

User manual

Stitch Frame U

Rev.: 17-01-2022



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List of revisions

Equipment	Stitch Frame U
Document	User manual
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00	10-05-14	Draft version
01	25-09-14	Minor text and photographs updates (RHD+ DV)
02	09-05-19	Add Patient Step (Option) + Update branding
03	09-03-20	Add Patient Step – Tilting Model (Option)
04	02-11-20	Update images and drawings
05	17-01-22	MDR Updates; New label design incl. UDI; Removed standard Patient Step. Small text / image updates.

Legal manufacturer



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Preface

Identification Manual

Manuals are identified by a part number.

ODB-100-5040ENG-04





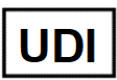





The part number is printed at the bottom of the title page. Numbers printed on other pages are for internal revision control and may differ.

CE Classification

Product meets the relevant provisions of the European MDR (EU 2017/745 - Medical Device Regulation); this is based on conformity of the products and the quality system according to ISO 13485:2016.


Symbols

Symbol	Meaning	Remarks
	Medical device	
	Legal manufacturer	
	Date of manufacture	
	Serial number	
	UDI code	Unique Device Identification
	Consulting the accompanying documents is a mandatory action.	
	General warning sign	Placed together with a supplementary symbol or text. The text associated shall be an affirmative statement (i.e., a safety notice) describing the principal risk(s) foreseen (e.g. "Causes burns", "Risk of explosion", etc.).
	The CE Mark is a declaration by the manufacturer that the product complies with the requirements of the applicable European Union (EU) Medical Device Regulation (MDR) and that the product has been subject to conformity assessment procedures as provided in that regulation.	

Conventions





The Stitch Frame U has been designed to meet all safety requirements applicable to medical equipment. However, anyone using the Stitch Frame U must be fully aware of potential safety hazards. The information contained in this chapter is provided to help users to operate the Stitch Frame U safely.

Throughout this manual certain conventions are used. These are Warnings, Cautions and Notes. They provide a means of prioritizing information to be brought to the attention of the user. They are given as follows:

 WARNING:	Indication of an important warning that is to be obeyed to eliminate the risk of personal injury or an incorrect clinical diagnosis.
CAUTION:	Indication of important information to avoid serious system equipment damage.
Note:	Additional information for reader understanding or simplification of a task.

Precautions

The user is expected to use the product (soft and hardware) in accordance with the instructions given in this manual, which must be read before the system is used. Any unauthorized deviation from the procedures laid down in this manual can affect the contractual obligations between purchaser and vendor.

 WARNING:	This product was designed and manufactured to ensure maximum safety of use. It should be installed and serviced in strict compliance with safety instructions described in this Document.
 WARNING:	Do not use the system before carefully study the user manuals, it is assumed that the operator is a professional and trained X-ray user or service engineer, who has gained sufficient knowledge to operate the system safely.
 WARNING:	Never attempt a shortcut to procedures which may degrade the safety considerations of the system.
 WARNING:	The user shall take care that potential interferences between the unit and other equipment is avoided. If necessary certain actions must be taken.



 WARNING:	<p>Do not modify any part of Oldelft Benelux supplied hardware, software or software configuration. Any modification, installation or running an application that has not explicitly been approved by Oldelft Benelux may compromise patient safety and will result in termination of all warranty and service contracts.</p> <ol style="list-style-type: none"> If this equipment is modified, repaired or maintained, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment. Do not leave problems unattended that may affect the safety of the product. In case you have doubts concerning the Stitch Frame U save operation, call the service number of your vender for further instructions. The Stitch Frame U should be cleaned regular to prevent the accumulation of dust. The contact surface should be cleaned after each patient for hygienic reasons.
 WARNING:	<p>The Oldelft Benelux products are designed for use and maintenance using only parts available from Oldelft Benelux. No liability for failure can be accepted by Oldelft Benelux through the use of parts obtained from other suppliers unless written permission is obtained from Oldelft Benelux.</p> <p>Copyright All rights reserved. No part of this manual may be reproduced or transmitted in any form whatsoever, including photocopying and recording without written permission of the copyright holder: Oldelft Benelux B.V., Wiltonstraat 41, 3961 KW VEENENDAAL, The Netherlands.</p> <p>Concerning this Publication Information contained in this publication is subject to change without notice. Whenever the equipment is delivered with a documentation medium such as a CD or DVD, the user shall always check the medium for latest information. This information is part of Release Notes and Document Upgrade files.</p> <p>Neither Oldelft Benelux B.V. and its subsidiaries nor anyone else who has been involved with the development, production or delivery of the documentation be liable for any special, incidental or consequential damages, whether based upon breach of warranty, breach of contract, negligence, strict liability in tort or any other legal theory.</p> <p>This manual was originally drafted in the English language.</p>
Note:	<p>Any serious incident with the user and/or patient that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.</p>

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1 Introduction












1.1 About this manual

This user manual is a guide for the operator of the Stitch Frame U Patient positioning system. In this manual it is assumed that the operator is a professional and trained X-ray user, who has gained sufficient knowledge to operate Stitch Frame U safely.

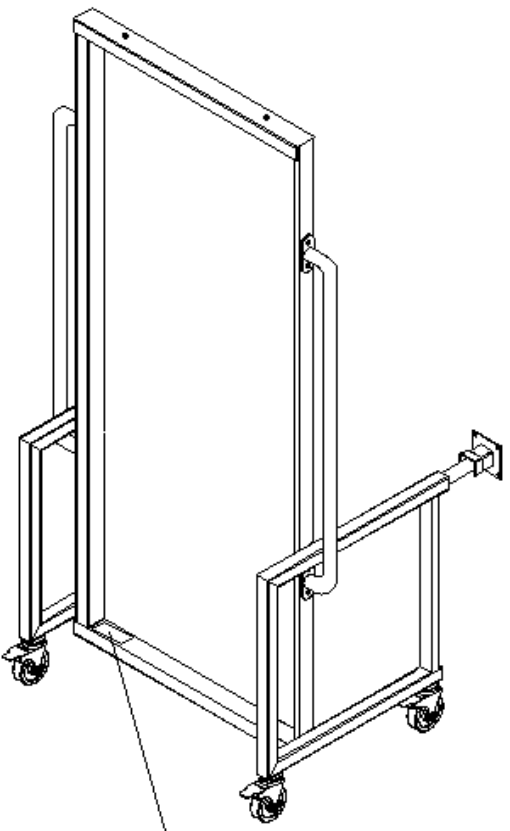
In particular this document describes the daily operation.

1.2 Identification label, Identification of device.

Label

Model / Type: Stitch Frame U		 Oldelft Benelux A CANON COMPANY	
			(01)18720256816314 (11)211012 (21)SF-U-2021-21146
	10-2021		 SN SF-U-2021-21146
 Oldelft Benelux BV, Wiltonstraat 41, 3905KW, Veenendaal, The Netherlands.			
		 MD  CE	
		 	
		 0.7mmAL	

Location



Position Label

2 General description

2.1 Description of the device

The Stitch Frame U is a single product, produced by Oldelft Benelux B.V.

The Stitch Frame U is available in one variation.

It consists of a painted metal supporting frame with a transparent front and on both sides handles for the patient. The frame is movable on wheels. During an X-ray exam the frame can be placed in front of the X-ray detector. Positioning of the frame is done by two adjustable telescope bars placed in cups on the wall. The patient can be fixed by a supporting belt (not part of Stitch Frame U) and support herself by holding the two handles on both sides of the Frame.

Because the patient is perfectly upright and stable, this will reduce remakes and improve the quality of the X-ray images.



Figure 1: *Stitch Frame U, in front of the detector*



Figure 2: *Stitch Frame U in Use*

2.2 Principles of operation of the device:

The Stitch Frame U is used as patient positioning system during an X-ray procedure for improving patient picture improvement by assisting the patient retaining a stable vertical position and in balance.

The wall stand docking must be able to move freely up and down behind the Stitch Frame U. Therefore, and for the stability of the frame, the Stitch frame U is equipped with two positioning bars (6) that are used to support the frame on the wall. The position of the frame is determined by the wall brackets (7) on the wall and the length of the positioning bars (6). The length of the positioning bars is adjustable with clamps (8).



figure 3: *Stitch Frame U in use*

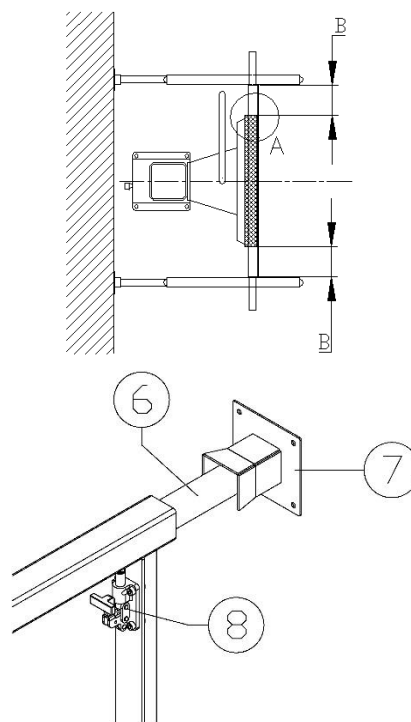


figure 4: *Frame positioning*

The Stitch Frame U is also available with Tilting Patient Step (Accessory - Option).

With Tilting Patient Step the feet of the patient can be positioned in the Field of View. When the patient Step is not required for taking the x-ray image, the patient Step can be folded/tilted against the frame so it's not in the way.






Figure 5: *Stitch Frame U with Tilting Patient Step*

2.3 Intended Purpose and patient population

Intended Purpose:	The Stitch Frame U is used as a patient positioning system during an X-ray procedure to improve the patient's x-ray picture by helping the patient maintain a stable vertical position and balance.
Variants:	The Stitch Frame U is available in one version.
Accessory:	Patient Step – Tilting Model (optional). Depending on the requirements of the customer the Stitch Frame U can be provided with a Patient Step – Tilting model (optional accessory). With the Patient Step installed, the feet of the patient can be positioned in the Field of View.
Intended indication:	General Radiography.
Intended Users:	Trained professional radiographers.
Patient Population:	There are no restrictions in patient population.
Duration:	Transient. Even when the device is used more than once on the same patient, the total duration will not exceed transient use.
Intended environment:	Dedicated X-ray room, in medical institutions.
Non-invasive device:	The device is non-invasive by its nature.
Active medical device:	The device is not an active medical device.

3 Instructions for Installation

 WARNING:	This product was designed and manufactured to ensure maximum safety of use. It should be installed and serviced in strict compliance with the instructions described in this Document.
 WARNING:	If the Stitch Frame U package is open or damaged inspect the product on damage and inform the distributor.
 WARNING:	If the Stitch Frame U seems to be broken or damaged DO NOT install or use it.

3.1 Material required

Locktite	
----------	--

Tools required

Hex Bit	5mm, 6mm
measurement device (caliper)	
spirit level	
marker	
Drill	
Drill bit	8mm
hammer	
screwdriver set	

3.2 Unpacking and assembling the stitch Frame U:

procedure

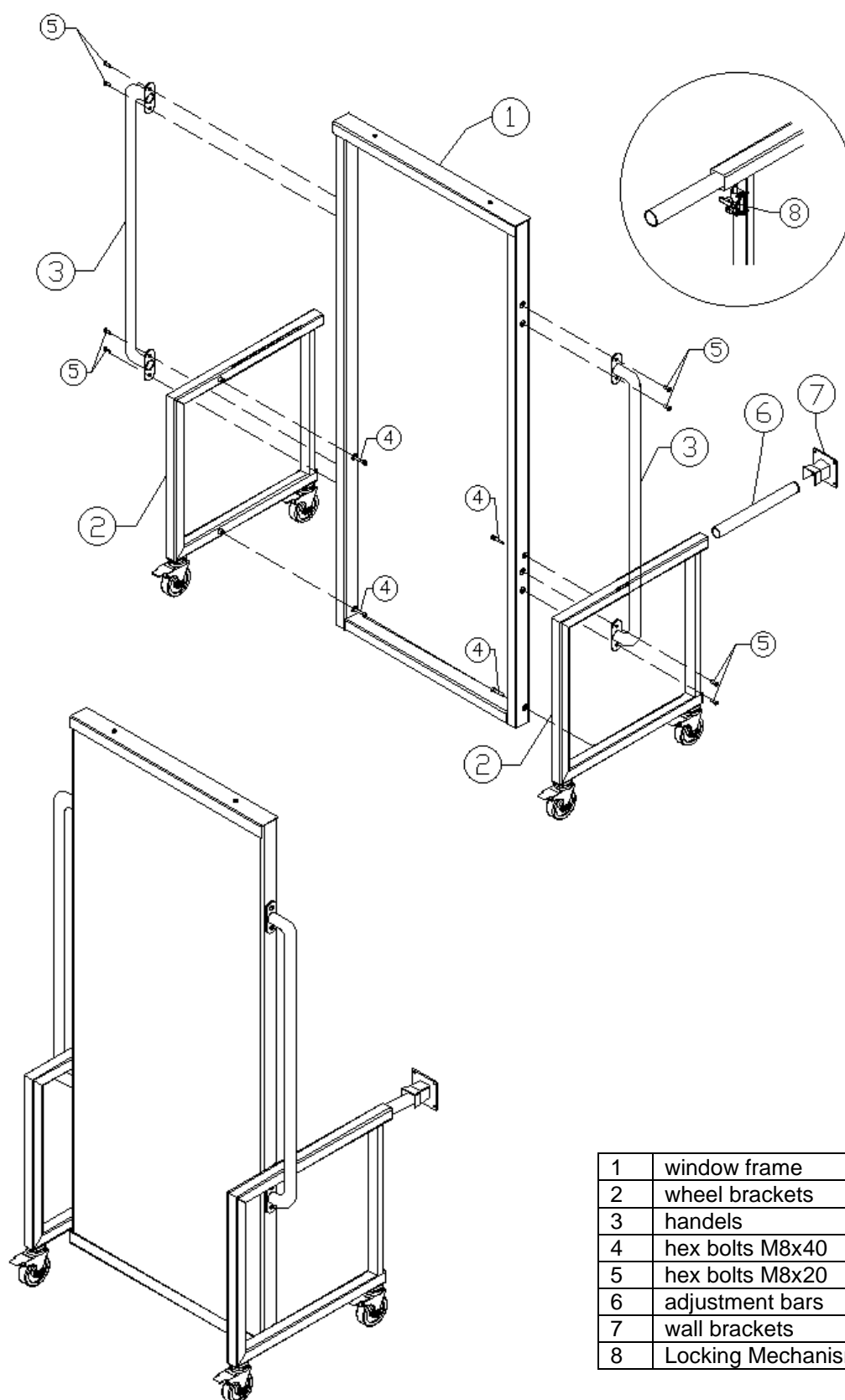
Remove the top panel of the crate containing the stitch frame. Unpack all items and check if all items are included. Please contact your distributor immediately if parts are missing or damaged.

Table of content

item	description		details
1	window frame	1x	
2	wheel brackets	2x	
3	RVS handles	2x	
4	hex bolts	4x	M8x40
5	hex bolts	8x	M8x20
6	adjustment bars	2x	
7	wall brackets	2x	

See Figure 6 for details

- Place the window frame (1) in the upright position.
- Mount the wheel brackets (2) to the window frame using hex bolts (4) (use Locktite to fix the bolts)
- Mount the RVS handles (3) to the window frame using hex bolts (5) (use Locktite to fix the bolts)
- Insert adjustment bars in the wheel brackets.



1	window frame
2	wheel brackets
3	handles
4	hex bolts M8x40
5	hex bolts M8x20
6	adjustment bars
7	wall brackets
8	Locking Mechanism

figure 6: Assembling the Stitch Frame U

3.3 How to install the Stitch Frame U:

procedure

- Slowly move the stitch frame toward the detector until the front plate touches the detector gently.
- Centre the stitch frame in relation to the detector. Distance B is equal on both sides. (See Figure 7)

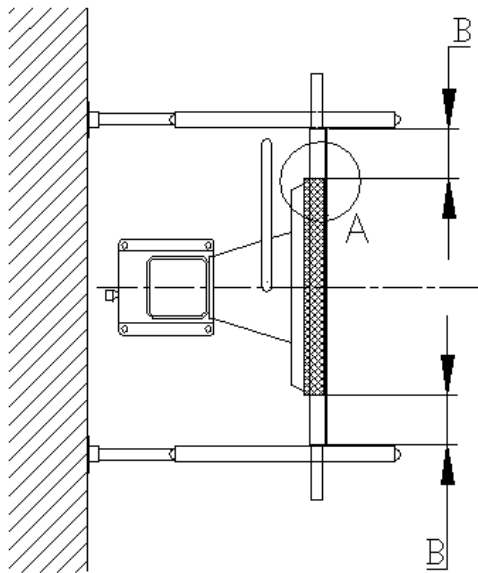


figure 7: *Position the stitch Frame U.*

- Open the locking mechanism (8) from the adjustment bars (6) and move the bars to the wall. Lock the bars in this position.
- Place the wall brackets (7) between the wall and the adjustment bars. (See Figure 8)
- Check to see that the stitch frame is still centred to the detector.
- Level the wall brackets. (7)
- Mark drilling holes using the wall brackets as guide.

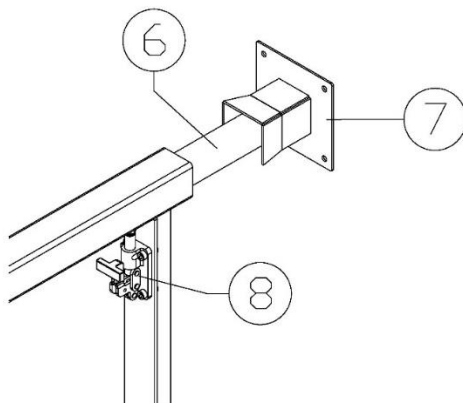
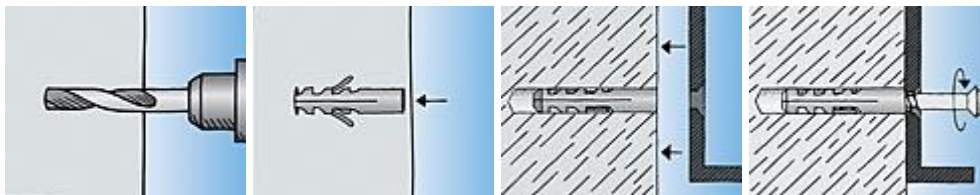


figure 8: *Position Wall brackets.*

- Remove the stitch frame and drill the Holes with an 8mm stone bit.
- Clean all the dust and debris from the holes and floor.
- Install Nylon Fixing Plugs into the holes and mount the wall brackets to the wall.



- Finally: Install the stitch frame and leave approximately 5 mm distance between the back of the stitch frame and the detector surface.

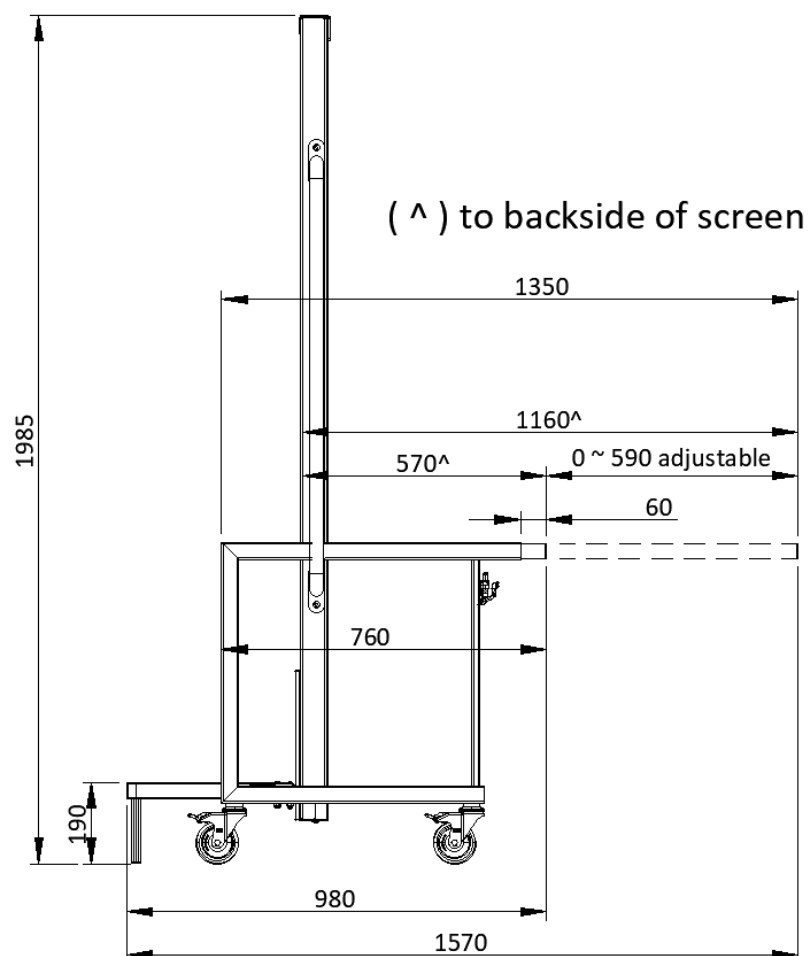








figure 9: *Dimensions of the stitch Frame U.*

4 Instructions for use

 WARNING:	<p>This product was designed and manufactured to ensure maximum safety of use. It should be installed and serviced in strict compliance with safety instructions described in this Document.</p>
 WARNING:	<p>Do not use the system before carefully study the user manuals, it is assumed that the operator is a professional and trained X-ray user, who has gained sufficient knowledge to operate the Stich Frame U safely.</p>
 WARNING:	<p>Never attempt a shortcut to procedures which may degrade the safety considerations of the system.</p>
 WARNING:	<p>If the Stich Frame U seems to be broken, damaged or otherwise different than normal: DO NOT use it and mark the it as defect system.</p>
 WARNING:	<p>In case of equipment malfunction, bring the patient into safety, mark the system as defect system and seek the assistance of a qualified technician.</p>
 WARNING:	<p>Always take radiation safety precautions</p>


 WARNING:	<p>Before positioning the Stich Frame U in front of the wall stand it is mandatory to put the wall stand patient bar in parking position to avoid injury to patient or operator and/or system equipment damage! See figure 9 and 10.</p>
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figure 10: Collision Danger



figure 11: Wall stand Patient bar parked

Position the Stitch Frame U in front of the wall stand gently and leave minimal 5 mm space between the front plate or ruler of the Stitch Frame U and wall stand detector.

Extend the two bars into the wall brackets and lock the bars with the locking mechanism. Check another time the 5mm free space.

Lock the wheels by pressing the wheel brakes down.
Ensure if the Stitch Frame U is fixed by pulling on both handlebars at the Stitch Frame U, the frame should not move, or tilt.

CAUTION:

Check if the wall stand can move freely behind the Stitch Frame without bumping against any obstacles.

Place the patient against the front plate. If needed for more patient stability, use a belt (not part of system) to fix the patient. See figure below.



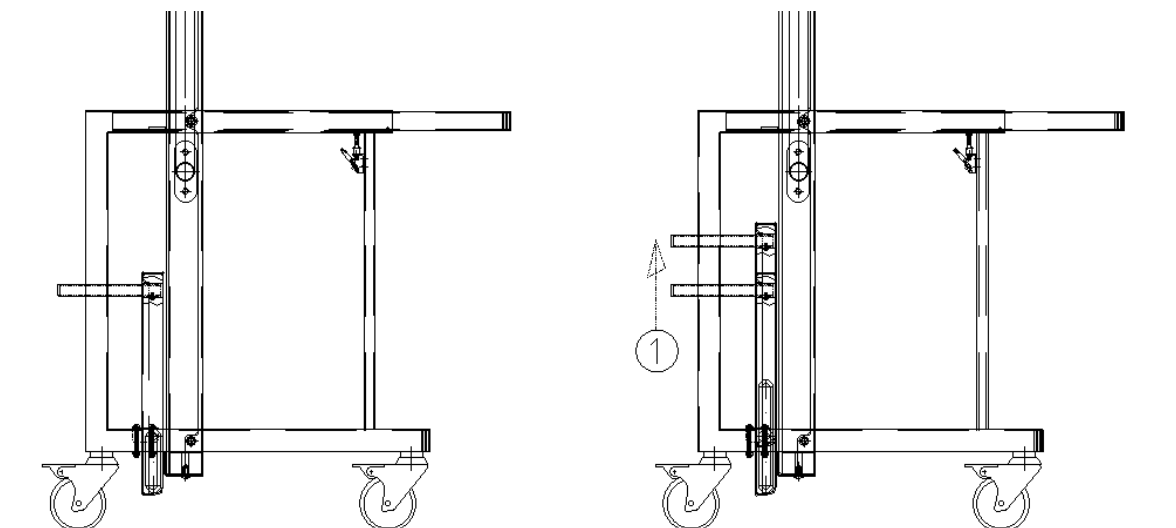
figure 12: *Stitch Frame U* in use

4.1 Transport of the Stitch Frame U

When the Stitch Frame U is not used any longer it can be parked/stored on another place. Before moving the Stitch Frame U insert the two bars completely into the frame and lock the bars with the locking mechanism. Unlock the wheels to move the Stitch Frame U to the parking position.

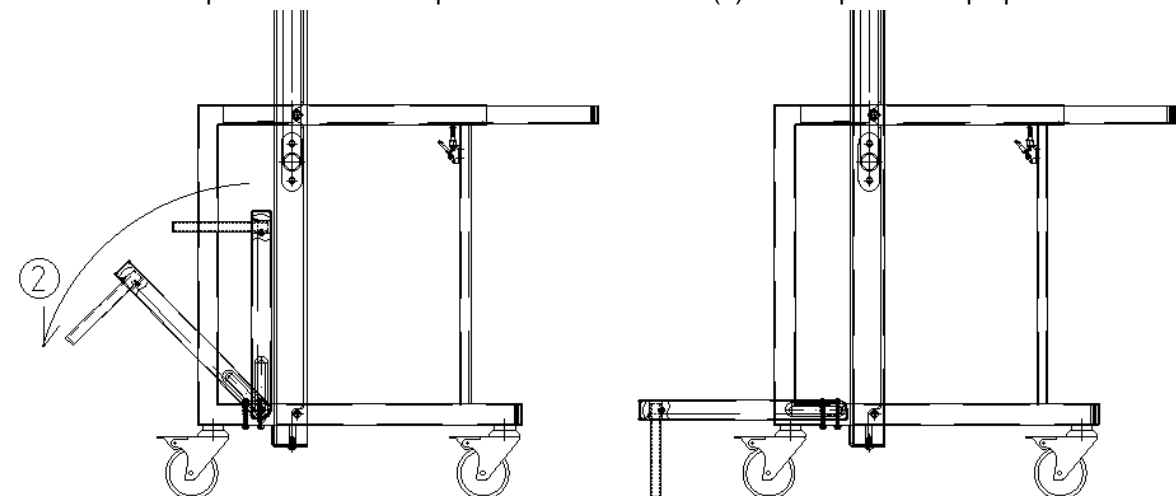
4.2 Optional Patient Step – Tilting Model

To Take an Exposure of the patient Feet the Patient Step can be used. This step must be tilted in front of the Stitch Frame U when the Stitch Frame U is positioned in the brackets against the wall. (Maximum Patient weight 200kg)



Park position Patient Step.


(1) Lift the patient Step upwards.



(2) Tilt the Patient Step to the Floor.

Patient can Stand on the Step.

figure 13: Positioning of Patient Step Tilting model (Option)

 WARNING:	<p>Maximum Patient weight 200kg</p> <p>Check properly attachment/fixation of the Patient Step to the Stitch Frame U before use.</p>
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5 Instructions for maintenance

The Stitch Frame U is maintenance free, but to help ensure the safe operation of your Stitch Frame U, there are integrity checks that should be performed before using the stitching frame U.



6 Integrity checks

Integrity checks are checks that must be performed to ensure that the Stitch Frame U is ready for use.

- a. Check overall condition of the stitching frame.
- b. Check transparent front plate for cracks or deep scratches.
- c. Check wall locking units. Verify the wall units are not loose
- d. Check wheels for proper operation and any signs of breakage.

If you have reasons to assume that the safe operation is not possible any longer, take the Stitch Frame U out of operation immediately and protect it against inadvertent operation.

7 Cleaning and disinfection

 WARNING:	Cleaning and disinfecting of the contact surface should be performed every time when a stitch procedure has been finished.
 WARNING:	Using biological safe and allergic free cleaning agents and wear surgical gloves during cleaning.
CAUTION:	Test cleaning products and disinfectants to ensure there is no adverse effect on the Stitch Frame U.

Cleaning

Wipe the Stitch Frame U with a piece of soft cloth soaked in water containing neutral detergent and wrung dry. **DO NOT USE** abrasive or chemical agents or detergents containing solvents as scouring compounds, gasoline, benzene, acetone and carbon tetrachloride, de-icing fluids, lacquer thinner, etc...

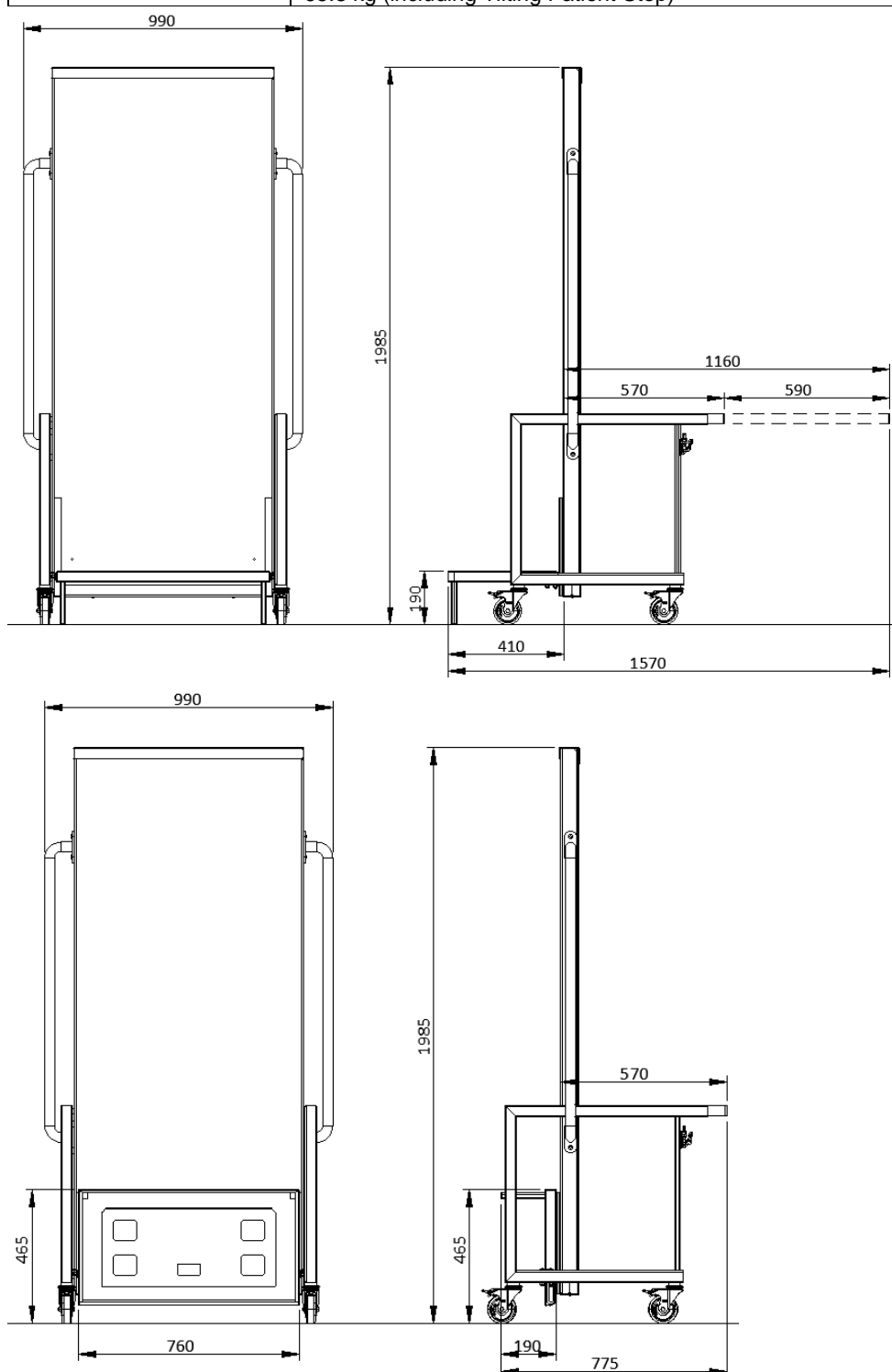
Disinfection

For infection prevention, it is advised to disinfect the contact surface such as the front plate and handles of the Stitch Frame U. Soak a piece of soft cloth with ethanol 80~90 %, or glutaraldehyde solution and wipe the surface thoroughly when a stitch procedure been finished.

8 Specifications

8.1 Stitch Frame U Specifications

Dimensions	
height	1985 mm
length	990 mm
depth	775 mm – 1575 mm (590mm adjustable)
weight	56.1 kg 65.8 kg (including Tilting Patient Step)



8.2 Environment conditions

Operative environment	Temperature range	10 ~ 35 °C
	Relative humidity range	Non-condensing
	Atmospheric pressure range	No restrictions
Transport and storage	Temperature range	-20 ~ 50 °C
	Relative humidity range	Non condensing
	Atmospheric pressure range	No restrictions

8.3 Used materials

Used materials	product description																	
PET-G	<ul style="list-style-type: none">Extruded Polyethyleneterephthalate - glycole sheet.Clear or transparent tinted sheet.Very good chemical resistance / very high impact resistanceBiocompatibility (skin contact) DIN EN 10993-5 - Non cytotoxic																	
Steel	<ul style="list-style-type: none">S 235 JRS – denotes the fact that it is Structural Steel235 – related to the minimum yield strength of the steel (tested at a thickness of 16mm) <table><tr><th>Grade</th><th>C%</th><th>Mn%</th><th>P%</th><th>S%</th><th>Si%</th></tr><tr><td>S235</td><td>0.22max</td><td>1.6max</td><td>0.05max</td><td>0.05max</td><td>0.05max</td></tr></table>						Grade	C%	Mn%	P%	S%	Si%	S235	0.22max	1.6max	0.05max	0.05max	0.05max
Grade	C%	Mn%	P%	S%	Si%													
S235	0.22max	1.6max	0.05max	0.05max	0.05max													
Stainless steel	<ul style="list-style-type: none">RVS 304 K3201.4301 stainless steel is a variation of the 18% chromium – 8% nickel austenitic stainless steel, the most familiar and most frequently used alloy in the stainless steel family. This stainless steel be considered for a wide variety of application on good corrosion resistance, ease fabrication, excellent formability, and high strength with low weight. <table><tr><th>Materialnr.</th><th>DIN 17006</th><th>ASTM/AISI</th><th>UNS</th></tr><tr><td>1.4301</td><td>X5CrNi18-10</td><td>304</td><td>S30400</td></tr></table>						Materialnr.	DIN 17006	ASTM/AISI	UNS	1.4301	X5CrNi18-10	304	S30400				
Materialnr.	DIN 17006	ASTM/AISI	UNS															
1.4301	X5CrNi18-10	304	S30400															
Powder coating	<ul style="list-style-type: none">Alesta® IP / Polyester Industrieel IF DiverseIF05019000223 GREY																	

8.4 Part List

Components used	
Stitch frame	1
wall brackets	2
Installation material	1 set
	8x Nylon Fixing Plugs 8x screws 6mm
Patient Step Tilting model	1x Patient Step Tilting Model (Optional)