rehmat FOR

walker®

LOWER - EXTREMITY SUPPORT
OKD-32 HKAFO

USER MANUAL

CE

walker®

ATTENTION!

The manufacturer is liable for the proper functioning of the product only if it has been purchased in a specialized medical supply store.

REH4MAT Sp. z o.o. reserves the right to introduce technical and commercial changes to the content of the manual without prior notice.

Medical device, Class I, in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
The manufacturer has issued an appropriate declaration of conformity for the product.

MD **MEDICAL DEVICE CLASS I**

REH4MAT Sp. z o.o. has implemented a quality management system that complies with the ISO 13485 standard for the design of the entire production, sales, and service process.

Contents

1. Purpose and contraindications for use

Przeznaczenie do stosowania:

- cerebral palsy (CP),
- paraplegia/quadriplegia/tetraplegia,
- dyskinesia (athetosis, chorea),
- dystonia,
- spinal muscular atrophy (SMA),
- spinal bifidia,
- small muscles contractures,
- multiple sclerosis (SM),
- abnormal gait pat tern.

Contraindications for use:

- severe muscles and tendons contractures,
- sprain/strain in the lower limb area,,
- severe body asymmetry (high degree of scoliosis, pelvic and/or spinal deformations),
- no medical recommendation to stand up for the patient.

If you have any doubts about using the product, consult a doctor or physical therapist.

2. Product description

2. Product description

STANDARD EQUIPMENT: W1 - Base orthosis.

ACCESSORIES:

T1 - Rigid plastic chest support with height, width and depth adjustment, equipped with soft pressure relief cushions and front stabilizing straps, equipped with a quick release buckle.
Purpose: Individual adjustment of the product to the anatomical and functional needs of the user. Possibility of using the product in the case of lower limbs length differences.

T2 - Soft chest support with suspension - soft band with stabilizing boning stays, quick release system, automatic adjustment system to the patient's body shape, buckles enabling suspension of the patient for rehabilitation in non-weight bearing mode, made of OekoTex100 certified materials, with thermoactive foam and a system of fastening straps.
Purpose: Improving the posture of the user with central hipotonia, including weakness of respiratory muscles.

R1 - Handles - two rear handles attached to the rigid pelvic part of the W1 base orthosis used for guiding the HKAFO by a caregiver during using.
Purpose: Control of the user during walking and improving the physiological gait pattern. Facilitating an alternating gait pattern, improving coordination and balance, and improving movement techniques.

P1 - Dynamic gait support system - system supporting the raising of the lower limbs during walking.
Purpose: Improving knee and hip flexion and raising the limb during walking.

P2/1 - Dynamic gait support system - ONE-SIDED system supporting the raising of the lower limb during walking and its abduction.
Purpose: Improving knee and hip flexion and raising the limb during walking. With the limb properly positioned in a neutral position, dynamic gait support system reflects the natural gait pattern, providing gentle external rotation.

P2/2 - Dynamic gait support system - DOUBLE-SIDED system supporting the raising of the lower limbs during walking and their abduction.
Purpose: Improving the flexion of the knee and hip joints and raising the lower limbs during walking. With the limbs properly positioned in a neutral position, dynamic gait support system reflects the natural gait pattern, providing appropriate external rotation of the limb.

S1 - Foot stir ups - two soft foot stir ups made of tape enabling the suspension of the rehabilitation product in a non-weight-bearing manner, preventing it from riding up.

2. Product description

S2 - Dorsal stabilizers - two dorsal feet stabilizers with adjustable width, preventing the HKAFO from falling when used without feet parts.
Purpose: Improving the correct gait pattern when using the product in people with full dorsal-plantar foot flexion and control of the ankle joints.

S3 - Rigid foot part - two professional rigid feet parts with ankle joint angle adjustment and width and length adjustment equipped with a system of stabilizing straps.
Purpose: Improving the gait pattern in the case of foot drop, walking on toes and severe deformations in the ankle or feet joints. Easy adjustment in the case of differences in the structure or deformation of both feet. The rigid sole of the element allows for the proprioception effect during walking and facilitation of appropriate movement patterns in the user's CNS.

S4 - Functional foot part - two soft plastic parts with adjustable width and stabilizing straps.
Purpose: Improve gait pattern. The slight sole's elasticity allows the use of the products even in the case of mild and moderate deformations in the foot and ankle joints and chronic walking on toes. Independent adjustment of both feet. Semi-rigid sole that bends slightly during use, compensates for the effect of rolling the foot during walking. Provides the effect of proprioception during walking, facilitating appropriate movement patterns in the user's CNS.

S4/P - Raising foot bands - dynamic braces preventing foot drop, for use only with S4.
Purpose: Improving of gait pattern through correct foot positioning and elimination of toe walking in CP. Improvement of dorsal flexion of the feet in the case of previous strokes, hemorrhages and other neurological conditions.

3. Safety rules

1. Before use, carefully read the user manual. Keep it for future reference. Using the product contrary to the instructions may result in serious complications.
2. The product is intended to be used by the user together with a caregiver only on an even, hardened surface.
3. The caregiver must be an adult who is physically and mentally fit.
4. Under no circumstances may the caregiver use the product while under the influence of intoxicants or medications that may impair their fitness, orientation, or coordination.
5. If any alarming symptoms occur during use (e.g., fainting, weakness) in either the caregiver or the user, the product must be stopped immediately, and the user must be safely removed from it. Each such incident must be reported to the attending physician or physiotherapist.
6. Remember that using the product on stairs is strictly prohibited!
7. For the safety of both the caregiver and the user, inspect the product before each use. Ensure that there are no damages, tears, frays on straps, seams, or other soft parts, and that the rigid components are not damaged. Do not use incomplete or damaged equipment! This may cause serious injury to both the caregiver and the user. Only an undamaged product and its correct use guarantee proper and safe functioning of the orthosis.
8. Before each use, check that all user restraint straps are securely fastened. Make sure they do not come undone under load. Improper fastening and stabilization may cause the user to slip out, fall, and sustain serious injuries!
9. Do not use the product near open flames. This poses a danger during use and may cause serious injury to the user and caregiver.
10. The product must not be modified independently. Any interference (sewing on elements, attaching, detaching) or use contrary to the instructions increases the risk of injury to both caregiver and user.
11. Adjusting circumferential ranges with Velcro, straps, or buckles must only be done with the user in a lying position. Do not adjust fastenings while standing! This may lead to a fall and serious injury to both the user and caregiver.
12. When adjusting the product, follow the guidelines in the "Instructions for Use" section of this manual. The product must always be put on and taken off in a lying position.
13. Maintain the product in a clean condition, following the rules of care and cleaning. Cleaning must be carried out regularly to ensure it remains in proper condition. Do not clean the product while it is in use.
14. Make sure the hip belt is fastened at the level of the pelvic girdle. Fastening it at the lumbar level may result in serious pain-related consequences.
15. User stabilization must only take place while wearing shoes. High-heeled shoes, platform shoes, slippers, sandals, and similar footwear must not be used when operating the product.
16. The product straps must not be fastened too loosely. They must also not be twisted or rolled up.
17. Before each use, ensure that the product is properly fitted to the user. Check that the straps do not chafe the skin or press too tightly on any part of the body. The user should feel comfortable in the product and be able to breathe freely.

3. Safety rules

18. The product should not come into direct contact with bare skin. If abrasions, pressure marks, or redness appear on the user's body, check whether the product has been fastened too tightly. If slightly loosening the straps does not help, discontinue use immediately and consult the attending physician or physiotherapist.
19. The manufacturer is responsible for the proper functioning of the product only if it has been purchased from an authorized distributor or a specialized medical store.
20. Do not exceed the maximum allowable load of the orthosis!
21. The manufacturer is only responsible for hidden defects or damages that occur during proper use as a result of a manufacturing defect.
22. The product must not be used in a manner inconsistent with its intended purpose. Using the product contrary to the instructions may result in serious complications.
23. Incorrect configuration of the device may lead to side effects such as fainting, body deformities, joint overload, etc. If these occur, immediately stop using the product, remove the user from the device, and lay them down. If adverse symptoms persist, contact a physician or physiotherapist immediately. If the symptoms subside, inform the attending physician or physiotherapist so that they may decide on the continuation of the rehabilitation process. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the member state in which the user resides.
24. Before using the product, remove all paper and plastic packaging. The packaging is not a toy! Keep away from children and animals.

4. Maintenance and cleaning

Soft elements of the product, i.e. chest belt, hip belt, padding inside the orthosis, straps:

- hand wash in lukewarm water with soap at 30°C,
- rinse thoroughly,
- do not iron or bleach,
- do not dry clean or tumble dry,
- do not store in damp places,
- avoid high temperatures and dry away from heat sources.

Footrests, rigid elements of the orthosis:

- do not wash, do not rinse,
- wipe with a damp cloth,
- use mild cleaning agents, preferably soap.

5. Product adjustment

Rigid trunk support
(or soft trunk corset)
accessories

Handles
accessories

Pelvic support

Buttock pad

Thigh supports

Knee pads

Calf supports

Rigid footers (foot stir ups,
dorsal stabilizers or functional foot part)
accessories

5. Product adjustment

5.1 Calf supports adjustment

The circumferential adjustment of the calf supports is carried out by:

- loosening the knobs,
- sliding the pads to the desired width,
- tightening the knobs.

After completing the adjustment, wrap the calves with the straps to ensure the proper level of compression. The straps are fastened with Velcro.

5. Product adjustment

5.2 Knee pads assembly

The knee pads have a central opening that does not exert pressure on the kneecap.

The knee pads are attached to the orthosis with straps threaded through loops and fastened with Velcro.

Each pad can be adjusted according to the user's needs by regulating it with the fastening straps.

The straps can be trimmed as needed.

5. Product adjustment

5.3 Flexion and extension adjustment in the knee joints

The orthosis is equipped with lateral splints that feature a flexion and extension lock for the knee joints.

Flexion lock range:

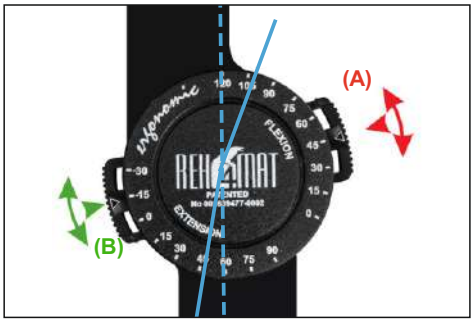
0°, 15°, 30°, 45°, 60°, 75°, 90°, 105°, 120°

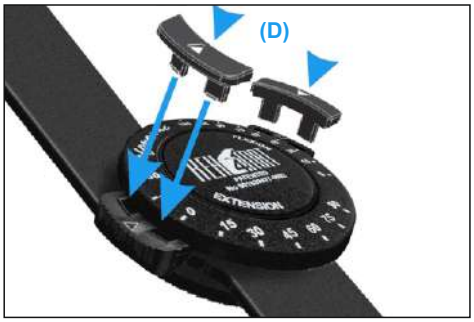
Extension lock range:

-30°, -15°, 0°, 15°, 30°, 45°, 60°, 75°, 90°

Adjustment must be made on both sides of each limb.

Failure to set symmetrical values on both sides of the limb may result in damage to the adjustment locks.





1. Set the approximate position where you want to limit flexion (A) or extension (B).
2. While pressing the stoppers (A) and (B), move them around the dial to the desired position marked with the angle value.
3. Lock the stoppers using the locks (D) supplied with the product.
4. Check the correct operation and range of motion of the dials.

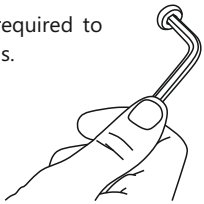
5. Product adjustment

5.4 Thigh supports adjustment

Adjustment of thigh supports height:

- undo the circumferential straps to access the thigh support height adjustment,
- use an Allen key to loosen the screws located on both sides of each support,
- slide the rails to the desired height,
- tighten the screws.

An Allen key in size 3 mm is required to adjust the height of the thigh pads.



5. Product adjustment

5.4 Thigh supports adjustment

Circumferential adjustment of the thigh supports is done by:

- loosening the knobs,
- sliding the supports to the desired width,
- tightening the knobs.

After completing the adjustment, wrap the thighs with the straps, ensuring a level of compression tailored to the user.

The straps are fastened with Velcro.

5. Product adjustment

5.5 Buttock pad adjustment

The buttock cover is mounted and adjusted using straps with adjusters, threaded through the orthosis frame.

5. Product adjustment

5.6 Flexion and extension adjustment in the hip joints

The orthosis is equipped with lateral rails featuring flexion and extension locks for the hip joints.

Flexion lock settings:

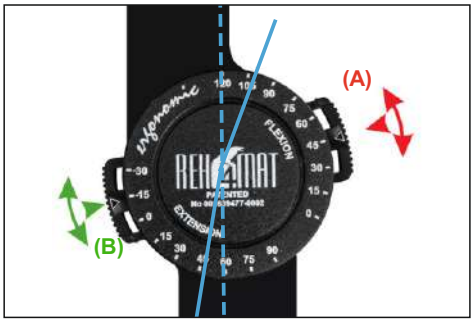
0°, 15°, 30°, 45°, 60°, 75°, 90°, 105°, 120°

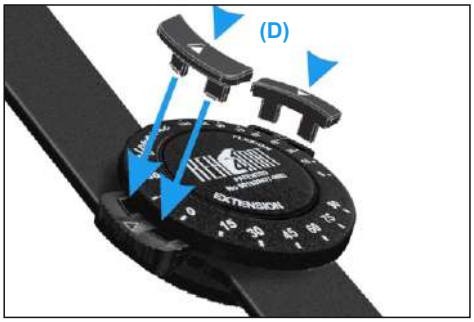
Extension lock settings:

-30°, -15°, 0°, 15°, 30°, 45°, 60°, 75°, 90°

Adjustments must be made on both sides.

Asymmetrical settings may cause damage to the adjustment locks.





1. Set the approximate position where you want to limit flexion (A) or extension (B).
2. While pressing the stoppers (A) and (B), move them around the dial to the desired position marked with the angle value.
3. Lock the stoppers using the locks (D) provided with the device.
4. Check the proper function and range of motion of the dials.

5. Product adjustment

5.7 Pelvic support adjustment

The pelvic support can be adjusted in height, width, and front-to-back positioning.

The width of the hip pad is adjusted by:

- loosening the knobs,
- sliding the pad to the desired width,
- tightening the knobs.

A 3 mm Allen key is required to adjust the height and/or front-to-back position. You should:

- loosen the screws,
- adjust the height and/or front-to-back position of the pad,
- tighten the screws.

5. Product adjustment

5.7 Pelvic support adjustment

After completing the adjustment, fasten the pelvic support strap, which is secured with Velcro. Additionally, secure the user with the buckle strap. The strap can be adjusted by tightening.
Attach the protective cover to the back of the pelvic support, at the width adjustment area.

5. Product adjustment

5.8 Footers assembly - accessories

There are four available accessory options designed to support the feet:

- foot stir ups,
- dorsal stabilizers,
- rigid foot part,
- functional foot part.

FOOT STIR UPS - two soft foot stir ups made of tape enabling the suspension of the rehabilitation product in a non-weight-bearing manner, preventing it from riding up.

DORSAL STABILIZERS - two dorsal feet stabilizers with adjustable width, preventing the HKAFO from falling when used without feet parts.

RIGID FOOT PART - two professional rigid feet parts with ankle joint angle adjustment and width and length adjustment equipped with a system of stabilizing straps.

FUNCTIONAL FOOT PART - two soft plastic parts with adjustable width and stabilizing straps.

FOOT STIR UPS

DORSAL STABILIZERS

RIGID FOOT PART

FUNCTIONAL FOOT PART

5. Product adjustment

5.8 Footers assembly - foot stir ups

Foot stir ups are straps that allow the device to be suspended for unloaded rehabilitation, preventing it from slipping upward.

A 3 mm Allen key is required for assembly.
The stirrups must be installed on both sides.

Foot stir ups feature an adjuster that allows their length to be customized.

5. Product adjustment

5.8 Footers assembly - dorsal stabilizers

After inserting the stabilizer mounting rails, adjust their height and secure them with the mounting screws.
A 3 mm Allen key is required for assembly.
Once the assembly is complete, cover the rails with protective covers - they can be trimmed to the desired height.

5. Product adjustment

5.8 Footers assembly - rigid foot part

After inserting the rigid foot part mounting rails, adjust their height and secure them with the mounting screws.
A 3 mm Allen key is required for assembly.
Once installation is complete, cover the rails with protective covers - these can be trimmed to the desired height.
The rigid foot part offer width and length adjustment.

A 3 mm Allen key is required to adjust the length and width.
After loosening the mounting screws, make the necessary adjustments.
Once adjusted, tighten the screws.

5. Product adjustment

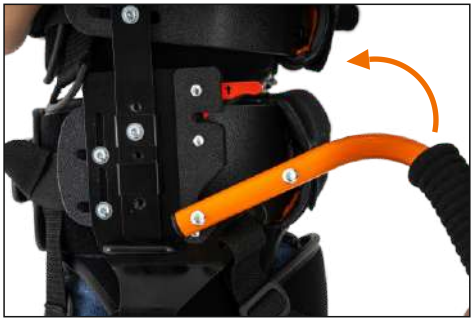
5.8 Footers assembly - functional foot part

After inserting the functional foot part mounting rails into the orthosis, adjust their height and secure them with the mounting screws.
A 3 mm Allen key is required for assembly.
Once assembly is complete, cover the rails with protective covers - these can be trimmed to the desired height.
The functional foot part offer width adjustment.

5. Product adjustment

5.9 Handles assembly - accessories

The handles should be inserted into the mounting points on both sides of the orthosis.
When correctly assembled, you should hear characteristic "CLICK" indicating that they are locked in place.
To remove them, pull up the red release element and take out each handle.



5. Product adjustment

5.10 Rigid trunk support assembly - accessories

Rigid trunk support rails should be inserted into the mounting points located on the side panels of the orthosis at the desired height - the rails have holes that must be aligned symmetrically on both sides.

Secure them with the mounting screws.

A 3 mm Allen key is required for assembly.

A 3 mm Allen key is required to adjust the front-to-back position. You should:

- loosen the screws,
- adjust the front-to-back position of the pad,
- tighten the screws.

5. Product adjustment

5.10 Rigid trunk support assembly - accessories

The rigid trunk support can be adjusted in width by:

- loosening the knobs,
- sliding the pad to the desired width,
- tightening the knobs.

Attach a protective cover at the back, at the width adjustment area.

After completing the adjustment, fasten the trunk support strap, which is secured with Velcro. Additionally, secure the user with the buckle strap. The strap can be adjusted by tightening.

5. Product adjustment

5.11 Soft trunk corset assembly with suspension - accessories

Trunk corset rails should be inserted into the mounting points located on the side panels of the orthosis at the desired height — the rails have holes that must be aligned symmetrically on both sides.

Secure them with the mounting screws.

A 3 mm Allen key is required for assembly.

The trunk corset is fastened with a Velcro strap, adjusting its circumference to the user.
The suspension straps have additional tightenings that allow length adjustment for suspension.
The trunk corset features buckles that enable quick release of the orthosis from the suspension.

5. Product adjustment

5.12 Dynamic gait assistance system assembly - accessories

A 3 mm Allen key is required for assembly.

5. Product adjustment

5.13 Soft footers lifts assembly - accessories

Before mounting the footer lifts, remove the shorter straps with eyelets, which are the front foot stabilizing straps.

5. Product adjustment

5.13 Soft footers lifts assembly - accessories

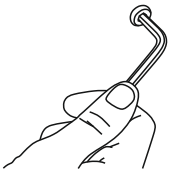
5. Product adjustment

5.14 Buttock straps assembly - accessories

5. Product adjustment

5.15 Ankle joint range of motion setting

The dials are locked using a 1.5 mm Allen key.



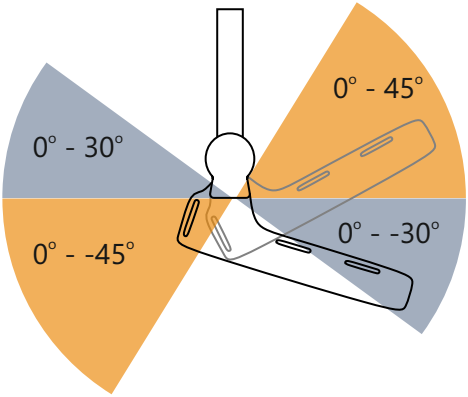
The range of motion of the ankle joints is set by inserting screws into the holes corresponding to the specified angle values.

Turn the screw clockwise to tighten.

Turn the screw counterclockwise to loosen.

The adjuster allows limitation of flexion and extension in the ankle joints. Adjustment is made on both sides for each lower limb.

The holes located closer to the heel part of the footer correspond to extension limitation, while the holes on the opposite side control the flexion angle limitation in the ankle joint.



Flexion lock settings: -30°, -15°, 0°, 15°, 30°, 45°
Extension lock settings: -45°, -30°, -15°, 0°, 15°, 30°

6. Technical inspection

Technical inspections should be carried out regularly. Before performing any maintenance, the device should be thoroughly cleaned to reveal any hidden damage.

FREQUENCY	WHAT SHOULD BE CHECKED	WHAT SHOULD BE DONE	REMARKS
BEFORE EACH USE	General condition of the product. Check: • the entire product for visible damage, cracks, and mechanical defects, • whether the product is complete, • whether all screws, bolts, knobs, nuts, and other structural components are present and properly tightened.	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.	
	Attachment of components. Inspect all mechanisms and moving parts of the device, paying particular attention to: • correct installation and functioning of user safety components, • whether all moving parts are complete, move through their full range, and do not jam, • proper functioning of adjustment mechanisms (if applicable).	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.	
	Upholstery elements. Check: • upholstery elements for any damage, tears, cracks, loose seams, or deformation, • whether user stabilization straps and safety belts are not frayed, twisted, and that buckles and clasps function properly, • whether user stabilization straps and safety belts are correctly installed and do not come undone under pressure or pulling.	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.	

6. Technical inspection

Technical inspections should be carried out regularly. Before performing any maintenance, the device should be thoroughly cleaned to reveal any hidden damage.

FREQUENCY	WHAT SHOULD BE CHECKED	WHAT SHOULD BE DONE	REMARKS

ONCE A WEEK

Cleaning the product.

Wipe the frame and upholstery of the product to remove dirt from daily use (such as dust, mud, or other contaminants) using a damp cloth with a mild, commonly available cleaning agent.
Remove debris (e.g., hair, food residues, etc.) from the moving parts of the device.

The product should be cleaned whenever necessary, but at least once a week. Do not use any cleaning agents containing chlorine or methyl alcohol.
The upholstery must be dry before using the device.

ONCE A MONTH

Product structural connections (welded, threaded, soldered).

Check:

- the condition of the frame at connection points (welds, threads, solder joints).

In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.

EVERY 6 MONTHS

Moving structural components.

Check:

- the moving structural components for any damage and maintain them using the recommended lubricant.

In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.

Labelling.

Check:

- markings and labels for legibility.

In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.

www.reh4mat.com

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