Spinal Traction Frame

User Manual

Advanced Instrumentations, Inc.

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Contents

User's responsibility ............................................................................................................ II
1. Introduction ...................................................................................................................... 1-1
2. Equipment structure .......................................................................................................... 2-1
3. Main technical parameters .............................................................................................. 3-1
4. Machine assembly ............................................................................................................ 4-1
5. Connection information .................................................................................................... 5-1
6. Operation and manual ...................................................................................................... 6-1
7. Installation and replacement ............................................................................................ 7-1
8. Cleaning and sterilization ................................................................................................. 8-1
9. User's maintenance ......................................................................................................... 9-1
10. List of host machine, optional accessories, and consumables ................................... 10-1
11. Pollution control and recycling .................................................................................... 11-1
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 user manual

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.

<table>
<thead>
<tr>
<th>Item</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Traction stirrup assembly</td>
<td>Can be adjusted during operation</td>
</tr>
<tr>
<td>3 Short bar connecting assembly</td>
<td>Can be adjusted during operation</td>
</tr>
<tr>
<td>4 Long left bar’s main parts</td>
<td>Can be adjusted during operation</td>
</tr>
<tr>
<td>5 Long right bar’s main parts</td>
<td>Can be adjusted during operation</td>
</tr>
<tr>
<td>6 Left foot plate longitudinal tray assembly</td>
<td>Can be adjusted gently during operation</td>
</tr>
<tr>
<td>7 Right foot plate longitudinal tray assembly</td>
<td>Can be adjusted gently during operation</td>
</tr>
<tr>
<td>8 Standing bar assembly</td>
<td>Can be adjusted during operation</td>
</tr>
</tbody>
</table>
3. **Main technical parameters**

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

![Diagram of Traction stirrup assembly installation](image)

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)
Tighten

1. Short bar connecting assembly  
2. main part connecting screw assembly  
3. traction frame

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)

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

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)

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

1. Foot plate longitudinal tray part (left & right)  2. Long bar inner cover assembly
3. Terminal track T-shape handle assembly
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- $19.6$ mm
- Centerline spacing: $440 \sim 476$ 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)

![Installation picture](image)

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 handle\(^4\), the sitting plate connectors\(^3\) 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 plate\(^1\) can be circled along the block combination\(^2\) which is used for detaching the legs(shown as 6 in the picture11-2) freely.

Connect the frame of the longer and shorter leg modules

Loosen the screw connected with the main body \(^8\) of the frame, both the shorter \(^6\) and longer leg\(^7\) 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)

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**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 shift⁸ to 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)
Connect the Supporting shift

Loosen T-type handle, the supporting shift components 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, transaction shoes can be circled to any angle along the supporting shift, so that the shoes can be fixed to any angle by locking the knob. (Shown as 6-4 in the picture)

Jiggle adjust the Supporting shift

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

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:  \(+10°C \sim +40°C\)
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:  \(-40°C \sim +55°C\)
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

<table>
<thead>
<tr>
<th>Checking Item</th>
<th>Maintenance Time</th>
<th>Effective Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning and Sterilization</td>
<td>Each Operation</td>
<td>Clean external surface</td>
</tr>
<tr>
<td>During installation</td>
<td></td>
<td>Check whether accessories are in good condition or not, and replace or service them when necessary</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Everyday</td>
<td>Check whether accessories are in good condition or not, and replace or service them when necessary</td>
</tr>
<tr>
<td>Jiggle adjust the screw pole</td>
<td>Always</td>
<td>Check the screw pole and supporting shelf and replace the oil, in order to keep it glide easily, shake it up and down.</td>
</tr>
</tbody>
</table>
10. List of host machine, optional accessories, and consumables

<table>
<thead>
<tr>
<th>Item</th>
<th>Name</th>
<th>Unit</th>
<th>Quantity</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main part</td>
<td>Spinal traction frame</td>
<td>set</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trolley for the frame</td>
<td>set</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Accessory</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumer goods</td>
<td>Stride mattress</td>
<td>set</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Documents</td>
<td>User manual</td>
<td>pc</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product qualified certificate</td>
<td>pc</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Guarantee card</td>
<td>pc</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Packing list</td>
<td>pc</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Installation report</td>
<td>pc</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**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:

<table>
<thead>
<tr>
<th>Name of the Accessories</th>
<th>Deleterious Substance or Element</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plumbium (Pb)</td>
</tr>
<tr>
<td></td>
<td>Hyçrargrum (Hg)</td>
</tr>
<tr>
<td></td>
<td>Cadmium (Cd)</td>
</tr>
<tr>
<td></td>
<td>Chrome (Cr6+)</td>
</tr>
<tr>
<td></td>
<td>Polybromide Biphenyl (PBB)</td>
</tr>
<tr>
<td></td>
<td>Polybromide diphenyl ether (PBDE)</td>
</tr>
<tr>
<td>Metal sheet part</td>
<td>○</td>
</tr>
<tr>
<td>Aluminum part</td>
<td>○</td>
</tr>
<tr>
<td>Copper part</td>
<td>○</td>
</tr>
<tr>
<td>Stainless steel part</td>
<td>○</td>
</tr>
<tr>
<td>Steel part</td>
<td>○</td>
</tr>
<tr>
<td>Wheel</td>
<td>○</td>
</tr>
<tr>
<td>Bolt</td>
<td>○</td>
</tr>
<tr>
<td>Gasket</td>
<td>○</td>
</tr>
<tr>
<td>Nut</td>
<td>○</td>
</tr>
<tr>
<td>Handwheel</td>
<td>○</td>
</tr>
<tr>
<td>Plastic Bag</td>
<td>○</td>
</tr>
<tr>
<td>Cable ties</td>
<td>○</td>
</tr>
<tr>
<td>Paper packaging box</td>
<td>○</td>
</tr>
<tr>
<td>PE expanded Pad</td>
<td>○</td>
</tr>
<tr>
<td>User Manual</td>
<td>○</td>
</tr>
<tr>
<td>Product qualified</td>
<td>○</td>
</tr>
<tr>
<td>Certificate</td>
<td>○</td>
</tr>
<tr>
<td>Guarantee Card</td>
<td>○</td>
</tr>
<tr>
<td>Packing list</td>
<td>○</td>
</tr>
<tr>
<td>Installation Report</td>
<td>○</td>
</tr>
</tbody>
</table>

○: means the deleterious substance or element's content of this accessory's material are below the SJ/T11363—2006 standard.
×: means the deleterious substance or element's content of this accessory's material are over the SJ/T11363—2006 standard.