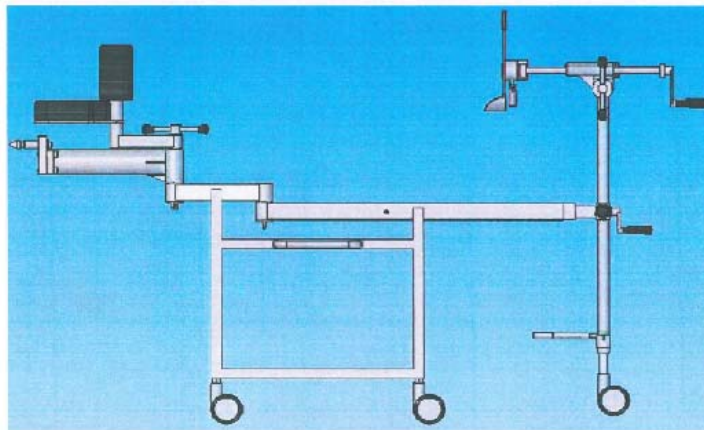




Spinal Traction Frame



User Manual

Advanced Instrumentations, Inc.

OM-OT500STF/ REV.00/SEP.2011

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User's responsibility

Please install, maintain and service this medical device according to user's manual, and operate it according to user's manual and appended labels and illustrations. This product should be checked-up periodically. Please replace the device in time when it is malfunction and replace the accessories if they are loss, wear, distortion or pollution.

Note Refer to any possibly applicable local law restriction when selling or ordering this product in any region.

Those other brand names or product names used in this user's manual belong to respective holder.

1. Introduction

About orthopedic frame

Orthopedic frame is a medical device for orthopedic traction surgery, and is auxiliary to operating table, mainly for limbs' orthopedic surgery. During surgery, it can provide lateral or lying position traction and outspread posture to patient's limbs, and can make surgery photographing and surgery image monitoring with C-arm. It is a necessary equipment in orthopedic clinics.

This equipment is of simple structure, many moveable joints and convenient operation, and can be used together with the various general operating tables to improve surgery efficiency.

As some spare parts are made or designed according to customer's requirement, please refer to final product if the product you buy has some difference from the product in this manual.

Our company promises that if necessary the relevant circuit diagrams, correction details, and list of elements and devices, and other needed data will be provided for the service personnel authorized by the company and users.

Symbols used in this manual and equipment in this manual

Warning and **Note** are used to describe the level of danger. Please be familiar with their definition and meaning.

Warning meaning the case that may cause injury to operator or patient

Note meaning the case that may cause injury to the equipment

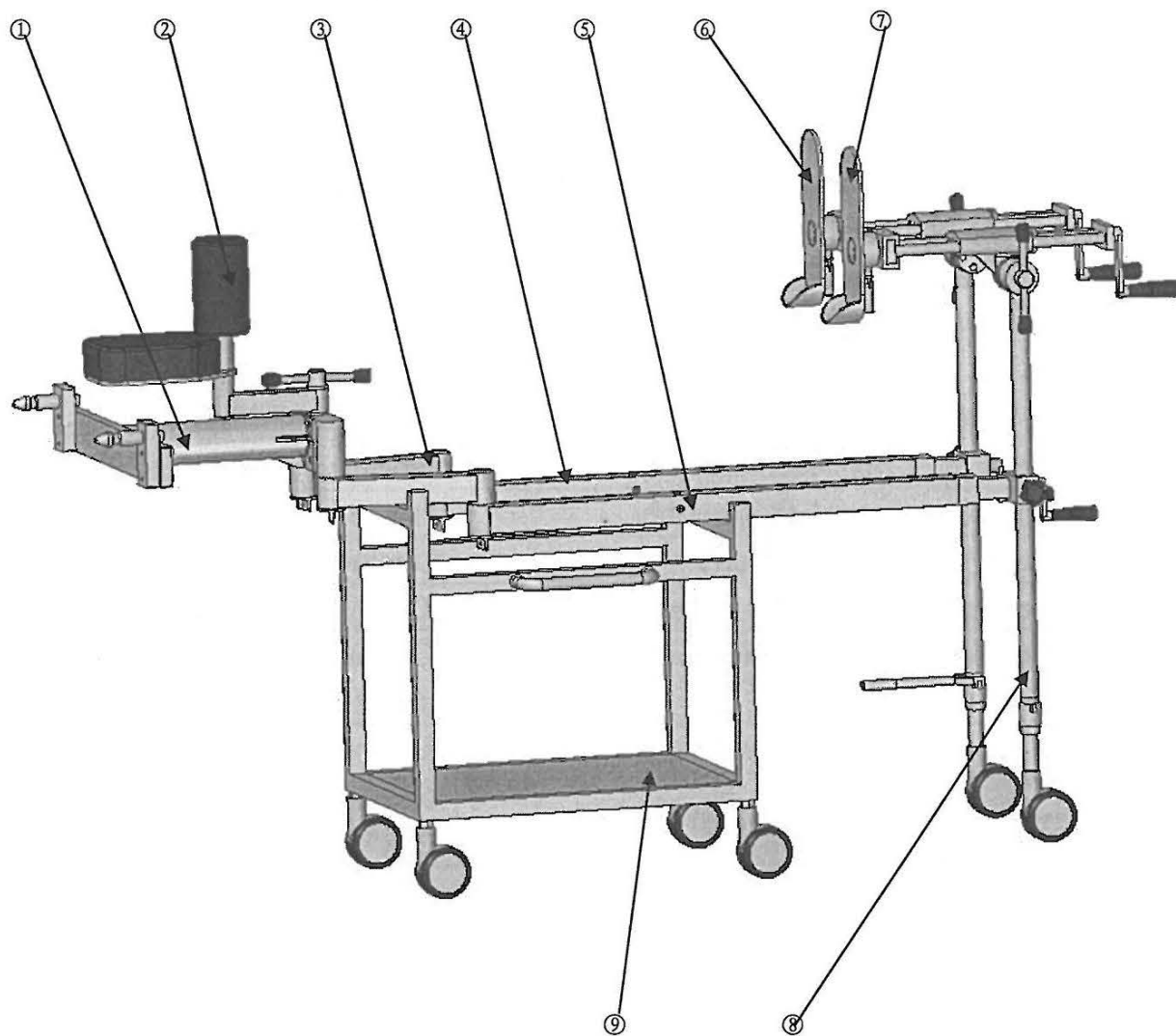
Important similar to note, but with emphasis

Warning Please read carefully this manual.

Warning Risk of cross contamination. After using this equipment, please clean with sterile alcohol to avoid patients' cross contamination.

2. Equipment structure

Structure as follow:



1. U-shape terminal rack assembly 2. Traction stirrup assembly 3. Short bar connecting assembly
4. Long left bar's main parts 5. Long right bar 's main parts 6. Left foot plate longitudinal tray
assembly 7. Right foot plate longitudinal tray assembly 8. Standing bar assembly 9. Traction
frame trolley

Fig 2-1 Orthopedic framediagram

Orthopedic frame is mechanical driven, using suspended two-part traction frame design, and can make traction movements of various angles and is convenient for C-arm application. It has fixing and locking device at the connecting points of various parts to ensure safe and stable operation.

Orthopedic frame makes traction movement by adjusting standing bar's height and gently adjusting longitudinal tray.

Unique cart design can hold orthopedic frame and orthopedic accessories which can be put on the trolley to save space.

The equipment is made of stainless steel and can stand big pulling strength without any loosening, and is also anti-corrosion and easy-to-clean.

Item	Remarks
2 Traction stirrup assembly	Can be adjusted during operation
3 Short bar connecting assembly	Can be adjusted during operation
4 Long left bar's main parts	Can be adjusted during operation
5 Long right bar 's main parts	Can be adjusted during operation
6 Left foot plate longitudinal tray assembly	Can be adjusted gently during operation
7 Right foot plate longitudinal tray assembly	Can be adjusted gently during operation
8 Standing bar assembly	Can be adjusted during operation

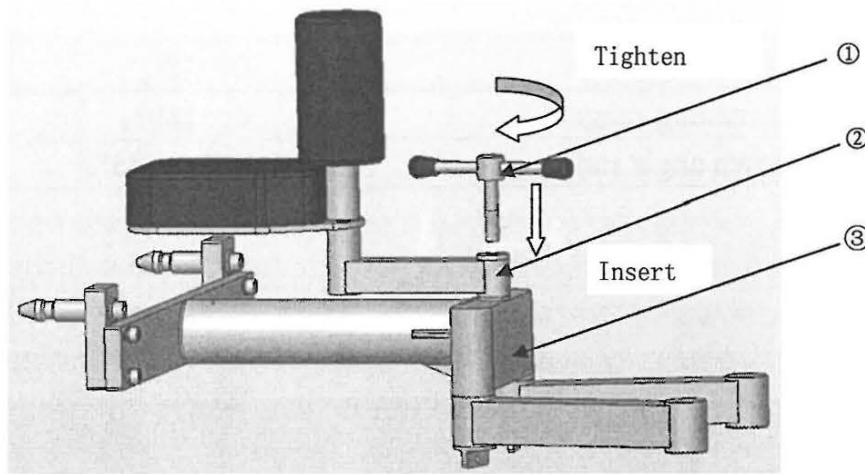
3. Main technical parameters

Item	Remarks
Complete machine length adjusting range	1120~2000±10mm;
Complete machine height adjusting range	700~1000±10mm;
Installation width adjusting distance	440~476 mm;
Traction range	400~1000 mm;
Micro-movement adjusting range	190 ±5mm;
Short bar outspreading range	0~180°;
Long bar outspreading range	0~180°;
Foot tray up/down angle range	-45°~+45°;

4. Machine assembly

Traction stirrup assembly installation

Sitting plate connecting assembly contrite gear joggle with traction frame body's contrate gear. Plugging T-shape handle assembly into sitting plate connecting assembly contrite gear's socket, and rotating clockwise to tighten it. (Fig 4-1)

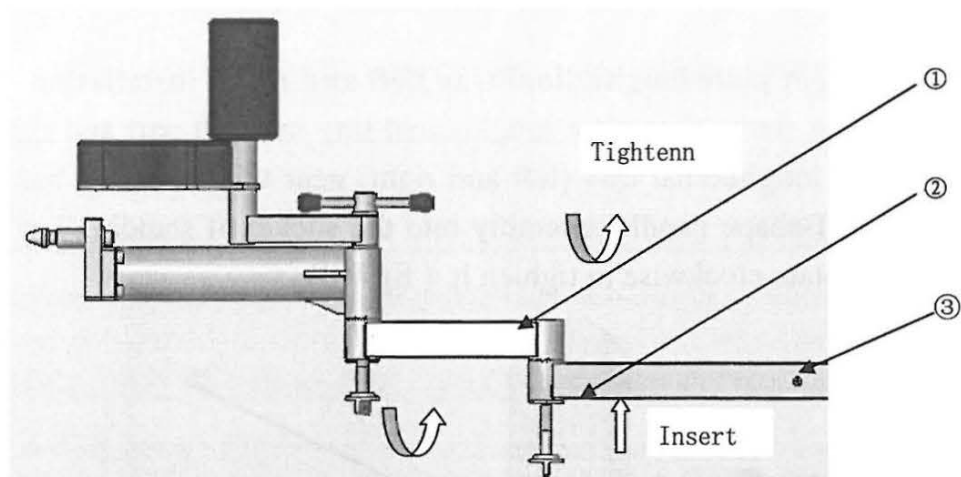


1. T-shape handle assembly 2. Sitting plate connecting assembly 3. Traction frame body

Fig 4-1 Traction stirrup assembly installation diagram

Traction frame long bar's main part (left and right) installation

Divide traction frame long bar's main part into left part and right part. Joggle short bar connecting assembly's contrate gear with contrite gear of traction frame long bar's main part (leg and right), plug main part connecting screw into the socket of long bar's main part contrite gear, and rotate clockwise to tighten it. (Fig 4-2)



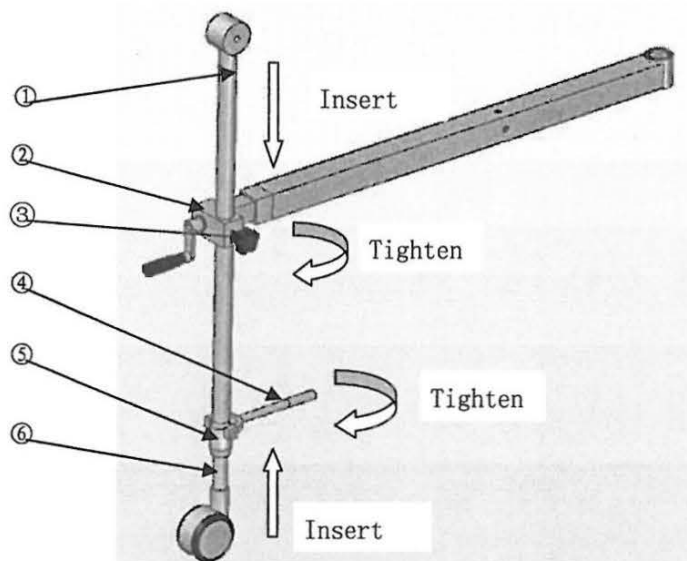
1. Short bar connecting assembly 2. main part connecting screw assembly 3. traction frame
long bar main parts (left and right)

Fig 4-2 Traction frame long bar's main parts installation diagram (leg and right)

Note When assembling to this status, we suggest making assembling procedures after putting on traction frame trolley.

Traction frame standing bar assembly installation

First insert traction frame's standing bar sliding cover into standing bar inner cover assembly, rotate clockwise to fix standing bar sliding cover. Insert traction frame's standing bar sliding pole into its sliding cover, and rotate clockwise with self-made spanner to tighten the locknut thus fix it. (fig 4-3)

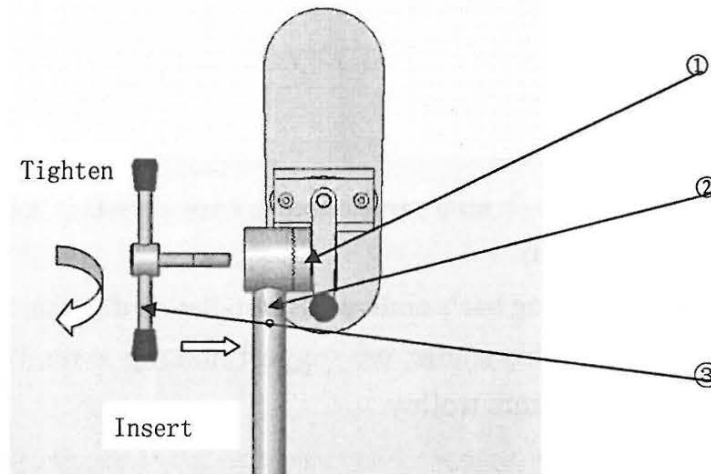


1. standing bar sliding cover 2. standing bar inner cover assembly 3. lock knob
4. self-made spanner 5. Locknut 6. standing bar sliding pole

Fig 4-3 Standing bar assembly installation diagram

Traction frame foot plate longitudinal tray (left and right) installation

Divide traction frame foot plate longitudinal tray into left part and right part. Joggle foot plate longitudinal tray (left and right) gear with standing bar sliding cover gear, plug T-shape handle assembly into the socket of standing bar sliding cover gear, and rotate clockwise to tighten it. (fig 4-4)



1. Foot plate longitudinal tray part (left & right) 2. Long bar inner cover assembly
3. Terminal track T-shape handle assembly

Fig 4-4 Foot plate longitudinal tray (left & right) installation

5. Connection information

This machine will be used together with other general operating table, and its main connecting size is as below:

U-shape terminal track assembly connecting needle

Connecting needle size	axis 2- ϕ 19.6mm ;
Centerline spacing	440~476 mm。

Note This specification is standard configuration product.

6. Operation and manual

Warning Only the trained and qualified professionals can operate this equipment.

Warning For alarms during operation, the operator should find the reasons, and take appropriate measures to ensure patient's safety.

Note It is best to place the equipment on small vehicle for easy operation and labors saving.

Preparation before operating the device

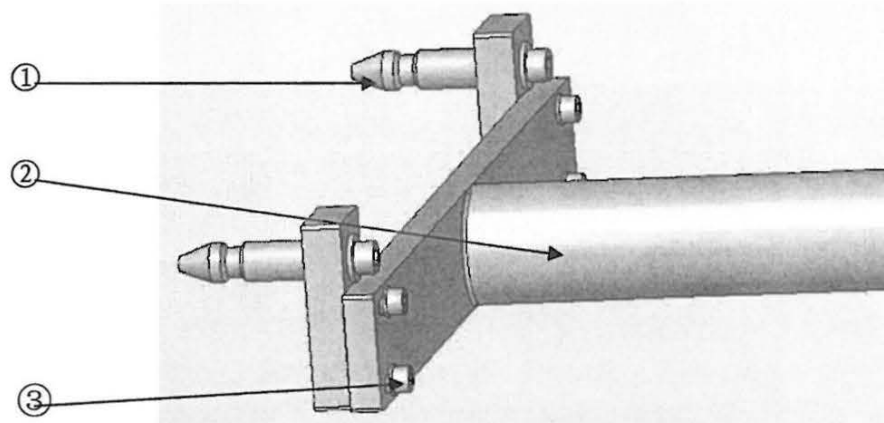
Before using, move the spinal traction frame to right position beside the operating table, respectively step the spinal traction frame's universal wheel locking pedal to guarantee ground solid.

Adjust the traction frame left and right foot board components nearest point of the jiggle screw to prepare traction.

The way of using

Connect the frame and operating table

Insert the cylindrical steel needle ① into the operating table and then fix it. If the distance between two cylindrical steel needles is at variance with that between two holes in the operating table, please unscrew the shown four hexagon ③ socket head screws in the picture, then adjust the distance of the two cylindrical steel needles, so that it can fit for the different models of the operating tables. (shown as 6-1 in the picture)



1. Cylindrical steel needle 2. U commutator 3. Hexagon socket head screw

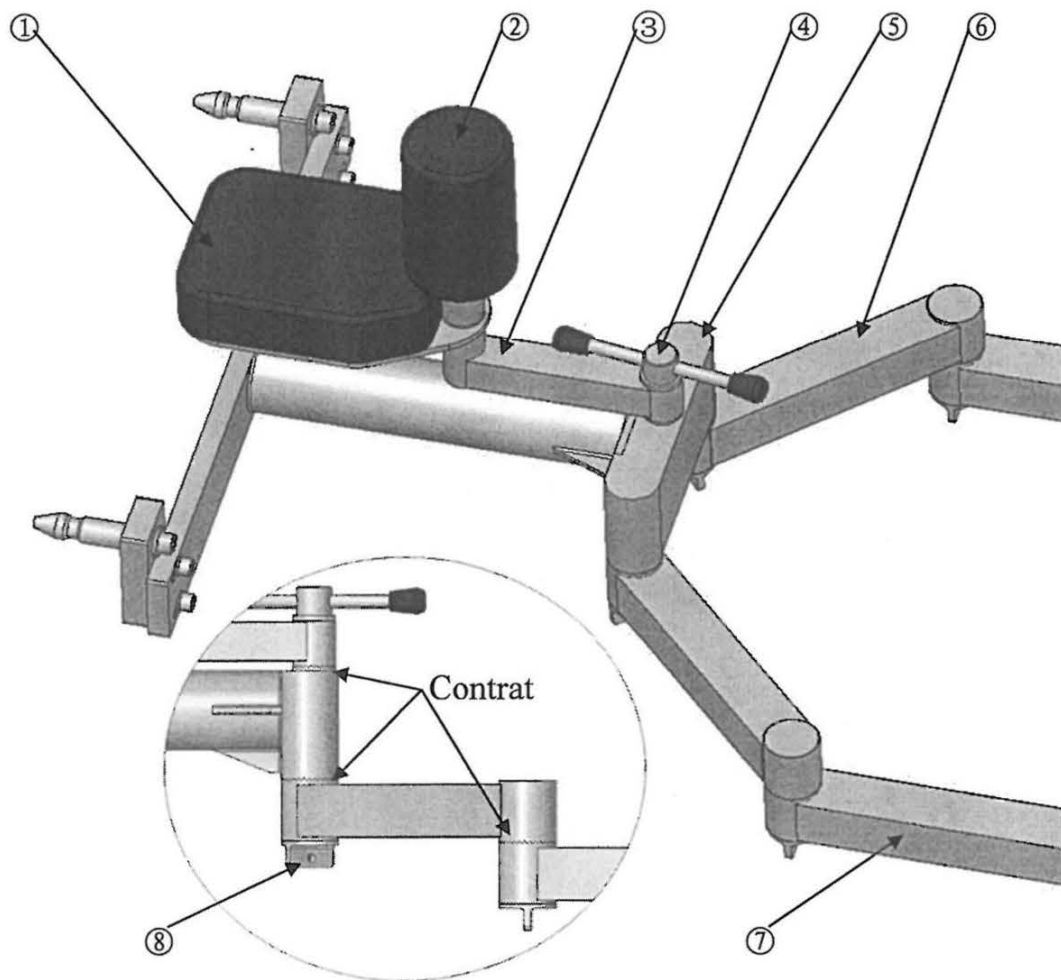
Fig 6-1 Installation picture

Connect the frame of the sitting plate

Loosen T-type handle④, the sitting plate connectors③ can be turned along the contrate wheels, adjusted it to the right position then crew down the T-type handle to fix the sitting plate connectors; The sitting plate① can be circled along the block combination② which is used for detaching the legs(shown as 6in the picture11-2) freely.

Connect the frame of the longer and shorter leg modules

Loosen the screw connected with the main body ⑧of the frame, both the shorter ⑥and longer leg⑦ modules can be circled along the contrite wheels, adjust them to a fit position ,then screw down the screws to fix them. (shown as 6-2 in the picture)



1. Sitting plate 2. Block combination 3. Sitting plate connectors 4. T-type handles
5. Main body of the frame 6. Short leg modules 7. Longer leg modules 8. Screw
connected with the main body

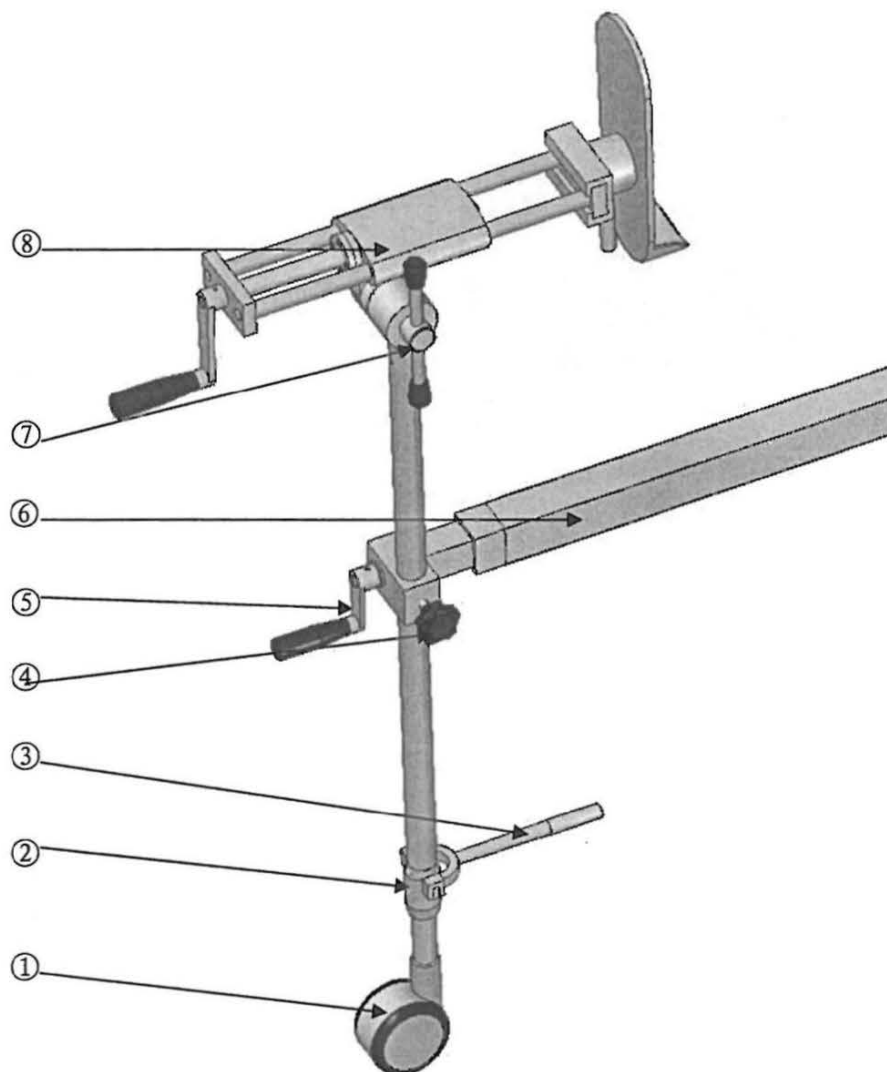
Fig 6-2 Installation picture

Adjust the longer leg modules

Rock the bell crank⑤, the longer leg module⑥ can be adjusted longer or shorter accordingly;stop the crank, the longer leg module can be locked in any position. (Shown as 6-3 in the picture)

Adjust the stand leg modules

Unscrew the locknut② with spanner③ and loosen the cam type knob④, adjust the supporting of shift ⑧to a proper point, then lock the cam type knob and adjust the universal wheel① to touch the ground.Finally, fix the locknut with spanner, the supporting of shift can be fixed to a right position. (Shown as 6-3 in the picture)



1. Universal wheel 2. Locknut 3. Spanner 4. Cam type knob 5. Bell crank
6. Longer leg module 7. T-type handle 8. Supporting shift

Fig 6-3 Installation picture

Connect the Supporting shift

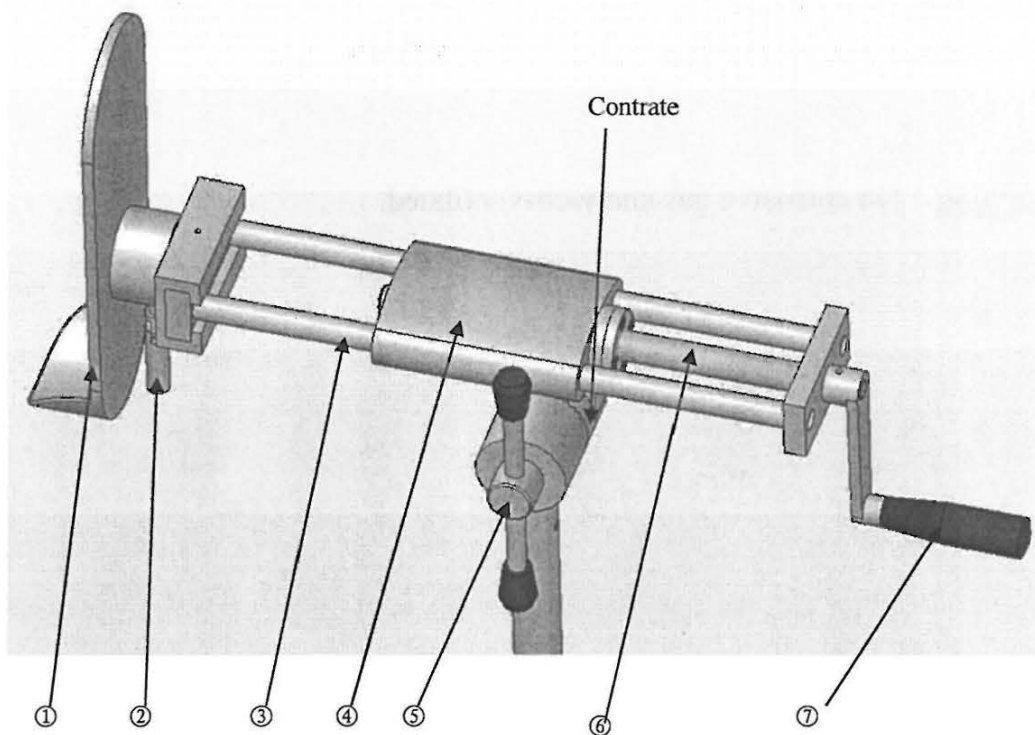
Loosen T-type handle⑤, the supporting shift components ④ can be turned along the contrate wheels, adjust the supporting part to a right position ,and then fix it by screwing down the T-type handle. (Shown as 6-4 in the picture)

Fasten the Supporting shift

Unscrew the knob ②, transaction shoes ①can be circled to any angle along the supporting shift ④, so that the shoes can be fixed to any angleby locking the knob. (Shown as 6-4 in the picture)

Jiggle adjust the Supporting shift

Rock the bell crank⑦, the supporting shift ④ can be extend or shorten along the direction of the guide pole③; when stop rocking, the supporting shift will be locked at any position.



1. transaction shoes 2. knob 3. guide pole 4. supporting shift 5. T-type handle
6. screw pole 7. bell crank

Fig 6-4 Jiggle adjust the Supporting shift picture

Warning Please be assured that all the lock bolt are locked before traction.

7. Installation and replacement

Note Before installation, check each parts to be assured is working well.

Installation and operation environment:

Ambient temperature range: $+10^{\circ}\text{C} \sim +40^{\circ}\text{C}$
Relative humidity range: $30\% \sim 70\%$
Atmospheric pressure range: $700 \text{ hPa} - 1060\text{hPa}$

Packed equipment should be stored in a room with:

Ambient temperature range: $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$
Relative humidity range: $\leq 93\%$;
Atmospheric pressure range: $500 \text{ hPa} \sim 1060\text{hPa}$

Warning No corrosive gas and well-ventilated.

8. Cleaning and sterilization

Warning Please complies with prescript of security defense in point:

- Reading carefully every cleaning agent, disinfectants, the safe use of criterion.
- Reading carefully all sterilization equipment user manual
- Ensuring that wearing the safe glove, respirator and glasses.
- The equipment has been strictly cleaned and packaged before leaving factory, but it is inevitable pollution during the transport, so the first time usage of the equipment should also be cleaned, disinfected.

Cleaning and sterilization of the mainframe workstation surface

Clean the machine's panel and all surfaces with soft cloth soaked in the common water soluble disinfectant. The confection of the disinfectant must be done in accordance with the directions given by the manufacturer. One must prevent the disinfectant drop from entering the machine when cleaning the machine.

Note

- Do not use organic, halogenated or petroleum-based solvents, narcotic drugs, glass cleaning agent
- Do not use attrited cleaning agents
- All liquid containers will be placed in as far away from electronic components
- Don't drop the liquid into the equipment within the shell.

Note Ensure the consumable is good before you use it.

Note Do not reuse disposable consumable.

Warning Please cleaning the table with disinfection alcohol to avoid inter infection; and disinfect the table with ultraviolet radiation one time every day.

9. User's maintenance

Warning Please comply with sterilization regulations and security disciplines because all used equipments possibly contain blood and body fluid of patients.

Warning Personnel without maintenance experience to this kind of equipments are prohibited undertaking maintenance tasks.

Maintenance schedule

Checking Item	Maintenance Time	Effective Measure
Cleaning and Sterilization	Each Operation	Clean external surface
During installation		Check whether accessories are in good condition or not, and replace or service them when necessary
Cleaning	Everyday	Check whether accessories are in good condition or not, and replace or service them when necessary
Jiggle adjust the screw pole	Always	Check the screw pole and supporting shelf and replace the oil, in order to keep it glide easily, shake it up and down.

10. List of host machine, optional accessories, and consumables

Item	Name	Unit	Quantity	Remark
Main part	Spinal traction frame	set	1	
Accessory	Trolley for the frame	set	1	
Consumer goods	Stride mattress	set	1	
Documents	User manual	pc	1	
	Product qualified certificate	pc	1	
	Guarantee card	pc	1	
	Packing list	pc	1	
	Installation report	pc	1	

Note: The final packing list may be different from this one for special requirement. Please refer to the final one.

11. Pollution control and recycling

The content and identification below are according to 《Regulation on the Pollution Control of Electronic Information Products》

The contents of the deleterious substance or element are as below:

Name of the Accessories	Deleterious Substance or Element					
	Plumbum (Pb)	hydrargyrum (Hg)	Cadmium (Cd)	Chrome (Cr6+)	Polybromide Biphenyl (PBB)	Polybromide diphenyl ether (PBDE)
Metal sheet part	○	○	○	○	○	○
Aluminum part	○	○	○	○	○	○
Copper part	○	○	○	○	○	○
Stainless steel part	○	○	○	○	○	○
Steel part	○	○	○	○	○	○
Wheel	○	○	○	○	○	○
Bolt	○	○	○	○	○	○
Gasket	○	○	○	○	○	○
Nut	○	○	○	○	○	○
Handwheel	○	○	○	○	○	○
Plastic Bag	○	○	○	○	○	○
Cable ties	○	○	○	○	○	○
Paper packaging box	○	○	○	○	○	○
PE expanded Pad	○	○	○	○	○	○
User Manual	○	○	○	○	○	○
Product qualified Certificate	○	○	○	○	○	○
Guarantee Card	○	○	○	○	○	○
Packing list	○	○	○	○	○	○
Installation Report	○	○	○	○	○	○
<p>○: means the deleterious substance or element's content of this accessory's material are below the SJ/T11363—2006 standard.</p> <p>✕: means the deleterious substance or element's content of this accessory's material are over the SJ/T11363—2006 standard.</p>						



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