


eik GAIT TRAINER**USER MANUAL**

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1 GENERAL INFORMATION

The **EIK Gait Trainer** is a medical device consisting of a balance system with a leg control mechanism. The device is designed to develop balance, walking and mobility, and is used in medical rehabilitation and therapy for people with disabilities.

The **EIK Gait Trainer** is designed for individuals experiencing difficulties with static or dynamic balance and mobility after an injury, operation, stroke or other health problem. Its design makes it possible to safely begin rehabilitation in an early phase of treatment; it is easily adaptable to the patient's physical abilities, and makes it easier to move independently.

The **EIK Gait Trainer** was developed in collaboration with scientists in the fields of physical education, sports, medicine and textile science, and has been improved taking user observations into account.

The **EIK Gait Trainer** complies with the requirements of Directive 93/42/EEC, MN 4:2009 and EN 12182:2012.








The instructions presented in this manual must be followed when using the EIK Gait Trainer.

The manufacturer is not liable for accidents and/or damage to the device that occur while using the device without following the instructions.

The manufacturer reserves the right to make technical changes which improve device performance and usability.

2 DESCRIPTION OF SYMBOLS

Safety requirements are provided in this manual. Warning symbols indicate potential hazards and/or risk factors. The warning symbols as well as their colour and design are provided below.

	General warning symbol. Meaning: <ul style="list-style-type: none"> - There is a specific risk or precautions related to risk. - Attention: refer to the user manual!
	MANUFACTURER symbol.
	YEAR OF PRODUCTION symbol.
	REFER TO THE USER MANUAL symbol.
	CE mark. This equipment complies with Medical Device Directive 93/42/EEC requirements.

3 TECHNICAL DATA

Dimensions (length x width x height)	1.23 m x 0.8 m x 0.9 m
Max. pneumatic pressure	10 atm
Weight of the device	48 kg
Patient weight limit	140 kg
Safety class	I
Warranty for metal construction	24 months

4 PURPOSE OF USE

The device is designed for individuals experiencing static or dynamic balance difficulties, impaired or incorrect gait, or signs of cerebral palsy or spinal, muscular or bone damage. The modular design allows for the device to be modified from a walker to an effective means of rehabilitation and/or exercise for individuals who have lost movement skills.

This device may only be used under the supervision of a medical professional or other qualified person. It is recommended that this device be used in accordance with a wellness or treatment programme put together by medical professionals.

5 FUNCTIONS OF THE EIK GAIT TRAINER

- Lifts the patient to a vertical position and develops balance skills.
- Allows the patient to remain in the device in a safe and comfortable manner for a long period of time.
- Facilitates movement when the patient does not have the physical ability to perform traditional rehabilitation exercises independently.
- Allows the patient's leg load to be easily adjusted depending on the patient's physical abilities and well-being.
- Allows for full trunk and hip rotation.
- The leg control mechanism helps carry out walking motions when the patient cannot do so deliberately.

6 PROHIBITIONS AND RESTRICTIONS ON USE OF THE DEVICE

- The device is designed for individuals who weigh no more than **140 kg**.
- The device can only be used after reading the user manual.
- Never leave children or mentally handicapped persons near the device unattended.
- It is prohibited to use the device under the influence of strong medication, alcohol or drugs.
- It is prohibited to use the device for anything other than its immediate and direct purpose.
- When using the device together with a treadmill or other equipment, you must comply not only with the instructions for the EIK Gait Trainer, but with the instructions set forth in the user manual for the treadmill and/or other equipment as well.

It is prohibited to use the device in the event of:

- bone instability (after fractures, unstable posture, severe osteoporosis symptoms);
- signs of an open wound in the areas of the body that come into contact with the device or its body support;
- bleeding;
- fever;

- blood circulation instability;
- signs of heart disorders;
- attention disorder;
- inability to understand commands;
- aggressive behaviour on the part of the patient;
- the need for continuous infusion therapy;
- breathing problems that require the constant use of a ventilator;
- the need to observe bed rest or stable immobilization;
- an unstable clinical condition of the patient;
- hip, knee and/or ankle arthrosis.

7 DESIGN OF THE GAIT TRAINER



Figure 1. Design of the EIK Gait Trainer

- 1 Frame
- 2 Lifting column control panel
- 3 Pneumatic cylinder
- 4 Suspension device
- 5 Arm support
- 6 Leg control mechanism

7.1 FRAME

The frame of the gait trainer is made from strong, powder-coated steel tubes.

The design of the frame makes it easy to assemble and disassemble the device. Disassembled, the frame can be transported by passenger car.

If necessary, the arm support (5) and the leg control mechanism (6) can be attached to the frame.

7.2 WHEELS

Four caster wheels with brakes are attached to the frame. The wheel can be locked in three positions:



Neutral



Directional



Braked

Figure 2. Caster wheel positions

- Neutral – the lever is horizontal and the wheel can move in any direction.
- Directional - the lever is tilted 45 degrees down and the wheel can move parallel to the frame.
- Braked - the lever is turned completely down and the wheel is braked.

7.3 LIFTING COLUMN

The lifting column consists of a foot pump (*Figure 3*), two pneumatic cylinders (*Figure 4*) and the lifting column control panel.

The patient is lifted to a vertical position by pumping the pneumatic cylinders with the foot pump.



Figure 3. Foot pump



Figure 4. Pneumatic cylinder

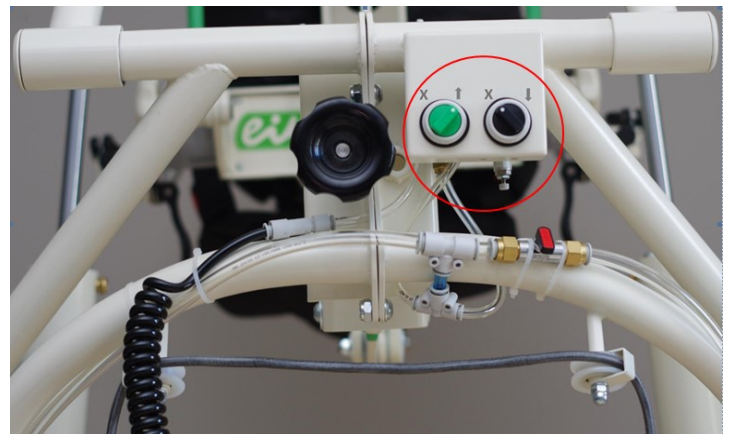


Figure 5. Lifting column control panel

The patient is lifted and lowered with two knobs that are mounted on the control panel (*Figure 5*).

The green knob is used for lifting and has two positions: **X** and **↑**. **X** is the operating position, when the pneumatic system is closed. When switched to **↑**, the pneumatic system is connected to the foot pump. In this position, the foot pump is used to raise the patient to the desired height and/or reduce leg load.

The black knob is used for lowering and has two positions: **X** and **↓**. **X** is the operating position, when the pneumatic system is closed. When switched to **↓**, the pneumatic system is opened and the patient is lowered to the desired height and/or leg load is increased.

7.4 SIDE-LEANING CORRECTION

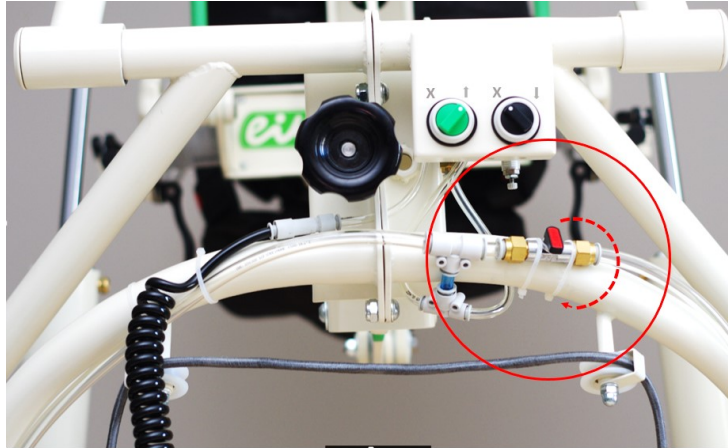


Figure 6. Suspension device tilt-angle knob

The trainer is designed to help the patient correct improper leaning to the side. If the patient leans to the side, the suspension device can be manually tilted in the other direction until the patient is in the correct position. The tilt angle is then locked by turning the knob perpendicular to the axis of the tubes (Figure 6). When the knob is in line with the axis of the tubes, leaning to the side is not restricted.

7.5 ADJUSTMENT OF ANTERIOR AND POSTERIOR TILT



Figure 7. Anterior/posterior tilt knob

The angle of anterior/posterior tilt is adjusted by a knob (Figure 7) which tilts the patient:

- forward by turning it clockwise;
- backward by turning it counter-clockwise.

7.6 SUSPENSION DEVICE

The suspension device (*Figure 8*) consists of the suspension frame (*Figure 9*) and the body support (*Figure 10*).

The suspension frame is designed to hold the body support in the place marked (*Figure 9*).



The bolts must be tightened firmly when fastening the body support to the suspension frame (*Figure 9*).



Figure 8. Suspension device



Figure 9. Suspension frame



Figure 10. Body support

The patient can be kept from swaying to the side by turning the knobs marked (*Figure 11*).



Figure 11. Sway stabilizer knobs



The sway stabilizer knobs must be completely turned off when lifting or lowering the patient (*Figure 11*)

The body support is made up of a trunk support, padded saddle (Figure 12) and thigh straps (Figure 14). The trunk support is fastened with buckles and attached to the suspension device by the hip belt clips, which are inserted and bolted into the suspension device holders (Figure 13).



Figure 12. Components of the body support



Figure 13. Fixation of the body support in the suspension device

The thigh straps are placed on the patient's leg in such a way that the padded saddle, when attached to the hip belts, covers the connective part of the thigh straps. The saddle pad (Figure 15) can be used to decrease the degree to which the lower part of the abdomen leans against the front part of the saddle.



Figure 14. Thigh straps



Figure 15. Saddle pad

7.7 ARM SUPPORT

The arm support (*Figure 16*) is inserted into the frame brackets (*Figure 17*) and locked with a lever (*Figure 18*). The height of the arm support can be adjusted as needed.



Figure 16. Arm support



Figure 17. Frame brackets

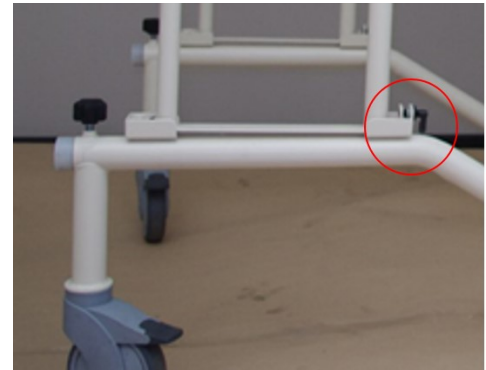


Figure 18. Arm support lock lever

If necessary, the stationary arm support can be replaced by arm bars which are inserted into the suspension frame and locked with the levers marked (*Figure 19*).



Figure 19. Arm bars



The arm support and arm bars must be locked with the corresponding levers (*Figures 18 and 19*).

7.8 LEG CONTROL MECHANISM

The leg control mechanism (*Figure 20*) is used for gait training by attaching it to the front part of the gait trainer's frame. The leg control mechanism has two vertical supports with a built-in pulley system equipped with elastic ropes. The elastic ropes are used to connect the knee straps (*Figure 21*) and overshoes (*Figure 22*) of the person using the trainer. As the person takes a step, the leg is raised at the knee and stretched forward by the foot, thus helping the patient perform a coordinated walking

motion. In order to straighten the legs, the leg extension straps on the back of the trainer (Figure 23) are affixed.

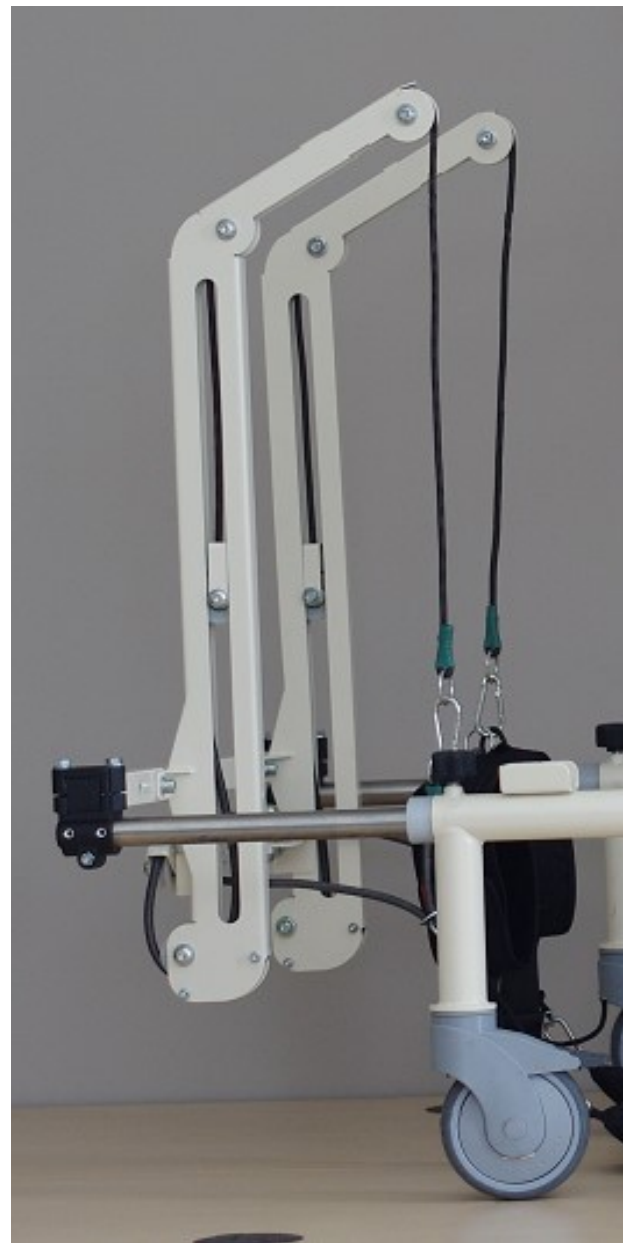


Figure 20. Leg control mechanism



Figure 21. Knee straps



Figure 22. Overshoes

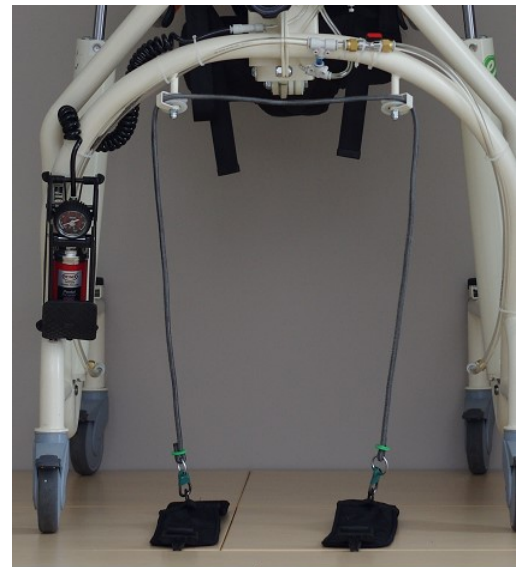


Figure 23. Leg extension straps

8 TRANSPORTATION AND STORAGE

The EIK Gait Trainer can be transported either assembled or disassembled.

- Assembled, the equipment can be transported with special transport, stably and securely fastened inside the vehicle.
- Disassembled, the equipment parts can be transported by stably and securely fastening them inside the vehicle.



If the gait trainer is transported disassembled, the part of the frame that weighs 15 kg or more should be carried by two people!

Before using the gait trainer, check the device and its accessories to make sure they were not damaged en route!

Assembly of the gait trainer should only be done by the manufacturer or trained representative!

9 PREPARING FOR USE

9.1 PREPARING THE GAIT TRAINER FOR USE

1. Place the gait trainer on an even surface.
2. Position the trainer in a place that provides enough space for the medical professional and that the patient can access by wheelchair.
3. Remove the arm support frame and the leg control mechanism.
4. Turn the knobs (green and black) on the lifting column control panel to **X**.
5. Turn the sway stabilizer knobs all the way off (*Figure 11*).
7. Lower the suspension device to waist-level of the person in the wheelchair.



Before putting the patient in the trainer, the knobs (green and black) on the lifting column control panel must be turned to **X** and the sway stabilizer knobs must be turned all the way off!

9.2 PREPARING THE BODY SUPPORT FOR USE

1. Inspect the body support and make sure that:
 - the material and belts are not ripped or otherwise damaged;
 - the buckles lock and unlock properly.
2. Adjust the trunk support to suit the patient.

9.3 PREPARING THE PATIENT



Make sure that the patient's weight complies with the technical data for the EIK Gait Trainer.

1. Put the padded saddle on a chair and sit the patient on top of it.
2. Once the patient is sitting on the chair, put on the thigh straps and tighten them so that they hug the thighs.
3. While the patient is in the chair, put on the trunk support, fastening the buckles from the bottom up. Tighten the belts that go through the buckles so that the support hugs the trunk.
4. Attach the padded saddle that covers the connective part of the thigh straps to the trunk support by first fastening the back buckles and only then – the front.

NB: If the belts cause pressure to the lower part of the abdomen, we recommend that you first place a saddle pad at the lower part of the abdomen and only then attach the saddle of the body support to the trunk support.

5. Check to make sure that the body support buckles are fastened properly.

10 USING THE GAIT TRAINER

10.1 SECURING THE PATIENT IN THE GAIT TRAINER

6. Bring the gait trainer over to the patient's chair from behind.
7. Lock the caster wheels in braked position.
8. Insert the patient's trunk support into the suspension frame and screw it in place.




Make sure that the trunk support is safely inserted into the frame brackets and screwed in place (*Figure 13*).

9. Attach the arm support frame.
10. If necessary, attach the chest belt, which helps the patient balance.

10.2 LIFTING THE PATIENT IN THE GAIT TRAINER



The sway stabilizer knobs must be turned all the way off when lifting the patient (*Figure 11*).

- When beginning to lift the patient, turn the green knob on the lifting column control panel to  (*Figure 4*).
- Then use the foot pump to lift the patient to the required height (*Figure 3*).
- Lock the adjusted leg load by turning the green knob to **X** (*Figure 4*).
- Use the sway stabilizer knobs to adjust the extent to which the patient can lean to the side (*Figure 11*).
- If necessary, use the knob to adjust the angle of anterior/posterior tilt (*Figure 7*).
- If necessary, use the knob to adjust the extent to which the suspension device can sway to the side (*Figure 6*).
- Fasten the front part of the leg control mechanism (*Figure 20*) to the frame and put on the knee straps (*Figure 21*) and the overshoes (*Figure 22*).
- If necessary, affix the leg extension straps on the back of the trainer (*Figure 23*).
- Make sure that the elastic cords on the leg control mechanism are taut.
- If you want to lock the direction of the gait trainer, switch the caster levers to the directional position (*Figure 2*).

10.3 USING THE GAIT TRAINER



The treating physician should determine the exercises performed with the gait trainer.

Do not leave a person in the device without supervision.

It is recommended that while using the gait trainer, the patient keep his or her hands on the arm support (*Figure 16*) or the arm bars (*Figure 19*).

Make sure that the areas shown in *Figure 24* are not touched while using the gait trainer.



Figure 24. Do not touch the areas marked!

10.4 DISMOUNTING THE PATIENT



The sway stabilizer knobs must be turned all the way off when lowering the patient (Figure 11).

- Remove the overshoes, knee and leg extension straps, and the front part of the leg control mechanism.
- Place a chair so that the patient can sit down comfortably when the body support is lowered.
- Slowly turn the black knob on the lifting column control panel to ↓ (Figure 5) so that the patient is lowered onto the chair in a slow and safe manner.
- Remove the arm support.
- Unbuckle the body support saddle and trunk support.
- Remove the thigh straps.
- Move the patient to a wheelchair or bed.

11 CLEANING AND DISINFECTING

- The medical device must be cleaned and disinfected using the methods and means specified in Lithuanian Hygiene Standard HN 47-1:2008.
- The medical device may be cleaned and disinfected by hand.
- When cleaning and disinfecting the medical device by hand, there must be a warm and cold water supply, manual cleaning agent and disinfection solution dispensers, and special brushes (for medical instruments) or other supplies (cloths, rags) to clean them.

- Intermediate-level disinfectant agents (which kill bacteria and mycobacterium tuberculosis as well as viruses and fungi) must be used; they must have anticorrosive additives and be suitable for medical device materials. The disinfectant agents should be produced according to the recommendations of the disinfectant agent manufacturer, i.e. requirements regarding dosing, the temperature of the solutions and the duration of disinfection (soaking).

We recommend disinfecting the medical device with **Incidin Liquid Spray**, which contains the following active ingredients per 100 g: 35 g of 2-propanol, 25 g of 1-propanol, and 0.375 g of amphoteric surfactants (20%). To disinfect a surface, spray **Incidin Liquid Spray** at a distance of 30 cm and then leave it to dry or wipe off with a clean cloth.

12 DISPOSAL

Once the operating period is over, the parts of the EIK Gait Trainer should be disposed of according to legal regulations.

13 SAFETY REQUIREMENTS

The user manual is an integral part of the equipment and should be kept near the equipment in a visible place.

You must read the user manual before using the gait trainer.

Only use the device on a flat and level surface.

Make sure that the patient's weight complies with the technical data for the EIK Gait Trainer.

Always consult with your treating physician and/or medical professional on the safe and effective use of the gait trainer!

While using the gait trainer, the patient should keep his or her hands on the arm support or the arm bars.

While using the gait trainer, the person assisting the patient should keep his or her hands on the frame and/or handles.

When the gait trainer is not being used, make sure that it is not within reach of children or people with special needs.

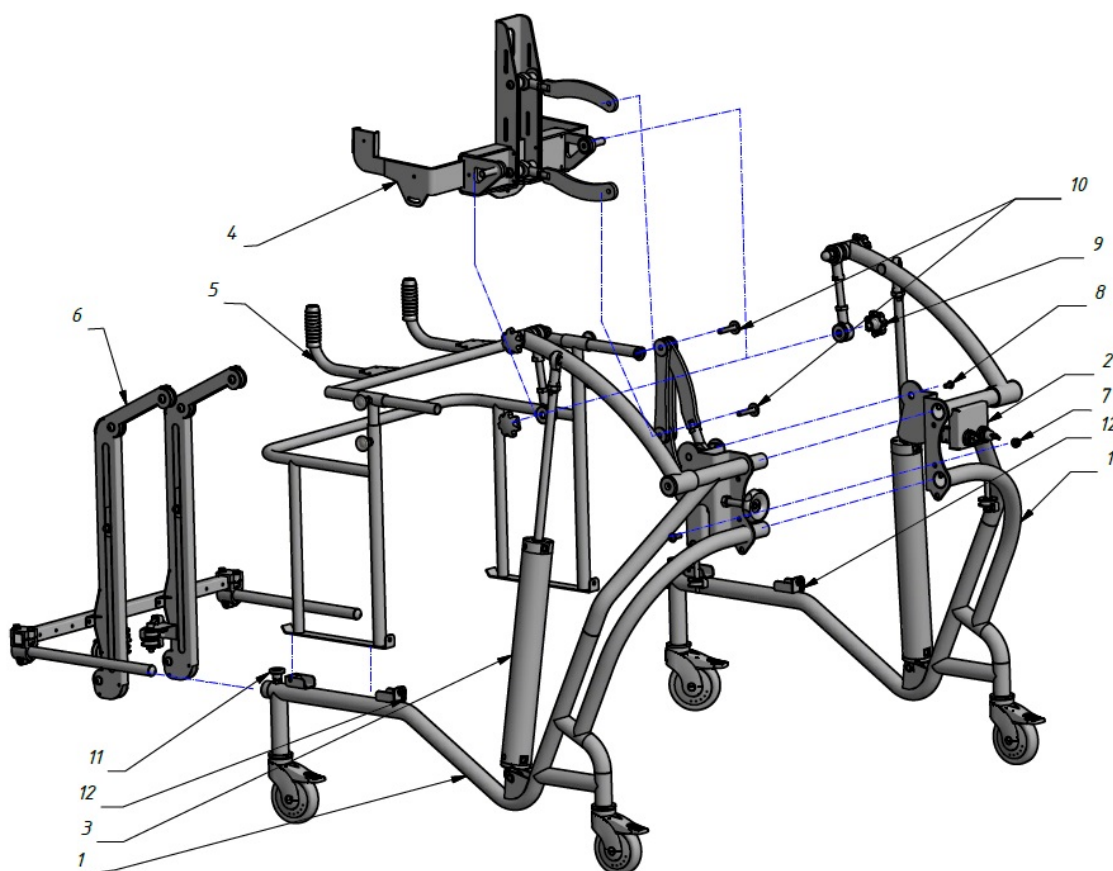
Make sure that the areas shown in Figure 24 are not touched while using the gait trainer.

Keep the gait trainer away from heat or fire.

The parts of the gait trainer's frame that weigh 15 kg or more should be carried by two people.



14 ASSEMBLY INSTRUCTIONS



1	Frame	7	Bolts
2	Lifting column control panel	8	
3	Pneumatic cylinder	9	
4	Suspension device	10	
5	Arm support	11	
6	Leg control mechanism	12	

ASSEMBLY

1. The frame (1) is assembled with bolts (7) and (8).
2. The suspension device (4) is connected to the frame (1) with bolts (9) and (10).
3. The arm support (5) is connected to the frame from both sides (1) with bolts (12).
4. The leg control mechanism (6) is inserted into the frame (1) and fastened with bolts (11).

15 MANUFACTURER WARRANTY

- The manufacturer guarantees that the EIK Gait Trainer is in line with technical data if the user follows the conditions for storage, transportation and operation.
- The warranty service period for metal parts is 24 months.
- For technical service of the equipment required during the warranty period, the client should call a UAB Vildoma specialist during the period specified.

Warranty service is not provided if the equipment was damaged due to non-compliance with the requirements set forth in the user manual.



GAIT TRAINER

CLASS I MEDICAL DEVICE

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