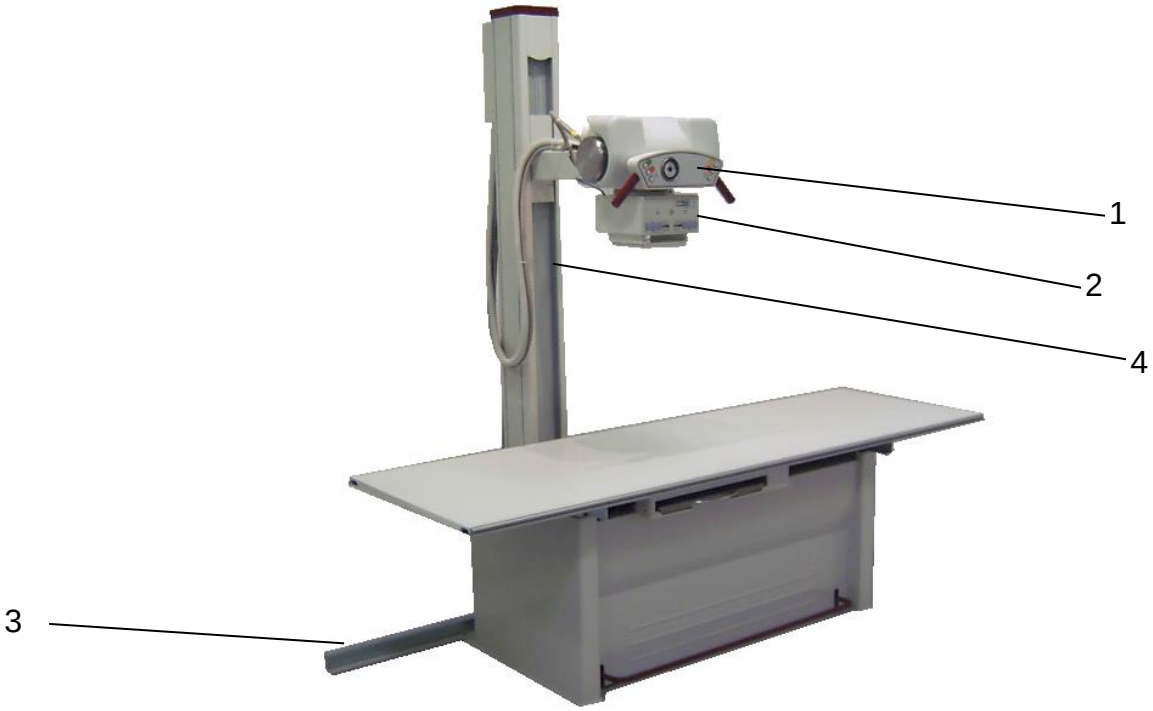

Figure 2-3

1. Control arm
2. Collimator
3. Focal spot to film distance (FFD) marking for bucky wall stand
4. Focal spot to film distance (FFD) scale for bucky table

2.5 Control arm

1. Angle indicator; indicates angle of the X-ray tube assembly
2. Central brake release switch; when actuated, all movements are released.
3. Angulation 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 tubestand.
6. X-ray tube cover

The controls are operated from the front (operator side) of the tubestand. With pressure by the operator's 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.

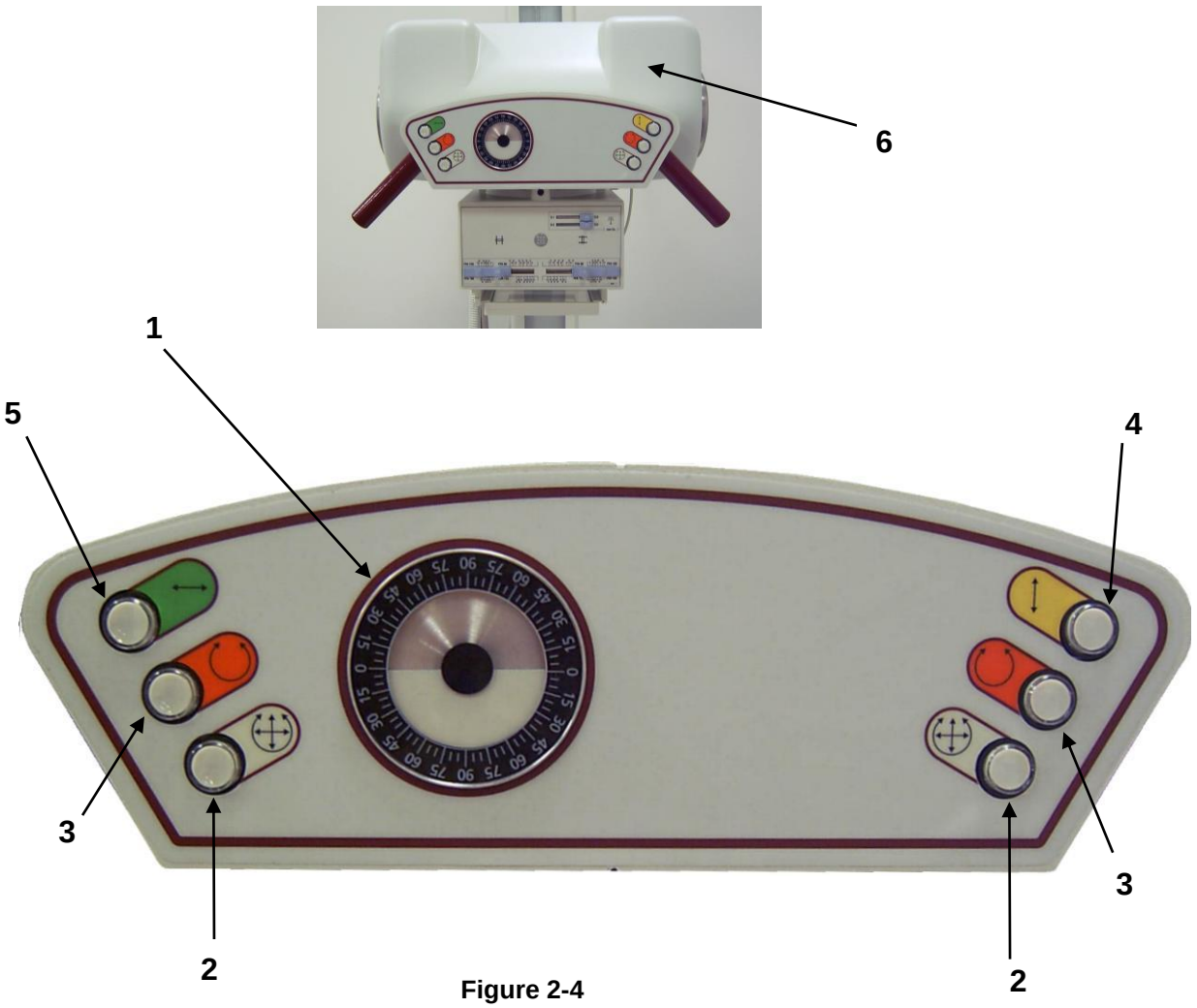

Figure 2-4

2.6 Collimator Example *

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

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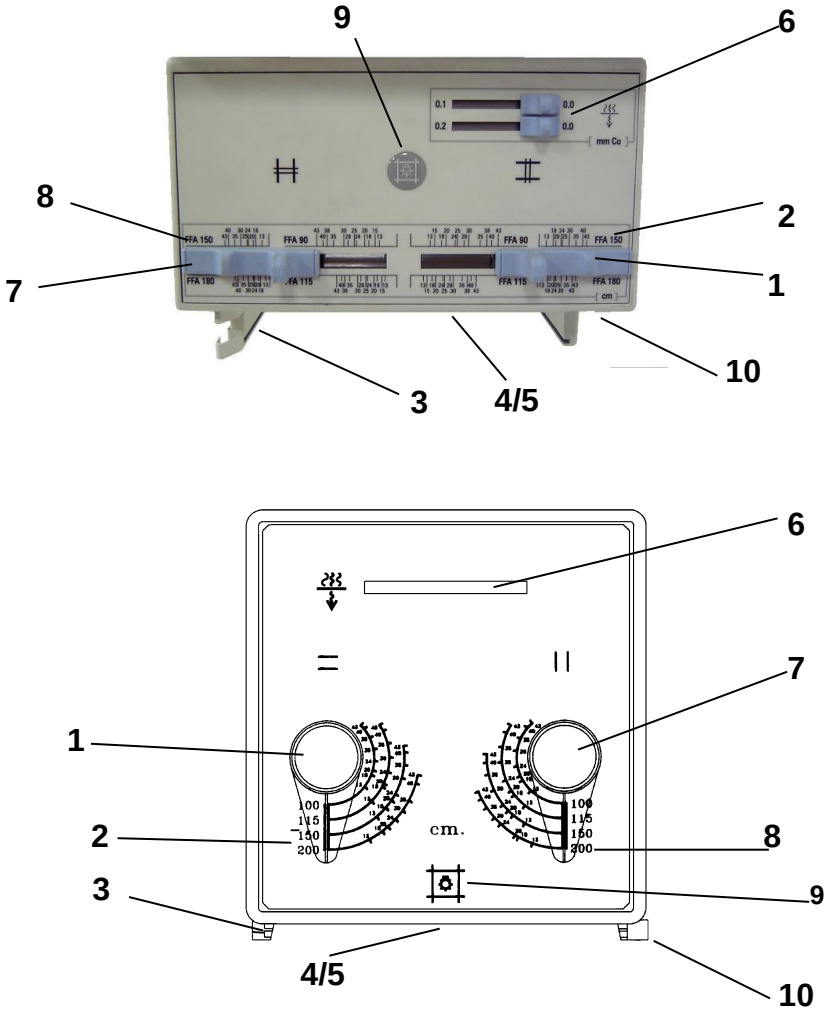


Figure 2-5 T

***** is not included with the Prognost FS and may vary depending on system

2.7 Turn Tube +/-90°*

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

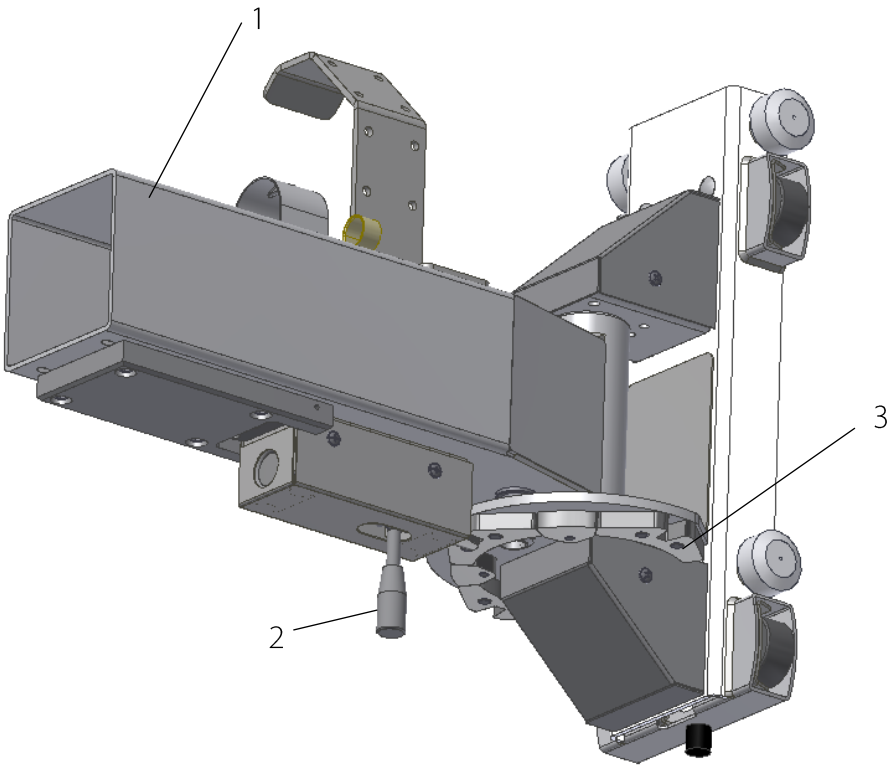


Figure 2-7

***** is not included with the Prognost FS and may vary depending on system

3 Operating Instructions

3.1 Safety Aspects

3.1.1 Requirements for Operation

The Prognost FS system may only be put into operation by the customer when the PROTEC customer service or an authorized sevice he has completed the installation, and the official transfer is made to the customer.
Likewise, make sure that before starting any necessary notifications were made.
The national rules for the release of the newly installed X-ray equipment and to its further monitoring during the operating period by testing organizations are respected.
Furthermore, it is essential to comply with the maintenance requirements (see Chapter 4) to respect.

3.1.2 Users

The **Prognost FS** 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 the owner provides an emergency OFF switch, 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 to 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. do
- **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 marking 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 Y-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.

Recordings are generally caused behind a protective wall. Eighth when shooting near the generative organs in the best possible protection (gonad protection or lead rubber covers).
People who have to be in the vicinity of the patient must wear protective clothing (eg. Lead apron). The same goes for maintenance and repair work.

3.1.6 Ventilation

It is imprortant to ensure that the air exchange of the X-ray generator in Prognost is not impeded. The ambient air temperature must not exceed 40°C.

3.1.7 Interferences to Other Devices

Interactions with other devices are not known. The system complies with the requirements of the standard 60601.

3.2 Patients getting on the table top

- Step on the brake release pedal bar (Figure 2-1/)
- Move the tabletop (Figure 2-1/1) into position for patients convenient getting on the tabletop.
- Release the brake release pedal bar (Figure 2-1/3) .
- Assist the patient in getting on and lying down on the tabletop (Figure 2-1/1)
- Step on the brake release pedal bar (Figure 2-1/3) and position the patient by moving the floating tabletop (Figure 2-1/1) .

3.3 Patients getting off the tabletop

- Step on the brake release pedal bar (Figure 2-1/3) .
- Move the tabletop (Figure 2-1/1) into position for patients convenient getting off the tabletop.
- Release the brake release pedal bar (Figure 2-1/3) .
- Assist the patient in getting off the tabletop (Figure 2-1/1).

3.4 Setting the X-ray unit on the mid moving grid unit

- Press the button (Figure 2-4/5) off the brake for the longitudinal motion of the tubestand.
- The handles on both sides of the control arm include.
- Moving the X-ray unit in the longitudinal direction of the Bucky table so unit the moving grid snaps into the safety coupling.

3.5 Adjusting the focus-film distance (FFD)

- Set the X-ray unit with a tape measure at the collimator or the display (Figure 2-3/4) on the tube to the desired focus-film distance (FFD).
- Press the button (Figure 2-4/4) off the brake to adjust the height of the X-ray unit.

3.6 Inserting a cassette into the cassette tray

- A film cassette may be placed into the cassette tray, when the X-ray tube assembly is positioned (see item 3.3 and item 3.4).
- Pull out the cassette tray (Figure 2-1/2) by its handle (Figure 2-3/2) from the bucky unit until it hits the forward stop.
- The cassette clamps (Figure 2-2/2) center the cassette transversely within the cassette tray. Rotate its latch counterclockwise to unlock it.
- Open the cassette clamps (Figure 2-2/2) far enough to insert a cassette of the desired size.
- At table bucky insert the cassette, with its transverse centerline aligned with the notch in the cassette clamps (Figure 2-2/2) or by engaging the cassette positioner (Figure 2-2/4) in the size of the cassette corresponding detent (13 cm, 18 cm. 35 cm, 40 cm or 43 cm), push the cartridge to the cassette positioner (Figure 2-2/4)
- Push the cassette clamps (Figure 2/2-2,) against the cassette, and rotate the latch into the locked position.
- Push the cassette tray (Figure 2/2-1) fully into the bucky unit.

3.7 Adjusting the light resp. X-ray field

- Press the collimator light switch (Figure 2-5/9) to turn on the collimator light, and view the opening of the collimator shutters in both axes relative to the cassette size scales.
- Several FFD scale (Figure 2-5/1 and Figure 2-5/7)are provided to indicate the correct settings of the collimator adjustment controls for the collimator shutters for several cassette sizes so that the light beam and the X-ray field can be limited to the desired cassette size in both axes. Adjust cassette size as required using the collimator adjustment controls. Reduce shutter openings to object size for better image quality.

3.8 Exposure preparation / exposure release

- At the X-ray generator operator console control panel, select the desired X-ray equipment (bucky table with bucky unit) by selecting the corresponding X-ray equipment/exposure technique switch.

- Press the desired Anatomically Programmed Radiography (APR) switch or manually select the desired exposure factors. Start the exposure by pressing the switches for exposure preparation/exposure release.

3.9 Overtable exposures

- Place a cassette to the desired position on the tabletop.
- Move x-ray tube to the desired position and adjust FFD.
- Press the collimator light switch (Figure 2-5/9) to turn on the collimator light, and view the opening of the collimator shutters in both axes relative to the cassette and object size.
- Place object on cassette
- Adjust collimator opening to max cassette size or smaller to the object size.
- At the X-ray generator operator console control panel, select the desired X-ray equipment (bucky table without bucky unit) by selecting the corresponding X-ray equipment/exposure technique switch.
- Press 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.

3.10 Shooting vertical bucky device

- Press the button (Figure 2-4/3) off the brake fort he rotation of the X-ray unit to the arm axis.
- The X-ray unit for vertical bucky device back swing.
- Set the running scanning device on vertical bucky device on the patient size.
- Press the button (Figure 2-4/5) off the brake fort he longitudinal motion of the tube stand, and set the X-ray unit to the focus-film distance (FFD), which is necessary for the investigation to be carried out, where in any case the to observe focus area of the grid of the moving grid direction. This setting is with tape on the collimator or the markers (Figure 2-3/4) made to the upper guide rail of the tube stand.
- Switch on by pressing the button (Figure 2-5/9) the visor light lamp.
- Press the button (Figure 2-4/4) off the brake to adjust the height of the X-ray unit.
- Set the X-ray unit to the desired height, and with the centering light the sighting device (Figure 2-5/4) align the X-ray unit at moving grid.
- Release the button (Figure 2-4/4) to the brake to adjust the height of the X-ray unit back on.
- Press the button (Figure 2-5/9) turn the light visor lamp to check the depth of the opening aperture blades for use cassette.
- Use the adjusters (Figure 2-5/1 and Figure 2-5/7) the low aperture blades on the size of the cassette. The adjustment is made on the scale (Figure 2-5/2 and Figure 2-5/8) for the corresponding source-image distance (SID). So that the light/radiation field is limited to the used cartridge size.
- Choose Pedestal X-ray generator, the application device (vertical grid recorder).
- Set the desired organ or program have the recorded data, and start the recording by operating the controls for recording preparation / collecting trip.

3.11 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!

3.11.1 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°)

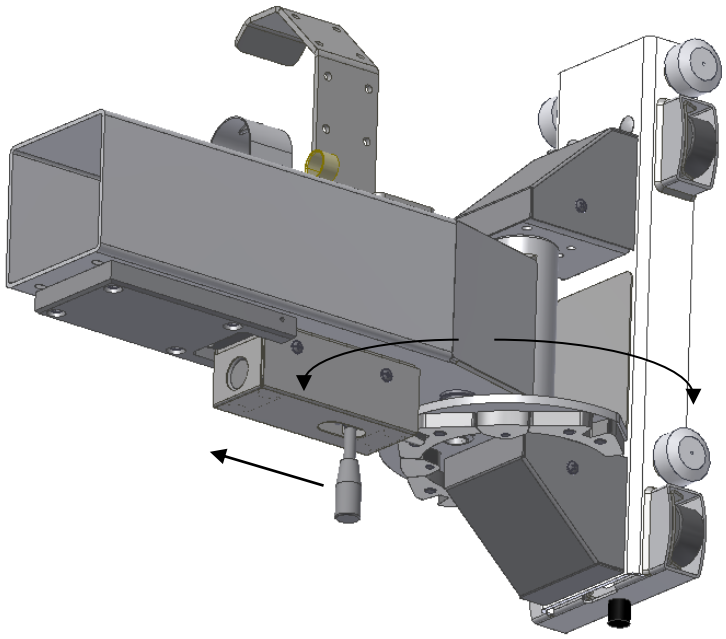


Figure 3-11-1

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.

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 this "Instructions for Use“ is permitted only from **PROTEC** service or the expressly authorized 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 this "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 authorized 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 according to the maintenance interval specified by the customer service PROTEC or authorized service essential.

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 authorized service providers at regular intervals.

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 authorized 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 Schedule

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 Disinfecting

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 is required during operation.

4.4.4 Monthly checks

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.

4.4.5 Maintenance

Required maintenance must be performed at 6-months intervals by **PROTEC** Service or specific authorized service provider to ensure the safe and reliable operation 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.

4.4.6 Duration of Life Time of the Product

The **PROTEC** Prognost FS 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 organization or by expressly authorized service providers.
PROTEC guarantees the supply of spare parts during these 10 years.

4.4.7 Disposal Remarks

The Prognost FS does not contain any toxicological materials.
All mechanical, electrical and plastic components have to be disposed according to the local or national regulations.
In case of doubt contact **PROTEC GmbH & Co.KG**

5 Combination with other Equipment

The Prognost FS standard it is prepared for Varian X-ray source. X-ray source can be adopted by other manufacturers.

Prior to the combination with these X-ray sources is the PROTEC GmbH to verify the compatibility to address.

All listed under optional extensions in Chapter 1 components.

Prognost FS can be connected to a standard generator.

Combination with other equipment, components or generators on request.

6 Technical Data

6.1 Bucky table

Tabletop dimensions:	2260 mm x 755 mm, standard
	2000 mm x 755 mm, optional
Max. patient weight :	230 kg TP compound
Max. patient weight:	250 kg TP carbon
Table height:	692 mm
Front/rear (transverse) travel:	± 150 mm
Heat/foot (longitudinal) travel:	± 470 mm

The tabletop brakes are released mechanically

Attenuation Equivalent of the tabletop

The aluminum attenuation of the table top is typical 0,7 mm and < 0,8 mm Al according to EN 60601-1-3 at 100 kV and a first half value of 3,7 mm Al.

6.2 Bucky

Travel:	560 mm
Minimum distance, film center to table head end:	330 mm
Minimum distance, film center to table foot end:	440 mm
Tabletop to film distance:	67 mm

Electrical connection of the bucky unit

The bucky unit with bucky grid and measuring chamber is connected to the X-ray generator.

Attenuation equivalent of covering the bucky

The aluminum attenuation equivalent of covering the bucky (if any) is i=<0,2 mm Al to EN 60601-1-3 at 100kV and a first halfvalue layer of 3,7mm Al.

6.3 Tube stand

Focal spot vertical travel (horizontal X-ray beam):		250 - 1892 mm
Vertikal focus- film distance:		max. 1267 mm
Vertikal focus- table distance:		max. 1200 mm
Around horizontal support arm axis:	± 120°	
Detents:	- 90°, 0°, + 90°	
Vertikal focus arm:	1642 mm	
Longitudinal travel, tubestand:	1285 mm	
Longitudinal travel, tubestand at 3m FFD:	1850mm	

6.4 Total weight

approx. 400 kg

6.5 Elektrical Data

6.5.1 Equipment classification

The device complies with protection Class I

6.5.2 Voltage

Voltage for electromagnetic brakes of tube stand and collimator is provided by the Generator.

6.6 Product Life Time

The **Prognost FS** is designed for a useful lifetime of 10 years if used according specifications and regular maintenance through **PROTEC** service or expressly authorized service providers by **PROTEC**.

6.7 Environmental Conditions

6.7.1 Operating Environment

Temperature range:	+10°C bis +40°C
Relative humidity range:	30% bis 70% (not condensing)
Atmospheric pressure range:	700 hPa bis 1060hPa

6.7.2 Transport and Stock Environment

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

6.8 Standards

EN 60601-1 (2006)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-3 (2008)	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
EN 60601-2-54 (2009)	Medical electrical equipment, Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

The CE-labeling states that this product is in conformity to the requirements of the European Community Medical Device Directive 93/42/EWG according to Article 11 Section 3 Appendix II

7 Description of Symbols, Labels and Abbreviations

7.1 Symbols

Attention, consult accompanying documents

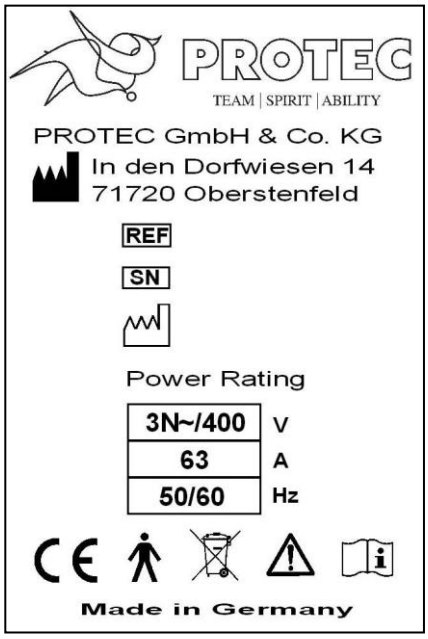
CE-marking

Protective earth

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

7.2 Labels

Nameplate



7.3 Abbreviations

mm	millimetre
cm	centimetre
kg	Kilogram
°C	Degree centigrade
hPa	Hektopascal
DIN	German Industrial Standard
EN	European Norm
CE	CE-marking