

Stitching Autotracking

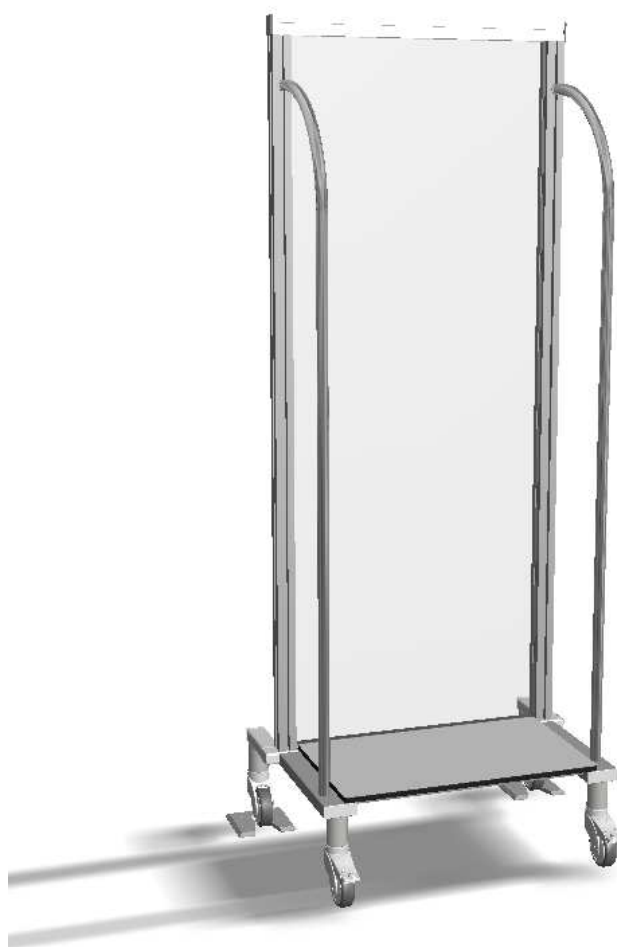
X-ray accessories for PRS 500 B

Model/ID: 4330-0-0022

Model/ID: 7010-0-0000

Additional Instructions for Use and Function for the PRS 500 B with option Stitching Autotracking

ID no. 5010-0-0012





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	2022-09-20	all	new	MB/DP

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.

1 Device Description

1.1 Introduction

This instructions for use describe the performance characteristics and operation required for efficient and effective use of Stitching Autotracking including the STITCHING TROLLEY.

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

1.2 Description

These instructions for use describe the Stitching Autotracking process of single X-ray exposures to a total image. This requires the use of the CONAXX 2 software with the "CONAXX 2 Stitching" module (4330-0-0022), the STITCHING TROLLEY (7010-0-5000) and a PROTEC RAPIXX detector.

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 Bucky wall stand for the exposures.

1.2.1 Components

In addition to the X-ray system PRS 500 B, following components are required for Stitching Autotracking:

- CONAXX 2 with Stitching Autotracking module
- STITCHING TROLLEY with floor fixation
- RAPIXX Detector

Accessories that can influence the EMC conditions

- Network cable ((take note of the max. cable length in the system documents)
- RAPIXX data connection cable (take note of the max. cable length in the system documents)
- WiFi router (Only use devices approved by PROTEC)

1.2.2 Installation



NOTE

The installation of Stitching Autotracking must be performed by PROTEC service department or a service company authorized by them.

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

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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 User Group

As an accessory of a diagnostic X-ray system PRS 500 B, 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.

2 Safety Instructions

**NOTE**

Contains information that must be observed during operation.

xxx

**CAUTION!**

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

xxx

**WARNING!**

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

xxx

**WARNING!**

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

xxx

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

**NOTE**

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

**NOTE**

Stitching 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 Stitching 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.

**WARNING!**

The STITCHING TROLLEY is not suitable for patient transport.

2.1 General Safety Instructions

2.1.1 Operation

In case of a malfunction, do not use Stitching Autotracking 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 with Stitching Autotracking.



NOTE

The operating personnel must be familiar with all warning signs attached to the Stitching Autotracking components. 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, 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.



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!

2.1.4 Explosion Protection

Stitching Autotracking 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

Stitching Autotracking is performed with switched on X-ray system. The main switch of the respective PRS 500 B is described in the corresponding instructions for use.

3.2 Emergency Stop Switches

Stitching Autotracking is performed with switched on X-ray system. The emergency stop switches of the respective PRS 500 B are described in the corresponding instructions for use.

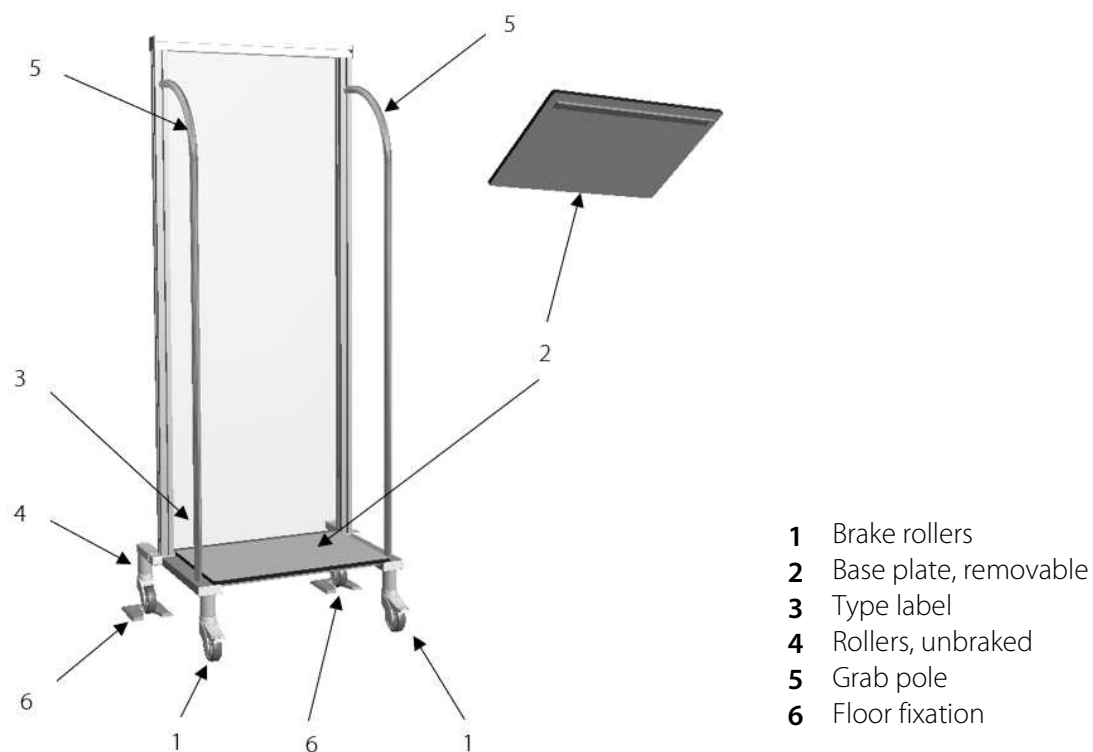
3.2.1 Generator Emergency Stop Switch

For the switch position of the corresponding X-ray generator, please refer to the enclosed instructions for use of the generator.

3.3 Control Elements and Displays of Stitching Autotracking

3.3.1 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.



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.

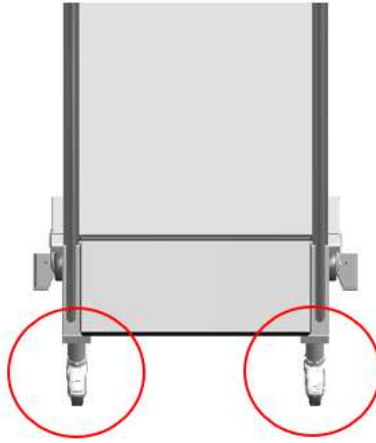


Fig. brake rollers

**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!

3.3.2 Stitching Assistant

When using the PRS 500 B system, the stitching area is displayed in case of stitching exposures. The display reflects the contents of the CONAXX2 Stitching assistant.



NOTE

The workflow corresponds to the procedure described in chapter "4.3 Operation of Stitching Autotracking".



NOTE

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

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).

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.

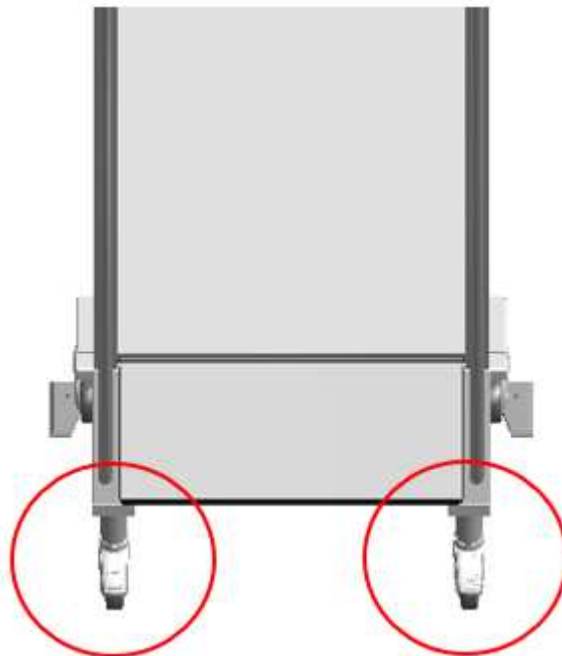


Fig. brake rollers

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.

**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.

4.3.1 Workflow Stitching Autotracking Full Leg

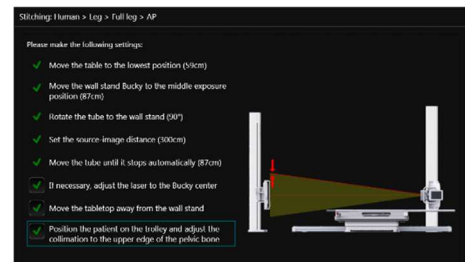


WARNING!

Stitching Autotracking for full leg exposures must be performed with the base plate inserted.

1. Select the quick job *"Full leg AP"* and click *"Create job"*. As a result, three x-ray jobs will be created in the x-ray job list.
2. Select the first x-ray job *"Pelvis > STITCHING pelvis with thigh > AP"* and click *"Start exposure"*. A warning dialog appears.
3. Please ensure that no person is on the table or in close vicinity to the system. Confirm the warning dialog with *"OK"*.
4. Observe the warning regarding the handling of the Stitching Trolley. Confirm the warning dialog with *"OK"*.

5. An assistant will appear, which guides you through the necessary settings.



- a. Move the table to the lowest position
(this step is done automatically by the system)



- b. Move the wall stand Bucky to the middle exposure position
(this step is done automatically by the system)



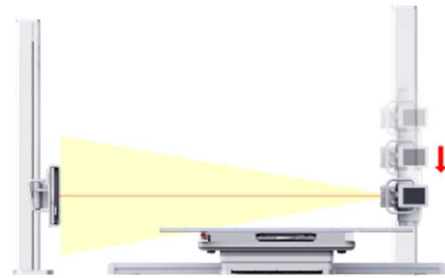
- c. Rotate the tube to the wall stand (90°)



- d. Set the source-image distance (300 cm)



- e. Move the tube down until it stops automatically



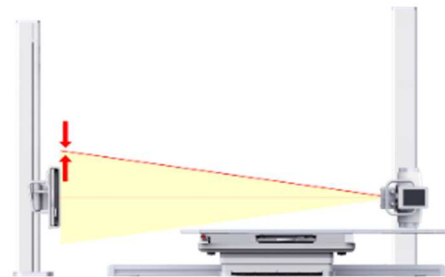
- f. If necessary, adjust the laser to the Bucky centre



- g. Move the tabletop away from the wall stand



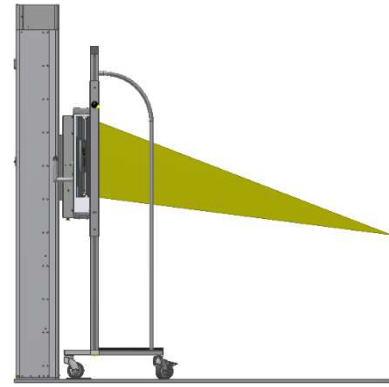
- h. Position the patient on the trolley and adjust the collimation to the upper edge of the pelvic bone



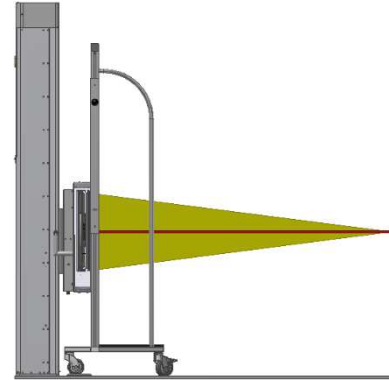
6. After all the settings have been made, confirm the steps f), g) and h) by ticking the respective check box. If all steps are ticked off with a green tick, you can continue by clicking on "OK".

7. The system will show the complete collimation of all exposures. Confirm it by clicking on "OK".

8. The exposure dialog appears. The Bucky of the wall stand automatically moves to the first exposure position (top) and the collimation will be adjusted for the first exposure. Wait until the Bucky has reached its position and the collimation is set. Check the generator settings. As soon as the generator and the detector are ready, the status changed from *"Preparing exposure..."* to *"Please perform the exposure"*.

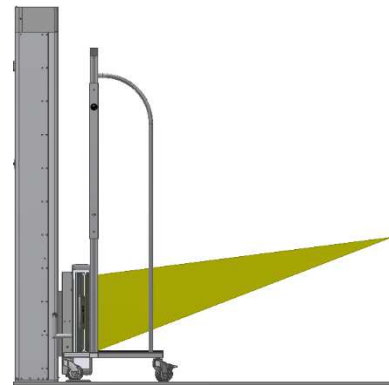


9. Perform the exposure with the hand switch of the generator. After the image has been transferred from the detector, the Bucky of the wall stand automatically moves to the second exposure position (middle) and the collimation will be adjusted for the second exposure. After the image optimization is completed, the image must be checked. Therefore, you can use the full screen mode (🖥️). If the exposure must be repeated click on *"Repeat"*, otherwise on *"Next"*.



10. The exposure dialog for the second exposure appears. Wait until the Bucky has reached its position and the collimation is set. Check the generator settings. As soon as the generator and the detector are ready, the status changed from *"Preparing exposure..."* to *"Please perform the exposure"*.

11. Perform the second exposure with the hand switch of the generator. After the image has been transferred from the detector, the Bucky of the wall stand automatically moves to the third exposure position (bottom) and the collimation will be adjusted for the third exposure. After the image optimization is completed, the image must be checked. If the exposure must be repeated click on *"Repeat"*, otherwise on *"Next"*.



12. The exposure dialog for the third exposure appears. Wait until the Bucky has reached its position and the collimation is set. Check the generator settings. As soon as the generator and the detector are ready, the status changed from *"Preparing exposure..."* to *"Please perform the exposure"*.

13. Perform the third exposure with the hand switch of the generator. After the image has been transferred from the detector and the image optimization is finished, the image must be checked. If the exposure must be repeated click on *"Repeat"*, otherwise on *"Next"*.

14. You will automatically be redirected to the X-ray area. There the single exposures will be automatically stitched to one exposure.

4.3.2 Workflow Stitching Autotracking Full Spine

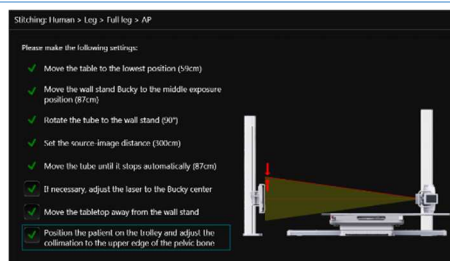


WARNING!

Stitching Autotracking for full spine exposures must be performed with the base plate removed.

1. Select the quick job "Full spine AP", "Full spine LL" or "Full spine RL" and click "Create job". As a result, two x-ray jobs will be created in the x-ray job list.
2. Select the first x-ray job ("Chest > STITCHING T-spine with C-spine > AP", "Chest > STITCHING T-spine with C-spine > LL" or "Chest > STITCHING T-spine with C-spine > RL") and click "Start exposure". A warning dialog appears.
3. Please ensure that no person is on the table or in close vicinity to the system. Confirm the warning dialog with "OK".
4. Observe the warning regarding the handling of the Stitching Trolley. Confirm the warning dialog with "OK".

5. An assistant will appear, which guides you through the necessary settings.



- a. Move the table to the lowest position
(this step is done automatically by the system)



- b. Rotate the tube to the wall stand (90°)



- c. Set the source-image distance (300 cm)



- d. If necessary, adjust the laser to lower border of the active area format

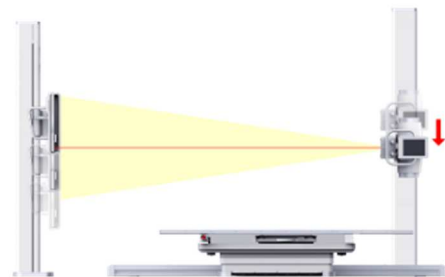


- e. Position the patient in the trolley and adjust the wall stand Bucky to the upper edge of the ears



- f. Move the tube stand to the height of the lower border of the active area format

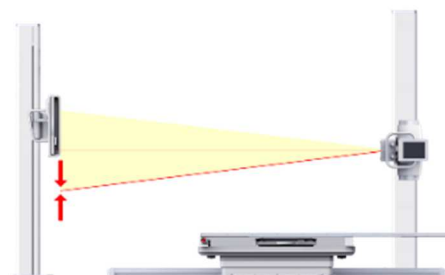
(this step is done automatically by the system)

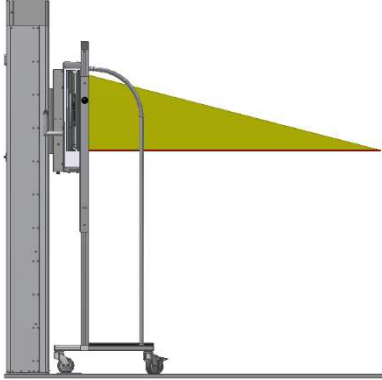
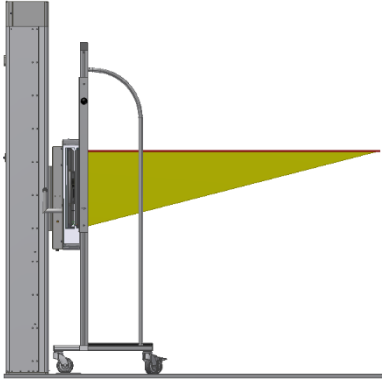


- g. Move the table top away from the wall stand



- h. Adjust the lower collimation to the height of the coccyx



6. After all the settings have been made, confirm the steps d), f), g) and h) by ticking the respective check box. If all steps are ticked off with a green tick, you can continue by clicking on "OK".	
7. The system will show the complete collimation of all exposures. Confirm it by clicking on "OK".	
8. The exposure dialog appears. The collimation will be adjusted for the first exposure (top). Check the generator settings. As soon as the generator and the detector are ready, the status changed from "Preparing exposure..." to "Please perform the exposure".	
9. Perform the exposure with the hand switch of the generator. After the image has been transferred from the detector, the Bucky of the wall stand automatically moves to the second exposure position (middle) and the collimation will be adjusted for the second exposure. After the image optimization is completed, the image must be checked. Therefore, you can use the full screen mode (🖥️). If the exposure must be repeated click on "Repeat", otherwise on "Next".	
10. The exposure dialog for the second exposure appears. Wait until the Bucky has reached its position and the collimation is set. Check the generator settings. As soon as the generator and the detector are ready, the status changed from "Preparing exposure..." to "Please perform the exposure".	
11. Perform the second exposure with the hand switch of the generator. After the image has been transferred from the detector and the image optimization is finished, the image must be checked. If the exposure must be repeated click on "Repeat", otherwise on "Next".	
12. You will be automatically redirected to the X-ray area. There, the single exposures will be automatically stitched to one exposure.	

4.4 Function of Stitching Autotracking

4.4.1 Switching Stitching Autotracking on and off

The X-ray system with integrated Stitching functionality is switched on via the generator console. All system components are supplied with voltage via the generator. If the system contains a Power Box, the power is supplied via the Power Box.

When the generator or Power Box is powered up using the switch-on button, a self-test runs on the generator and the control desk. After successful completion of the self-test, the parameters are displayed.

Stitching exposures can be started and performed via the CONAXX2 operating software.

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

Stitching Autotracking 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., 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



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 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 Stitching Autotracking 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 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.

5.4.3 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.

5.4.4 Disposal Notes



The STITCHING TROLLEY contains various plastics and metals. 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

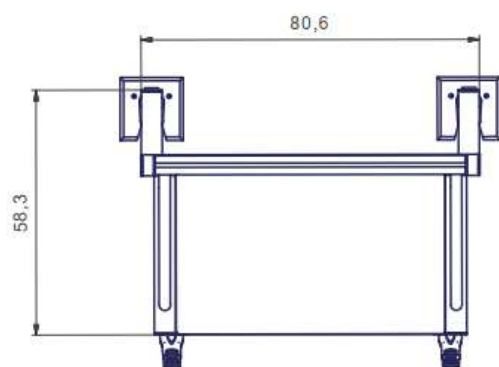
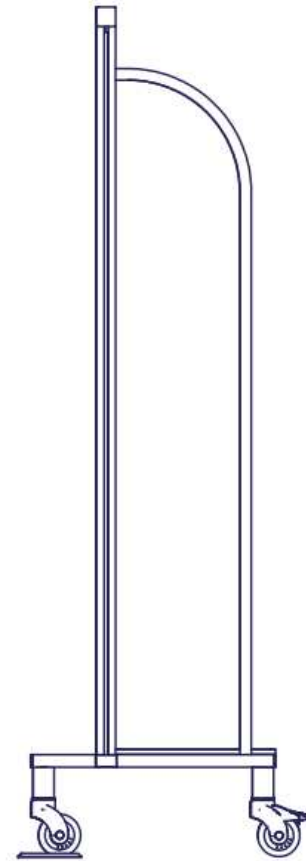
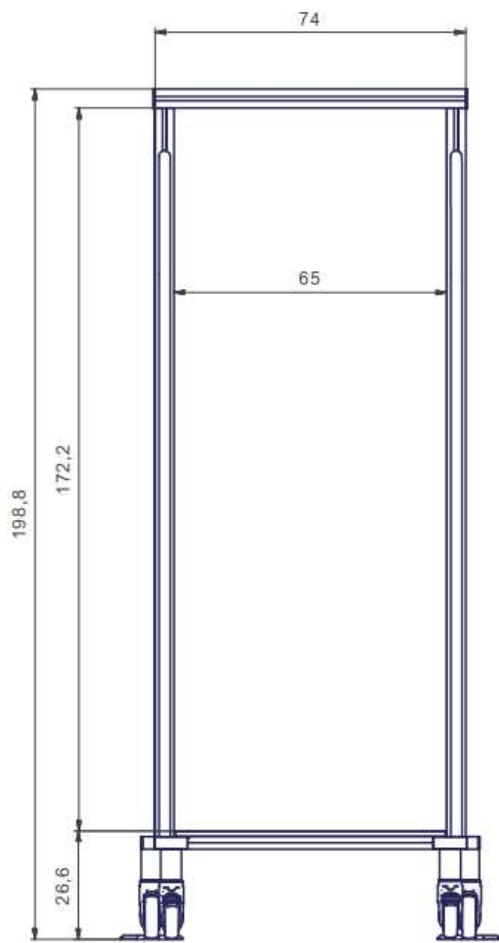


NOTE

The Stitching Trolley does not require a power supply.

7 Technical Data

7.1 Dimensions Stitching Trolley



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



CAUTION!

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 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

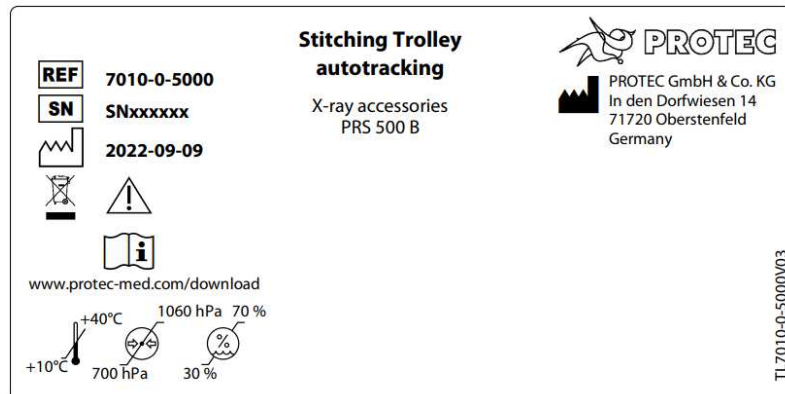
8 Description of Symbols, Labels and Abbreviations

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
	Manufacturer
	Order reference
	Serial number
	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
 230kg 506lb	Maximum patient weight on the base plate

8.2 Type Label



8.3 Labels

Labels on the base plate

 230kg 506lb	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
Hz	Hertz
SN	Serial number