For The Long Run®

WOODWAY®

Electro-mechanic Rehabilitation Medical Device for Walk Simulation LokoHelp® LH 300M, LH 400M

Translation of the Original German Operating Manual

Version: 02/2023-v1.4en

CE 1023

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1 Introduction

1.1 Operating Instruction Information

This manual provides information on the safe operation of the LokoHelp® gait trainer.

One condition for safe operation is compliance with all safety and operating instructions.

⚠ CAUTION

Improper operation can cause accidents!

Not using the gait trainer as intended according to the manufacturer's instructions can cause accidents and equipment damage.

- ► These operating instructions must be completely read and understood before using the treadmill.
- ► Keep these instructions close at hand for all users of the device!

Read and observe the operating instructions!

Read these instructions carefully before beginning any work on the treadmill! It is a part of the device and must be kept accessible at all times and in the immediate vicinity of the treadmill for operating and maintenance personnel.

Observe the instructions!

WOODWAY accepts no liability for accidents, equipment damage and consequences of equipment failure that are a result of failure to follow the operating instructions. In addition, the local accident prevention regulations and general safety conditions for intended use of the treadmill apply.

WOODWAY reserves the right to make technical changes in the context of improving the performance properties and further development without prior notice. Illustrations are for basic understanding and may differ from the actual design of the device.

Accessories from other suppliers have further safety regulations and guidelines. **WOODWAY** accepts no liability for accidents, equipment damage and personal injury caused by the use of accessories from other suppliers.

1.2 Model Designation

The LokoHelp® gait trainer may only be used in combination with a weight support system with a patient harness and a **WOODWAY** PPS series medical treadmill.

The following table shows the possible LokoHelp® gait trainer combinations with a weight relief system with patient harness and a **WOODWAY** PPS series medical treadmill.

Model Designations		
LokoHelp® Gait Trainer	**Weight Relief System with Patient Harness**	**WOODWAY PPS Series Treadmills**
LH 300M	LokoStation 55	PPS 55 Plus
	LokoStation 55 ELVETA	PPS 55 Plus
	LokoStation 70	PPS 70 Plus
	LokoStation 70 ELVETA	PPS 70 Plus
LH 400M	LokoStation 55	PPS 55 Plus
	LokoStation 55 ELVETA	PPS 55 Plus
	LokoStation 70	PPS 70 Plus
	LokoStation 70 ELVETA	PPS 70 Plus

1.3 Limitation of Liability

All information and instructions in this manual have been compiled in accordance with applicable standards and regulations, the current state of technology and our knowledge and experience.

WOODWAY accepts no responsibility for damages resulting from:

- Disregarding the operating instructions,
- Improper use,
- Use by non-authorized persons,
- Use of replacement parts which were not approved by **WOODWAY**,
- Unauthorized modifications to the device or accessories.

The **WOODWAY** general terms and conditions and delivery conditions apply, as well as the legal regulations valid at the time of contract conclusion.

1.4 Copyright

The release of the operating instructions to third parties without the written permission of **WOODWAY** is prohibited.

NOTE

All contents, text, drawings, images or other illustrations are copyright protected and are subject to intellectual property rights.
Any misuse is punishable by law!

Duplication in any manner and form - including excerpts - as well as use and/or communication of the content are not permitted without written permission from **WOODWAY**.

1.5 Replacement Parts

WOODWAY recommends the use original replacement parts. Original replacement parts have particular qualities and ensure reliable and safe operation;

- Developed for specific use with the device,
- Manufactured in high quality and excellence,
- Ensured the legal warranty period
  (excluding wear parts) or other reached agreements.

NOTE

The use of NON-original replacement parts may change the characteristics of the device and interfere with the safe use!
WOODWAY does not accept liability for damages resulting from this.

Disposal! Wear parts are considered hazardous waste!

After being replaced, wear parts must be disposed of according to country-specific waste laws.

For further information on disposal, see section 10 page 67.

1.6 Customer Service

For service questions contact the following:

Woodway GmbH
Steinackerstrasse 20
79576 Weil am Rhein
Germany

Contact: Tel. +49 (0) 7621 - 940 999 - 14
Fax. +49 (0) 7621 - 940 999 - 40
Email: service@woodway.de

For faster processing of your request please have the following data and information available:

- Information on the nameplate (specifically model/serial number)
- An accurate description of the circumstances
- What action has already been taken

Servicing: When servicing on site, the gait trainer and connected devices must be disconnected from the power supply by a qualified electrician, so that the device cannot switch on accidentally.

The address of your responsible service center can be obtained from **WOODWAY**. After repair or re-commissioning, the actions listed under "Installation" and "Commissioning" are to be performed as during commissioning.

1.7 EU Declaration of Conformity

EU Declaration of Conformity
EU - Konformitätserklärung

Parabel s.r.o.
SOLUTIONS FOR YOUR VISIONS

Manufacturer: Parabel s.r.o.
Hersteller: Padělky 192
763 17 Lukov, Czech Republic
Single Registration Number: CZ-MF-000002892

Product Description: Electro-mechanic rehabilitation medical device for walk simulation
Produktbezeichnung: Elektro-mechanisches Rehabilitations-Medizinprodukt für Schrittsimulation

Product: LokoHelp
Produkt:

Product Types: LH 400M, LH 300M
Typenbezeichnung:

Classification: IIa (per Annex IX Rule 9 directive 93/42/EWG)
Klassifizierung: IIa (gemäß Anhang IX Regel 9 der Richtlinie 93/42/EWG)

Basic UDI-DI: 859420759LH2D
Basis UDI-DI:

GMDN Code: 58873

We declare under our sole responsibility that the product specified above, in the delivered version, conforms to the requirements of directive 93/42/EEC and directive 2007/47/EC in the revised version. Annex I and II of directive 93/42/EEC apply (exclusion of the segment/article 4 from the annex II 93/42/EEC). The associated documentation will be kept at the manufacturer's premises.
Hiermit erklären wir in alleiniger Verantwortung, dass das oben genannte Produkt in der gelieferten Ausführung den Anforderungen der Richtlinie 93/42/EWG und der in Richtlinie 2007/47/EG revidierter Fassung entspricht. Zur Anwendung kommen Anhang I + II der Richtlinie 93/42/EWG (ausschließlich das Segment/Absatz 4 in dem Anhang II 93/42/EWG). Die dazugehörige Dokumentation wird in den Räumlichkeiten des Herstellers aufbewahrt.

The CE **1023** symbol will be applied to the products.
Das CE **1023** *Zeichen wird auf den Produkten angebracht.*

Applicable Standards:	ČSN EN 62304:2007+ A1:2016	EN ISO 14971:2019
Anwendbare Normen:	ČSN EN 60601-1-2 ed.3:2016	EN 60601-1 ed.2:2007
	ČSN EN ISO 13485:2016 ČSN	

The conformity is confirmed by **EC-Certificate no. 20 0080 QS/NB,** which was created by Notified Body no. 1023, Institute for Testing and Certification (ITC Zlín), valid until 27.05.2024.
Die Konformität wurde mit dem ***EG-Zertifikat Nr. 20 0080 QS/NB,*** *welches von der Benannte Stelle Nr. 1023, Institute for Testing and Certification (ITC Zlín) erstellt wurde, bestätigt. Gültig bis 27.05.2024.*

This declaration of conformity is valid for all the models listed above, which were produced on or after 01.09. 2021 by Parabel s.r.o. The validity of this declaration of conformity ends with the publication of a new declaration of conformity if this becomes necessary due to technical modifications or changes in the standards.
Die Konformitätserklärung gilt für alle oben gelisteten Modelle die ab dem 09.03.2020 durch Parabel s.r.o. hergestellt worden sind. Die Gültigkeit dieser Konformitätserklärung endet mit der Veröffentlichung einer Konformitätserklärung neueren Datums, falls dies durch technische Änderungen oder durch gesetzliche Änderungen der Normen und Standards erfolgen muss.

CZ 763 17, Lukov, 01.09.2021

Michael Krüsselin
Managing Director
Geschäftsführer

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Fig. 1 EU Declaration of Conformity, LokoHelp®

2 Safety

2.1 General

The LokoHelp® gait trainer has been reliably designed, manufactured and tested according to the latest state of technology and is in safe and technically perfect condition. Nevertheless, the device can cause risk to persons and property if it is operated improperly.

For this reason the operating instructions should be read completely and safety instructions must be observed.

Warnings attached directly to the device must be observed and kept in a legible condition.

Inappropriate use will result in the rejection of any liability or guarantee by **WOODWAY**.

2.2 Description of Warning Notices

Warning notices indicate potential hazards or safety risks. They are indicated in this manual by a color-coded signal word panel (symbol with the appropriate signal word).

All warning notices have the same design and the same standardized content design.

Sample of a Warning Notice:

⚠ SIGNAL WORD
Warning Text, Type and Source of Danger Description of the consequences of ignoring the danger. ► Measures, instructions and forbidden actions for avoiding hazards.

Classification:

NOTE	NOTE or WARNING (not a danger symbol) No risk of injury, pertinent information and warning against material damage.
⚠ CAUTION	CAUTION (with danger symbol) Slight possibility of injury.
⚠ WARNING	WARNING (with danger symbol) In a dangerous situation a serious accident is possible with the possibility of injury or death.
⚠ DANGER	DANGER (with danger symbol) In the event of an accident immediate danger of death or serious injury.

2.3 Markings on Device

Safety relevant information is identified on the device using stickers with the following symbols:

2.3.1 Stretching Warning

	**Warning:** Danger of injury caused by stretching the patient during lifting operations. When lowering the treadmill during operation, during a power failure and when switching the treadmill off, always extend the length of the rope in body weight support system.

2.3.2 Warning, Remove Bracket (crossbar)

	**Warning:** Remove this bracket when operating without LokoHelp®.

2.3.3 Warning, Danger Due to Electric Voltage

	**Warning:** This symbol warns the user of dangerous voltage inside the device.

2.3.4 Warning, Danger Due to Chain Drive

	**Warning:** Danger of hand injury when device is running. Do not reach into the opening in the chain area.

2.3.5 Protective Ground Wire Connection

	**Protective conductor connection** The LokoHelp® is an electrical device of protection class I.

2.3.6 Electrical Class

	**Type B applied part** Equipment providing a particular degree of protection against electric shock, particularly regarding allowable leakage currents and reliability of the protective earth connection.

2.3.7 Brace Lock

	UNLOCKED/LOCKED symbol on braces.

2.3.8 IRC Lever

	**Lever mechanism to protect the IRC sensor** Top position: “Training” Down position: “Transport”

2.3.9 Warning, Do Not Use Water to Extinguish Fire

	**Warning:** Strictly forbidden to use water or foam to extinguish fire.

2.3.10 Warning, Not to Be Moved

	**Warning:** Strictly forbidden to move the switchboard.

2.3.11 Warning, Risk of equipment damage!

	Turn off the device when connecting and disconnecting the mains plug.

2.3.12 Read Instruction Manual

	Carefully read the instruction manual before use of this device. It is part of the product and must be available at any time within the reach. For use of the device and its service, instruction manual must be stored in accessible place.

2.4 Personnel Qualification and Responsibility

⚠ WARNING

Danger Due to Improper Use!

Improper handling of the device can lead to serious personal injury and property damage.

- ► The device may only be operated by persons who have received instructions from qualified service personnel.
- ► **WOODWAY** recommends the use of a training record (see appendix) for proof of instructions.

Representative: *The representative is the person or company that is responsible for setting up, use and maintenance of the device.*

The representative of the device is responsible for the regular maintenance and testing as required by law. They are also obligated to provide adequate training/instruction to the operating personnel. **WOODWAY** recommends the training be carried out by trained and authorized **WOODWAY** dealer or service partner.

Operator: *Operators of treadmills for medical applications are persons who use the device and have the "power of control" over the device. This can be e.g. therapists, sports physicians or any other supervisor. The operator of a medical device is any person who - regardless of their qualifications - independently uses a medical product in the commercial sector.*

The operator is personally responsible for the safety of the user (e.g. patient, test subject). Due to the high degree of responsibility these persons have a special obligation to provide information on all aspects of safety for the device and its intended use.

For further information on the national regulations for the use of this device, contact your authorized **WOODWAY** dealer.

2.5 Intended Use

⚠ WARNING

Danger from Improper Use!

Any improper use and/or other use of the device can lead to dangerous situations with significant personal injury and/or property damage.

- ► Only use LokoHelp® for its intended use.
- ► Read and strictly adhere to all information in the operating instructions.

LokoHelp® gait trainer is a rehabilitation device which uses an auxiliary motor, lower leg braces and an electric control unit for gait simulation. It serves the rehabilitation of patients with impairment or loss of walking ability after illness or accident and is designed for use with a treadmill as an accessory for the body weight relief system.

Using the LokoHelp® gait trainer the legs of the weight-relieved patients are guided in a physiological walking pattern on the treadmill.

The operating instructions are an integral part of the device and are to be available to all users at all times the exact observance of the instructions is a prerequisite for the intended use of the device.

Special User Groups!

Special attention must apply to these user groups. Compared to treadmill exercise with healthy people the risk of injury is considerably higher with these users. Strict adherence to and compliance with all safety instructions and operating information is the highest priority.

The patient may only use the gait trainer with a treadmill and the body weight support system under the supervision of a physician and/or therapist! The training program must be medically prescribed and monitored.

⚠ WARNING

Risk of Injury Through Increased Risk of Falling!

Because of their illness or their physical/mental condition certain people have of an increased risk of falling.

- ► We strongly recommend the use of a fall protection system, support belt or body weight support system (partial or complete).
- ► **WOODWAY** is not liable for personal injury and/or property damage, which could have been prevented through the use of a fall protection system, support belt or body weight support system.

ATTENTION

Claims to **WOODWAY** of any kind due to damage from improper use are excluded.

The representative alone is liable for all damages resulting from improper use!

2.6 Authorized Modes of Operation

2.6.1 Medical Application

- Patients with paraplegia
  (below C6 with ability to support the upper extremities)
- Patients with paralysis of the lower extremities through paralysis of the peripheral nervous system
- Patients with hemiparesis after stroke or traumatic brain injury
- Patients with paraparesis of the lower extremities after head trauma, infections and brain surgery
- Patients with cerebral palsy and spina bifida
- Patients with central nervous system disorders (multiple sclerosis, Parkinson's disease, Guillain-Barré syndrome and other neurological disorders)
- Patients with neuromuscular disorders
- Patients after hip and knee replacement
- Geriatric and orthopedic patients

In case of doubt the attending physician decides if LokoHelp® treatment is appropriate.

2.6.2 Therapeutic Application

- for improving:
  - gait speed, gait endurance
  - gait symmetry and stride length
  - joint mobility, muscle length
  - cardiovascular functions
- for spasm reduction
- for scientific research in the field of locomotion

2.6.3 Safety Information Regarding Patient Health

- The use of the device is only possible on the basis of a doctor's recommendation. The gait trainer may only be used under supervision by a trained professional. Ensure that a standby system is available, such as a mobile phone or an emergency phone system.
- Do not use the device with patients with suspected skin or other infectious disease.
- Patients with inserted probes or catheters or who are taking medication that affects the awareness use the device at their own risk. The decision whether to use the gait trainer must be made by a doctor.

2.7 Unauthorized Modes of Operation

The LokoHelp® may only be used for the aforementioned purpose. Any additional uses may result in serious personal injury and/or property damage.

The following restrictions and prohibitions must be strictly adhered to:

- The LokoHelp® may not be operated without prior instruction by qualified personnel.
- Children may not be left near the device unattended.
- The use of the LokoHelp® under the influence of alcohol or drugs and/or narcotics is prohibited.
- When being used in conjunction with a treadmill or body weight support system, the Safety Instructions in this manual must be observed.
- The device may not be installed or used in an environment where flammable anesthetics with oxygen or nitrous oxide or other flammable mixtures are present.

2.8 Contraindications

The application of a body weight support system during training is not useful in every case. LokoHelp® with a body weight support must not be used when:

- body weight exceeds 150 kg (adults LH 400 M)
- body weight exceeds 60 kg (children LH 300 M)
- osseous instability (non-consolidated fractures, unstable spine, severe osteoporosis)
- open lesions in the torso area
- circulatory instability
- cardial contraindications
- excessive attention deficit disorder
- patients with aggressive behavior
- patients with (permanent) infusions
- patients on a breathing apparatus
- in general, patients with prescribed bed rest or immobilization, for example osteomyelitis or other inflammatory/infectious diseases
- hip, knee and ankle arthrodesis
- infectious diseases
- all diseases in an acute state
- condition after deep thrombosis within three months after the disease for less than three months
- cancer during and after treatment with clinically detectable signs of disease activity in malignant (tumors in advanced stages)
- uncompensated epilepsy
- active attacks or phases of psychosis and aggressive behavior with psychotic mental disorders and other psychiatric diagnoses
- decubitus ulcers in the leg or pelvic region
- hernia (is a relative contraindication and must be considered when putting on the belts)
- poor cognitive function
- insufficient cardio-pulmonary capacity
- high spinal marrow lesions (higher than C6)

The attending physician and competent therapist are responsible for assessing the therapy capability and thus for making individual decisions for each patient, determining possible risks and side effects of therapy compared to their benefits.

Medicine as a scientific discipline is subject to constant change with new insights and progress. It is the responsibility of the physician to constantly adapt their knowledge and to acquire new knowledge in the progress of therapy using the latest scientific literature. The technically-related contraindications are absolute and therefore do not fall under the decision making authority of the physician or therapist.

2.9 Special Safety Instructions for Use

The LokoHelp® gait trainer is designed for a slat-belt treadmill with body weight support system and may only be used with this system, unless other arrangements have been expressly made with **WOODWAY**. It is also not permitted to use the gait trainer without the supplied braces.

- The gait trainer may only be operated by persons over the age of 18 who have read and understood this manual before the first use.
- The operating person (therapist) is responsible for the safety of operation on the gait trainer. **WOODWAY** accepts no responsibility for injury to persons or damage to the gait trainer, which was caused by the fact that it was not used and operated in accordance with the operating and maintenance instructions and valid safety requirements.
- Never use the device differently than described in the operating instructions. In the event of misuse or use for another purpose, any liability by **WOODWAY** and warranty claims are void.
- Never use a damaged or defective gait trainer!
- Each user of the device shall be instructed on potential hazards and shall follow the safety instructions.
- The gait trainer is not a toy! Children should never be left unattended in the vicinity of the device. The duty of supervision is the parents/guardian's responsibility. Liability of any type for non-compliance is the parents/guardian's responsibility!
- If the gait trainer is not being used, the main switch is to be switched off.
- Repairs may only be carried out by **WOODWAY** or by a person authorized by **WOODWAY**. If you do not have the necessary qualifications, please contact a service center.
- The treadmill must be plugged into the intended power supply in the LokoHelp® gait trainer.

ATTENTION
The separate operating instructions from the treadmill and the body weight support system with patient straps being used must be considered when using the LokoHelp®!

2.10 Electromagnetic Compatibility (EMC)

It is expressly noted that ELECTRICAL MEDICAL EQUIPMENT is subject to special precautions regarding electromagnetic compatibility (EMC). They must be installed and operated accordingly. It should be noted that portable and mobile RF communications equipment and other devices with interference beyond the permissible values can affect the electronics of the LokoHelp® and/or treadmill.

The manufacturer guarantees that the unit complies with the EMC requirements only when using the original accessories. The use of other accessories may lead to increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

The device must not be placed directly next to or stacked with other equipment. If such an arrangement is nevertheless required together with other devices, the device must be observed to check its intended operation in this arrangement.

Additional EMC information can be found in section 11, page 69 of this user manual.

3 Technical Data

3.1 Name Plate

There are two name plates located on the LokoHelp® gait trainer. The first and larger one is fixed to the control unit. The second and smaller one is stuck between the rear wheels. The nameplate contains the device's main technical details.

Keep Handy for Questions!

For service questions, the technical information on the nameplate must be kept handy.

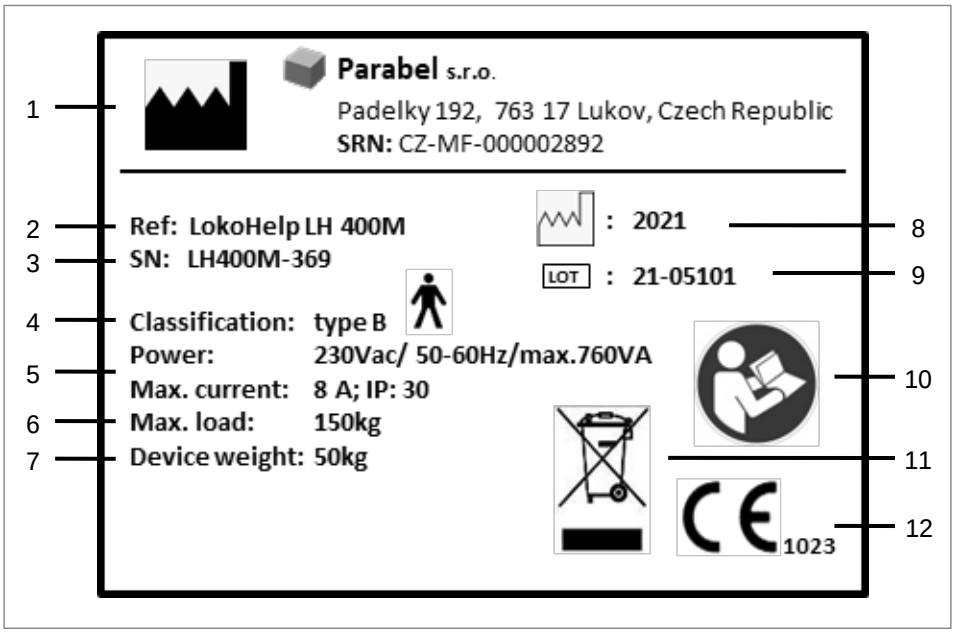


Fig. 2 Name Plate on the Electric Control Unit

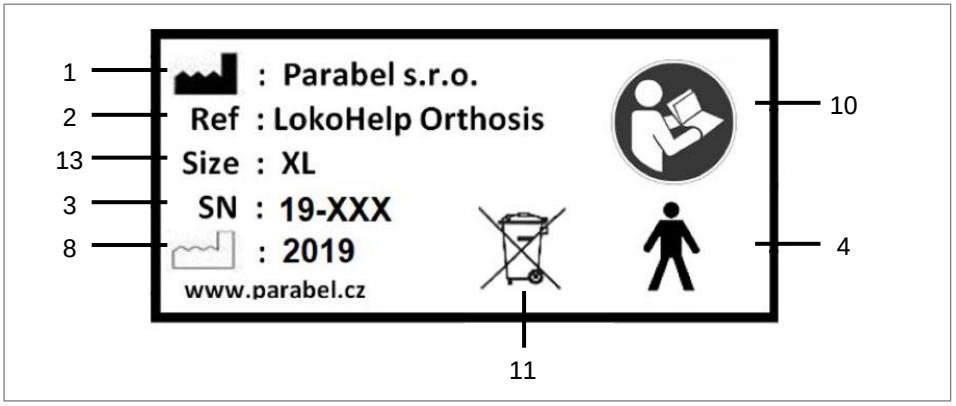


Fig. 3 Name Plate on the Lower Leg Braces

1. Manufacturer
2. Product description
3. Serial number
4. Type B applied part (i.a. DIN EN 60601-1)
5. Electric information
6. LokoHelp® maximal load capacity
7. LokoHelp® device weight (without control unit)
8. Year built
9. LOT number
10. Note to read and observe the operating instructions!

11. Disposal note
12. Device CE symbol
13. Orthosis size

Information and identification plates with the electric information are located on the control unit.

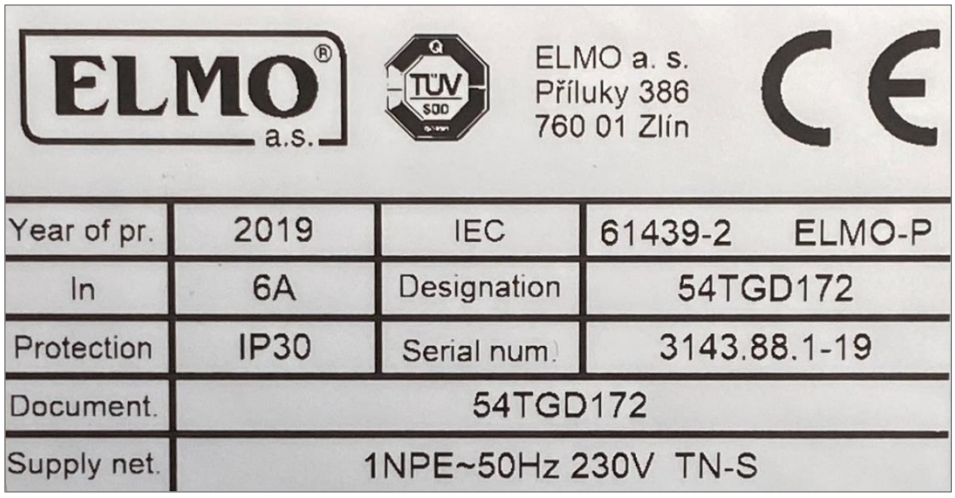


Fig. 4 Electric Info Plates

3.2 Safety Elements

The gait trainer is equipped with protective elements which ensure safety during operation. The elements are arranged on the panel of the control unit.

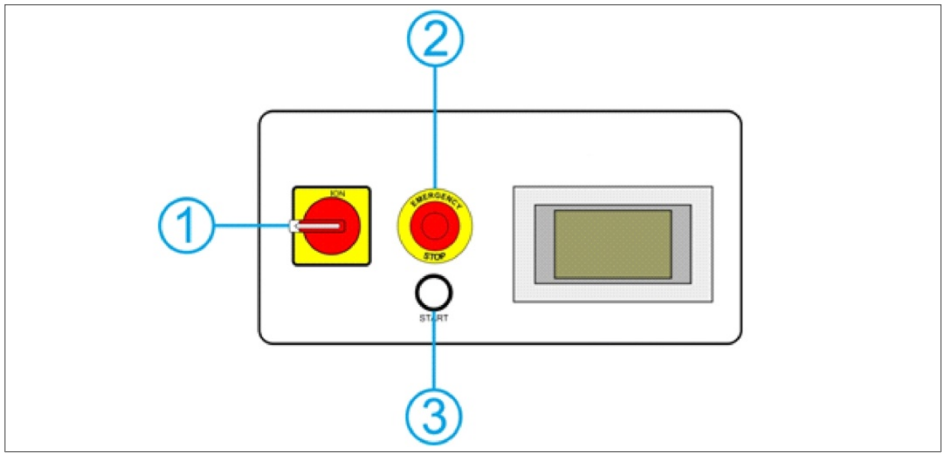


Fig. 5 Safety Elements

1. Main switch "ON": In addition to turning the gait trainer on, it also serves to immediately interrupt electrical power supply to the control unit.
2. "EMERGENCY STOP" switch: When this button is pressed, the system stops immediately. This stops the movement of the treadmill and the gait trainer.
3. "START" button: After the "START" button is pressed, the treadmill must be started within 999 seconds (approx. 16 min.). If the treadmill does not start during this time, the system switches off for safety reasons.

3.3 Technical Specifications

Parameters	LH 400M	LH 300M
version	Adult	Children
Material	Aluminum, steel, stainless steel, plastic, fiber glass	
Drive & controls	Servo drive; senses treadmill speed with an incremental sensor	
Patient weight	max. 150 kg	max. 60 kg
Power supply	~230V / 50-60Hz	
Power consumption	max. 8A (2 kW)	
Electrical circuit	max. 760VA	
Power lead	3x1.5mm2 (H05 VV-F)	
Ground	1x2.5mm2	
Classification	Class I, Type B	
Ingress protection	IP 30	
Safety equipment	LokoHelp® is controlled electronically according to the patient weight; Emergency stop	
Mode of operation	Periodic intermittent operation	
Control	Touchscreen	
Speed	0 - 2 km/h	
Dimensions (gait trainer) L x W x H	105x35x38 cm	100x35x38 cm
Dimensions (control unit) L x W x H	40x25x60 cm	
Weight (gait trainer, without support and braces)*1	50 kg	48 kg
Certified*2	CE 1023	

*1 *The total device weight can increase with additional equipment options.*

*2 *CE marking approved by N.B. 1023 is applied only on device LokoHelp®, no other components. CE marking is not present on USA/CAN Version.*

4 Transportation and Storage

4.1 Safety Notices for Transportation

Check the LokoHelp® gait trainer for transport damage on receipt. Check the corresponding delivery note including the scope of delivery with accessories.

WOODWAY is not liable for transport damages and missing parts if this information was not recorded in writing on the delivery note upon delivery of the unit. Damage or defects must be reported to the carrier and to the responsible **WOODWAY** dealer immediately.

⚠ WARNING

Risk of Injury by Machine Falling Over!

Improper transportation of the device may lead to it falling over and causing injury or equipment damage.

- ► Only transport in compliance with the safety regulations.
- ► Carry the device with at least two persons.
- ► Ensure stable center of gravity and steadiness during transportation.

WOODWAY Service: If necessary, transport or relocation can be carried out by authorized **WOODWAY** service partners.

For further information please contact **WOODWAY** customer service.

Fig. 6 Transport position

Prior to transport or handling, the lever mechanism to protect the IRC sensor, located at the front of the LokoHelp®, must always be set in the “TRANSPORT” position.

NOTE

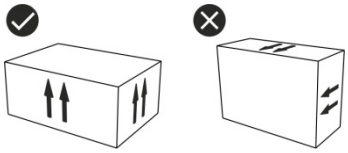
Risk of damaging the device!

Not setting the lever mechanism at the “TRANSPORT” position prior to transport or handling, might result in damage to the IRC sensor.

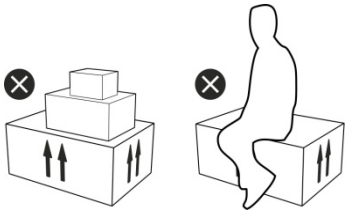
4.2 Storage

The device may only be stored in closed, dry rooms. It is absolutely necessary to prevent contact with moisture (rain, fog, etc.)

The following environmental conditions are prescribed for transportation and storage:

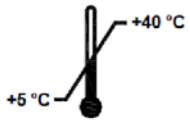


The box the gait trainer is shipped in may only be stored with the top side up (see arrow markings on the box). Do not tip the box on its side or top.

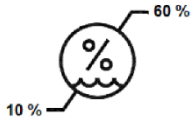


Do not store other objects on the box.

Do not sit or stand on the box.



The temperature of the storage space must remain between +5° C and +40°C.



The humidity in the store room may not exceed 60%.

The gait trainer must not be subjected to direct sunlight or other weather conditions.

5 Product Description

5.1 Function Description

The LokoHelp® gait trainer is used in the rehabilitation for gait therapy for patients with impairment or loss of walking ability after illness or accident. When using LokoHelp®, manual assistance by a therapist is not necessary during therapy. The gait trainer must be used in conjunction with a body weight support system.

Body Weight Support System

LokoStation is a body weight support system which allows a patient to hang in a vertical position above the surface of a moving belt using a special support strap, and to relieve them from their body weight.

Before the patient is put onto the treadmill, the gait trainer is positioned on the stationary treadmill, secured and connected to the control unit. Then the patient is placed on the treadmill, secured in body weight support system and if necessary relieved of weight. Once the treadmill is started, the patient's legs, which are attached to the LokoHelp® by means of the previously applied leg braces, are guided on the treadmill in a physiological gait pattern which is synchronous to the treadmill speed.

Gait Simulation

The gait simulation is caused by the movement of the fastener unit for the leg braces (brace seat), which simulates the cycle of the natural gait. The patient's legs are fixed to the seat using the leg braces. The mechanical movement of the gait trainer is synchronized with the movement of the treadmill and enables independent movement of the lower limbs in a physiological gait pattern. Even if the patient's lower extremities are completely motionless, the LokoHelp® gait trainer puts the legs in motion.

The patient is put onto the treadmill and secured in the LokoStation body weight support system. The braces are inserted into the fastening seat on the side of LokoHelp® and are secured against slipping out. After the gait trainer is switched on, the treadmill is set in motion using the control element. The LokoHelp® starts synchronously and guides the patient's legs.

Fixed Step Length

The individual step length on ground level is fundamentally related to body size. However, when relearning to walk, the step length is usually shortened. Clinical experience shows that the 40 cm step length of the LH400 is suitable for patients with a height of approx. 1.50 m - 1.90 m. The step length of 30 cm of the LH300 is suitable for patients with a height of approx. 1.10 m - 1.50 m. If necessary, the LH400 can also be used with children from approx. 1.35 m, as it allows for better stretching of the hip joint muscles (adductors, flexors).

NOTE

Patient Notice - Body Weight Support!

Patients who cannot stand on their own or who feel insecure using the dynamic body weight support should use the static body weight support.

A requirement for using dynamic body weight support is that the patient can stand on their own with no outside help.

Fig. 7 Application

⚠ WARNING

Danger of Injury!

The use of the LokoHelp® gait trainer without suspending the patient for the purpose of body weight support or protection against falling is prohibited.

- ► Use body weight support!
- ► Use fall protection!
- ► Only use with the patient in the upright standing position!

Although LokoHelp® has its own drive it cannot be operated without treadmill movement. The signal for starting the servo-drive is transmitted from the treadmill via the incremental sensor. The front wheel of the LokoHelp® which rolls over the walking surface transfers the speed of the servo drive via chain to the LokoHelp® moving elements (brace seat).

After it has been disconnected from the control unit and the mounting bracket, the LokoHelp® can be easily rolled off of the treadmill on the front wheels.

After the completion of training the braces are released from the seat. Then the patient's full body weight is lowered in an upright standing position or on a wheel chair. Then they are released from the body weight support system and rolled or led down the ramp.

NOTE

Patient Notice - Gait Simulator!

The control unit is an integral component of the LokoHelp® and cannot be used for other purposes. The LokoHelp® cannot function without the control unit.

5.2 Mounting System - Brackets

The brackets make it possible to mount the LokoHelp® gait trainer on the treadmill.

Fig. 8 Mounting system on treadmill

5.3 Lower Leg Braces

The braces consist of a hard horizontal sole and three vertical leg braces. The fixing section consists of a fabric that spans the lower leg and the back of the foot. The fixing system consists of straps.

The removable inner lining of the braces is made of a cushioning material and should not cause pressure points when put on.

NOTE

Patient Notice – Lower Leg Braces!

The lower leg braces are integral components of the LokoHelp® and cannot be used for other purposes.

5.3.1 Lower Leg Brace Size Table

Brace Markings	MINI	CHILDREN	S	M	L	XL
Shoe length (outer size in mm)	to 175	to 250	to 250	to 275	to 310	to 360

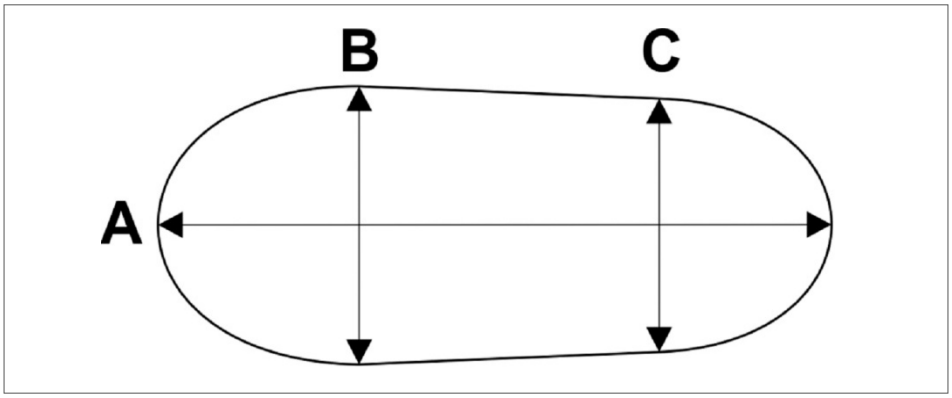


Fig. 9 Brace Inner dimensions

Size (mm)	A	B	C
MINI	175	77	74
CHILDREN	240	89	88
S	248	102	92
M	265	102	92
L	300	113	104
XL	350	127	114

6 Commissioning

6.1 General

Commissioning is the initial intended use of the device. Ensure that the conditions applicable to basic safety and health requirements are met. Read these operating instructions completely before commissioning.

Before commissioning the device, operating and functional safety is to be tested. This includes correct positioning and installation, electrical connection, and operator training.

6.2 Mounting the Brackets

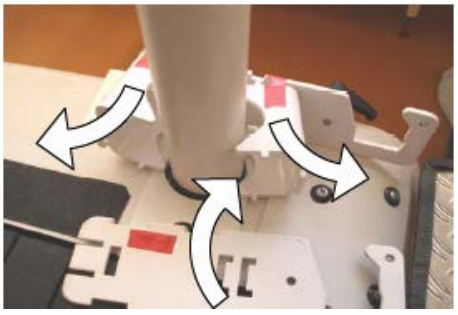
The brackets make it possible to mount the LokoHelp® gait trainer on the **WOODWAY** PPS Series medical treadmill.

The mount consists of the following parts:

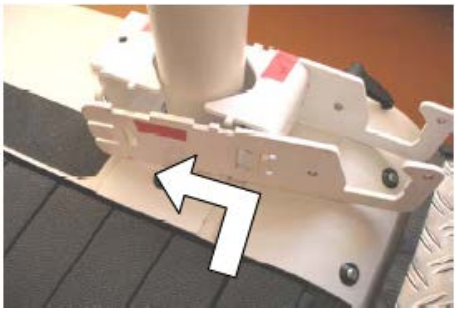
- Tube brackets (2 pcs. – to remain mounted)
- Mounting crossbar (1 pc. – removable)
- Fixing bracket with crank for securing the LokoHelp® to the mounting crossbar

The tube brackets are clamped to the front vertical bars of the treadmill railing. The tube brackets are universally suitable for the diameter of vertical railing tubes 50 to 76.5 mm.

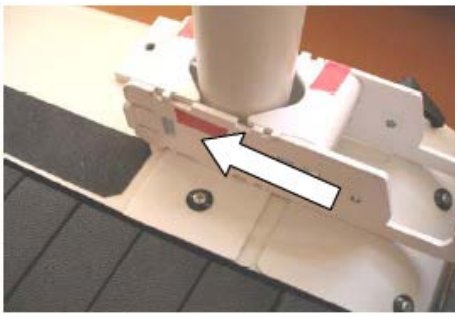
Mount as Follows:



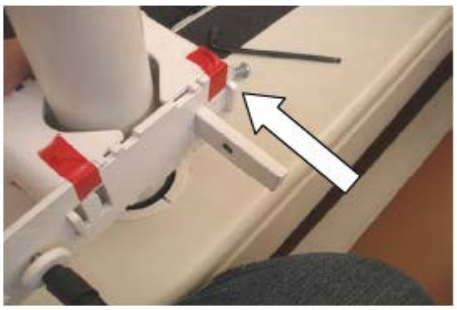
1. Install the tube brackets on the left and right as shown in the figure. The bottom edge of the tube brackets must be about 75-77 mm above the tread-mill.



2. Mount the tube brackets by rotating those 20° and inserting them into the slots. Fix by rotating back 20° horizontally.

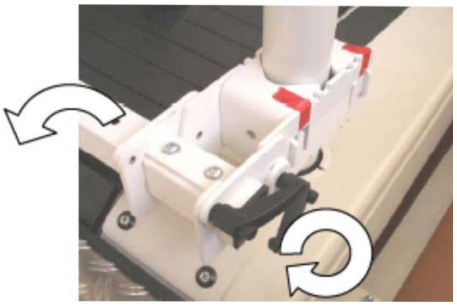


3. Fix the bracket using the levers on each side of the brackets.



4. Position the center bracket so that the handle faces toward the treadmill.

5. Place the LokoHelp® as far forward as possible in the bracket teeth. Ensure the teeth fit properly!
Fix the LokoHelp® by turning the hand screws clockwise until the LokoHelp® bracket stop is reached. Secure the position using the safety lock on the flange of the crank screw.



6. Loosen the tube bracket screws slightly and mount the cross bar level with the treadmill (important: use a water level!). The LokoHelp® front wheel should be approx. 1 mm above the walking surface – with no contact or minimum contact!
This measurement is important for achieving the correct distance between the running surface and braces during therapy!

7. Tighten tube bracket screws.

NOTE

During the first installation it is recommended to repeat the process as follows:

Open safety lock. Release the LokoHelp® from the mount by turning the crank screw counter-clockwise and pulling the LokoHelp® back. Use the water level to check whether the position of the mount has changed. We recommend standing on the LokoHelp® for a while to simulate the patient's weight. Check again with the water level. Check all screws for correct position and tightness.

6.3 Connecting the Control Unit to the LokoHelp®

Set the LokoHelp® gait trainer in the correct position using the steps described above. After mounting, set the lever mechanism to protect the IRC sensor, located at the front of the LokoHelp®, to the “TRAINING” position. The distance of the front wheel of the gait trainer to the surface of the treadmill should be ca. 1 mm, slight contact with the treadmill surface is allowed. Use a water level to ensure that the LokoHelp® is in a horizontal position to the treadmill. Check whether the LokoHelp® mount is fixed correctly and the unit is firmly mounted. Ensure that the crank screw is tightened to the stop, and that the safety screw is tightened.

Lever mechanism to protect the IRC sensor set in the “TRAINING” position

Fig. 10 Training position

ATTENTION

Risk of damaging the device!

The control unit may only be connected by an authorized representative from Parabel s.r.o. or an authorized service company!

The LokoHelp® receives direct feedback from the IRC sensor connected to the front wheel. Therefore, the device will not start running if the lever mechanism is not set at the “TRAINING” position when starting the training session.

Setting the lever mechanism at the “TRAINING” position after starting the training session (while the treadmill running belt is moving), might cause an “overload error” and damage to the IRC sensor!

Preparing the Control Unit:

Place the controls (control unit) on the floor to the left or right of the treadmill. Do not open the control box unless expressly instructed to do so by **WOODWAY**.

Connect the control unit main wire with the LokoHelp®.

The special arrangement of differently shaped pins in the connector plug and socket is fixed and cannot be connected incorrectly. The connector side-locking clamp must be properly locked.

NOTE

The direction of the connector on the LokoHelp® can be rotated 180°. For further information please contact **WOODWAY** customer service.

Fig. 11 Connecting and locking control unit connector to the LokoHelp®

ATTENTION

Risk of damaging the device!

Do **NOT** disconnect the main wire (from the control unit to the LokoHelp®) when the power is on.
First switch the power off using the main switch before disconnecting the main wire!

To prevent damage to the LokoHelp® connection, use the protective cap when the main connection is not used:

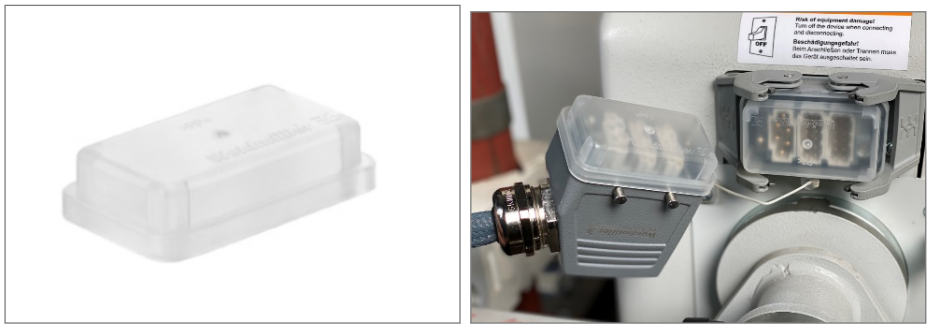


Fig. 12 Protective cap, control unit connection

6.4 Mounting the Gait Trainer

After installing the mount the following steps should be taken to verify the installation status:

- After mounting check the distance of the front wheel of the gait trainer to the surface of the treadmill. It should be 1 mm. Slight contact with the treadmill surface is allowed.
- Use a water level to ensure that the gait trainer is in the correct horizontal position.
- Check that the LokoHelp® mount is secure and the unit is stable.
- Ensure that the crank screw is tightened to the stop and the safety screw is tightened.

Fig. 13 Mounting crossbar and crank

Fig. 14 Fixing bracket

6.5 Before Using the Gait Trainer

Instruct the patient on the treatment measures on the device before the starting therapy and make sure you have their consent.

Before using the device check that the main wire is not damaged and that it is properly connected.

Before each use ensure that:

- there are no signs of damage to the system
- the braces are properly positioned
- the lower leg braces are securely fixed to the LokoHelp®

Only use the device after a proper function check. Check the device in your own interest and for the protection of the patient prior to each use, (loose screws, worn parts) and also for proper power connection. A device with a defect may not be used until it is properly repaired.

Ensure that no persons are close to moving parts.

7 Operation

7.1 Basics

The LokoHelp® gait trainer was developed as an advanced option for locomotion on treadmills.

The auxiliary drive and the required components for its function and operation are described below.

The current treadmill speed is determined by a sensor wheel which moves with slight contact to the running surface of the treadmill. This wheel is integrated into the incremental sensor unit.

The signals are controlled and displayed via a graphical touch panel, which is linked to a servo amplifier via CAN-bus RTU.

When the emergency stop button is pressed all electrical components are switched off. The treadmill is also switched off provided it is plugged into the LokoHelp® power supply as prescribed.

7.2 LokoHelp® in the System

The LokoHelp® gait trainer is designed for a slat-belt treadmill with body weight support system (see section 1.2) and may only be used with this system, unless other arrangements have been expressly made with **the manufacturer**.

ATTENTION

The LokoHelp® gait trainer may only be used in combination with a body weight support system with patient harness and a treadmill (see section 1.2)!

For information on using the treadmill and the patient harness as well as the necessary settings for body weight support, refer to the separate operating instructions for these corresponding devices.

The additional options for hip stabilization via rubber belts and belt fixation are also described in the operating instructions from the body weight support system.

7.3 Operational Safety

When using the LokoHelp® system, special attention should be paid to the distance between the inner and outer slide track (visible chain area).

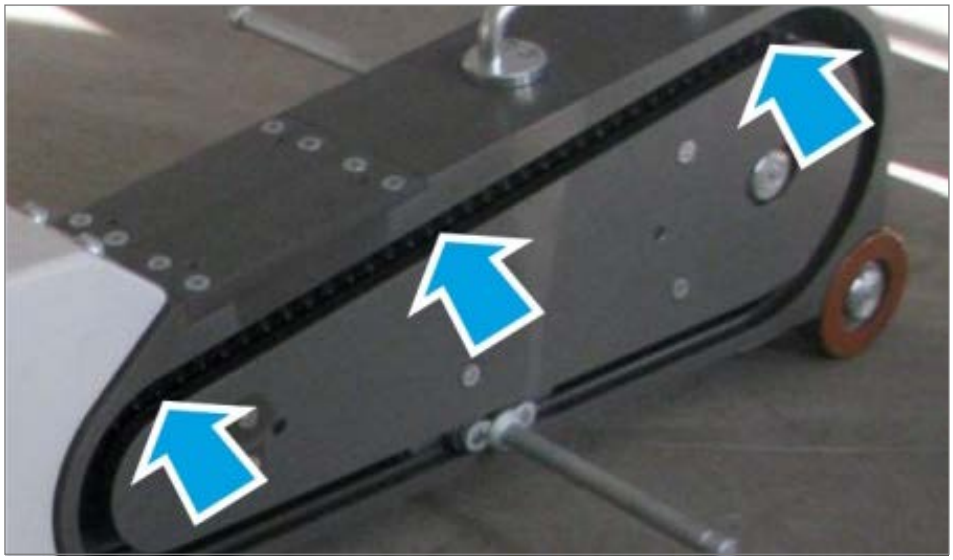


Fig. 15 Visible chain area

⚠ WARNING

Danger of Injury!

Between the inner and outer slide track there is the possibility of injury.

- ► Do not reach into the opening in the chain area.
- ► The braces may not be held by hand during therapy.
- ► Do not tamper with the brace mounts or brace fasteners during therapy.

The therapist may, under no circumstances, hold the braces, tamper with brace grips or fasteners, or insert fingers or foreign objects in the vicinity of the moving chains during therapy!

Do not lay any foreign objects, food or drink on the gait trainer or parts of it. Do not rest on the device and do not carry out any improper movements. There is a danger of falling!

Ensure that when using the gait trainer on a treadmill with the possibility to incline that, should the treadmill be inclined and the belt switch off suddenly, the treadmill does not automatically return to the horizontal position. This can cause a fall.

⚠ WARNING

Danger of Injury!

Danger of injury during operation with mounted crossbar without LokoHelp®.

- ► Remove the mount/crossbar when operating without LokoHelp®.
  (For information on the mount see 6.2 page 29)

7.4 Patient Preparation

7.4.1 Process

1. Hold the gait trainer by the handles roll it onto the treadmill on the front wheels.
2. Place the control unit on the floor to the left or right of the treadmill. Connect the control unit main wire with the gait trainer.
3. Connect the control unit to an electrical socket.
4. Apply the patient harness to the patient according to the operating instructions
5. Put the lower leg braces on the patient and fix them with the fastening straps, see section 7.4.2.
6. Move the patient onto the treadmill.
7. Position and secure the patient in the body weight support system using the patient harness (hanging).
8. Fix the braces to the gait trainer.

The patient is now prepared for therapy.

ATTENTION

The operating staff is to be trained separately and in detail on the preparation of the device and the patient before use!

7.4.2 Applying the Lower Leg Braces

The size of the braces is adapted to the size of the patient's feet. The braces can be completely opened in the front. This makes putting them on easy and comfortable for the patient. The braces fixe the feet at a 90° position with respect to the shinbone and extend to below the knees. After consultation, the patient's own braces can be worn if necessary.

Correct application of braces is essential for safe operation of the gait trainer!

NOTE

For reasons of hygiene braces may not be worn on bare feet.
Using braces with shoes is more comfortable for the patient during therapy and provides for a greater sense of security.

1. The braces must be completely opened before application:
   - sufficiently loosen all straps
   - open Velcro fasteners completely
   - open the braces textile inserts completely

ATTENTION!
To avoid confusing the left and right braces, ensure that the fasteners are on the outside.

2. Lift the patient's lower leg slightly. Apply the braces from the back of the lower leg and place the foot in the braces so that the heel is in contact with the back of the brace. Ensure that the brace insert is not under the heel. Ensure that the heel rests on the back of the brace!

3. With the help of Velcro fasteners close the brace insert and fix the foot firmly over the instep with the Velcro strap.

4. Set the lower leg tension straps in a horizontal position. Insert them into the buckles and tighten each buckle with the tightening mechanism so that the leg is firmly fixed in the brace.
   Adapt to the patient's handicap and sensitivity, but the fasteners should be as tight as possible.

NOTE

Excessive tightening of the tension straps can cause swelling on the edge of the foot (toe area). Insufficient/incorrect tightening of the tension straps reduces functionality.

Each brace is engraved with the serial number and L (left) and R (right) on the fastening mechanism (bottom).

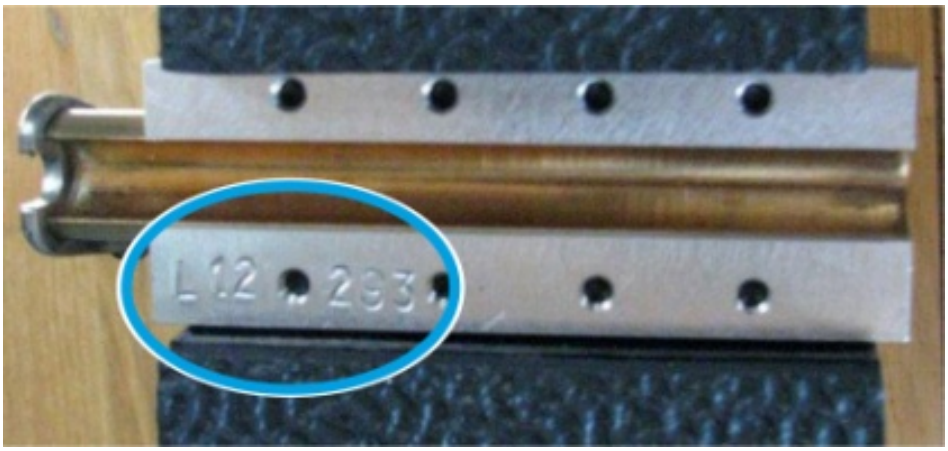


Fig. 16 Brace serial number

7.5 Safety Under Inclined Operation

When using the treadmill for inclined operation, special safety regulations apply.

⚠ WARNING

Danger of Injury!

There is a danger of stretching the patient when using the treadmill inclined. Lowering the treadmill during operation, during a power failure and switching the treadmill off, can cause uncontrolled stretching of the patient.

► When lowering the treadmill during operation, during a power failure and when switching the treadmill off, always extend the length of the rope in body weight support system.

7.6 Basics of Gait Training

After fixing the patient using the patient harness and strap, adaptation to gait trainer can begin.

- Place the braces in the gait trainer fastening device (brace seats) right/left and secure them with the locking mechanism, see section 7.4.2 page 36.
- Lift the patient into the upright position using the crank system.
- Remove wheel chair and other aids from the treadmill and ramp.
- Lower the patient so that they stand firmly and securely on the treadmill.
- Then check for correct positioning and tightness of the patient harness.

For the best possible physiological gait pattern on the LokoHelp® gait trainer, the patient's center of gravity is crucial. The imaginary vertical line must be in the center of the standing phase before the bending axis and the extension of the knee.

For details on positioning and movement see Fig. 17.

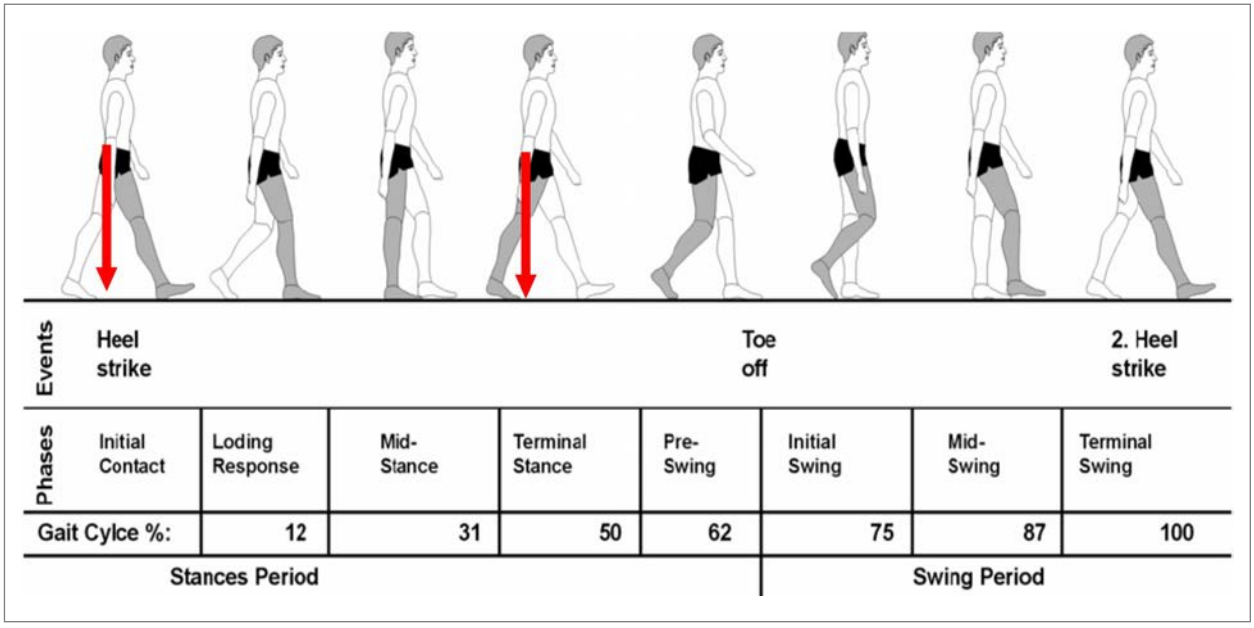


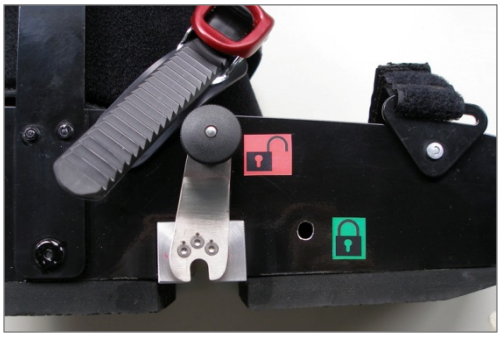
Fig. 17 Walking Sequence, step cycle

The position of the patient's center of gravity is important the hip extension.

Hip Stabilization: To adapt the body's center of gravity and stabilize the hip use additional hip stabilizers.

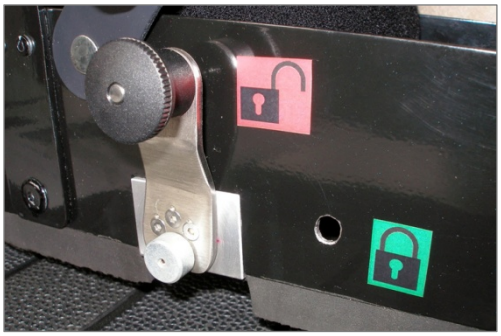
Fixing the Straps A fixing strap is also available (elastic belt with carabiner hooks) with which the patient can be fixed to the front crossbar by fixing the carabiner hooks to the metal rings on the side of the patient harness. Using the fixing strap the center of gravity of the patient's body can also be adjusted to an even greater hip extension can be achieved.

7.7 Fixing the Braces on the LokoHelp®

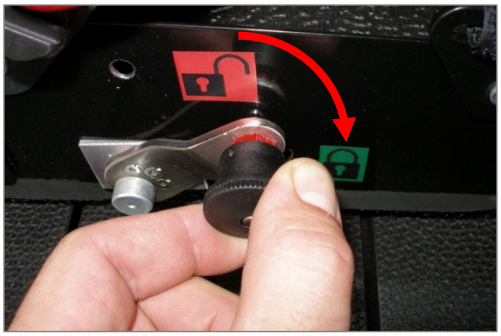


The locking mechanism with notch on the outside is used to secure the brace on LokoHelp®.

The braces can only be connected to LokoHelp® or the brace seat if the locking mechanism is open.



1. Place the brace on the brace seat so that it fits exactly in the slot in the sole of the brace.



2. Pull the black plastic knob on the locking element out and move the lever to the lock position to the **green** symbol at the bottom. Then release the plastic knob.
   The locking element must lock in the bottom position.

3. The brace is now locked in place on the LokoHelp®.

4. To release, proceed in the opposite order.
   Pull the black plastic knob on the locking element out and move the lever to the **red** symbol at the top. Then release the plastic knob (3).
   The locking element must lock in the top position.

5. The red ring on the locking element indicates correct locking and unlocking.

   ATTENTION!
   When the red ring is visible the lock is NOT in engaged!

7.8 Control Panel

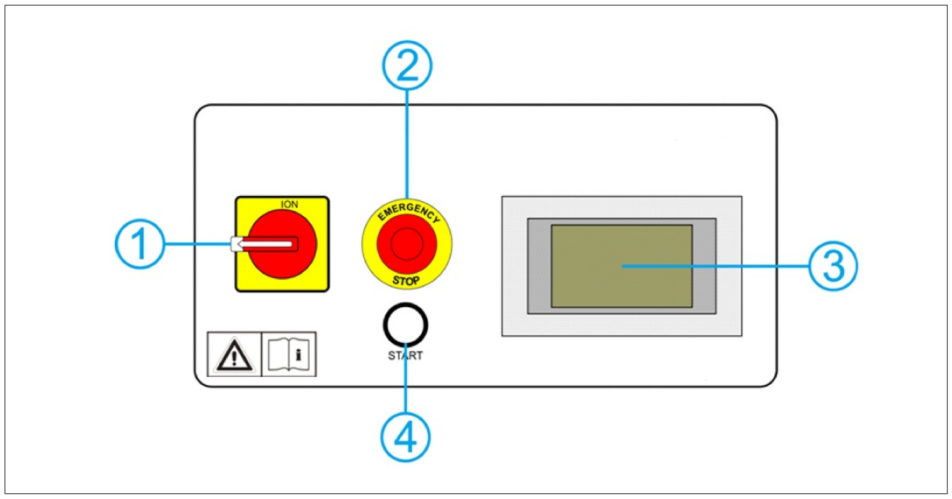


Fig. 18 Control Panel, Control Elements

1. Main switch "ON": it is used to turn the electrical power supply to the gait trainer on and off.
2. "EMERGENCY STOP" switch: it is used to immediately stop all system movements, i.e. the movement of the treadmill and the gait trainer.
3. Touchscreen: it indicates the gait trainer functions and enables its operation.
4. "START" button: it is used to start the treadmill.

7.9 Start System

The system is activated by turning the main switch clockwise 90°. The following screen will appear:

Fig. 19 System start screen

Press "Press to continue" on the screen to proceed to the Start menu:

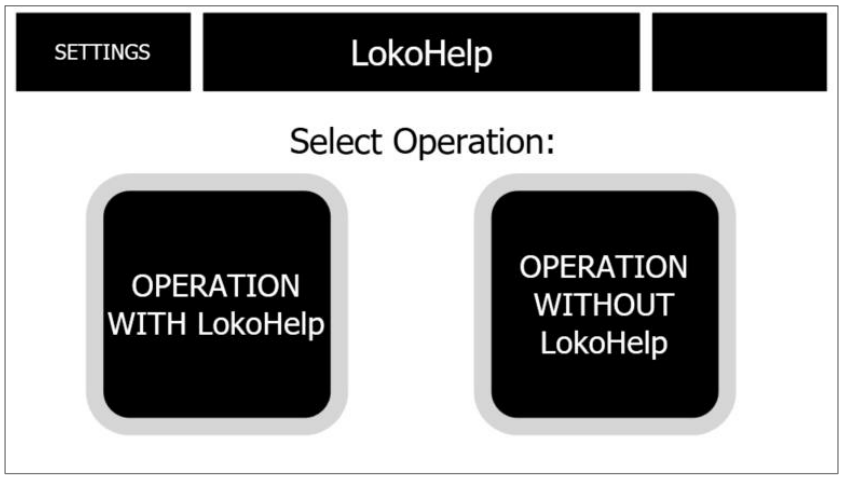


Fig. 20 Start menu screen

The following options can be chosen in the start menu:

- OPERATION WITH LokoHelp
- OPERATION WITHOUT LokoHelp
- SETTINGS - e.g. language, parameters, etc.

7.9.1 Treadmill Operation with the LokoHelp® Gait Trainer

To use the system with the LokoHelp® installed on the treadmill press "OPERATION WITH LokoHelp" on the Touchscreen.

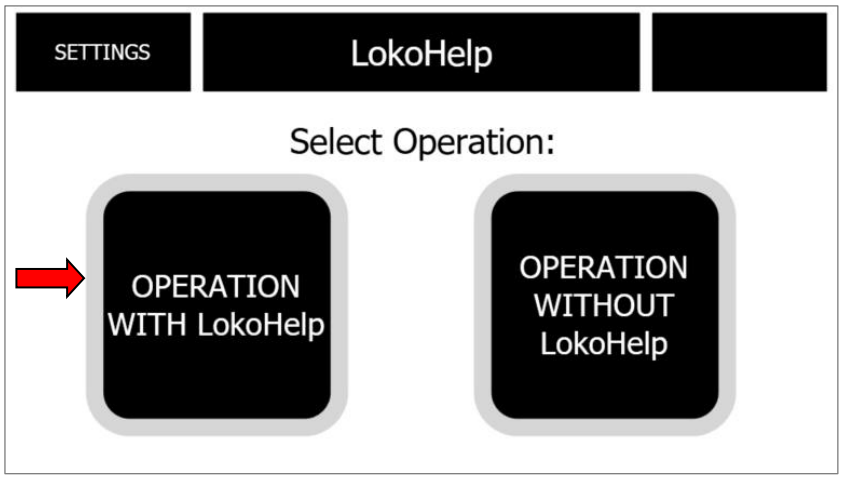


Fig. 21 OPERATION WITH LokoHelp screen

The next step is to enter the patient's weight and level of resistance:

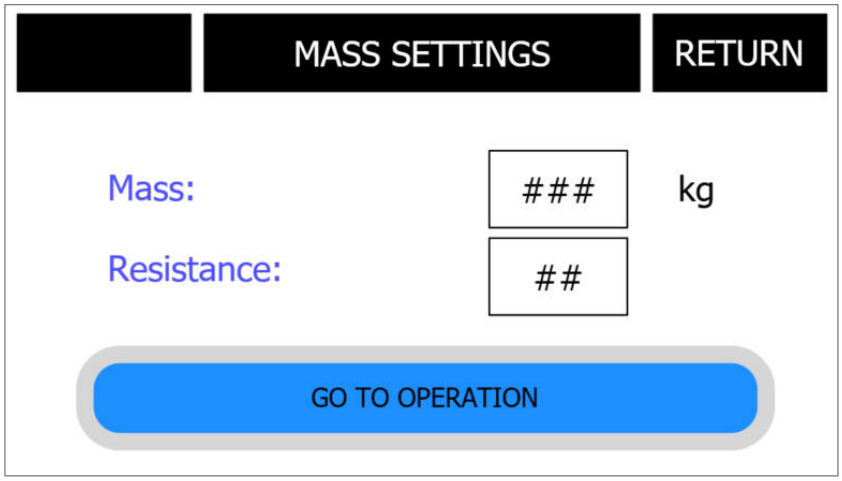


Fig. 22 Weight and resistance settings screen

When the weight field is pressed a window with keypad opens. There the body weight can be entered. Then press "Enter" to enter the weight into the system.

Resistance The resistance entry depends on the patient's weight, the speed the strength and spasticity; for details on this entry see page 45.

After making the body weight and resistance entries press "CONTINUE TO START". The following screen will appear:

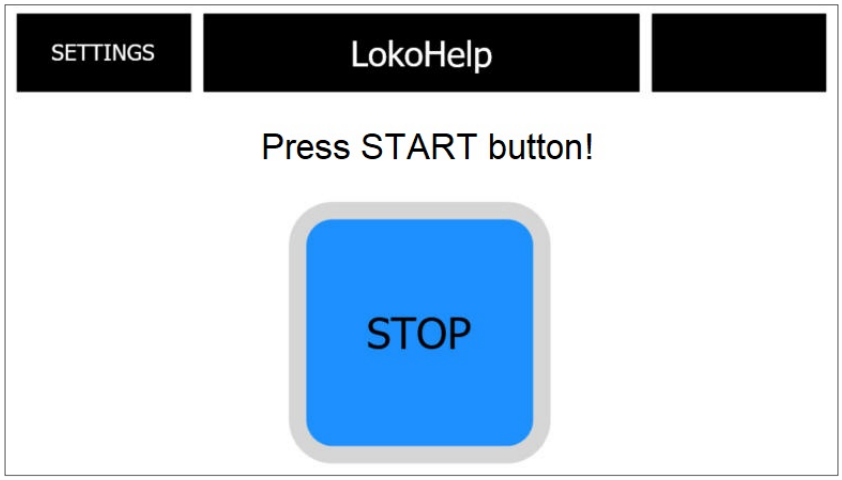


Fig. 23 Press start button screen

Now you will be asked to press the start button (white), see Fig. 18 page 41. Press "START" on the control panel. The following screen will appear.

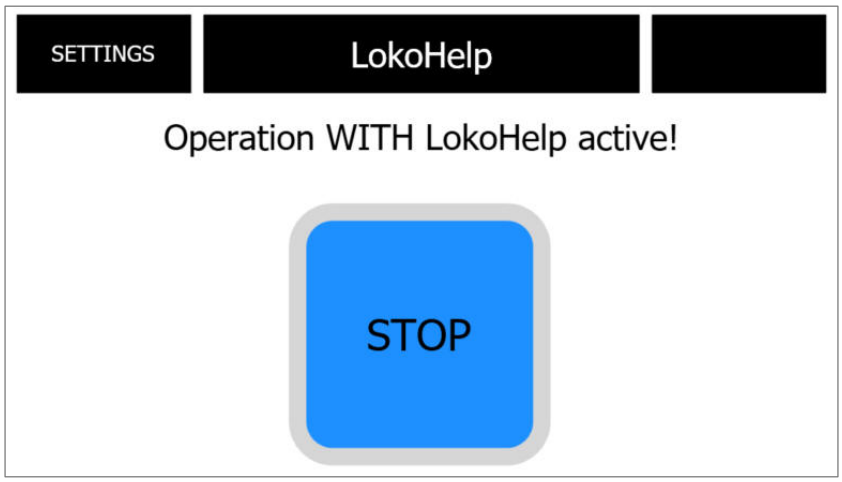


Fig. 24 Operation WITH LokoHelp active screen

When this screen appears, start the treadmill on the control unit (Data monitor or WUS) and follow the operating instructions for the **WOODWAY** treadmill.

- To interrupt the therapy, press and hold the treadmill stop button.
- To end the therapy, press the STOP button on the LokoHelp® control panel.

NOTE

When the STOP button on the LokoHelp® control panel is pressed, the preset weight and resistance entries are set back to default settings (Weight: 5 kg, Resistance: 2). The power to the treadmill will also be cut.

7.9.2 Weight and Resistance Settings

Weight:

The patient weight is entered here. The system calculates the required drive motor torque using the weight setting and the resistance setting (described in the following section).

The body weight can be set to between 5 and 150 kg.

Default setting = 5 kg.

When the weight field is pressed a window with a keypad opens. There the patient's body weight can be entered. When "Enter" is pressed the system accepts the entered values.

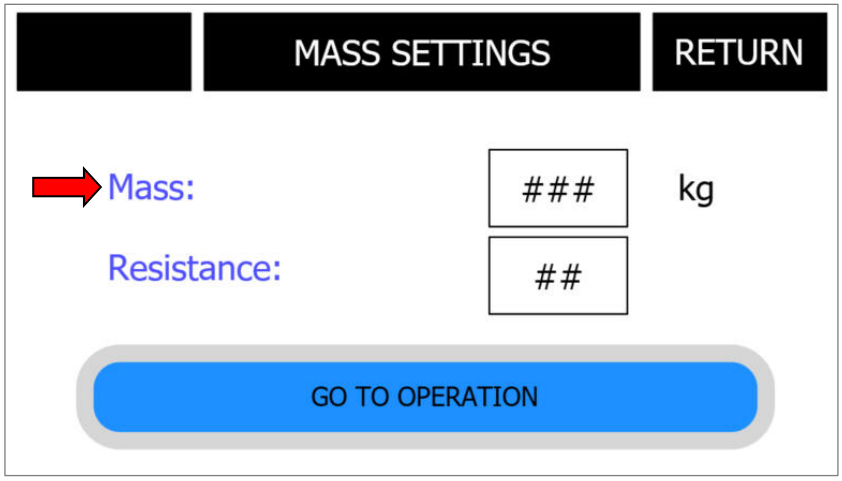


Fig. 25 Weight settings screen

Resistance:

For safety reasons the LokoHelp® system checks whether the brace fastening system will be overloaded. With the resistance value the "overload sensitivity" or the "reaction time for switching off due to overload" is determined. When the load is exceeded, the system assumes that the brace mount (brace seat) is mechanically blocked, e.g. by a muscle cramp (spasm). In this case the power supply to the treadmill is interrupted, so the treadmill and LokoHelp® stop. The system then displays the error message "LokoHelp Error - LokoHelp overload".

The setting for the resistance represents the time after which the system switches off due to overload. The reaction time depends on the patient`s body weight, strength, and spasticity as well as the walking speed. For strong patients this value can be set higher than for patients who must be treated very carefully.

ATTENTION

To avoid accidents always start with a low resistance value!

It is advisable to inform the patient about the following treatment steps before starting treatment. If possible ensure that the patient gives their consent. During therapy maintain contact with the patient and monitor their health.

The resistance can be set from 1 to 60. Default setting = 2

Below are a table and a chart with the recommended values. For each patient the resistance must be individually selected for each patient according to personal strength and spasticity.

NOTE

If you have selected and set the recommended value for a patient using the table and chart and the system still shuts down during therapy due to overload, the resistance can be set 1 or two points higher depending on the patient's comfort!

The following table and chart show the relationship of resistance to weight and speed.

ATTENTION

The values specified here are recommended values. The "resistance" setting must be adjusted individually for each patient according to their strength and spasticity.

Resistance Table:

	Resistance at											
km/h	**10 kg**	**16 kg**	**24 kg**	**32 kg**	**48 kg**	**64 kg**	**80 kg**	**96 kg**	**122 kg**	**128 kg**	**144 kg**	**160 kg**
0.1 km/h	1	3	5	7	10	14	18	21	24	27	30	33
0.2 km/h	1	3	5	7	10	14	18	21	24	27	30	33
0.4 km/h	1	3	5	7	11	14	18	21	24	27	31	34
0.6 km/h	1	3	6	8	12	15	18	21	24	28	32	35
0.8 km/h	1	4	7	9	13	16	19	22	25	29	33	36
1.0 km/h	1	5	8	10	14	17	20	23	26	30	34	37
1.2 km/h	1	6	9	11	15	18	21	24	27	31	35	38
1.4 km/h	2	7	10	12	16	19	22	25	28	32	36	39
1.6 km/h	3	8	11	13	17	20	23	26	29	33	37	40
1.8 km/h	4	9	12	14	18	21	24	27	30	34	38	41
2.0 km/h	5	10	13	15	19	22	25	28	31	35	39	42

Resistance Chart

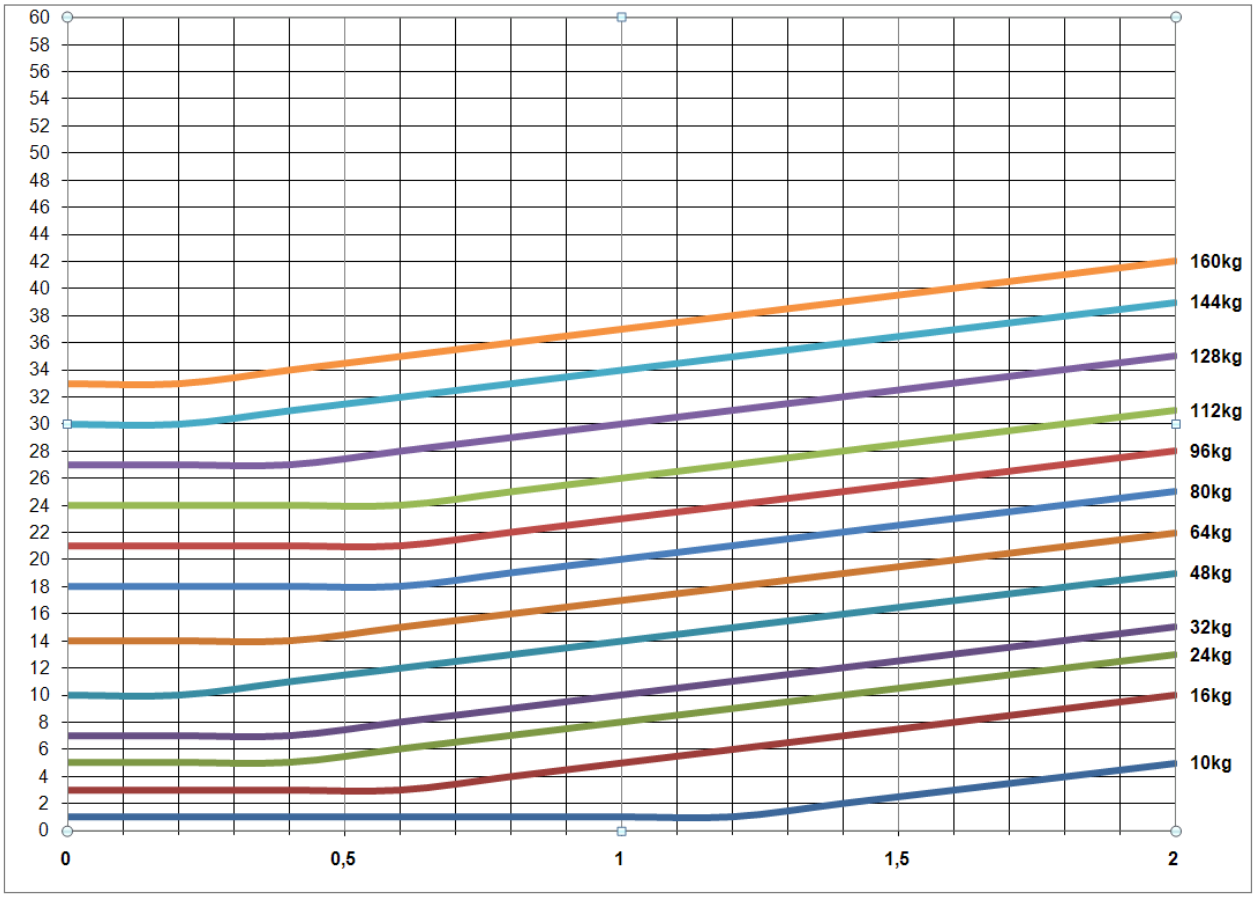


Fig. 26 Resistance chart

Calculation Example: The patient weighs 80 kg. His strength and spasticity allows therapy at a walking speed of 1.5 km/h.

System settings

- Weight: 80 kg
- Resistance: 23.

7.9.3 Treadmill Operation without the LokoHelp® Gait Trainer

If the treadmill is used without the LokoHelp® gait trainer, the following measures must be carried out:

Press "OPERATION WITHOUT LokoHelp" in the start menu:

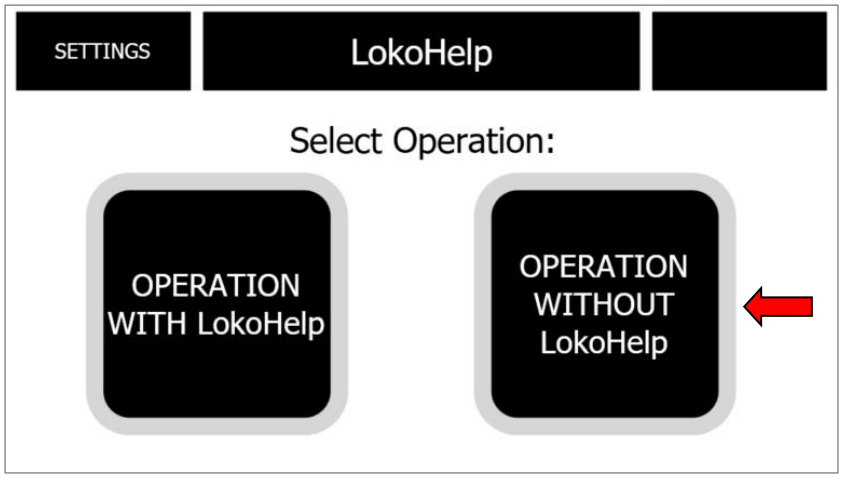


Fig. 27 OPERATION WITHOUT LokoHelp screen

Press "YES" in the following screen:

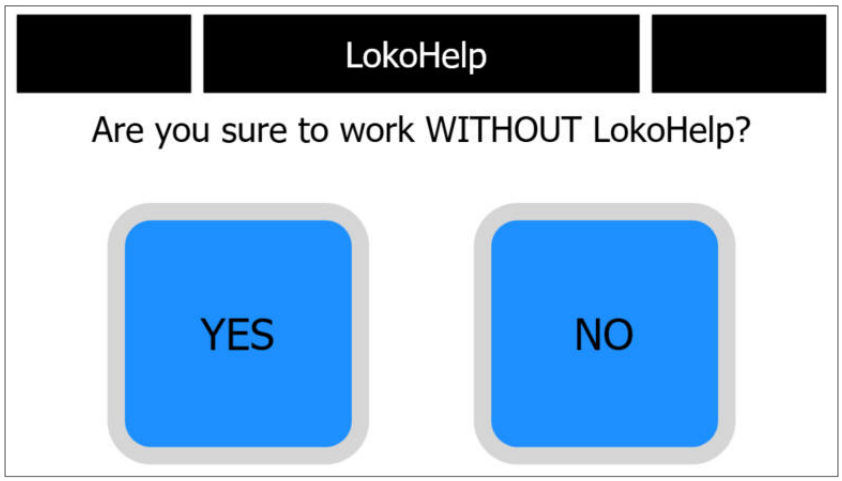


Fig. 28 Confirm operation WITHOUT LokoHelp® screen

Then the following screen appears:

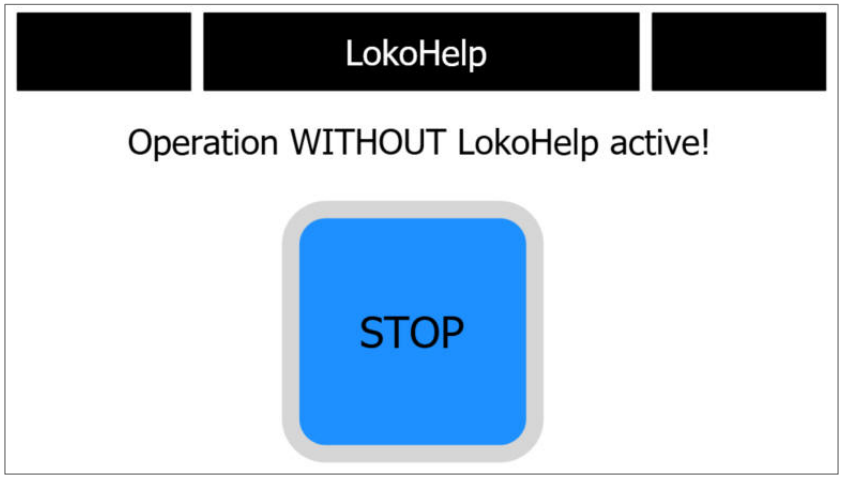


Fig. 29 Operation WITHOUT LokoHelp active screen

Now the treadmill can be started without the LokoHelp® gait trainer.

NOTE
If you want to stop using the treadmill in "OPERATION WITHOUT LokoHelp", press "STOP" on the screen.

7.10 System Settings

By pressing the settings field, the following screen appears for selecting the Loko-Help® system parameters:

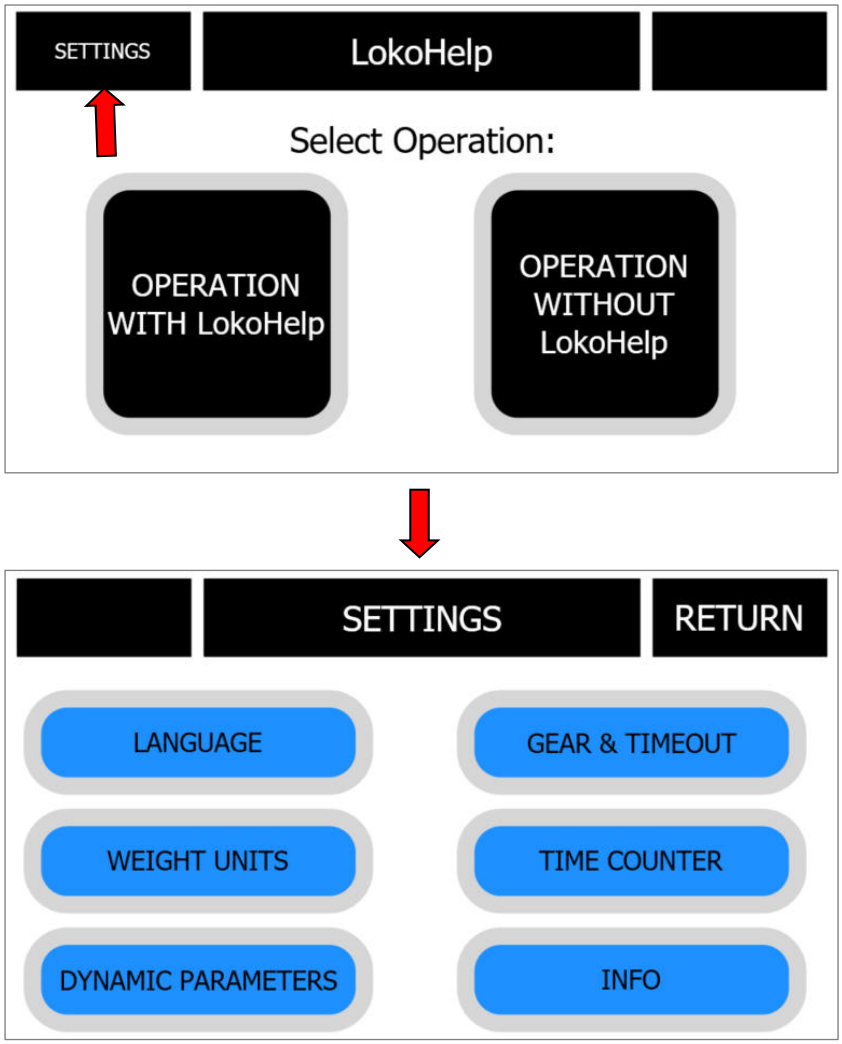


Fig. 30 LokoHelp® system parameters screen

7.10.1 Language

For setting the software language see available languages:

- English
- German
- French
- Spanish

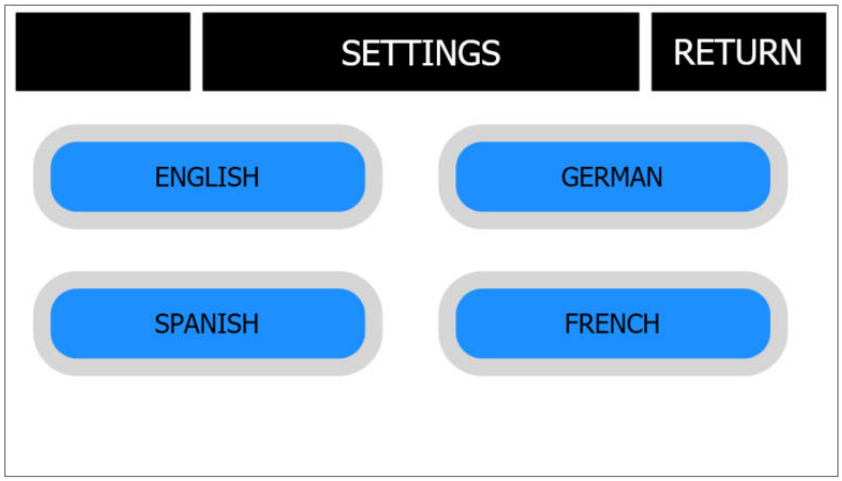


Fig. 31 System language settings screen

7.10.2 Weight Units

For setting the weight units see available weights:

- kg
- lbs (pounds)

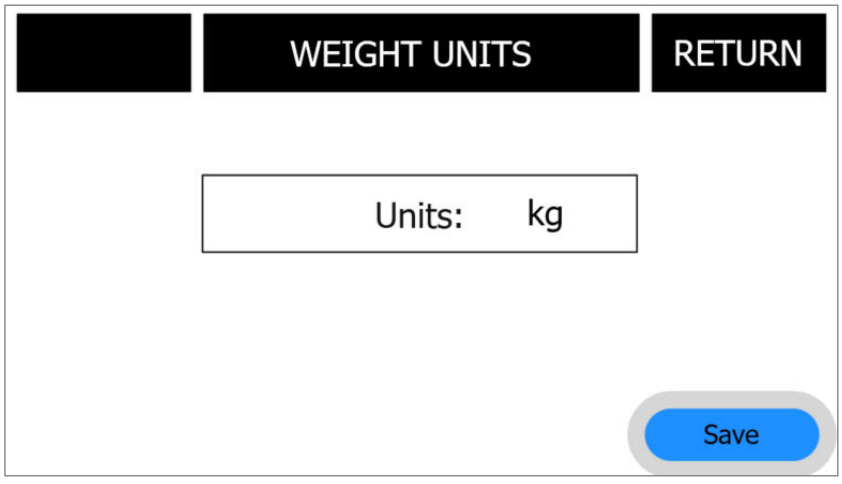


Fig. 32 System weight unit settings screen

7.10.3 Dynamic Parameter

For setting the control system settings.
This function is password-protected and is used for service purposes only.
Drive & time to start: For setting the motor translation ratio and the switch-off time for the treadmill start.

7.10.4 Gear & Time Out

For setting the motor translation ratio and the switch-off time for the treadmill start. If the treadmill does not start during this time, the system switches off for safety reasons.
Default setting is 999 seconds (approx. 16 min.)

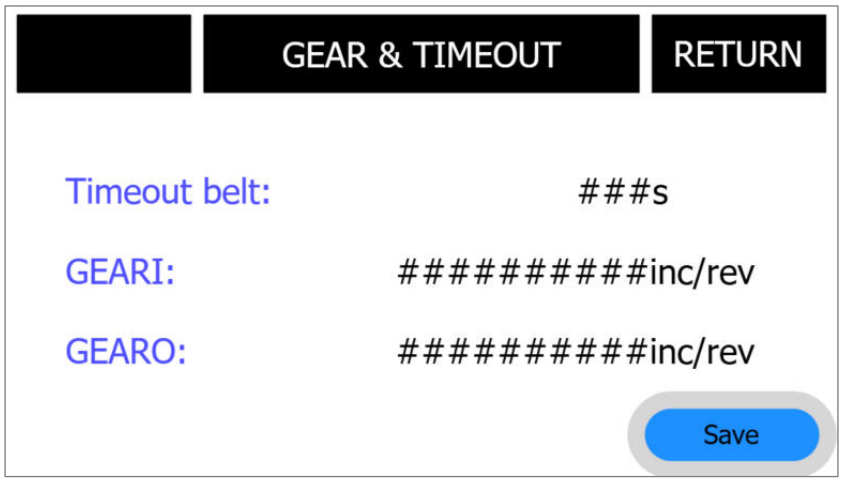


Fig. 33 Gear & timeout screen

7.10.5 Time Counter

"TIME NEXT SERVICE": ": displays when the LokoHelp® must be serviced.

"TIME TO LUBRICATION": displays when the LokoHelp® brace seats must be lubricated.

"ADVANCE SETTINGS": displays more options for service.

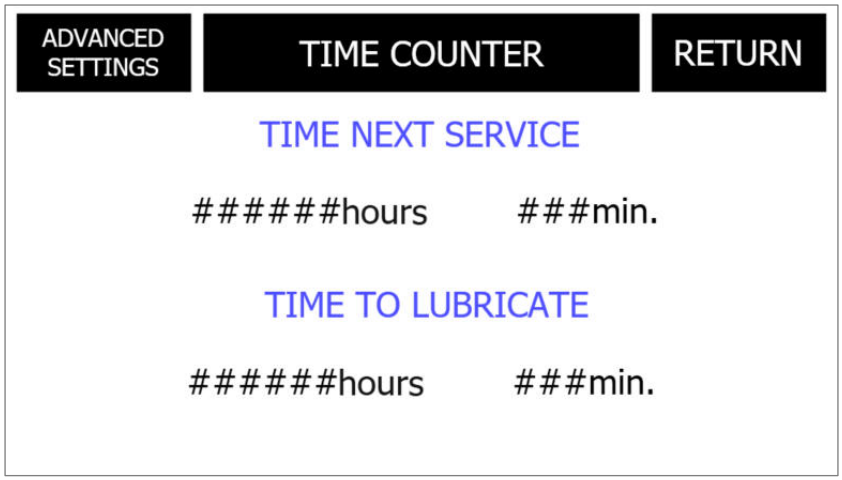


Fig. 34 Time counter screen

7.10.6 Advanced Settings

"RESET TIME NEXT SERVICE": This function is password-protected and is used for service purposes only.
"RESET TIME TO LUBRICATE": This function is password-protected and is used for service purposes only.

"SERVICE RECORD": displays the "TOTAL OPERATION TIME" and additional information for service purposes.

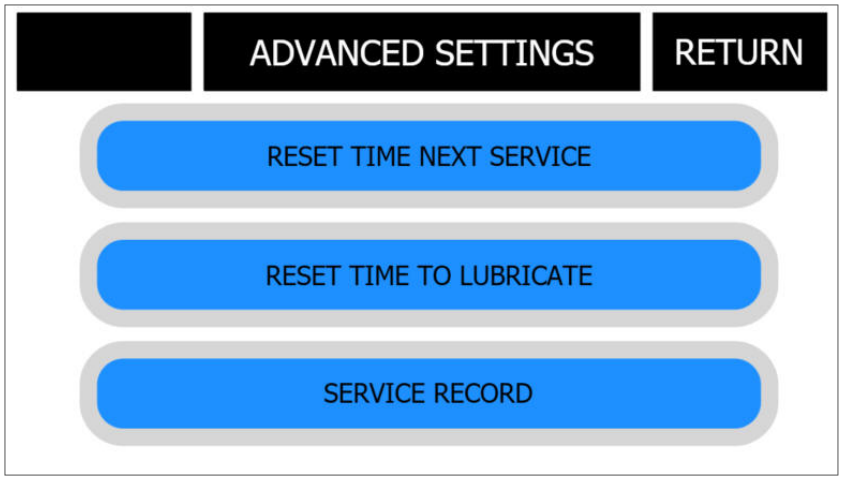


Fig. 35 Advanced settings screen

7.10.7 Service Record

"TOTAL OPERATION TIME": provides information about the operating time in hours and minutes.
"Last action": displays the last service action registered.

"Last time to lubricate / Last time next service": displays the last value before resetting the "TIME NEXT SERVICE" / "TIME TO LUBRICATE".

These values can be reset only through special commands in the DriveGUI terminal.

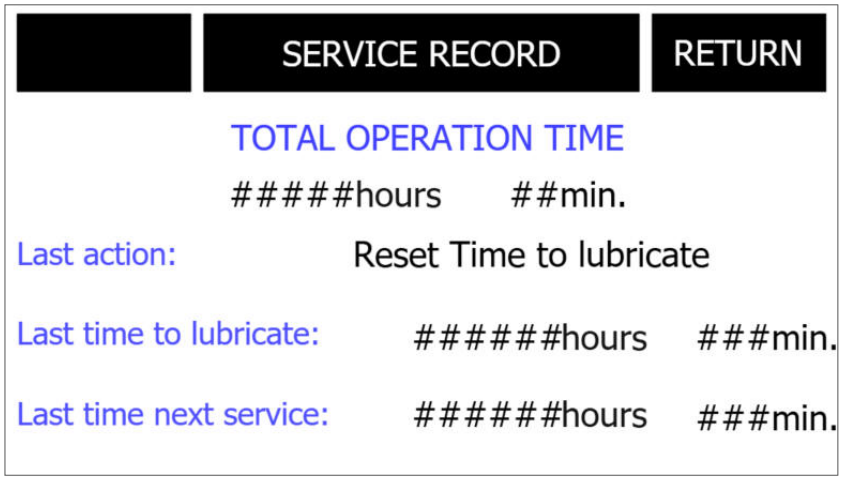


Fig. 36 Service record screen

7.10.8 INFO

Contact information for service and information about the system software version.

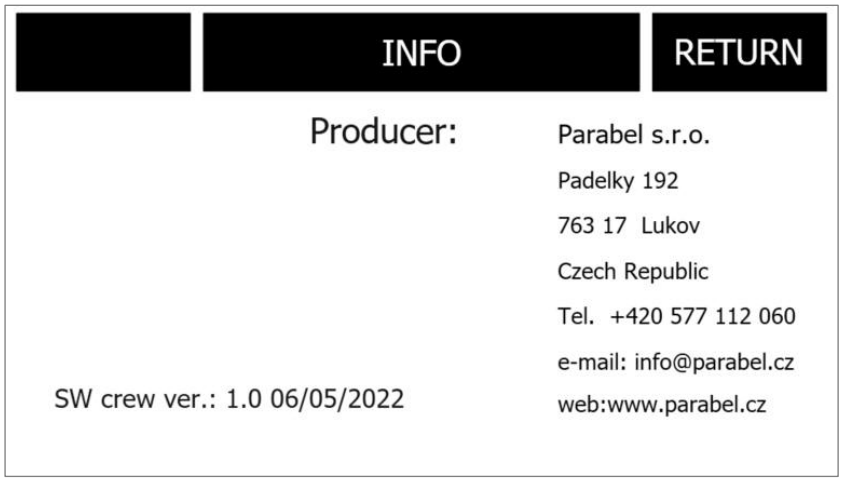


Fig. 37 System information screen

7.11 Starting and Therapy with the Gait Trainer

⚠ WARNING

Risk of injury due lacking of monitoring the patient!

During therapy or use of the device, accidents or dangerous situations may occur due to inadequate monitoring by the treating physician/therapist.

- ► The therapist must be present during the entire therapy period.
- ► The patient must not be left unattended during gait training on the LokoHelp® gait trainer.
- ► The patient must be instructed that the system may only be operated by the treating physician/therapist.
- ► The patient must be instructed that he or the emergency stop function may only be used in dangerous situations (overexertion, anxiety, pain, etc.).

Function Check! Every day before starting use, the treadmill including the gait trainer must run at a speed of 1 km/h for 1 minute and at a speed of 2 km/h for 1 minute without a load (without a patient). This function is used to check and ensure trouble-free operation.

NOTE

The maximum LokoHelp® gait trainer speed is 2 km/h. The system must not run faster.

For a description of gait trainer operation using the control panel, see section 7.9 page 42.

Prepare the patient for the therapy as described above and then start therapy as follows:

- Attach the clip with rip-cord to the treadmill emergency stop magnet and to the patient's clothing. The magnet is to be placed on the space provided on the treadmill control panel (or on the emergency stop mushroom on the railing).
- Before starting the treadmill turn on the LokoHelp® gait trainer using the main switch on the control unit. Then follow the instructions on the screen.
  After the "START" button is pressed, the treadmill must be started within 999 seconds (approx. 16 min.). If the treadmill does not start during this time, the system switches off for safety reasons.
- Switch on the treadmill with the main switch and then on the treadmill control panel. Treadmill operation is described in separate treadmill operating instructions. If you have treadmill operation selection on the screen (depending on the treadmill model), select "Manual operation".
- Take the magnetic operation keypad and move away from the device. From this position you can observe the patient's leg movements from the side.
- Press the appropriate key on the hand keypad to set the treadmill in motion and let the patient take 2 steps at the minimum speed (0.1 km/h). Regulate the speed of belt movement and thus the leg movement according to the treating physician's recommendations. The maximum speed is 2 km/h.
- The training time depends mainly on the assessment of the treating physician/therapist.

Therapy Effectiveness

The effectiveness of the therapy depends on the patient's health, the degree of impairment and the duration of therapy.

- For stroke patients we recommend rehabilitation training at least 3 times a week for a period of at least 6 weeks. For severely injured patients therapy may be extended.
- For patients with cerebral palsy, spinal cord injury, Parkinson's disease or multiple sclerosis, significantly longer therapy duration (several months to years) is recommended.
- Recommendation: 800 - 1000 steps per therapy unit (this equals at least 400 m).

Responsibility!

All gait trainer therapy is to be prescribed by the treating physician/therapist! The recommendations given here are only guidelines and cannot be applied universally. The type of therapy and therapy duration are the sole responsibility of the treating physician/therapist!

NOTE

The exercises on the LokoHelp® gait trainer are not subject to a time limit. The system requires virtually no maintenance.

Also, before operation begins check that all connections are tight and that the settings are correct - horizontal or vertical position as required (check with a water level). Especially patients with high body weight may cause changes in the LokoHelp® gait trainer position. These can lead to damage to the treadmill.

7.12 Ending Operation

7.12.1 Patient Dismount

After completion of gait training, stop the belt movement by pressing the "STOP" button on the hand keypad. Ideally the motion should be stopped at the moment when the left and right brace seat is opposite each other on the gait trainer (braces approximately centered on the treadmill).

- Loosen the patient's legs from the brace seats. The patient should not be carrying their weight (suspended above the treadmill).
  The braces can also be released from the brace seats after lowering the patient into a wheel chair. This is easier if the patient cannot lift their legs themselves.
- Then lower the patient's complete weight onto the treadmill.
- Remove elastic bands for hip stabilization from the handrails by opening the buckles.
- Place a wheel chair on the treadmill behind the patient and prepare the patient to be lowered into the wheel chair.
  Lower the patient into the wheel chair or into a controlled standing position. For this leave the patient in the body weight support system.
- Once the patient is securely seated in the wheelchair or standing securely, release the carabiner from the metal eyelets on the patient harness and lead the patient down the ramp on foot or in a wheelchair.
- Remove the patient harness and the braces.

7.12.2 Switching the Device Off

Turn the gait trainer off after use and disconnect it from the power supply. Ensure that gait trainer parts (e.g. control unit, power cable) do not obstruct other people.

If the gait trainer is no longer in use, it is to be stored in a suitable place so as not to obstruct others.

8 Errors and Service Notifications

NOTE

Displayed error messages are cleared by pressing the “RESET” field.

After “RESET” has been pressed, wait about 5 seconds (unless resetting the system for troubleshooting and warning/alarm goes off beforehand).

8.1 Warning Symbols in the Start Menu

Warning symbol in the Start menu can be caused by the following

- The max. of five seconds to reset the system by pressing the "RESET" button after the error correction have not expired.
- System errors are mainly caused by a poor connection between switch cabinet and gait trainer.

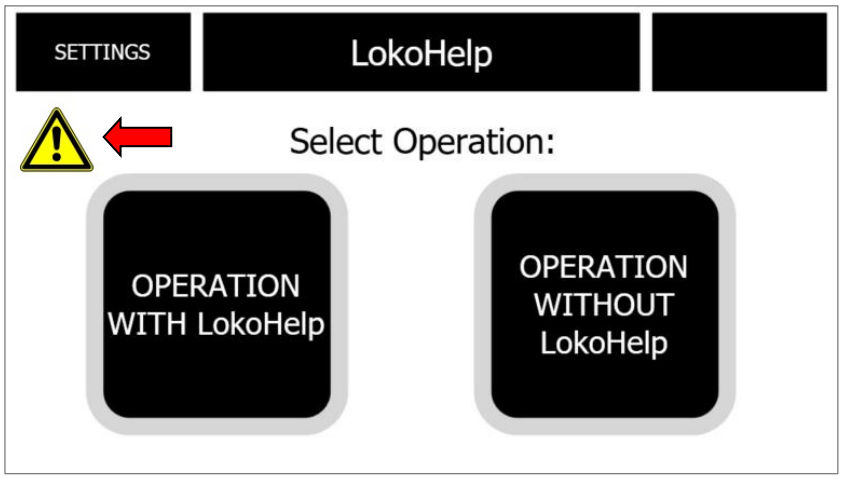


Fig. 38 Error screen

Check the main plug connection. Disconnect the main plug from the LokoHelp® and reconnect it:

Fig. 39 Checking main plug

ATTENTION
When connecting/disconnecting the system must be switched off!

If you select "OPERATION WITHOUT LokoHelp" the warning symbols in the Start menu disappear automatically and you can easily use the treadmill without LokoHelp®.

If you select "OPERATION WITH LokoHelp", the system immediately displays a corresponding error message.

8.2 Error Messages

8.2.1 LokoHelp® is Still Installed

When "OPERATION WITHOUT LokoHelp" has been pressed, for safety reasons, the system checks whether the LokoHelp® is still installed on the treadmill or not. This is checked by the increment sensor. If the sensor detects motion although "OPERATION WITHOUT LokoHelp" has been selected, the system assumes an error has been made.

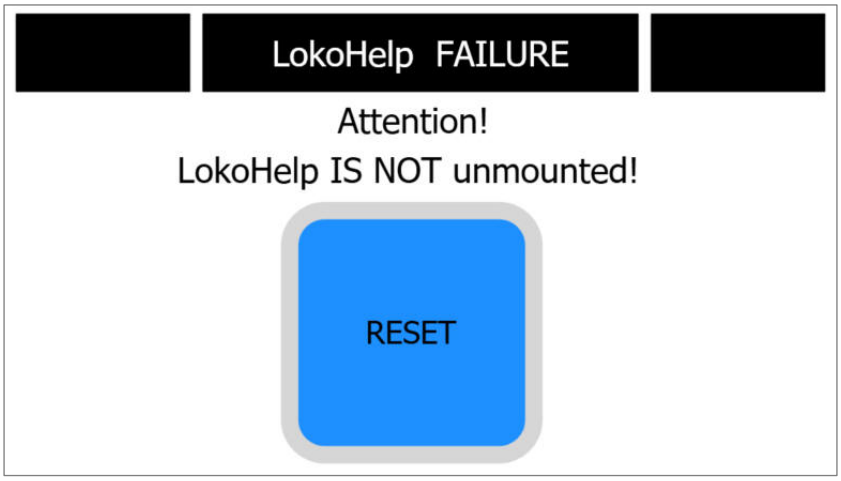


Fig. 40 Error screen - LokoHelp IS NOT unmounted!

8.2.2 LokoHelp® - Servo Error

Check the main plug connection. Disconnect the main plug from the LokoHelp® and reconnect it:

ATTENTION
When connecting/disconnecting the system must be switched off!

Check the main plug, see Fig. 39 page 57.

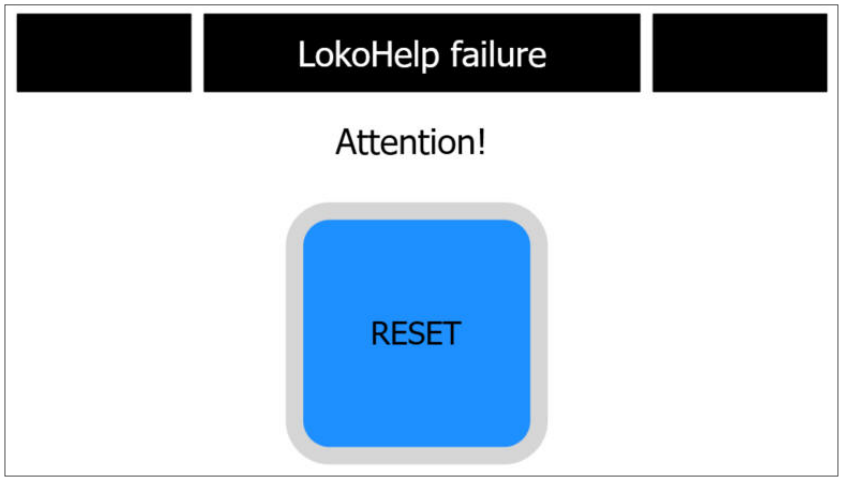


Fig. 41 Error screen - LokoHelp servo error

If this warning appears again, please contact your LokoHelp® supplier.

8.2.3 LokoHelp® - Time Limit Exceeded

After pressing "START", the treadmill must be started within the next 999 seconds (approx. 16 minutes). If the belt does not move during this period, an error message appears with "Time Limit Exceeded".

8.2.4 LokoHelp® - Treadmill in wrong socket

This error occurs when the motion sensor detects belt motion, but the treadmill is not plugged in to the LokoHelp® control cabinet or is not turned on.

8.2.5 LokoHelp® - Emergency stop button activated

The message appears when the emergency stop button is activated and the function "OPERATION WITH LokoHelp" is selected.

8.2.6 LokoHelp® Overload

This error occurs when the LokoHelp® drive is overloaded. The reason for this can be the patient's weight, for example, if the value entered for the patient's weight is below the actual patient weight and the motor is then forced to produce more power, or if the patient suffers a muscle spasm during therapy.

8.3 Service Message

8.3.1 Lubricate the Brace Seat Guide

After every 40 hours of operation the unit must be checked and, if necessary, rollers and guides must lubricated.

Lubricant! Only use LokoHelp®- lubricant "GREASE" for lubrication!

The system has an operating hours counter. After every 40 hours of operation the following display will appear when "OPERATION WITH LokoHelp" is activated:

Fig. 42 Request for lubrication screen

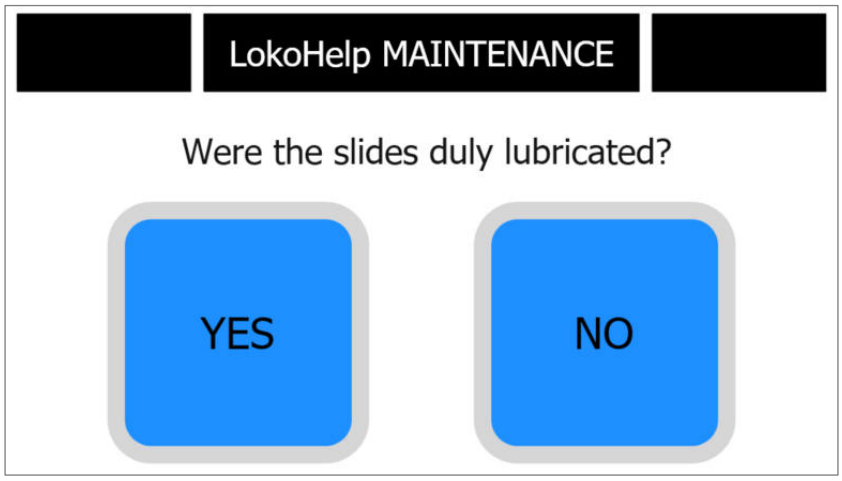


Fig. 43 Confirmation of lubrication screen

Ensure that the brace seat guides have been properly lubricated.

- When the NO field is pressed, the system allows the therapy to continue. The next time "OPERATION WITH LokoHelp" is activated you will be prompted to confirm lubrication of the system. Press OK when the lubrication was carried out.
- By pressing the YES field you acknowledge that the lubrication has been carried out. From this point the next interval of 40 hours is counted by the operating hour counter.

Information on the time remaining until the next lubrication can be seen in the menu at any time under "SETTINGS" → "TIME COUNTER".

8.3.2 LokoHelp® Service

The LokoHelp® system must be serviced by an authorized service technician from the supplier after every 1500 operating hours. The first message is displayed on the screen when 1000 operating hours have been reached:

Fig. 44 Request for service screen

ATTENTION

By pressing the "OK" field you acknowledge that the service has been carried out. **Failure to comply with the prescribed intervals as described will void all guarantee claims!**

ATTENTION

- ► "**TIME TO NEXT SERVICE**" counter should be reset after replacing the brace seats and chains ("Service after 1500 Operating Hours").
- ► "**TIME TO LUBRICATE**" counter should be reset after lubricating guide tracks and brace seats.

For details on how to reset the counters see section 9.4 page 65.

9 Maintenance and Cleaning

⚠ WARNING

Danger of injury due to lack of qualifications!

If maintenance or repairs are not carried out by professionally qualified personnel, this may cause material damage and serious injury.

- ► Maintenance and repair work may only be performed by qualified personnel!
- ► It is the sole responsibility of the representative to assign qualified personnel for maintenance and repair work.
- ► In case of doubt or questions, always contact the **WOODWAY** customer service or dealer!
- ► **WOODWAY** is not liable for personal injury and material damage caused by a lack of qualifications!

9.1 Cleaning

⚠ DANGER

Danger of death by electric shock!

The use of water and liquid detergents as part of cleaning work can cause serious or fatal electrical shock.

- ► No liquids may come in contact with electrical parts such as motor, power cord and power switch, control monitors.
- ► Do not spray the device with water.
- ► Pull power plug before cleaning, equipment must not be connected to power! Ensure the device cannot be switched back on.

The LokoHelp® should be thoroughly cleaned at regular intervals, depending on the intensity of use.

Remove light dirt and dust with a soft cloth. Dirt can be removed with damp cloth and mild soapy water. After cleaning dry with a dry cloth!

Cleaning Notes:

- Do not use sharp tools for cleaning (knife, metal scraper) or aggressive solvents.
- Do not clean with a high-pressure cleaner.
- Clean all surfaces with a non-abrasive, mild detergent.
- To avoid damage to component surfaces, observe the instructions for detergent use.

Disinfection:

For cleaning and disinfection of parts that are touched a formaldehyde-free rapid disinfectant such as "Bacillol plus" or "Descosept" is recommended. For cleaning, never use sharp brushes or abrasive cleaning agents, paint and plastic surfaces can be damaged.

9.2 Maintenance Intervals

The specified maintenance intervals or the replacement of parts specified by the manufacturer must be carried out earlier if there are signs of wear.

For proper inspection and regular review, we recommend a **WOODWAY** maintenance contract.

ATTENTION

Worn or damaged components must be replaced immediately. If the observed deficiency can cause danger to the LokoHelp® user or operator, it may not be used until it has been repaired.

9.2.1 Daily Maintenance

- A visual inspection of the mechanical and electrical parts should be carried out prior to daily use.

9.2.2 Weekly Maintenance

- Checking the gait trainer functions
- Lubricating the guide (see sec. 9.3.1 page 64) and grooves
- Check the brace fasteners.

9.2.3 Monthly Measures

- Chain lubrication

9.2.4 As Needed

- Cleaning and disinfection (parts that patients come into contact with)
- Washing the brace inserts

9.2.5 Annual Measures by a Qualified Service Partner

The manufacturer requires regular annual maintenance. Any liability and warranty will be rejected by non-compliance.

- Function and visual inspection, mechanical and electronic
- Lubrication (brace seat guide, chains)
- Inspection of motor belts and chains (condition, tension)
- Electric checks and inspection in accordance with EN 62 353
- Inspection of safety functions
- Inspection of brace fasteners (replace if badly worn)
- Software update (if possible)

ATTENTION

The brace fasteners are wear parts that wear more or less after use. The brace must sit securely on the brace seat.

9.2.6 Service After 1500 Operating Hours

- Replace the brace seats
- Replace the chains

9.3 Lubrication

9.3.1 Rollers and Guides

The device must be inspected after 40 operating hours. Rollers and guides must be lubricated if necessary.

Only "LokoHelp® lubricant GREASE" is to be used for lubrication.

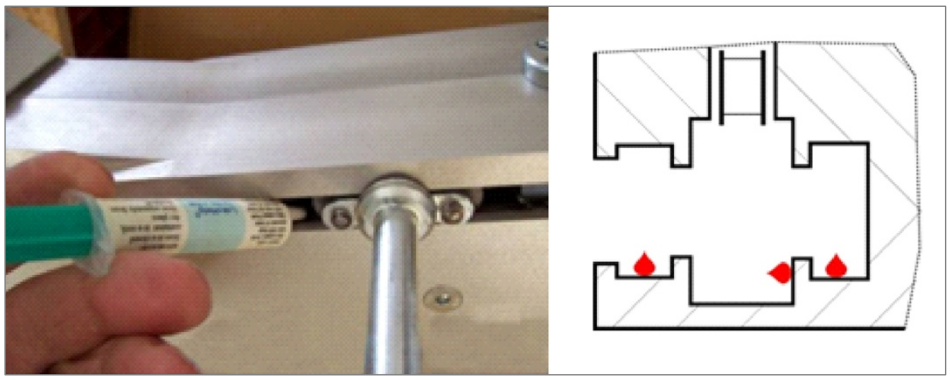


Fig. 45 Lubrication of brace seat guide

The brace seat guide (rollers) consists of 3 guide tracks. These are to be lubricated regularly (apply drops of lubricant about 3 cm apart on the entire track).

The illustration shows a cross-section of the tracks, the red dots mark the optimum lubrication points.

After lubrication slide the rollers along the entire track about 3 times. This distributes the drops and forms a continuous lubricant film on the surface.

9.3.2 Chains

Lubricate the chains (1) once a month depending on the use. We recommend standard bicycle chain oil.

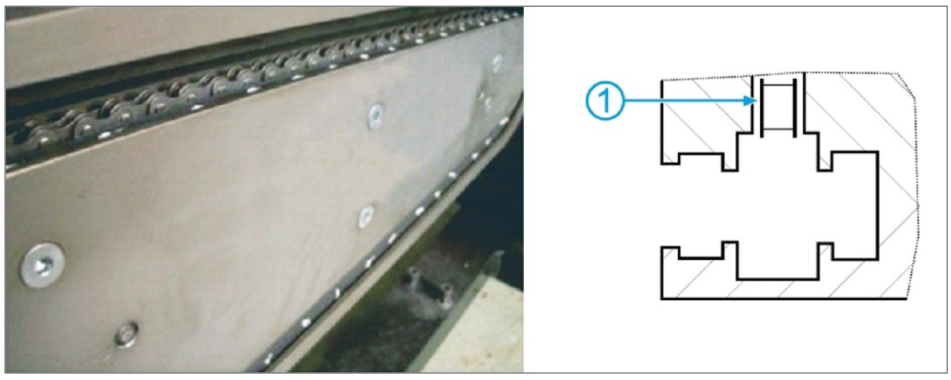


Fig. 46 Chain lubrication

9.4 Time to Lubricate Counter Reset

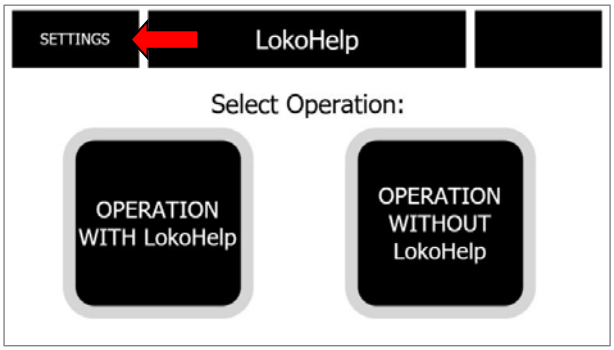


Fig. 47 Select operation screen

- In the select operation screen, press "SETTINGS".

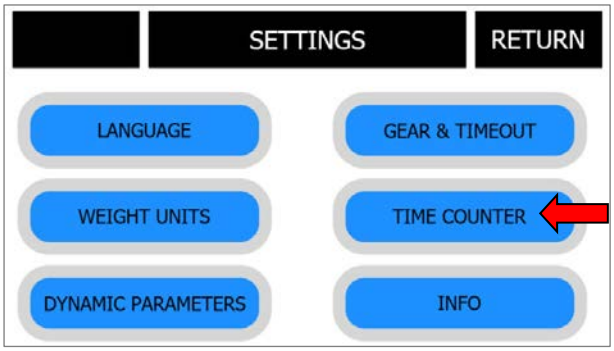


Fig. 48 Settings screen

- Press "TIME COUNTER".

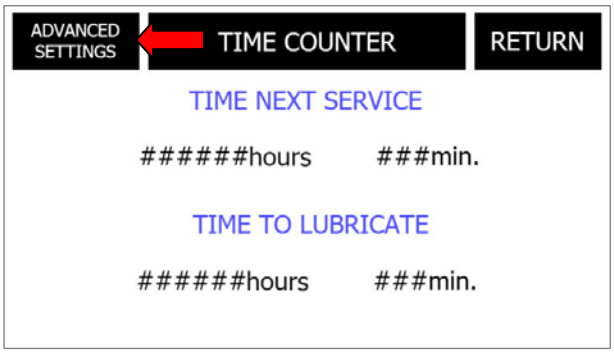


Fig. 49 Time counter screen

- Check whether the minutes are being counted during operation.
- Press "ADVANCE SETTINGS".

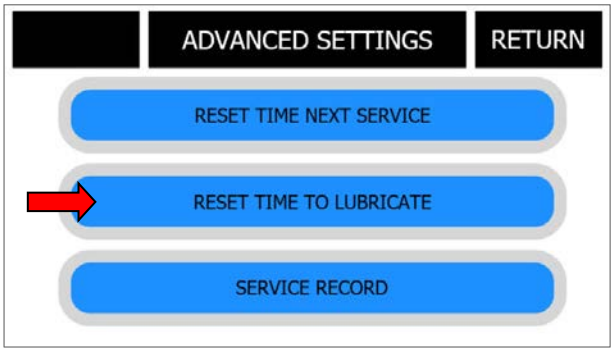


Fig. 50 Advance settings screen

- Press "RESET TIME TO LUBRICATE" after lubricating guide tracks and brace seats.

NOTE: This function is password-protected and it should be activated only after lubrication!

PASSWORD: 8020

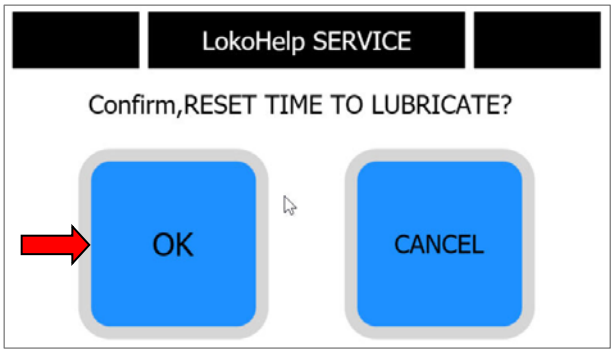


Fig. 51 Confirmation screens

- After entering the password, the LokoHelp® will ask for an action confirmation.
- Press "OK" to confirm.

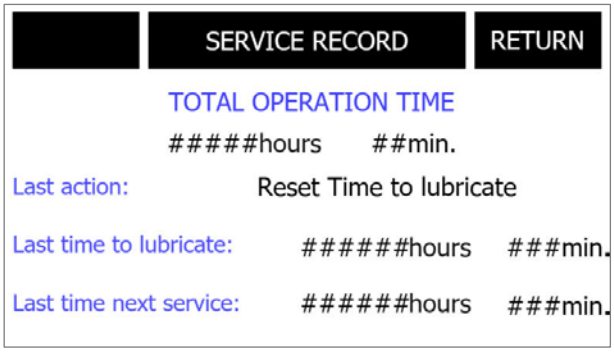


Fig. 52 Service record screens

- After the confirmation, the LokoHelp® will store the last "TIME TO LUBRICATE" counter value in the "SERVICE RECORD".

9.5 Lower Leg Braces

The brace inserts are to be washed with commercial detergents at a water temperature of max. 40°C.

The Velcro fasteners must be closed when washed; otherwise they will lose their ability to function.

Washing Instructions: Washing and care instructions are located on the brace:

10 LokoHelp® Record of Instructions

Once the LokoHelp® gait trainer is delivered, installed, and a function test has been carried out, instruction is to be carried out by a competent **WOODWAY** employee or the authorized **WOODWAY** dealer. All persons who will work with the device in the future must participate in the instruction. As soon as the commissioning and training have taken place, the instruction protocol must be signed by the instructor and all participants and a copy must be sent back to Woodway GmbH.

Step	Description	Status
1	Transfer of operating and maintenance instructions. **Important Notice:** The manual is always to be kept within easy reach of users! The availability of the manual is required and will be checked at each inspection.	☐
2	Reference to the general hazard statements and safety requirements according to the manual. Thereby indicate specific LokoHelp® hazard statements according to area of application (benefit/risk assessment by the therapist, etc.).	☐
3	Special instruction on the stretching warning notice. Danger of injury caused by stretching the patient during lifting operations. When lowering the treadmill during operation, during a power failure and when switching the treadmill off, always extend the length of the rope in body weight support system.	☐
4	Special instruction on the warning notice "Remove mount (crossbar)": Remove this mount when operating without LokoHelp®.	☐
5	Special instruction on the warning notice "Danger from chain drive": Danger of hand injury when device is running. Do not reach into the opening in the chain area.	☐
6	Instruction on selection of the appropriate size patient harness and harness application.	☐
7	Instruction and information on special attention when securing the braces on LokoHelp®.	☐
8	Instruction and demonstration of device safety equipment.	☐
9	Instruction on LokoHelp® operation.	☐
10	Instruction and information on possible LokoHelp® error and service messages.	☐
11	Instruction and information on the implementation of regular and recurring maintenance intervals.	☐
12	Instruction on proper lubrication and cleaning.	☐
13	Explanation of possible errors that will lead to disabling of the treadmill:	☐
14	Final photographs of the device from two different perspectives (Include with the instruction record).	☐

LokoHelp® Record of Instructions

Confirmation of commissioning and training record

With the signing of the instruction record, the instructor and the customer confirm the carrying out of qualified instruction and commissioning. Disregarding of warnings, safety requirements, intended and the prohibited use, as well as unauthorized or improper maintenance and/or repair and/or technical safety inspection can cause injury or even death, and/or may damage the device and/or lead to loss of all material defect liability claims and any other liability claims. Please fill out the instruction protocol completely and return it to **WOODWAY**.

LokoHelp® gait trainer

Serial no.: _____

Model: _____

The above device was properly set up / installed on: _____ (Date)

Technical instruction was completed on: _____ (Date)

Place of transfer / instruction: _____

_____

_____

The following persons received instructions:

_____ (Name and function) _____ (Signature)

_____ (Name and function) _____ (Signature)

_____ (Name and function) _____ (Signature)

_____ (Name and function) _____ (Signature)

Remarks: _____

_____

_____

_____ (Location, Date) _____ Name (printed capital letters) and signature Instructor (Medical device consultant)

11 Guidance and Manufacturer´s Declaration

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Statement

LokoHelp® is a MEDICAL ELECTRICAL EQUIPMENT and needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

Declaration

The device under test has no essential performance.

⚠ WARNING

Danger of injury due to lack of qualifications!

Device LokoHelp® conforms to EN 60601-1-2:2015 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- ► The use of accessories and cables other than those specified by manufacturer, with the exception of cables sold by Distributor as replacement parts for internal components, may result in increased emission or decreased immunity of the device. The braces may not be held by hand during therapy.
- ► LokoHelp® should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- ► Refer to further guidance below regarding the EMC environment in which the device should be used.

ELECTROMAGNETIC EMISSIONS for all ME EQUIPMENT and ME systems (See IEC 60601-1-2:2015, chapter 6.8.3.201 a) 3)		
Emission Test	**Compliance**	**Electromagnetic Environment Guidance**
RF-emission CISPR 11	Group 1 Class B	The LokoHelp® use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF-emission CISPR 11	Group 1 Class B	The LokoHelp® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	complies	

Electromagnetic IMMUNITY - for all ME EQUIPMENT and ME systems (see IEC 60601-1-2:2015, Chapter 6.8.3.201 a) 6)			
The LokoHelp® is suitable for use in a specific electromagnetic environment. The customer and/or the user of the LokoHelp® should assure that it is used in an electromagnetic environment as described below.			
Immunity Test IEC 61000-4-2Stor	**IEC 60601 IEC 61000-4-2**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	< 5 % *UT* (>95 % dip in *UT*) for ½ cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles < 5 % *UT* (>95 % dip in UT) for 5 sec	< 5 % *UT* (>95 % dip in *UT*) for ½ cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles < 5 % *UT* (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the LokoHelp® requires continued operation during power mains interruptions, it is recommended that the LokoHelp® be powered from an uninterruptible power supply or a battery. Warning! For its effective propulsion systems LokoHelp® devices need very powerful emergency generators.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the mains (AC) voltage before apply test levels			

Guidance and MANUFACTURER'S declaration - electromagnetic IMMUNITY - for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201. b)			
The LokoHelp® is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.			
Immunity Test	**IEC 60601-Level**	**Compliance - Level**	**Electromagnetic Environment Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the LokoHelp®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}17 \ 1/V*\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1,17 1/V*√P for 80 MHz to 800 MHz
			d = 2,33 m/V*√P for 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the re-commended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level b in each frequency range.  Interference may occur in the vicinity of equipment marked with the symbol described lateral.
Note 1: At 80 MHz and 800MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretical-ly with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the LokoHelp® is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the LokoHelp®. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Manufacturer's declaration – Recommended Separation Distances between portable and mobile HF-communications equipment and the product			
The LokoHelp® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LokoHelp® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LokoHelp® – according on output power and frequency of the communications equipment – as recommended in the following table.			
Rated maximum output power of transmitter in watts (W)	**Separation distance according to the frequency of transmitter in meter (m)**		
	150 kHz to 80 MHz d = 1,17 1/V*√P	**80 MHz to 800 MHz** d = 1,17 m/V*√P	**800 MHz to 2,5 GHz** d = 2,33 m/V*√P
0,01 W	0,12 m	0,12 m	0,23 m
0,1 W	0,37 m	0,37 m	0,74 m
1 W	1,17 m	1,17 m	2,33 m
10 W	3,69 m	3,70 m	7,37 m
100 W	11,67 m	11,7 m	23,3 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals			

12 Incident Report

According to European Medical Device Regulation (MDR 2017/745) Vigilance Reporting Requirements and MEDDEV 2.12-1

Reporting of a suspected serious incident:

The user and / or patient must report all serious incidents that occur in connection with the product to the manufacturer and the competent authority of the EU member state in which the user and / or patient is resident.

By reporting a suspected serious incident, you can help obtain more information about the safety of this device.

13 Disposal

The disposal of the equipment must be in accordance with the respective national regulations.

Electrical and electronic devices must be disposed of separately from normal household waste.

An appropriate waste disposal company should be contacted. Properly dispose of the device at the end of its service life
(e.g. the local collection point for waste separation):

- The device packaging is disposed of through resource recycling.
- The metal parts of the machine go to scrap metal disposal.
- Plastic parts are given to plastic recycling.
- Electric components and printed circuit boards are disposed of as electronic scrap.
- Rubber parts are disposed of as hazardous waste.

	This symbol indicates electrical and electronic equipment that cannot be disposed of with as standard waste, but must be handled separately. Disposal must be carried out to prevent problems with heavy metals and flame retardants in accordance with relevant waste management. Please contact the manufacturer's authorized representative in order to obtain information concerning disposal of your equipment.
	The disposal of the equipment must be in accordance with the respective national regulations. Wear parts are considered hazardous waste! After being replaced wear parts must be disposed of according to country-specific waste laws.

14 Table of Figures

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