

User manual

Stitch Frame U

Rev.: 02 [09-05-19]



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List of revisions

Equipment	Stitch Frame U
Document	User manual
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Version	02

revision	Date	Comment
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

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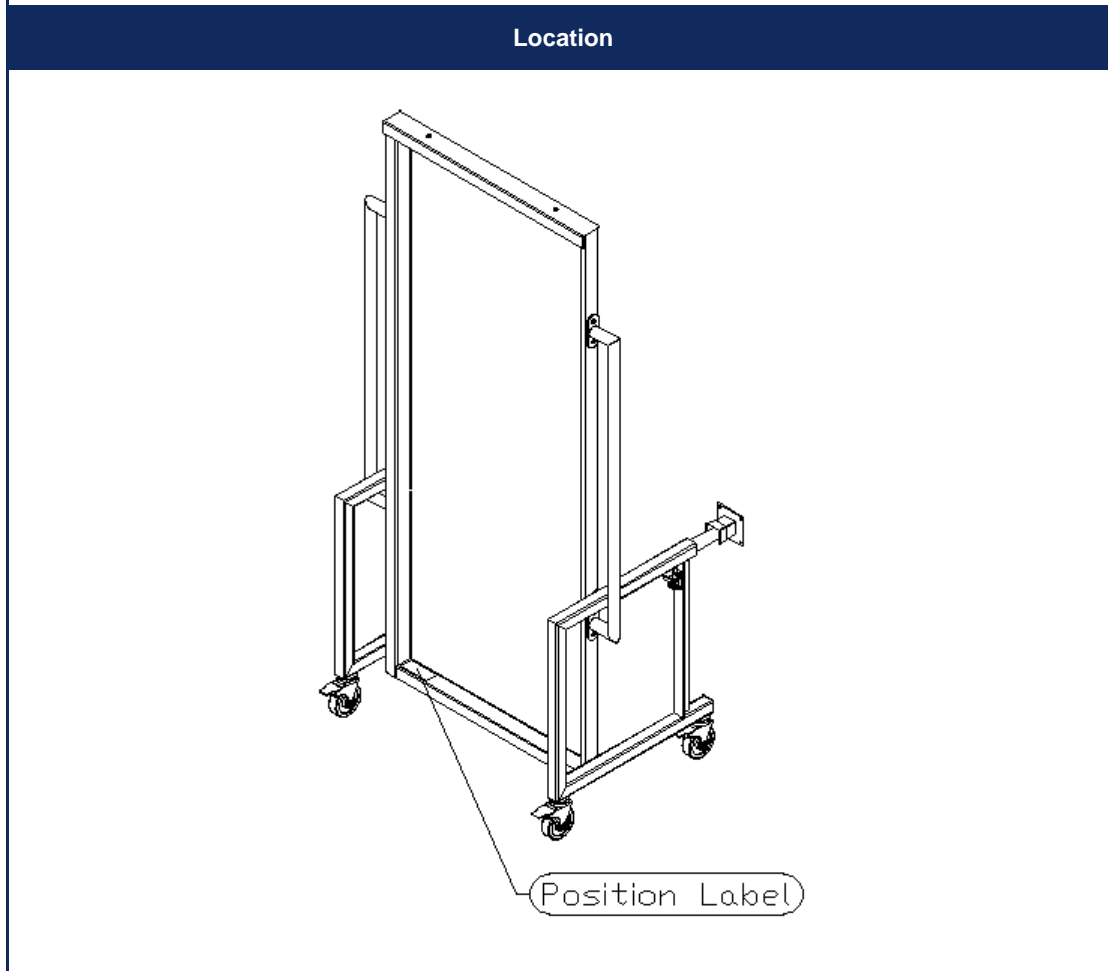
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1. Identification label


Label			
Type / model		Stitch Frame U	
Serial Number:	SN	SF-U-2013-1301	
Manufactured by:		Oldelft Benelux BV, Wiltonstraat 41, 3905 KW, Veenendaal, The Netherlands	
			



2. Safety overview

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.

Before using the stitch Frame U, be sure to review the warnings in this chapter. Warnings, Cautions and Notes will also be used throughout this manual in the following manner:

	This sign indicates 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.

NEVER ATTEMPT A SHORTCUT TO PROCEDURES WHICH MAY DEGRADE THE SAFETY CONSIDERATIONS OF THE SYSTEM.

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.

No changes, additions or removal of any part are permitted without prior written approval of Oldelft Benelux BV.

- a. Do not leave problems unattended that may affect the safety of the product. In case you have doubts concerning the stitch frame 's safe operation, call the service number of your vender for further instructions
- b. The Stitch Frame U should be cleaned regular to prevent the accumulation of dust. The Perspex plate should be cleaned after each patient for hygienic reasons.

3. Installation Instructions

If the Stitch Frame U package is opened or damaged inspect the product on damage and inform the distributor. If the Stitch Frame U seems to be broken or damaged DO NOT use it.

Material required

Locktite	
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Tools required

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

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 locking brackets	2x	

See Figure 2.1 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.

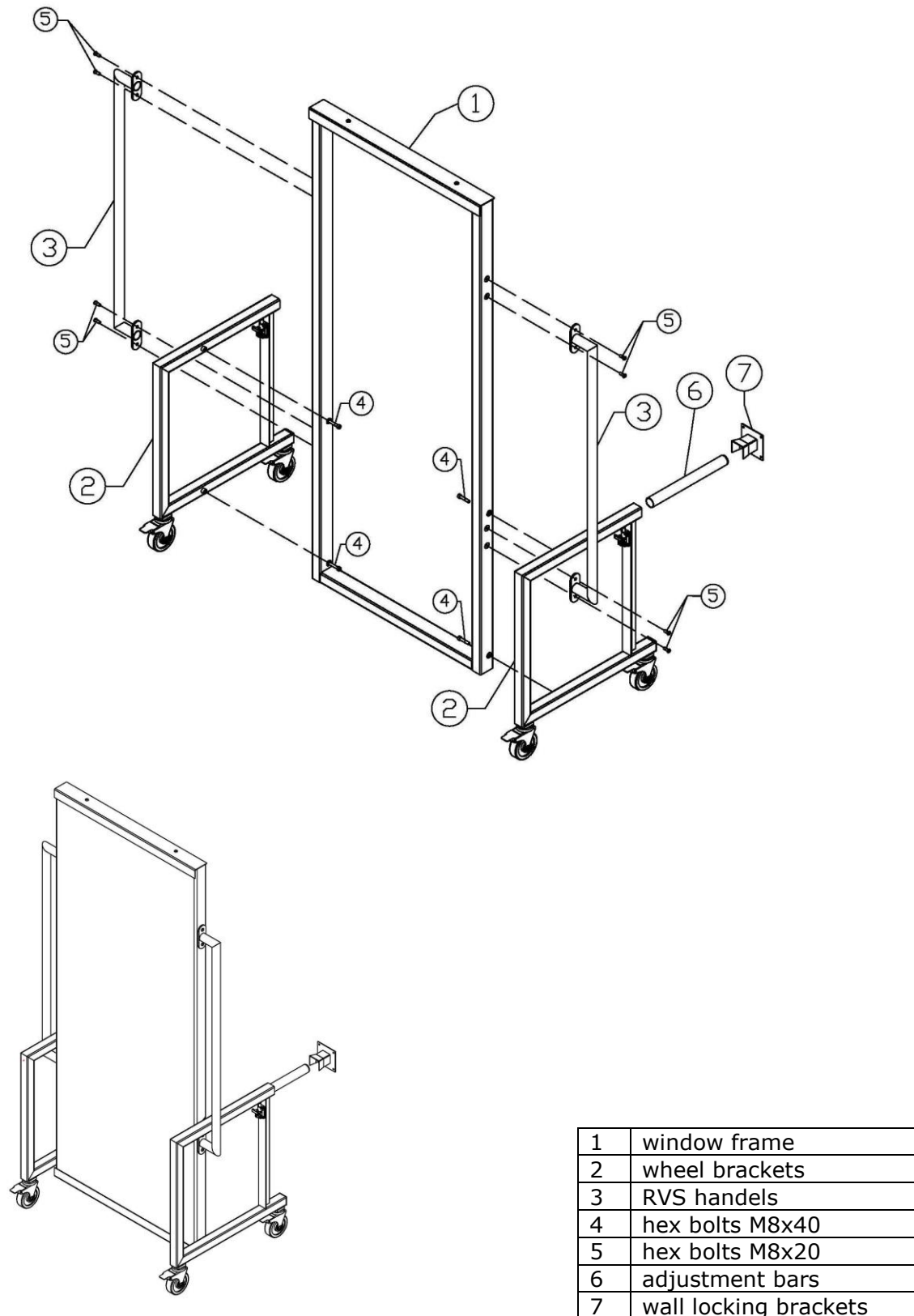


Figure 2.1 assembling the Stitch Frame U

1	window frame
2	wheel brackets
3	RVS handles
4	hex bolts M8x40
5	hex bolts M8x20
6	adjustment bars
7	wall locking brackets



How to install the Stitch Frame U:

procedure

- Slowly move the stitch frame toward the detector until the Perspex plate touches the detector gently.
- Centre the stitch frame in relation to the detector. Distance B is equal on both sides. (See Figure 2.2)

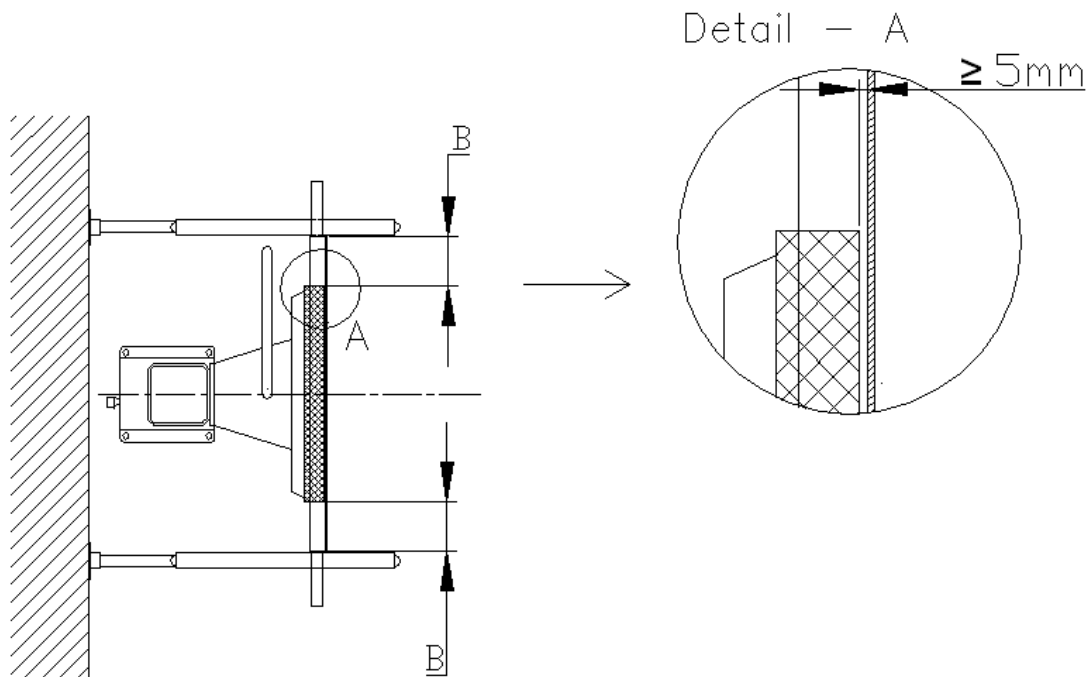


Figure 2.2 position the stitch Frame U.

- 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 locking brackets (7) between the wall and the adjustment bars. (See Figure 2.3)
- Check to see that the stitch frame is still centered to the detector.
- Level the wall locking brackets. (7)
- Mark drilling holes using the wall locking brackets as guide.

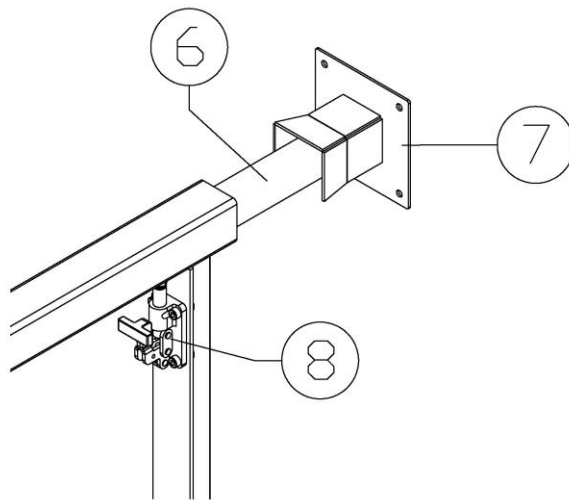
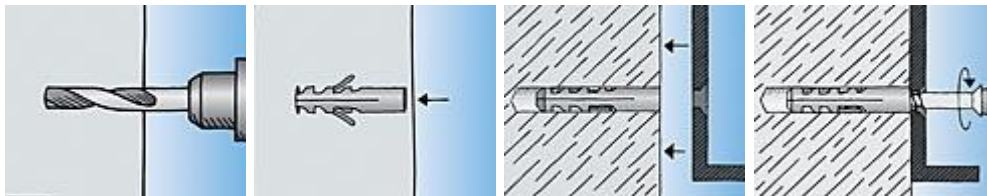


Figure 2.3 Position Wall Locking Brackets.

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




- Finally: Install the stitch frame and leave approximately 5 mm distance between the back of the stitch frame (Perspex plate) and the detector surface. See Figure 2.2

4. General description

Intended purpose:

The Stitch Frame U is used as patient positioning system during an X-ray procedure. It will assist the patient retaining a stable vertical position.

5. Instructions for use



Before positioning the Stitch 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 2.3 and 2.4




figure 2.3 Collision Danger

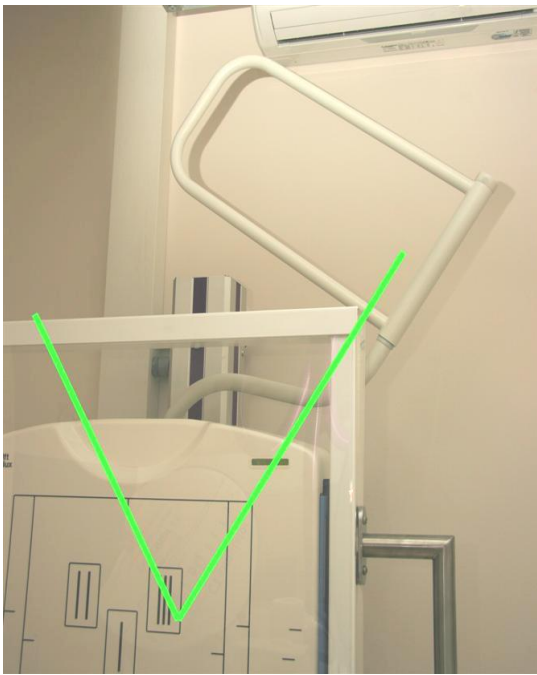


figure 2.4 Wall stand Patient bar parked

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

Extend the two bars into the wall locking brackets and lock the bars with the locking mechanism.

Lock the two front 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.
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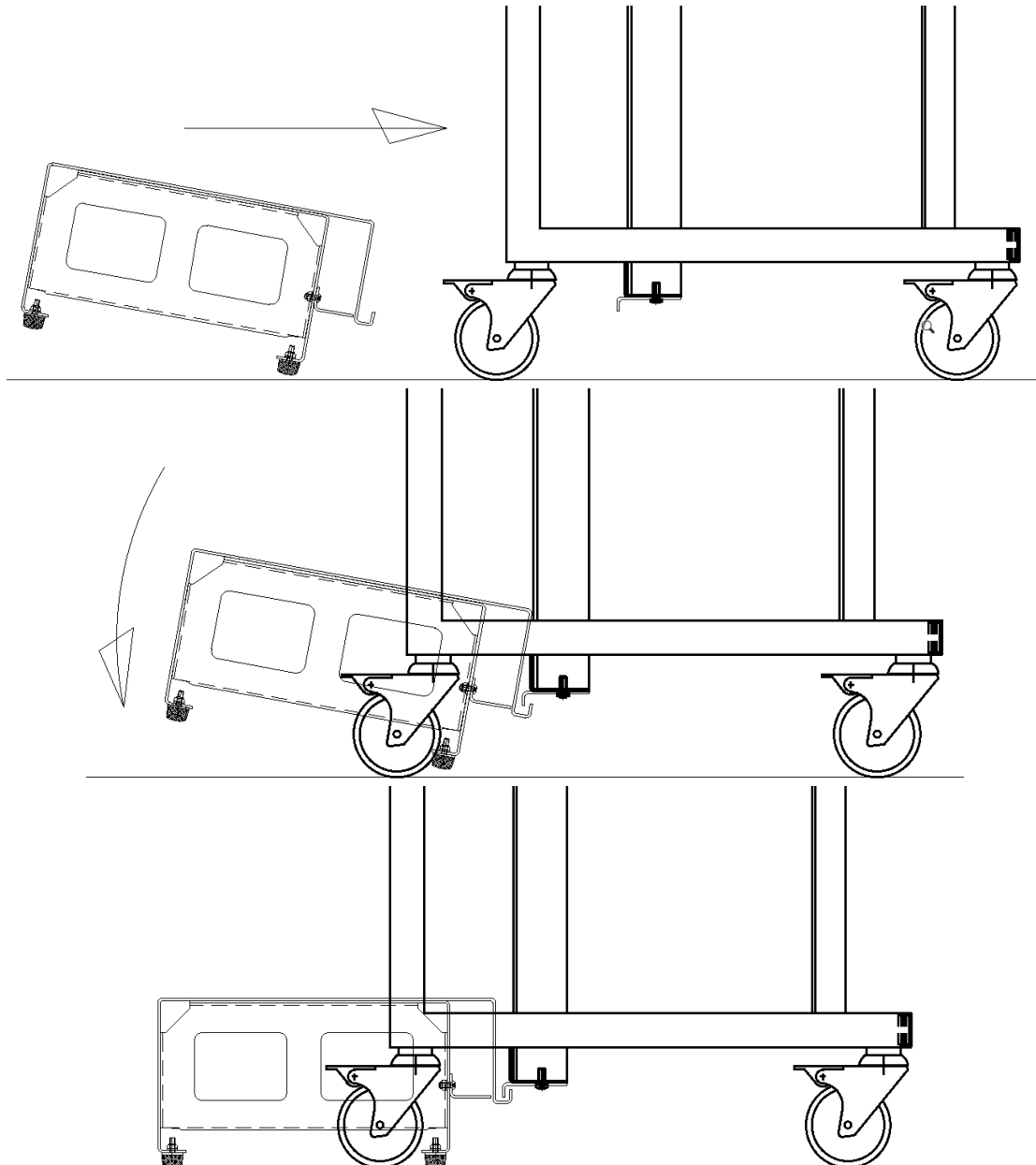
Place the patient against the Perspex plate. If needed fore more patient stability, use the Velcro (optional) to fix the patient. See figure 2.5




2.5 Stitch Frame U in use

Optional Patient Step:

To Take an Exposure of the patient Feet a Patient Step can be used. This step must be fixed to the Stitch Frame U when the Stitch Frame U is positioned in the brackets against the wall. The Fixation is done by hooking the step up the Stich Frame U as shown below. (Maximum Patient weight 200kg)

**2.6 Positioning of Patient Step (Option)**

	<p style="text-align: center;">Maximum Patient weight 200kg</p> <p style="text-align: center;">Check properly attachment/fixation of the Patient Step to the Stitch Frame U before use.</p>
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6. Maintenance

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

7. Integrity checks

- a. Check overall condition of the stitching frame.
- b. Check Perspex for cracks or damage.
- c. Check wall locking units. Verify the wall units are not loose
- d. Check wheels for proper operation and any signs of breakage.
- e. Check the state of the Velcro, if there are signs of ruptures or if the two sides do not stick together anymore, replace the Velcro for a new one.

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.

8. Cleaning and disinfection

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.

For infection prevention is advised to disinfect the Perspex plate of the Stitch Frame U. Soak a piece of soft cloth with ethanol 80~90 %, or glutaraldehyde solution and wipe the Perspex surface thoroughly when a stitch procedure for a patient has been finished.

The Velcro (optional) can be disconnected from the stitch frame for cleaning.



9. Specifications

Dimensions	
height	1985 mm
length	1074 mm
depth	1010 mm – 760 mm (250mm adjustable)
weight	40 kg

Used materials	product description												
Acrylate / Perspex	<ul style="list-style-type: none"> • Clear or transparent tinted sheet. • A high molecular weight acrylic sheet used in a wide range of applications. Does not include PERSPEX AS 017. • Polymethyl methacrylate : greater than 90%. • CAS No: 009011-14-7 												
Steel	<ul style="list-style-type: none"> • S 235 JR • S – denotes the fact that it is Structural Steel • 235 – related to the minimum yield strength of the steel (tested at a thickness of 16mm) <table border="1"> <thead> <tr> <th>Grade</th> <th>C%</th> <th>Mn%</th> <th>P%</th> <th>S%</th> <th>Si%</th> </tr> </thead> <tbody> <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> </tbody> </table>	Grade	C%	Mn%	P%	S%	Si%	S235	0.22max	1.6max	0.05max	0.05max	0.05max
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S235	0.22max	1.6max	0.05max	0.05max	0.05max								
Stainless steel	<ul style="list-style-type: none"> • RVS 304 K320 • 1.4301 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 border="1"> <thead> <tr> <th>Materialnr.</th> <th>DIN 17006</th> <th>ASTM/AISI</th> <th>UNS</th> </tr> </thead> <tbody> <tr> <td>1.4301</td> <td>X5CrNi18-10</td> <td>304</td> <td>S30400</td> </tr> </tbody> </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										
Paint	<ul style="list-style-type: none"> • Interpon D1036 Gloss (85) is a range of powder coatings intended for use on architectural aluminium and galvanised steel. • Available in a wide stock range Interpon D1036 Gloss (85) has been specifically formulated using the Perform System, Akzo Nobel's TGIC-free technology. As part of the abcd D series of architectural powders, Interpon D1036 Gloss (85) gives excellent exterior durability and colour retention and conforms with the requirements of all the major European architectural finishing standards. • All Interpon D1036 Gloss (85) powders are lead-free and meet the requirements of GSB, Qualicoat Class 1 and EN 12206 (formerly BS6496), BS6497:1984. 												

Components used	
Stitch frame	1
wall locking brackets	2
Installation material	1 set
	8x Nylon Fixing Plugs 8x screws 6mm
Patient Step	1x Patient Step included 1x Hook bracket (Optional)