

APPENDIX E: USER MANUAL**WARNING**

Read and understand the information in this product manual before using this product. If the procedures and instructions in this product manual are not followed, serious injury or death could occur.

- A qualified professional must assess the appropriateness and safety of all equipment for each user.
- This product is intended for use by clients of unreliable judgment. Adult supervision is required at all times.
- To prevent falls and injuries:
 - Do not use this product on rough and uneven terrain or near stairways.
 - Ensure the appropriate use of straps and supports at all times. Straps and supports are provided for the safety of the user and must be carefully adjusted for comfort and security.
 - Tighten all adjustment knobs before use and immediately after making any adjustments.
 - Position accessories so that the client's weight is centered between the wheels.
 - Make sure breaks are applied whenever the gait trainer is not in use or the client is not ready to use.
- Do not use this product for clients outside the height and weight limits specified in this manual.
- To prevent structural failure, which may result in serious injury or death:
 - Inspect this product and accessories regularly for loose or missing screws, metal fatigue, cracks, broken welds, missing attachments, general instability or other signs of excessive wear.
 - Immediately remove this product from use when any condition develops that might make operation unsafe.
 - Do not use product components for any purpose other than their intended use.
- Adequately supervise use of the device to prevent:
 - Excessive movement and speed

- Sudden stops from hitting a curb, cracks, or debris
- Use adequate accessories to ensure that user's feet remain within boundaries of the lower frame.
- Use special care and supervision when using the product under conditions which might affect stability, including:
 - Uneven ground
 - Ramps, slopes, or hills
 - Clients who experience strong involuntary movements or seizures

RECOMMENDED USE

This product is classified as a Class 1: Low risk medical device. It is designed to help people with physical disabilities walk. Through the use of this device, patients will gradually learn how to walk independently. It is recommended that patients do not use this device alone. Proper supervision is recommended at all times. The use of this device is recommended for patients with a hip height from 30" to 40" and with a max weight capacity of 200lbs.

PRODUCT AND ACCESSORY DIMENSIONS

Dimensions	Max	Min	Adjustability
Height	56.11"	38.59"	17.52"
Width	31.38"	24.5"	6.88"
Thorax Support	53.18"	32.22"	20.96"
Arms Support	45.58"	32.58	13"
Pelvic Support	38.69"	29.15"	9.54"

BASIC COMPONENTS

Frame

Installation:

To install frame, insert top frame telescopic tubing into the lower frame telescopic tube. Once inserted, set to desired height and lock in with pins. Figure 57 demonstrates how to connect the two halves of the frame and lock with pins.

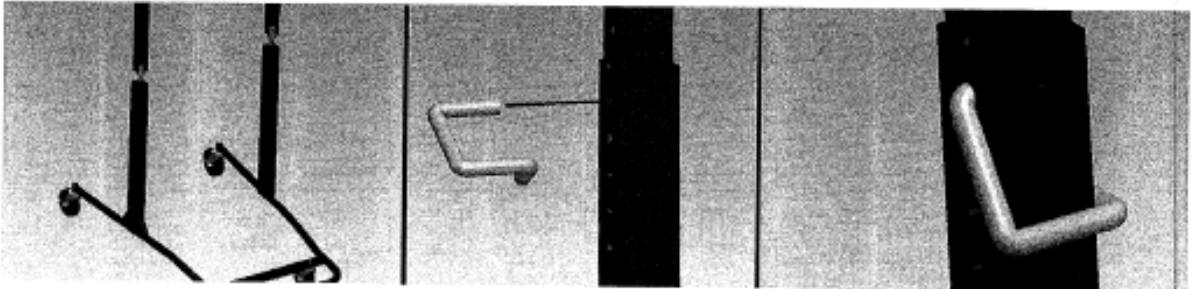


Figure 57. Telescopic tubes with locking pin

Adjustments:

To adjust height of the frame, remove pin and move upper frame upwards or downwards depending on desired height. Once in the desired height, lock with both pins. It is recommended to ask for assistance when adjusting the height of the frame. Also, ensure locking the breaks when adjusting the frame height. Figure 58 shows how to adjust and lock the frame.

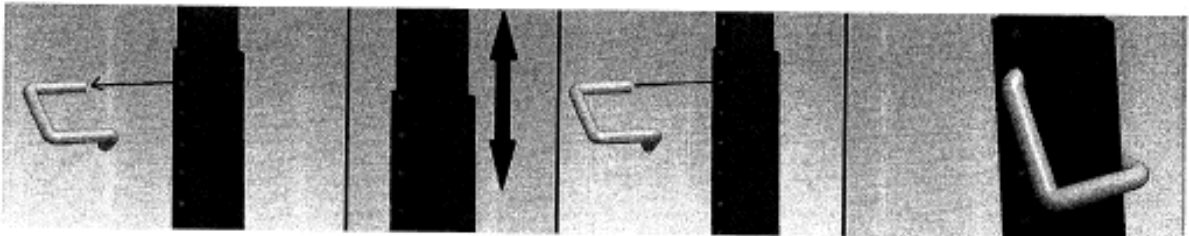


Figure 58. Adjusting frame

Wheels:

The four wheels on the device are free to move in any direction. These can all be completely locked by using the breaks. Make sure to lock the breaks whenever the device is not in use. Figure 59 shows how to lock the breaks.

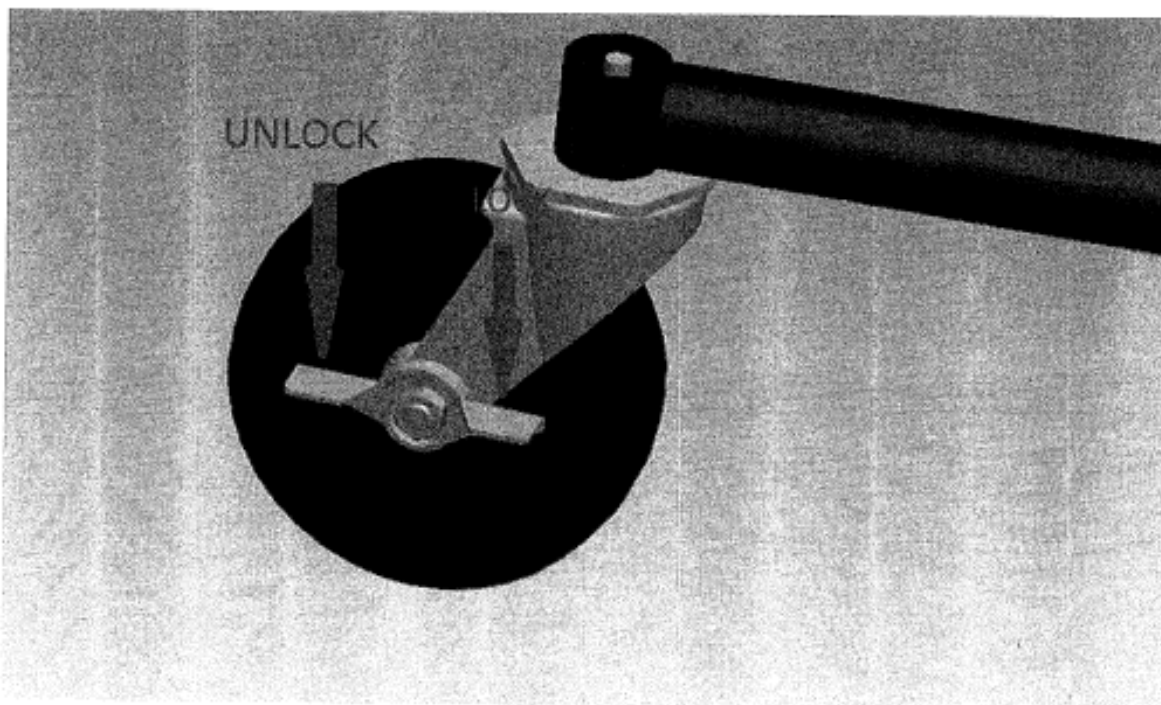


Figure 59. Wheel lock

ACCESORIES

All accessories can be attached in any part of the frame. Accessories may also be easily unattached if patient does not require such support. These are also adjustable in order to support each individual comfortably.

Thorax Support:

Attachment and Adjustment

To attach the thorax support to the frame, place each of the thorax support's sides individually on the frame. These are attached by inserting the tube into the clamp and tightening the clamp. Figure 60 shows how to properly set up the clamps onto the frame. Figure 61 demonstrates how the clamps can be set up facing the inside of the frame or the outside. This allows for a larger range of adjustability if needed. To adjust the thorax support, move the tube within the clamp in order to set the thorax support at the desired height and width. The thorax support's upper limit should be a little over the chest area of the patient in order to help keep the patient stable and straight. Figure 62 shows the final assembly.

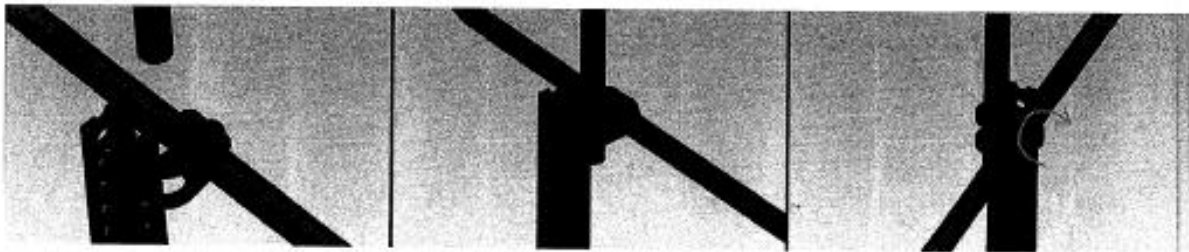


Figure 60. Thorax support assembly

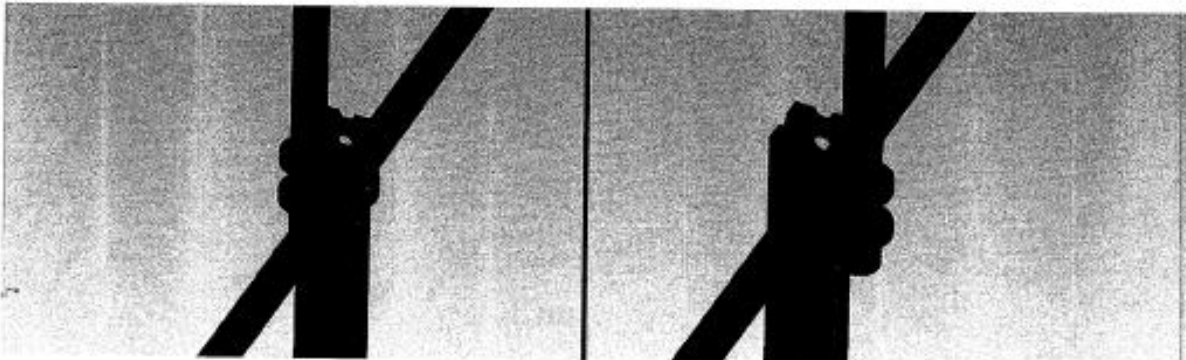


Figure 61. Facing inside (left), facing outside (right)

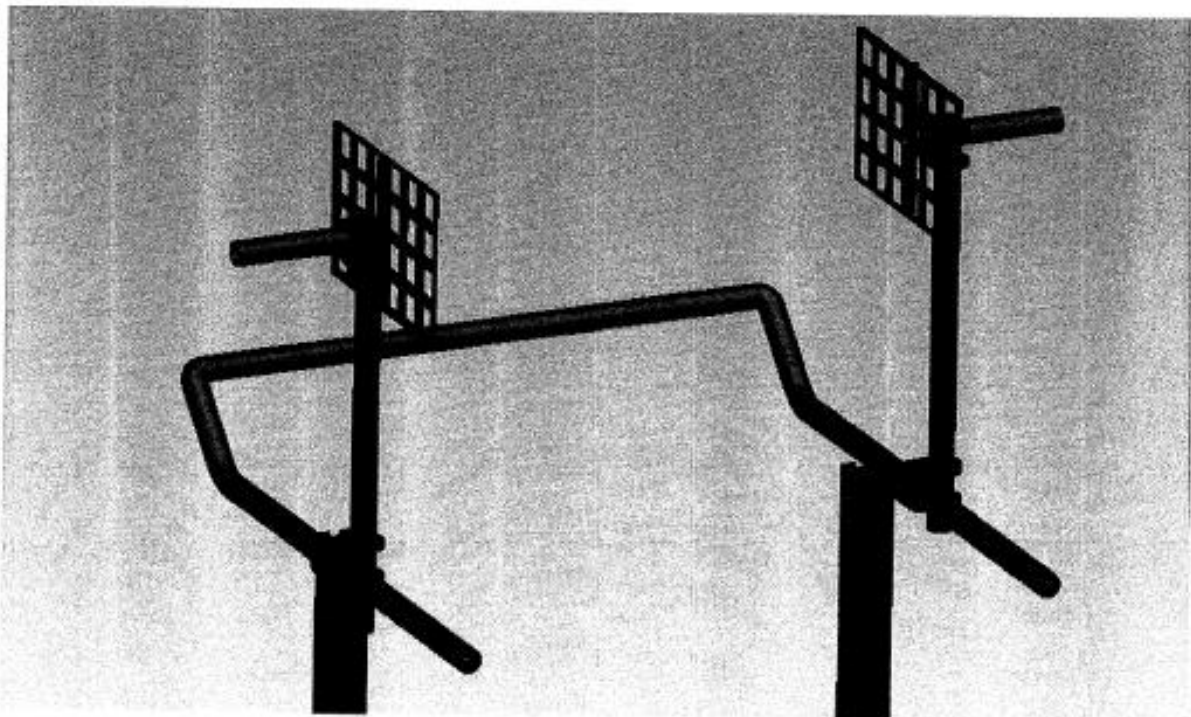


Figure 62. Final thorax support assembly

Using the Thorax Support

Once the thorax support has been attached to the frame and adjusted, the patient will stand in between the support system and raise their arms in order for the assistant to set up the thorax support. Once the patient is in between the thorax support, adjust the cushioning and close the velcro belt. The velcro should be firmly adjusted, so that the patient is not loose inside the thorax support. The padding can be removed from the thorax support in order to wash.

Arms Support:

Attachment and Adjustment

To attach the arms support to the frame, place each of the arms support's sides individually on the frame. These are attached by inserting the tube into the clamp and tightening the clamp. Figure 63 shows how to properly set up the clamps onto the frame. Setup the clamps facing the outside of the frame. If there is too much space between the arm support and the patient, the clamps can be set to face the inside. This allows for a larger range of adjustability it needed. To adjust the arms support around the frame, move the tube within the clamp in order to set the arms support at the desired position in the upper frame. To adjust the arms support to the desired arm length of the patient, the arm support bar can be extended forward or backward. Adjust to a position where the arm of the patient is at about 135 degrees.

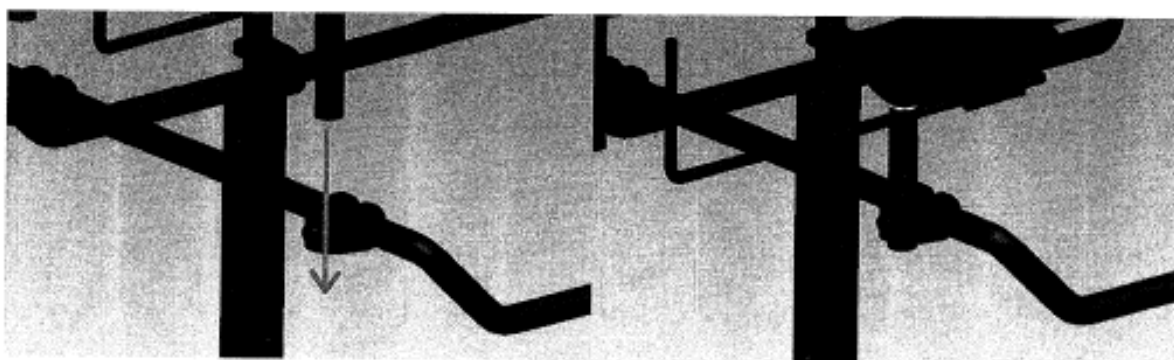


Figure 63. Arm support assembly

Using the Arms Support

The patient will place their forearm on the padding holding on to the end of the support with their hands. If a bigger grip is needed, a foam add on grip is provided. The

patient's elbow should be at the end of the padding to ensure proper support. The padding of the arm support can be removed in order to wash.

Pelvic Support:**Attachment, Adjustment and Use**

To attach the pelvic support to the gait trainer, open all of the pelvic support's buckles. The thinner part of the pelvic support should be facing the forward part of the gait trainer. Take the front end of the pelvic support and buckle into the front part of the upper frame. The back part of the pelvic support should be buckled in their respective sides of the gait trainer. To adjust, pull the adjustable buckle. It is important to adjust the pelvic support according to the patient's needs. If the patient does not require much help to walk, do not tighten the support because this will cause the patient to rely on the support instead of using their leg strength. The pelvic support is completely washable.

OPERATION

Once the accessories are all attached and adjusted in the appropriate position, the user can either use the gait trainer in anterior or posterior positioning.

Anterior Positioning

1. Lock the brakes to immobilize the gait trainer.
2. Approximate the adjustments of:
 - Thorax Support
 - Arms Support
 - Pelvic Support
 - Frame height
3. Unfasten thorax and arm support
4. Place the user in the gait trainer
5. Fasten the thorax support
6. Pull the pelvic support through the legs and:
 - Connect the buckles to the frame
7. Secure the forearms with arm support straps.
8. Release breaks and hold on to assistant grip to control first steps of user.

Some users tend to lean forward on the gait trainer. To adjust to users who lean forward, lock breaks and then:

1. Use the thorax support's ability to tilt.
 - Position the top of the thorax support away from the armpits to avoid pressure and discomfort.
2. Adjust pelvic support:
3. Adjust the width, height and angle of arm support.
4. Use straps to adjust pelvic support angle and to position the user's pelvis in the desired forward leaning angle in relation to the thorax support.
5. Release the caster brakes

Posterior Positioning

Some patients have a greater ability to walk than others. These patients can use the gait trainer in the posterior position, or open end of the gait trainer to the front. Usually these patients require less use of accessories. The following instructions for each accessory only apply to those users that decide to use each of the accessories. It is possible for advanced patients to not use any accessories.

1. Lock breaks to immobilize gait trainer.
2. The arm supports should be attached in the sides of the frame, facing the open end of the frame. These should be angled towards the user.
3. Thorax and pelvic supports are used as in anterior position.
4. Release caster brakes.

MAINTENANCE

At all times, users must ensure that the product remains in a safe and useable condition, including regular maintenance and inspections as specified in this product manual. To prevent structural failure, which may result in serious injury or death:

- Inspect this product and accessories regularly for loose or missing screws, metal fatigue, cracks, broken welds, missing attachments, general instability or other signs of excessive wear.

- Immediately remove this product from use when any condition develops that might make operation unsafe.
- Do not use product components for any purpose other than their intended use.
- Replace or repair components or products that are damaged or appear to be unstable.
- Do not use petroleum-based or solvent-based lubricants on casters, but lubricate when necessary with silicone spray or graphite.

CLEANING

As needed, clean with disinfectant wipes or a solution of up to 10% bleach. Do not use excessive amounts of water. After outdoor use, wash wheels with water. Avoid mud and sand. Wash padding used in thorax and arm supports. Do not iron. Wash the pelvic support with water. Engage the buckle closures before washing.

MATERIALS

- AISI 1020 Steel- Frame, nails and bolts.
- Nylon- pelvic support mesh and belts.
- Plastic and PVC- Clamps, Arm and Thorax supports.
- Memory Foam- Arm and Thorax supports.