PROGNOST XS

Mobile
Patient Table
with fixed tabletop

Model/ID: 7034-0-0000

Instructions for Use

Ident. Nr. 5034-0-0002

CE

2021-02-25 Protec GmbH & Co . KG, In den Dorfwiesen 14, 71720 Oberstenfeld, Germany

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Contents

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. KGTechnical Service Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
	12/06/2012		Original Issue
01	05/08/2013		Standard changed
02	07/01/2014		Technical Safety check interval 2 years
03	2021-02-25	3; 5; 6; 10; 11	All wheels with brake, cleaning the floor and wheels,

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 personnel 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** customer. Assemblers and other personnel 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

This „Instruction for Use“ describes the special, characteristic features and the correct operational instructions which are necessary for the efficient and effective use of the PROGNOST XS

It is suggested that you review the operation instructions, the safety notes and the controls described in this “Instruction for Use” before using the PROGNOST XS. Each control device and each display is described in order to make you acquaint with its function.

1.2 Intended Purpose

The PROGNOST XS is a patient table for examinations with X-ray units (e.g. type of L/U-arm units) for general radiography in diagnostic human medicine use. It has to used as movable patient table in medically used rooms only.

The PROGNOST XS is not suitable for patient transportation.

The PROGNOST XSS 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.

Upon request the declaration of conformity is available from:

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1.4 Description

1.4.1 Specific Characteristics

- Large range of application
- High reliability
- Easy movement
- Floating tabeltop

1.4.2 Unit versions

PROGNOST XS Basic

Frame color RAL 9003	7034-0-0000

1.5 Nameplate

For nameplate location refer to Figure (2-1/4).

2 Control Elements and Indicators

2.6 Brakes

In order to fix the patient table in all directions, it is fitted with 4 brake wheels, which have to be fixed with a fastener (Figure 2-1/1) on the left or right side before a patient gets on or off the tabletop.

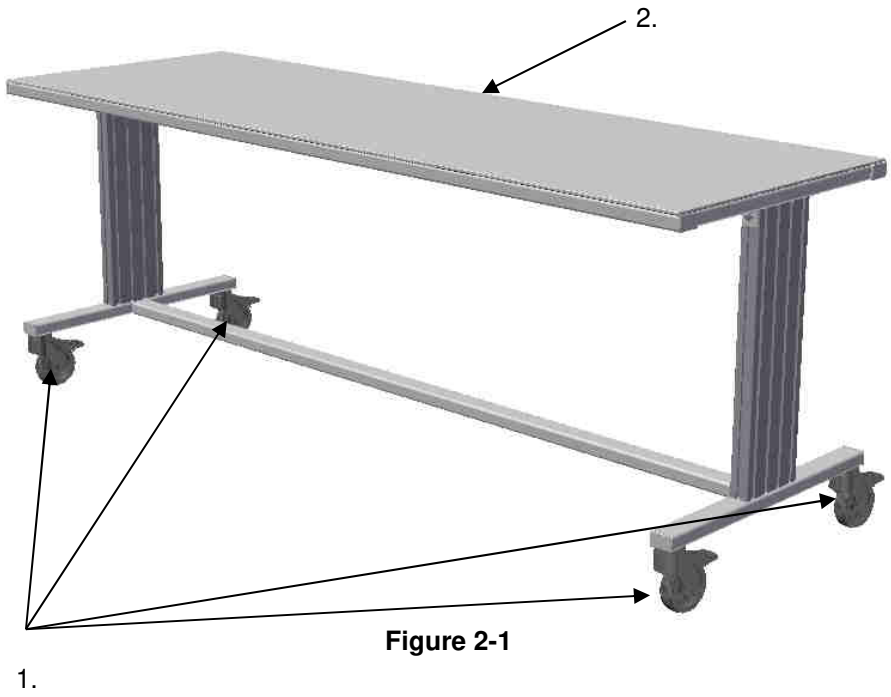


Figure 2-1

1. Brake lever
2. Table top

Caution:

The brake wheels must be locked before a patient can get on and off (Fig. 2-1/1) must be activated. All wheels can be braked, but at least the two rear wheels that are furthest away from the patient.

2.7 Label on table top

180kg
400lb

Max. allowed Patient weight on table top (distributed load)

2.8 Label on front side frame

3 Operating Instructions

3.1 Safety Aspects

3.1.1 Requirements for Operation

Floor condition:

In order to achieve an optimal braking effect for the table, the floor covering should correspond to the slip resistance class R10 or better in the entire area of use the table. The floor should also be level and comply with the evenness tolerance according to DIN 18202.

Care of the floor:

For optimal wheel adhesion, the floor must be cleaned regularly.

The mobile patient tables are a component of the general x-ray systems as e.g. L/U-arm units.

The X-ray system with the mobile patient table PROGNOST XP must be completely installed and officially handed over by **PROTEC** personnel or by service personnel, authorized by **PROTEC,** before it can be used by the customer.

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

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

The brake wheels must be locked before a patient can get on and off (Abb. 2-1/1) must be activated. All wheels can be braked, but at least the two rear wheels that are furthest away from the patient.

3.1.2 Users

The system 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 user is necessary.

3.1.3 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.

- **Keep 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.

3.1.4 Interferences to other devices

There are no interferences to other devices known.

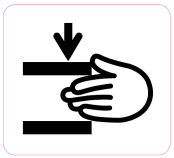
3.1.5 Warnings

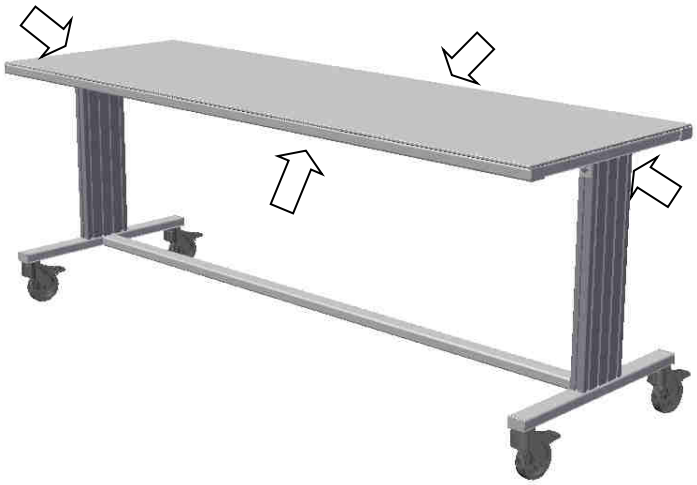
	Keep enough distance between moving parts during movements**.**

3.1.6 Pinch points and possible collisions

CAUTION!

Hands and fingers may be squeezed at the shown arrow positions.
Be sure that during movement of the table, tabletop and x-ray unit neither the patient or personal are within an uncontrolled movement area.





CAUTION!

Take care that at equipment, which can be raised or lowered or which can be moved in different directions yourself or other persons are not within the movement area.
Remove objects, as e.g. chairs, out of the collision area, before using the table.

Pay attention that careless movements of the PROGNOST XS table and table top may injure patients, users or other persons and may cause damages to the X-ray tube assembly or the X-ray image receptor.
Non-observance can cause bodily injuries and damages of the x-ray unit.

3.2 Adjustment of Exposure Position

Before positioning of table with patient, bring x-ray unit into right exposure position.

3.2.1 Exposures with PROGNOST XS

The following handling is necessary in order to avoid a collision between PROGNOST XP, X-ray image receptor and other furnishing

- Bring X-ray unit as e.g. a L/U-arm in 0-degree position.
- Adjust height of X-ray image receptor to table height
- Move table to check there is no collision with image receptor
- Move table into a position for convenient patient get on the table top.
- Actuate brake lever for front brake wheels and check that wheels are effective fixed.

The brake wheels must be locked before a patient can get on and off (Abb. 2-1/1) must be activated. All wheels can be braked, but at least the two rear wheels that are furthest away from the patient.

Attention:

**The PROGNOST XS is not suitable for patient transportation.
It only can be used as a support for the patient during examination.
Patients are only allowed to get on or off the tabletop if the brakes are fixed (Chap. 3.1.7) and under supervision and assistance from the examining personnel, as otherwise the whole table may tilt.**

- Assist patient to get on the table top
- Place patient for examination. Use where required (e.g. at open wounds) suitable clothes to cover the table top surface.

CAUTION:

Caution for squeeze points at table boarders and below and above table top

At horizontal movement of the table and the table top extremities can be squeezed between table top and fixed obstacles (wall, columns, x-ray unit).

Therefore:

Watch during movement of the PROGNOST XP that patient and personal are not within area of movement direction.

Especially take care that no patient extremities protrude over the table top boarders

- Release brake lever and move PROGNOST XS into exposure position.
- Actuate brake lever.

- Depress foot pedal to release table top brake and move table top with patient to exact exposure position and release foot pedal to fix table top brakes.
- Follow instructions of the x-ray unit to take an exposure.
- After the examination release wheel brakes and move table to a position for convenient patient to get off the table top.
- Actuate brake lever and assist patient to get off the table top.

4 Operator Maintenance

4.1 Introduction

This chapter provides a maintenance schedule to ensure proper and safe operation after installation.
Further adjustments or calibrations not contained in this “Instructions for Use”, refer to the applicable “Technical Description” and have to be made by **PROTEC** personnel or expressly by **PROTEC** authorized service personnel.

Before operating this X-ray unit, user have to make themselves acquaint with all control elements and their functions.

The preventative maintenance procedures required to ensure the operational integrity and safety of the equipment are listed in the following paragraphs. It is the owner/user's responsibility to perform preventative maintenance at the specified intervals or arrange for such service with an authorized service representative.

Maintenance has to be recorded.

4.1.1 Operating

1. Careless movements of the whole table or the table top may can hit the image receptor and cause damages to it.

2. Watch for obstacles (persons, chairs, tables, carriages etc.) inside the obvious movement area of the table. Disregard can cause injuries to patient or damages to the X-ray unit or the obstacles.

1. **Only trained and authorized persons are allowed to operate the system.**
2. For replacement use original parts only.

4.2 Safety Information

The user and the personal have to follow the warnings and safety information’s, placed on the device, disregard may lead to injuries.

The operator must make himself familiar with all warnings, placed on the device.

This is necessary for the safety and ensure the correct operation.

In the event of a malfunction do not an longer the unit and notify **PROTEC** service or the expressly authorized service provider.

4.3 Technical Safety Information

To protect the safety of patients, users and third parties, it is absolutely necessary that Checks, which ensure the reliable function and operational safety are made in intervals of 12 months by **PROTEC** service or expressly authorized service providers.
All parts of this equipment that could create a hazard through wear and tear must be checked in at least intervals of 24 months 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.

Before 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 Technical safety checks

The technical safety checks have to be carried out all 24 month by PROTEC Service or authorized service providers 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.
For maintenance check list refer to the manual „Technical Description“.

4.5 Maintenance schedule

4.5.1 User’s maintenance schedule

Prior to cleaning or disinfecting, ensure that no liquids can penetrate into the equipment.

4.5.1.1 Cleaning

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.

To ensure sufficient grip on the floor, the roller must be cleaned once a week.

4.5.1.2 Disinfection

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.

For safety reasons, no spray disinfectant may be used.

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.

4.5.2 User’s daily maintenance before and during operation

Check fixing and easy movement of tabletop by using the brake foot-pedal bar (Abb. 2-1/1).

Check that wheels brakes are in function. (Fig. 2-1/1).

If they are heavy soiling, they must be cleaned to ensure sufficient floor adhesion. The wheels must be cleaned once a week.

4.5.3 Monthly Checks

4.5.3.1 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 a monthly consistency testing.

4.5.4 Maintenance

Required maintenance must be performed at 24-months intervals by **PROTEC** Service or authorized service providers 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.

4.5.5 Duration of Lifetime of the Product

The **PROTEC** PROGNOST XS 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.

4.5.6 Disposal Remarks

The PROGNOST XP does not contain any toxicological materials.
All mechanical, electrical and plastic components have to be disposed according to local or national regulations. In case of doubt contact **PROTEC.**

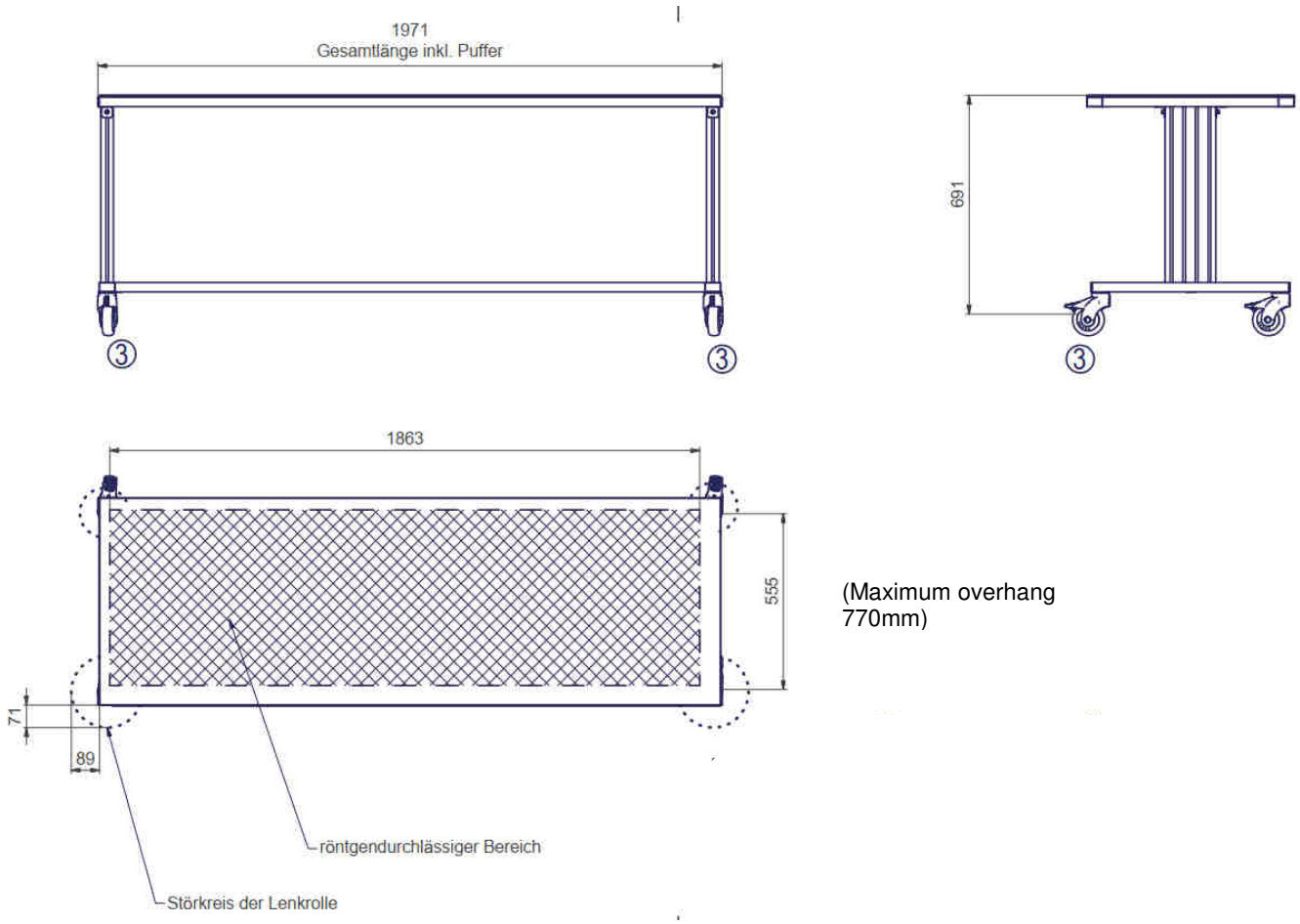
5 Combination with other equipment

- The PROGNOST XS is normally prepared for the use with X-ray units as e.g. L/U-arms for general radiography in diagnostic human medicine use.

- For combination with other equipments please contact **PROTEC** for compatibility tests and release.

6 Technical Data

6.1 Measurements



(Maximum overhang 770mm)

Tabletop:	1963 x 655 mm
Max. Patient weight (Distributed load):	180 kg
Total weight without patient:	47 kg
Height:	760 mm
Dimension of the plane penetrable by X-Ray	1863 x 555 mm

Brakes of tabletop are mechanically operated.

6.2 Attenuation equivalent of Tabletop

The aluminum attenuation of the tabletop is typical 0,7 and <0,8 mm AL according to EN 60601-1-3 at 100kV and a first half value of 3,7 mm Al and typical 0,6 mm AL and <0,8 mm according to 21CFR § 1020-30 (n) at 100 kV and a first half value layer of 1,2 mm.

6.3 Product Life Time

The PROGNOST XS is designed for a useful lifetime of ten years if used according to specifications and regular maintenance through **PROTEC** service or authorized service providers.

6.4 Environmental Conditions

6.4.1 Operating Environment

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

6.4.2 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

6.5 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 60601-1-6 (2010)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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 of this product is in conformity to the requirements of the European Community Medical Device Directive 93/42/ECC according to Article 11 Appendix VII.

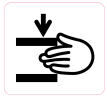
7 Description of Symbols, Labels and Abbreviations

7.1 Symbols

Attention, consult accompanying documents

CE-marking

Classification according to EN 60601-1, Equipment Type B

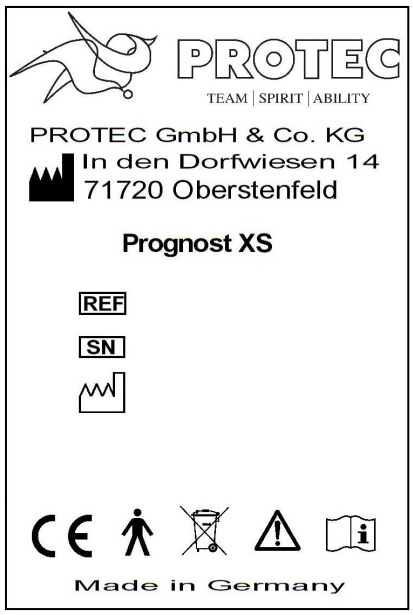


Caution: Squeeze possibilities of fingers or hands

Don´t exceed maximum stated permissible load

7.2 Labels

Nameplate

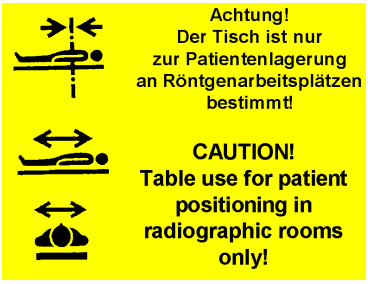


Labels on table top

Caution: Squeeze possibilities of fingers or hands

180kg
400lb

Label on front side frame



7.3 Abbreviations

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