

STITCHING TROLLEY

Autotracking

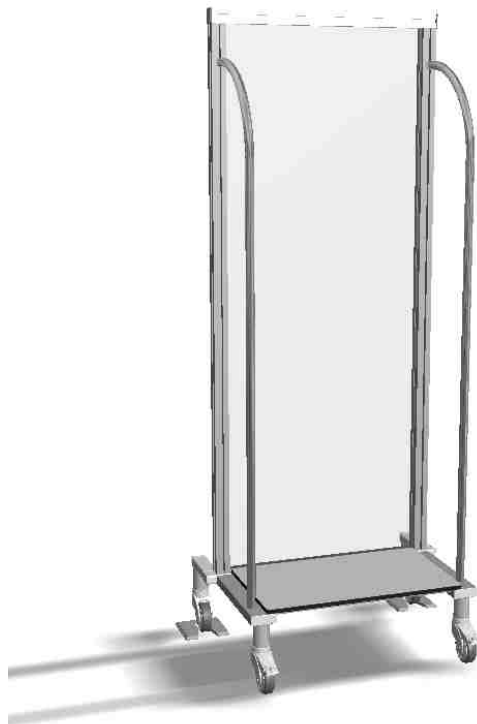
X-ray accessories for PRS 500 B

Model/ID: 7010-0-5000

Basis UDI-DI: 426050264X022ZK

Instructions for Use

ID no. 5010-0-5002





NOTE

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**NOTE**

The information contained in this document conforms to the configuration of the equipment as of the date of manufacture. Revisions to the equipment subsequent to the date of manufacture will be addressed in service updates distributed to the PROTEC Technical Service Organisation.

Revision Status

Revision	Date	Updated pages	Comments	Author
1.0	2023-02-14	all	Original issue	ML

General Notes



WARNING!

In order to maintain the set and tested requirements of the 60601 series of standards, the ME system must not be modified during its actual operating life.

Mechanical and Electric Warning



WARNING!

All of the movable assemblies and parts of this equipment should be operated with care and routinely inspected in accordance with the manufacturer's recommendations contained in the equipment accompanying documents. Maintenance and service is only to be performed by customers authorized by PROTEC GmbH & Co. KG.

Live electrical terminals are deadly.

Do not remove flexible high-tension cables from X-ray tube cover 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.

To the user



NOTE

The user of these accompanying documents is required to carefully read through and carefully consider the instructions, warnings and cautions contained therein before starting operation.

Even if you have already operated similar systems, changes in the design, production and functional routine of the system described here may have been made, which have a significant influence on the operation.

Assembly and service works on the system described here must be carried out by authorised and qualified personnel from PROTEC GmbH & Co. KG. Assembly personnel and other persons who are not employees of the technical service department of PROTEC GmbH & Co. KG are requested to contact the local branch of PROTEC GmbH & Co. KG before assembly or service work is started.

For assembly and service works, it is necessary to use the "Technical Description" of the product and to observe the points it contains.



NOTE

The use of the product with add-on or accessory parts not authorized by PROTEC or other unapproved components is not permitted.



NOTE

According to Regulation (EU) 2017/745 of medical devices, all serious incidents related to the device must be reported to the manufacturer and the responsible authority of the Member State where the user and/or the patient is established.

1 Device Description

1.1 Introduction

The instructions for use describe the performance characteristics and operation required for efficient and effective use of the STITCHING TROLLEY.

Before you work with the STITCHING TROLLEY, the complete instructions for use must be read, especially the Safety Instructions and the chapter Handling.

1.2 Description

The STITCHING TROLLEY is a patient carriage for digital stitching exposures at X-ray system PRS 500 B. It is positioned in front of the Image receptor stand for the exposures.

1.2.1 Component

In addition to the X-ray system PRS 500 B, the following components are required to use the X-ray accessory STITCHING TROLLEY:

- CONAXX 2 with Stitching Autotracking module
- RAPIXX Detector

1.2.2 Versions

STITCHING TROLLEY Autotracking 7010-0-5000

1.2.3 Hardware and Network System Requirements

As a stand-alone product, the STITCHING TROLLEY has no hardware or network connection and therefore no hardware or network requirements.

1.2.4 Installation



NOTE

The installation of the STITCHING TROLLEY must be performed by PROTEC service department or a service company authorized by them.

For more information, please see separate Mounting manual STITCHING TROLLEY.

Contact information of persons qualified to perform installations are available upon request at:

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1.2.4.1 Floor Loading Capacity



NOTE

The STITCHING TROLLEY has a weight of 36kg.
Every technician is obliged to check the floor load. Raised floors and hollow floors must also be considered.

1.3 Performance Characteristics

- Large stitching range
- Images of full leg and full spine possible
- Integrated Stitching assistant for easy operation
- Easy manoeuvrability of the STITCHING TROLLEY
- Easy positioning of the patient on the STITCHING TROLLEY

1.4 Intended Use

The STITCHING TROLLEY is intended to be used as an accessory to a diagnostic X-ray system for the proper positioning of a patient's whole body to achieve reproducible positioning for stitching exposures.

1.5 Clinical Benefit

Considered in isolation, no clinical benefit can be shown for positioning racks.

As accessories for diagnostic X-ray systems in human medicine, they contribute to the clinical benefit of X-ray systems, which consists of the generation of conventional two-dimensional X-ray images for creation or specification of findings as a basis for treatment decisions.

1.6 Patient Target Group(s)

The intended patient group includes all people for whom a justifying indication for a medical X-ray has been given by a physician with the necessary expertise in radiation protection.

There are no general or fundamental restrictions on the patient group regarding age, gender, origin and patient condition.

1.7 Medical Conditions to be diagnosed

As standalone products, positioning racks, have no function to diagnose, treat and/or monitor medical conditions.

1.8 Indications and Contraindications

As standalone products, positioning racks, have no intended main effect in or on the human body. Therefore, considered in isolation, no contraindications can be shown for them.

1.9 Intended User Group

As an accessory of a diagnostic X-ray system, the STITCHING TROLLEY is intended exclusively for use by professional users who are trained in the operation of diagnostic X-ray systems in accordance with the respective national regulations and who are familiar with the proper handling, use and operation and also have been instructed in the permitted conjunction with other medical products, objects and accessories.

Appropriate users can be, for example: X-ray technicians, X-ray assistants, medical technical X-ray assistants, surgeons, casualty surgeons, orthopaedists and other trained medical personnel.

1.10 Declaration of Conformity



This product complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, including all applicable corrigenda.

The declaration of conformity is available upon request from PROTEC:

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2 Safety Instructions

**NOTE**

xxx

Contains information that must be observed during operation.

**CAUTION!**

xxx

Contains information which, if not observed, can cause property damage.

**WARNING!**

xxx

Contains information which, if not followed, can cause personal injury.

**WARNING!**

xxx

Warning of radioactive substances or ionizing radiation. Contains information which, if not observed, can cause personal injury.

Settings and calibrations that are not described in these instructions for use must be carried out using the technical description of the device by PROTEC service department or a service company authorized by them.

**NOTE**

All instructions supplied with the STITCHING TROLLEY must be observed and the safety instructions contained therein must be carefully read and adhered to.

**NOTE**

After the initial installation, the commissioning must be recorded with the PROTEC acceptance protocol FB-04-07A4.3.

**NOTE**

The STITCHING TROLLEY may only be commissioned if all safety measures for operator protection have been met and checked. These protective measures can include door contact, designated area, dosimeter, protective clothing, etc.

**CAUTION!**

The instructions for use contain all the information relevant to safety in order to generally put the STITCHING TROLLEY into operation. The device may only be operated by appropriately trained and trained personnel. In this context, operation is ensured by clear symbols on the control elements. All further information and instructions can be found on the supplied data carrier (USB, CD or DVD). This information applies in its entirety as an appendix to these instructions for use and must be observed.

**NOTE**

All control elements are described again in detail in these operating instructions.

2.1 General Safety Instructions

2.1.1 Device Operation

In case of a malfunction, do not use the STITCHING TROLLEY anymore and notify PROTEC service department or a service company authorized by them.

2.1.2 Operating Personnel



NOTE

Only trained and authorized personnel are allowed to work on the STITCHING TROLLEY.



NOTE

The operating personnel must be familiar with all warning signs attached to the STITCHING TROLLEY. They are used for your own safety and that of others and ensure proper operation.

2.1.3 Crushing and Collision Hazard



WARNING!

It must be ensured that when operating the moving parts of STITCHING TROLLEY, no persons or objects are in the obvious danger area of the device. If not observed, it can result in personal injury or damage to the STITCHING TROLLEY or other objects.

2.1.4 Explosion Protection

The STITCHING TROLLEY is not designated for use within areas with explosive hazards.

2.1.5 Interaction with Other Devices

Interactions with other devices are not known.

3 Control Elements and Displays

3.1 Main Switch of the STITCHING TROLLEY

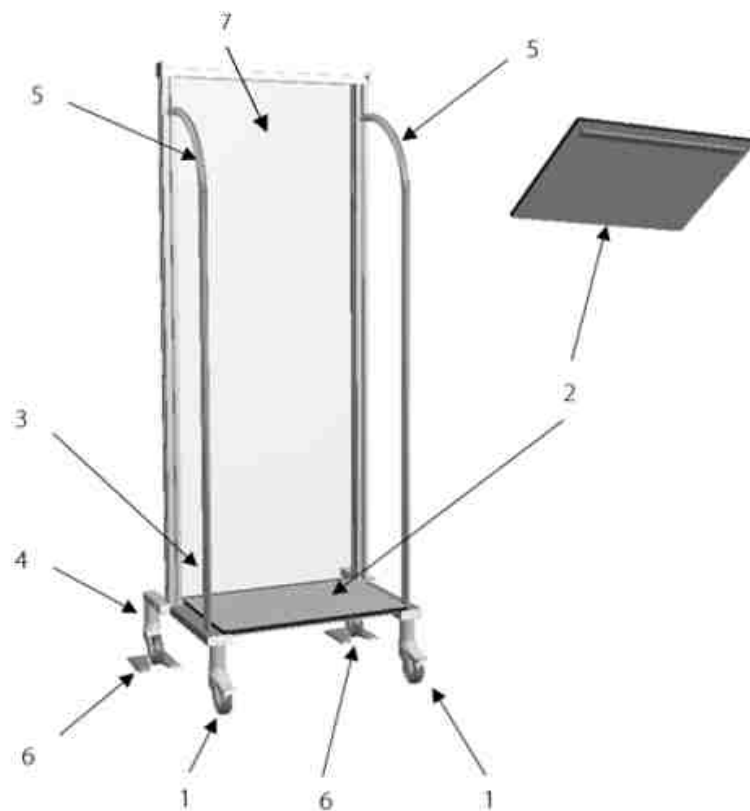
The STITCHING TROLLEY do not have a main switch.

3.2 Emergency Stop Switches of the STITCHING TROLLEY

The STITCHING TROLLEY does not have an emergency stop switch.

3.3 Control Elements and Display of STITCHING TROLLEY

In order to fix the STITCHING TROLLEY on the floor in all directions, it has two rollers at the rear, which must be retracted into the floor fixation, it has two brake rollers at the front side, which must be locked with the locking device before the patient is ascending or descending.



- 1 Brake rollers
- 2 Base plate, removable
- 3 Type table
- 4 Rollers, unbraked
- 5 Grab pole
- 6 Floor fixation
- 7 Plexiglass plate



WARNING!

The brake rollers must be locked before the patient is positioned on the Stitching Trolley.

**WARNING!**

It is imperative to ensure that the brake rollers with the brake lever are pointing forwards, as shown in the illustration, and are not rotated under the STITCHING TROLLEY.

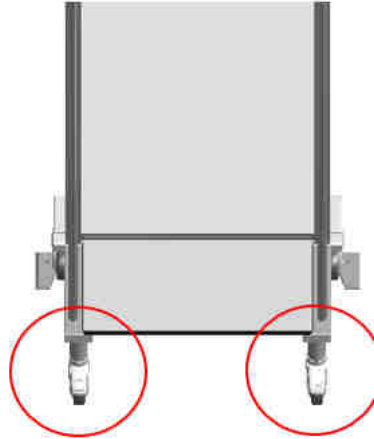


Fig. brake rollers

**WARNING!**

When inserting the base plate, the light side must face up and the strut below the base plate must engage in the notch provided on the metal frame.

**WARNING!**

The STITCHING TROLLEY is not suitable for patient transport.

**WARNING!**

Danger if tipping! Don't step on the edge of the board! Do not shift your body weight backwards when stepping on! Do not pull your body weight up on the grab pole!

4 Handling

4.1 Requirements before and during Operation

It must be ensured that the surfaces in contact with patients are disinfected before the X-ray examination of each patient (see chapter 5.3.2).

4.2 Operation of the STITCHING TROLLEY

4.2.1 Adjustment of the exposure position

Move the STITCHING TROLLEY into the exposure position in front of the wall stand. The rollers on the backside must be placed into the floor fixation (1) and the holding brake (2) must be locked.

Before the patient is ascending (positioned), check again that the STITCHING TROLLEY is securely in place, the rollers are in the floor fixation and the holding brakes are activated.



WARNING!

Danger if tipping! Don't step on the edge of the board! Do not shift your body weight backwards when stepping on! Do not pull your body weight up on the grab pole!



**WARNING!**

It is imperative to ensure that the brake rollers with the brake lever are pointing forwards, as shown in the illustration, and are not rotated under the STITCHING TROLLEY.

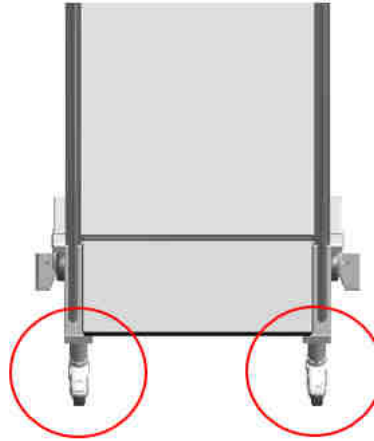


Fig. brake rollers

4.3 Operation of Stitching Autotracking

**NOTE**

- The patient must not move during the exposures.
- The distance between the detector and the radiation source should be 300 cm for Stitching Autotracking exposures.

**NOTE**

See CONAXX2 instructions for use for a detailed description of CONAXX2.

**NOTE**

See Stitching Autotracking instructions for use and functional instructions for a detailed workflow of Stitching Autotracking.

**WARNING!**

The exposures with Stitching Autotracking can and may only be triggered if all points in the stitching assistant in CONAXX2 are checked off in green.

4.4 Function of the STITCHING TROLLEY

4.4.1 Switching the STITCHING TROLLEY on and off

The STITCHING TROLLEY do not have a separate on and off switch.

5 Safety and Maintenance

5.1 Introduction

In this chapter you will find information about safety and maintenance that are necessary to ensure the correct and reliable function of the device after installation.

5.2 Reusability

The STITCHING TROLLEY can be reused without any special preparation procedures.

However, it must be ensured that the surfaces in contact with patients are disinfected before the X-ray examination of each patient (see also chapter 4.1).

The STITCHING TROLLEY must no longer be used with patients if it shows signs of wear (e.g. metal abrasion, wear of insulations) or dangerous technical defects (e.g. torn cable, bent parts) or if the resulting image quality (e.g. artifacts in the image) is insufficient.

In this case, please contact PROTEC service department or a service company authorized by them immediately.

5.3 Cleaning and Disinfection



NOTE

Caution!

Possible material changes!

5.3.1 Cleaning

The cleaning of the STITCHING TROLLEY is very easy due to the very good quality surface coating. This is usually only done with a dry cloth.

Do not use corrosive, dissolving or abrasive cleaning agents, which could damage the device surfaces or the coating.

Clean the device surfaces and painted parts with a damp cloth and a mild to slightly alkaline cleaning solution (e.g. RBS® Neutral T) and wipe dry.

Chrome parts may only be wiped with a dry woollen cloth.

5.3.2 Disinfection

The disinfection must be performed in accordance with the current applicable legal requirements and guidelines corresponding for disinfection and explosion protection.

For disinfection of surfaces in contact with patients, we recommend commercially available medical rapid disinfection wipes (e.g. Dr. Schumacher Descosept Sensitive Wipes).

All mechanical parts of the STITCHING TROLLEY, including accessories, may only be cleaned with a wipe disinfection with suitable surface disinfectants (e.g. Melsept® SF, 15 min. application time at 2% concentration). The information provided by the disinfectant manufacturer on concentrations and application times must be observed.

5.4 Inspection and maintenance



WARNING!

No maintenance or repair work may be performed while the STITCHING TROLLEY is being used with a patient!

All maintenance and repair work may only be performed by personnel trained or authorized by PROTEC.

5.4.1 Daily Monitoring before and during the Examination Operation

The user must check the locking of the rollers by operation the holding brakes. The base plate and transparent plastic pane must be checked for damage.

Wear parts must be replaced with original components.

5.4.2 Maintenance

n/a.

5.4.3 Warranty



NOTE

You will find the current warranty conditions in your order documents or in the price list valid at the time of purchase.

Repairs and spare parts in the event of improper use are also excluded.

Warranty work may only be carried out by trained specialists.

5.4.4 Product Service Life

The STITCHING TROLLEY is designed for a service life of 10 years when used in accordance with the specifications and regular maintenance by PROTEC service department or a service company authorized by them. After the product has reached the end of its service life, further use is at your own risk.

5.4.5 Applied Parts and Parts Considered as Applied Parts

Part	Definition
	Applied part or part that is treated like an applied part but is not defined as an applied part.
Base plate	Applied part
Plexiglass plate	Applied part
Grab pole	Applied part

5.4.6 Disposal Notes



The STITCHING TROLLEY contains various plastics, oil and heavy metal. When disposing exchange and spare parts, or if necessary, the entire device, the valid rules and regulations must be observed. Please contact your contractual partner or service company or commission a company specialized in disposing the respective components.

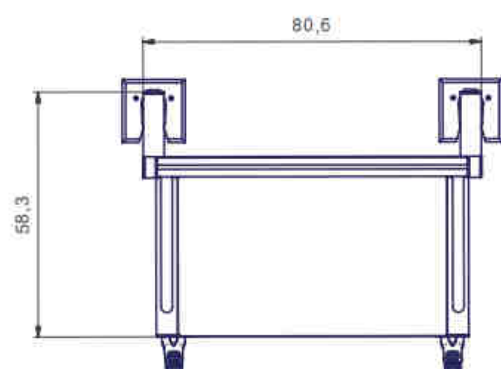
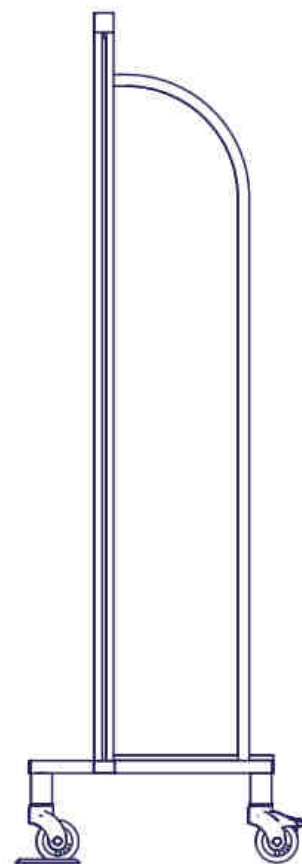
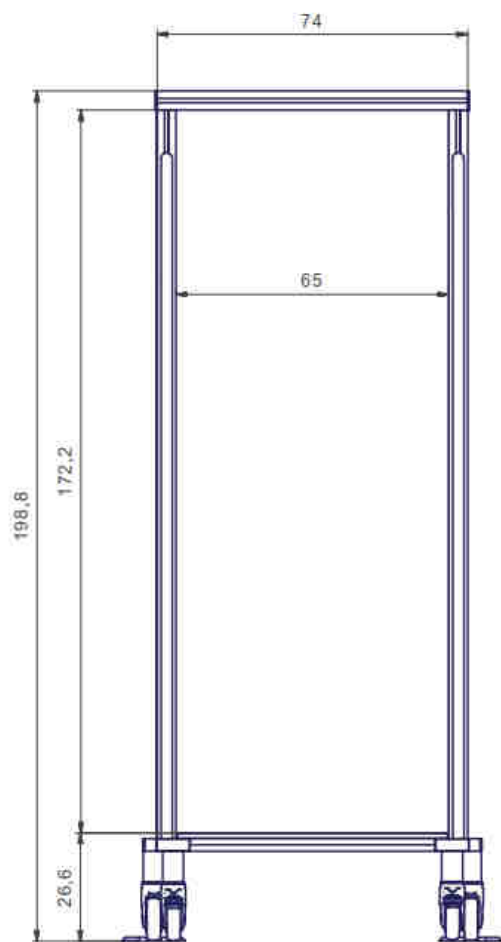
6 Power Supply

**NOTE**

The STITCHING TROLLEY does not require a power supply.

7 Technical Data

7.1 Dimensions



Space requirement STITCHING TROLLEY:	80.6 x 58 cm
Max. patient weight:	230 kg
Total weight without patient:	36 kg
Dimension of radiolucent area:	172.2 x 65 cm

Mechanical operation if the brake rollers. In front

7.2 Attenuation Equivalent



WARNING!

The attenuation equivalent of the STITCHING TROLLEY may have to be considered during the acceptance test of the X-ray system.

The aluminum attenuation of the transparent Stitching plate (Plexiglass plate) 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 Al.

7.3 Environmental Conditions

7.3.1 Environmental Conditions during Operation
















Ambient temperature	+ 10°C to + 40°C
Relative humidity	30% to 70% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa





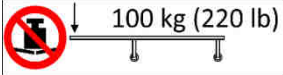
7.3.2 Environmental Conditions for Shipping and Storage

Ambient Temperature	- 10°C to + 70°C
Relative humidity	10% to 95% (non-condensing)
Atmospheric pressure	500 hPa to 1060 hPa

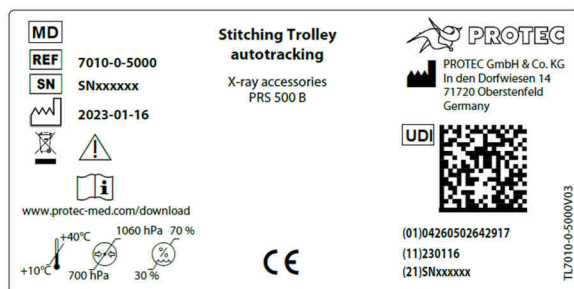
8 Description of Symbols, Labels and Abbreviations

8.1 Symbols

	Atmospheric pressure limit
	Temperature limit
	Humidity limit
	Keep dry
	Fragile, handle with care
	This way up
	Attention, observe accompanying documents
	Refer to Instructions for use
	CE marking
	Manufacturer
	Medical Device
	Order reference
	Serial number
	Unique Device Identification
	Production date




	Attention: Danger if tipping! Don't step on the edge of the board! Do not shift your body weight backwards when stepping on! Do not pull your body weight up on the grab pole!
 www.protec-med.com/download	This symbol indicates the need to observe the instructions for use. This is provided in an electronic format (eIFU) on our website.
	Disposal instructions; WEEE (Waste of Electrical and Electronic Equipment)
	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight

8.2 Type Label



8.3 Labels

Labels on the base plate

	Maximum patient weight (distributed load) on the base plate
	Do not exceed the maximum indicated weight
	Attention: Danger if tipping! Don't step on the edge of the board! Do not shift your body weight backwards when stepping on! Do not pull your body weight up on the grab pole!

8.4 Positions of the Signs and Labels



8.5 Abbreviations

Mm	Millimetres
cm	Centimetres
lb.	Pound
Kg	Kilogram
°C	Degree - Celsius
hPa	Hectopascal
DIN	German Industry Standard
EN	European Standard
CE	CE marking
Hz	Hertz
ED	Duty Cycle
A	Ampere
SN	Serial number