Prognost F

Model/ID: 7041-5-XXXX

Instructions for Use

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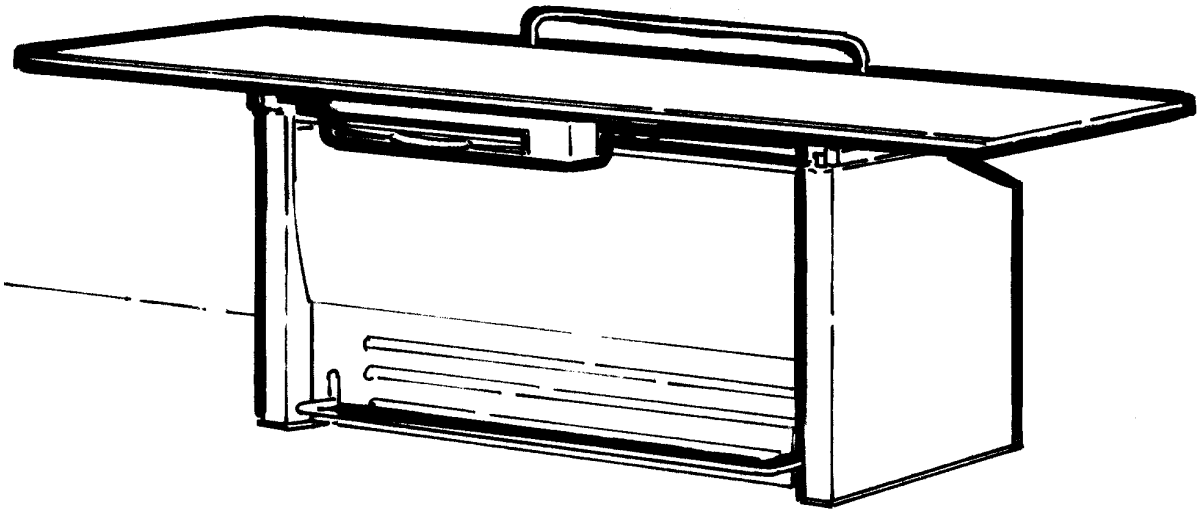

CE

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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 GmbH Technical Service Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
	25/07/2004	all	Original Issues
Rev. 1	09/03/2005	all	new layout
Rev. 2	14/01/2011	All	Modified address
Rev. 3	14/11/2011	All	New Lable; Protec
Rev. 4	31/07/13	All	Changed standard
Rev. 5	17/12/13	4-1	250kg patient weight

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 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 & 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 Description

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

1.2 Intended Purpose

The Prognost F 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 F 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 F consists of a horizontal bucky table with a floating tabletop and is prepared for installation of an electronically controlled, longitudinally movable bucky unit for manual or automatic cassette loading with bucky grid and 3-field measuring chamber for operation with Automatic Exposure Control (AEC).
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 motion of the tabletop and its wide range of displacement ensure convenient patient positioning. A long handgrip at the rear side of the tabletop facilitates the patients getting on and off the bucky table.

1.4.2 Features

- Prepared for installation of the microprocessor-controlled X-ray generator ProVario 50 inside the bucky table.
- Wide range of applications.
- Short installation time due to the integrated tubestand.
- High reliability.
- 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 white
- Long handgrip at the rear side of the tabletop is standard.
- Short tabletop-to-film distance.
- Wide range of tabletop displacement for convenient patient positioning.
- Clearly marked tabletop centerline (white version only) for transverse tabletop travel.
- 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.
- Extensive cassette program with nominal film sizes from 13 x 18 cm up to 35,6 x 43 cm.

1.5 Equipment Components

The Prognost F can comprise the following equipment components:

- Horizontal bucky table with floating, flat tabletop
- Electronically controlled bucky unit with cassette tray and adaptation parts *
- 3-field measuring chamber with mounting parts *
- Bucky grid *

1.6 Optional Equipment

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

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 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.

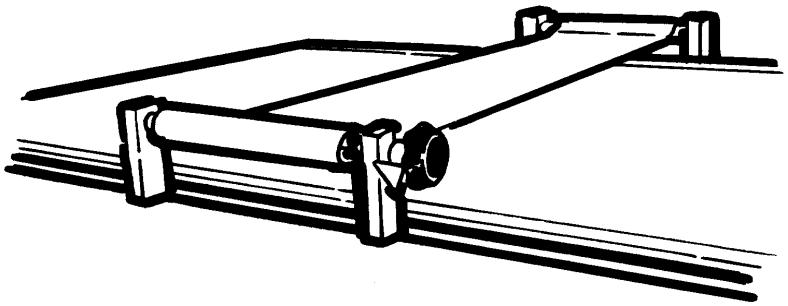


Figure 1-1

1.6.4 Tübinger positioning device

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

1.6.5 Urological Accessories

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

1.7 Nameplate

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

2 Controls and Indicators

Brake release pedal bar and hand grip

The long handgrip (Figure 2-5) 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 2-4) 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!

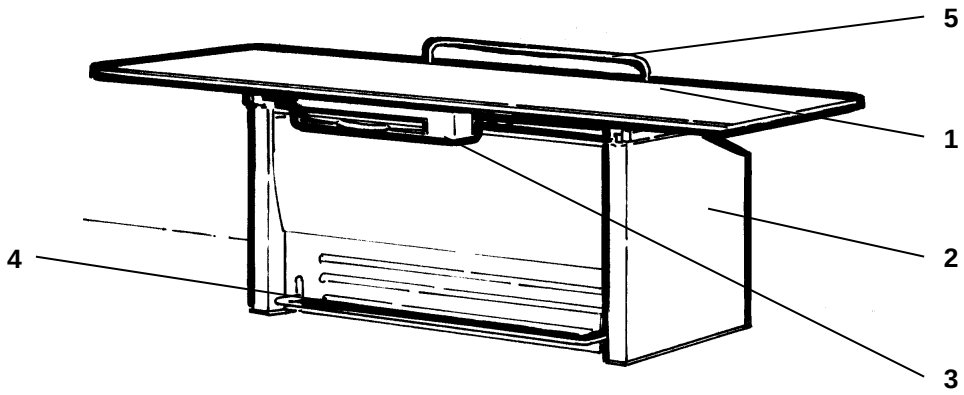


Figure 2-1

Tabletop
Table base
Bucky
Foot pedal brake release bar
Hand grip

Bucky unit *

The bucky unit consists of a cassette tray (Figure 2/2-1). The cassette tray positions the cassette in the bucky unit.
Pull out the cassette tray (Figure 2/2-1) by its handle (Figure 2/2-3) 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 2/2-3) to push the cassette tray (Figure 2/2-1) fully into the bucky unit. Maximum bucky unit travel is 560 mm.

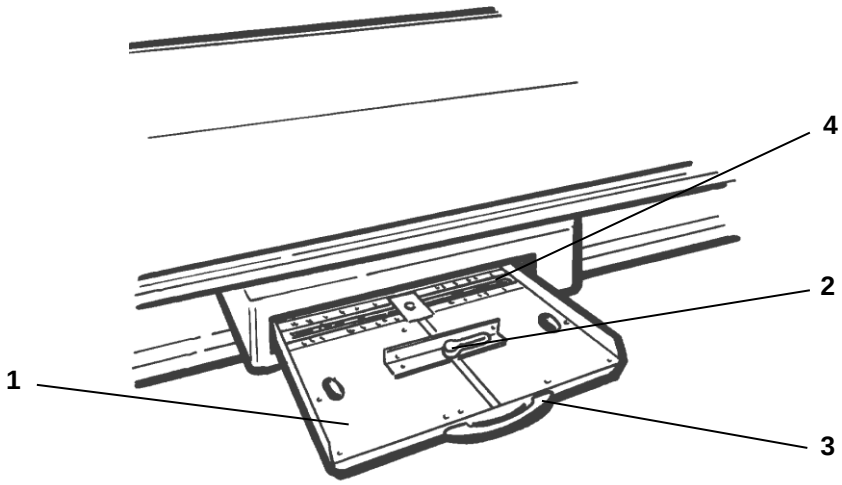


Figure 2-2

3 Operating Instructions

Safety Aspects

3.7.1 Requirements for Operation

The **Prognost F** must to be completely installed and officially handed over to the customer before the customer can use it.

The national regulations concerning announcement of new installed X-ray equipment and monitoring of the operating system must be met.

The Maintenance has to be carried out according instructions in chapter 4.

3.7.2 Users

The **Prognost F** 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.

3.7.3 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).

3.7.4 Explosion Protection

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

3.7.5 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.

4 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.

1. **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).

1 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.

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.

1 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.

1.7.1 Ventilation

If an x-ray generator is installed inside the Prognost F bucky table the air ventilation shall not be hindered.

1.7.2 Interferences to Other Devices

There are no interferences to other devices known.

1.8 Patients getting on the tabletop

Step on the brake release pedal bar (Figure 2-1, item 3)

Move the tabletop (Figure 2-1, item 1) into position for patients convenient getting on the tabletop.

Release the brake release pedal bar (Figure 2-1, item 3).

Assist the patient in getting on and lying down on the tabletop (Figure 3-1, item 1).

Step on the brake release pedal bar (Figure 2-1, item3) and position the patient by moving the floating tabletop (Figure 2-1, item 1).

1.9 Patients getting off the tabletop

Step on the brake release pedal bar (Figure 2-1, item 3)

Move the tabletop (Figure 2-1, item 1) into position for patients convenient getting off the tabletop.

Release the brake release pedal bar (Figure 321, item 3).

Assist the patient in getting off the tabletop (Figure 2-1, item 1).

1.10 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.

Pull out the cassette tray (Figure 2/2-1) by its handle (Figure 2/2-3) 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).

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.

1.11 Adjusting the light resp. X-ray field

Press the collimator light switch 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 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.

1.12 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.

1.13 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 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.

2 Maintenance through the User

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".

2.14 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.

2.15 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 intervals displayed at chapter 4.4.5.1 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 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.

2.16 Maintenance Schedule

2.16.1 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.

2.16.1.1 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.

2.16.1.2 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.

2.16.2 User's Daily Maintenance Prior to Operation

No daily maintenance check is required prior to operation.

2.16.3 User's Daily Maintenance During Operation

No daily maintenance check is required during operation.

2.16.4 Monthly checks

2.16.5 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.

2.16.6 Maintenance

Required maintenance must be performed at 12-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.

2.17 Duration of Life Time of the Product

The **PROTEC** Prognost F 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.

2.18 Disposal Remarks

The Prognost F 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.**

3 Combination with other Equipment

The Prognost F is prepared for use with all standard over-table tube-stands.

All components mentioned in chapter 1 under optional equipment.

The Prognost F with **PROTEC** bucky's can be interfaced to all ProVario X-ray generators from **PROTEC**.

Combination with other units, components or alternative generators on inquiry only.

4 Technical Data

Bucky table

Tabletop dimensions:	2260 mm x 755 mm, standard
	2000 mm x 755 mm, optional
Table height:	697 mm
Max. patient weight:	230 kg TP compound
Max. patient weight:	250 kg TP carbon

Tabletop movement from center position

Front/rear (transverse) travel:	±150 mm
Head/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.

4.19 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.

4.20 Total weight

Approx. 140 kg

4.21 Equipment classification

The unit is a Class I, type B equipment according to EN 60601-1.

4.22 Product Life Time

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

4.23 Environmental Conditions

4.23.1 Operating Environment

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

4.23.2 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

4.24 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

5 Description of Symbols, Labels and Abbreviations

Symbols

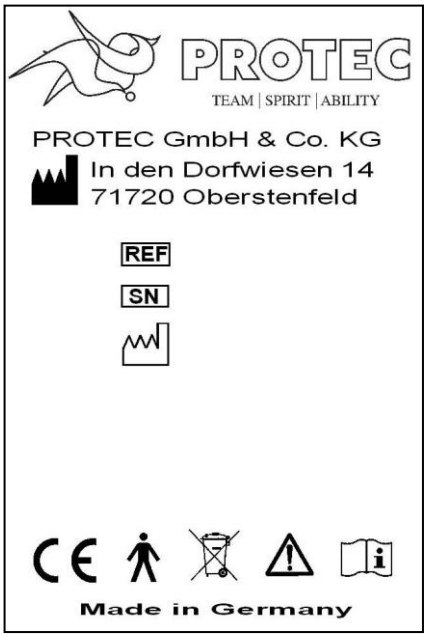
Attention, consult accompanying documents

CE-marking

Protective earth

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

Labels



Nameplate

Abbreviations

mm	millimetre
cm	centimetre
kg	kilogram
°C	Degree centigrade
hPa	Hektopascal
DIN	German Industrial Standard
EN	European Norm
CE	CE-marking
FFD	film-focus distance