

USE AND MAINTENANCE HANDBOOK

ORMESA

MADE IN ITALY SINCE 1980



ORMESA thanks you for the confidence placed in choosing our GRILLO gait trainer.

GRILLO is a medical device designed and manufactured by ORMESA srl.

ORMESA then suggests you to read this handbook very carefully. It will help you in becoming familiar with GRILLO soon and more efficaciously, and you will also find many practical pieces of advice to use it safely and in the best possible way and to keep it perfectly efficient.

In the end, should you still have something to ask for or to clear, don't hesitate to contact your Dealer, who will be glad to give you all the necessary assistance, or directly call ORMESA. Our phone number is +39 0742 22927, our fax number is +39 0742 22637 and our E-mail is: info @ormesa.com.

Ormesa Team



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WARNINGS

- Before using the aid carefully read the instructions in this handbook because it was written for your safety and to guide you in the necessary learning process of the right use and Maintenance of this product. It is integrant part of the product and it must be kept with care for future references.
- This handbook is for Dealers, Retailers Assistants and Users; it gives instructions about the correct use of the product and it has to be integrated by an adequate knowledge of the aid by the prescribing specialist.
- The handbook reflects the state of technique at the moment of taking the aid into the market. ORMESA srl reserves the right to carry out any modification to the aid and to its handbook which can be suggested by the experience, by technical considerations or by the change of standards. These modifications will be made without being obliged to update the previous production and its handbooks.
- The use of the gait trainer and its additional parts must be checked by qualified personnel, according to the laws, rules and regulations in force.
- GRILLO can be only used by people who have well read the instructions specified in this handbook.
- Training for the use of GRILLO must be carried out in rehabilitation centres with the help of qualified personnel.
- The walking frame has to be used by people whose body size and weight are just like the ones specified in the paragraph "TECHNICAL SPECIFICATIONS".
- DO NOT use the pelvic and thoracic supports as a support point while transferring the User from the sitting to the standing position and vice versa. The components are in fact destined to be used as anatomical supports in the walking phase. Use the HANDLES for the patient transfer
- Before each use check that all adjustable parts are well locked.
- Always lock brakes when you stop, even on flat ground.
- Always lock brakes before adjusting any part.



Always make sure that there are no obstacles which could cause GRILLO to tip up, such as mats, steps and different objects on the floor. Beware of dangerous points and obstacles in the area of use. Remove any knick-knacks or objects which could be knocked down while using GRILLO.



 Avoid areas near unprotected artificial or natural water basin and water courses.



 Always lock brakes when parking, even on flat ground, and before making any adjustments



 Before each use always check that the components and the green levers for the adjustments are effectively locked



Before each use always check the effectiveness of brakes, the wear of the wheel, the effectiveness of the green lever locking and in general of all those parts that can loosen by the time and use. Should you notice a loss of efficacy, please contact your ORTHOPAEDIC WORKSHOP following the directions on maintenance at pages 67, 68, 69, 70, 71, 72, 73, 74, 75, 76.



GRILLO IS A MECHANICAL MEDICAL DEVICE:



THE USER has to perform REGULAR

MAINTENANCE and CLEANING following the instructions shown in the "Maintenance" chapter on page 67,68, 69, 70, 71, 72, 73, 74,75, 76 and HAVE THE DEVICE INSPECTED AT THE INTERVALS INDICATED to VERIFY that it is WORKING PROPERLY and in GOOD CONDITION, otherwise warranty will fail and (marking will lapse



PRODUCT REPAIRS other than the regular maintenance shown on page 67,68, 69, 70, 71, 72, 73, 74,75, 76 of the manual must be ONLY MADE by a SPECIALIZED SERVICE CENTER in the maintenance of mechanical aids for disables, otherwise warranty and € marking will be voided



Any CHANGES in the product ARE NOT

AUTHORIZED. REFER ONLY TO ORMESA,

otherwise warranty and CE marking will be voided



The REPLACEMENT <u>WITHOUT ORIGINAL</u>

PARTS OR COMPONENTS ARE NOT

AUTHORIZED. REFER ONLY TO ORMESA, <u>otherwise</u>

warranty and C marking will be voided



In case of DOUBT about the SAFETY of the product or DAMAGE to parts or components, you are urged to IMMEDIATELY DISCONTINUE USE and CONTACT a SPECIALIZED SERVICE CENTER in the maintenance of mechanical aids for disables, or directly ORMESA.

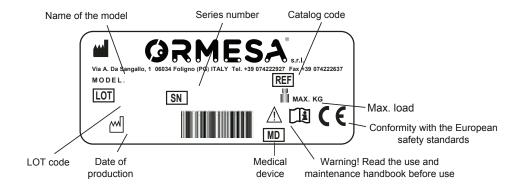


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WHAT NOT TO DO WITH THE PRODUCT

- GRILLO MUSTN'T BE USED UNLESS A MEMBER OF THE USER'S FAMILY OR QUALIFIED PERSON IS PRESENT AT ALL TIME
- DO NOT CARRY OUT ANY OPERATION OR MANOEUVRE UNLESS YOU ARE SURE OF THE RESULT: IF IN DOUBT, CONTACT YOUR NEAREST TECHNICAL SERVICE OR CONTACT THE MANUFACTURER DIRECTLY
- GRILLO MUST BE USED BY PEOPLE WHOSE HEIGHT AND WEIGHT ARE SUFFICIENT TO CONTROL ITS MOVEMENTS
- NEVER INSERT COMPONENTS OR COMPONENTS ON THE DEVICE WITHOUT FOLLOWING THE INSTRUCTIONS GIVEN IN THE HANDBOOK
- DO NOT ADJUST THE FRAME AND THE COMPONENTS IN EXTREME POSITIONS IN ORDER NOT TO PREJUDICE THE STABILITY AND SAFETY OF THE DEVICE
- NEVER USE GRILLO ON UNEVEN GROUND. STEEP SLOPES OR STAIRS
- NEVER ALLOW UNKNOWN PEOPLE TO USE GRILLO
- NEVER LEAVE THE USER UNATTENDED WHILE USING GRILLO
- NEVER LEAVE GRILLO ON A SLOPE
- NEVER LIFT THE AID TO MOVE IT WHILE THE USER IS ON IT
- AVOID EXCESSIVE SPEED OF MOVEMENT TO GUARANTEE STABILITY AND SAFETY OF THE DEVICE
- NEVER USE GRILLO IF THERE ARE DAMAGED OR MISSING PARTS

LABELS AND PLATES



THE CE MARKING CERTIFIES THAT GRILLO CONFORMS TO THE SAFETY REQUIREMENTS defined with the REGULATION (EU) 2017/745 OF THE EURO-PEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 applicable for MEDICAL DEVICE



⚠ GUARANTEE

ORMESA warrants the product for 2 years; in case of problems, contact the retailer where you purchased it. Always ask for original parts and components.

ORMESA will not be liable for damage in the following cases:

- use by an unsuitable person;
- incorrect assembly of parts or components;
- unauthorized modifications or service:
- use of other than original replacement parts and parts subject to wear (upholstery, wheels, etc);
- improper use (such as, transporting objects or loads larger or heavier than those shown in the instruction manual);
- damage caused by incorrect use and lack of regular maintenance, as shown in the instruction manual;
- exceptional events;
- failure to follow the instructions in this manual.

THE GUARANTEE DOES NOT COVER WEAR PARTS, which are subject to wear and tear, such as the upholsteries and the wheels.



HOW TO STORE AND TRANSPORT THE MEDICAL DEVICE

THE DEVICE MUST BE STORED AND PACKED using the Ormesa original packaging materials. THE AID MUST BE ALWAYS ACCOMPANIED BY THE PRESENT HANDBOOK unless the guarantee will be voided.

- Once unpacked, THE TRANSPORT OF THE DEVICE must be done by ANCHORING IT ADEQUATELY to the vehicle.
- When travelling by plane, or by car, DO NOT SUBJECT THE FOLDED FRAME TO LOADS THAT, especially with road bumps, COULD DAMAGE ITS STRUCTURE.

THE DEVICE MUST BE PARKED / STORED IN CLOSED AND DRY PLACES

- The operating environment has no particular influence on the device unless it is used incorrectly, such as by leaving it parked for a long time in direct sunlight or exposed to bad weather such as rain, or in marine environments, where the salt air could corrode the paint and the sliding parts. In this case, we recommend to clean and dry the frame carefully following the instructions shown in the "Maintenance and Cleaning" chapter on pages 67, 68, 69, 70, 71, 72, 73, 74, 75, 76 and the warnings △ on page 73.



WHAT GRILLO IS AND WHAT IT IS FOR, INTENDED USE

GRILLO is a gait trainer, that's to say a product that was designed to help and make the independent moving of a User easier. The intended use is for spasthic/distonic users, for subjects with hyposthenia and/or exhaustion of the antigravity response, to subjects with difficulty in coordination and motor control, and to subjects beginning to ambulate.

It was designed and made for the user to:

- walk without help when independent walking is impossible or not safe enough;
- train and start the walking process so that it may be continued without the aid at a future stage. It can be used to practice the actions of walking or simply as a permanent mean of moving around.

We remind that the process of walking is the movement of a body in an upright position from one point in space to another and it is possible by:

- Supporting reaction, ahead of the force of gravity, even if exhaustible
- maintaining the balance of the trunk and pelvis, first on both feet and then on one only during the moving
- awareness of peripersonal space
- Central Pattern Generator, capable of generating rhythmic patterns of motor activity

GRILLO is used:

- a) to elicit and help the step pattern;
- b) to train in maintaining balance of the trunk and pelvis;
- to organize a wider structured vision of space, distance and the User's surroundings in the upright position;
- to enable the user to plan "projects" and "actions", for example having the
 possibility to see an object, think of its use, work the movement out to reach
 the object and use it;
- e) to develop physical self-sufficiency and psychological independence by experimenting the possibility of acting alone.

HOW GRILLO WORKS

Grillo compensates the user's lack of balance and support thanks to its ergonomic support and wide base, it allows the user to concentrate his/her residual abilities on walking.

The wide range of components and supports offer maximum versatility.

All components are interchangeable quickly and without the use of tools to suit different clinical pictures.

Adequate training to use it must be given at a rehabilitation centre.

The following information will ensure the best way to use this aid.

Adjustment of the aid

Insert wheel stop

As soon as the User is into the aid, the supports must be closed and the straps must be fastened. The following heights must be adjusted:

- the frame height
- the thoracic support height
- the pelvic support height
- the harness height

These adjustments must be made before positioning the user according to the anatomical measures taken.

Once the User has been positioned, you can proceed with a micro adjustment until the optimal setting is reached.



There is no predetermined position!

Each position must be decided according to the User and it must be modified according to his physical development, to the change in his motory situation and rehabilitation programme.

The pelvic support should be adjusted around the higher part of the pelvis at the height of the upper, anterior and posterior iliac spines.

The support of the pelvis and the weight on his feet can be increased or decreased by adjusting the harness height or ergonomic saddle height.

The height of the **thoracic support** is usually adjusted according to the child's ability to control his trunk. If the User has a sufficient trunk control, the chest support may be removed.

THE NEXT STEP IS TO ADJUST THE CORRECT LINE-UP OF THE TWO SUPPORTS ON VERTICAL AND TEST PLANE. THIS IS AN IMPORTANT AND DELICATE OPERATION BECAUSE THE CORRECT POSITIONING OF THE TRUNK ON THE PELVIS DEPENDS ON IT. Use the locking levers to position the **thoracic support** and move the support backwards or forwards.

THE IDEAL POSITION TO LOOK FOR IS THE ONE WHICH LINES SHOULDERS, TRUNK AND HIPS UP.

By pushing the thoracic support further forward as regards to the pelvic support and by putting the hands on the handlebar, the trunk is moved forwards, thus stimulating walking. This position must not be forced, otherwise it might have the opposite effect. The handlebar must be adjusted depending on how much the User has to bend or straighten

The **handlebar** must be adjusted depending on how much the User has to bend or straighten his arms in order to push and guide GRILLO.

WHEN THESE OPERATIONS ARE COMPLETED, GRILLO CAN BE USED AS DESCRIBED BELOW.

First of all it is important to know the aid and how to use it.

Children are not usually afraid to use the aid. On the contrary they are often extremely pleased and happy and they want to move in all directions. These "rash" children must not be prevented from doing so. In fact they should be encouraged. In the first days it is a good idea to let the child use GRILLO freely so that he can try the different ways of using it.

For "fearful" children who are afraid to use GRILLO (probably due to problems of perception which make awareness of space and distance altered) it is better to start its use in a different way.

In his first steps the User mustn't be left alone, but he must be accompanied by qualified personnel either therapist or parent who will stand either in front or to one side and will move GRILLO slowly and gently.

This gives the User a feeling of safeness particularly if the therapist or parent speaks to him at the same time and explains what they are doing (for instance, "now we are going towards the table, we are reaching the TV, we are going to get the ball on the table, we are going back ...")

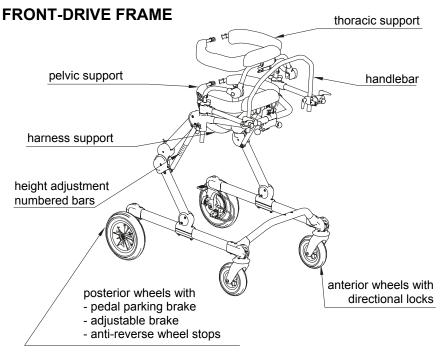
The first steps are always made forwards, then backwards and finally sideways.

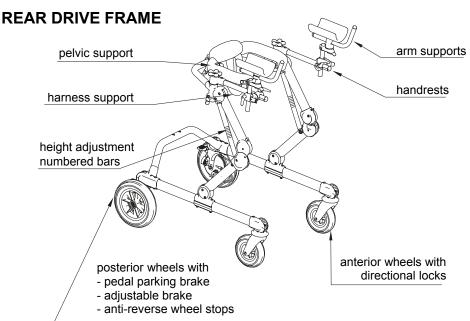
At first walking will be at a constant speed, then a change in step will be asked for so that speed will be faster or slower.

We suggest to follow well defined paths specifically designed to help orientate both "rash" and "fearful" Users

For those children who cannot easily walk, it is better to position the thoracic support forwards respect to the pelvic support in order to get the flexion of the trunk. In this way it will be easier to start moving the lower limbs.

HOW GRILLO IS COMPOSED



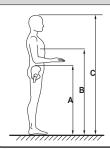




TECHNICAL SPECIFICATIONS - GRILLO GAIT TRAINER

- Available in 3 SIZES [S, M and L] and 2 MODELS (GRILLO Front drive and REAR DRIVE gait trainer).
- ALUMINIUM FRAME, foldable for easy transportation and with PATENTED HEIGHT-ADJUSTMENT SYSTEM.
- PELVIC SUPPORT and THORACIC SUPPORT, padded, independently adjustable in height, width and circumference; allow an easy access thanks to the back opening. They hold the user just like two hands and this gives him/her a sense of security and stability allowing the user to concentrate only on walking without any fear.
- GRADUATED BARS as a reference on height adjustments.
- PELVIC HARNESS, ergonomic, comfortable, adjustable and easily removable for washing. It supports the users in case of necessity without generating painful pressures.
- HANDLEBAR removable and adjustable in height, it is used as a reference and as an armrest.
- Adjustable HANDLES.
- ARM SUPPORTS, adjustable in height, tilting, rotation and depth.
- LUMBAR SUPPORT.
- Manually FOLDABLE SEAT. It gives a support in case of need.
- PROXIMAL ABDUCTOR adjustable in height and foldable.
- Exclusive **ORMESA DESIGN WHEELS**, light and puncture-proof: 2 front swiveling, Ø15 (size "S") and cm 17,5 (size "M" and "L") and 2 rear fixed, Ø cm 20 [size "S"] and Ø cm 25 [size "M" and size "L"].
- DIRECTIONAL LOCKS on front wheels.
- ADJUSTABLE BRAKES.
- ANTIREVERSE DEVICE.
- PEDAL PARKING BRAKE
- SEMI-ELASTIC BUFFERS on front wheels to protect against bumps.
- LEG DIVIDER avoids adduction and helps to follow the right gait pattern.
- PUSH HANDLE FOR THE ASSISTANT
- WEIGHT BARS. They make the aid heavier according to the size: Grillo S + 2,6 kg. (Lbs. 5.7) x2, Grillo M and L+ 3,4 kg. (Lbs. 7.5) x 2
- PAIR OF REAR WHEELS NARROW BASE [for size M and L]

User dimensions



USER HEIGHT (C):

cm 90 -135 GRILLO S cm 110-165 GRILLO M cm 160-190 GRILLO L

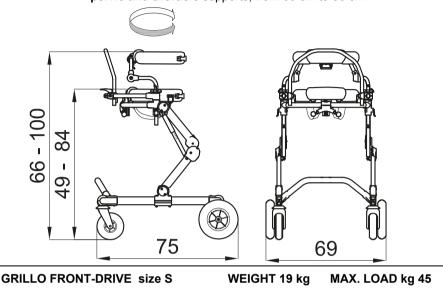
IMPORTANT:

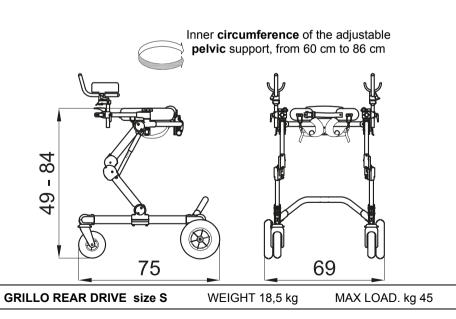
Make sure that measures A and B indicated in the figure do not exceed the suggested range indicated for the supports (see pages 13,14 and 15)



DIMENSIONS in cm

Inner circumference of the adjustable pelvic and thoracic supports, from 60 cm to 86 cm

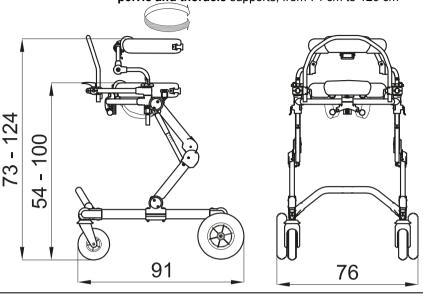






DIMENSIONS in cm

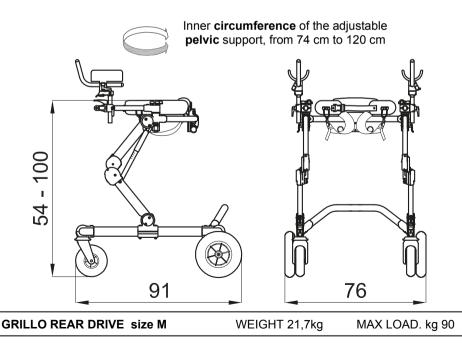
Inner circumference of the adjustable pelvic and thoracic supports, from 74 cm to 120 cm



GRILLO FRONT-DRIVE size M

WEIGHT 22,5 kg

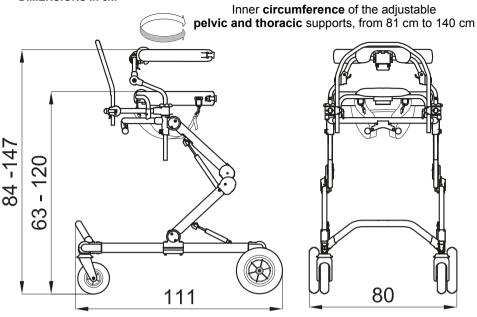
MAX. LOAD kg 90



HYPHEN-SEPARATED NUMBERS INDICATE THE MINIMUM AND MAXIMUM RANGE OF ADJUSTMENT



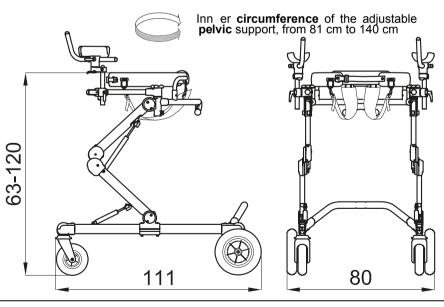
DIMENSIONS in cm



GRILLO FRONT-DRIVE size L

WEIGHT 29.5 kg

MAX. LOAD kg 110



GRILLO REAR DRIVE size L

WEIGHT 28.5 kg

MAX LOAD. kg 110

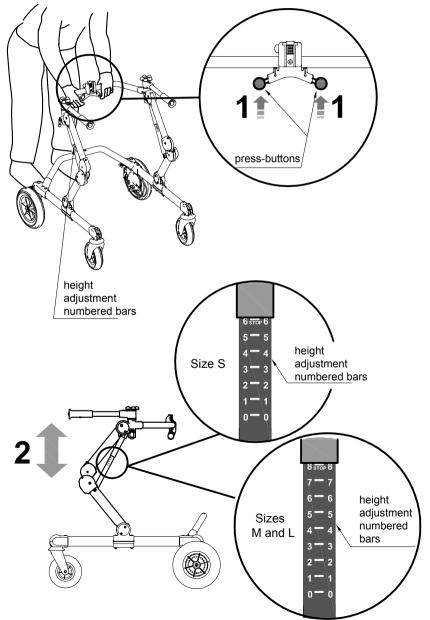
HYPHEN-SEPARATED NUMBERS INDICATE THE MINIMUM AND MAXIMUM RANGE OF ADJUSTMENT



HOW TO USE GRILLO, FRONT DRIVE and REAR DRIVE GAIT TRAINER

FRAME: HEIGHT ADJUSTMENT

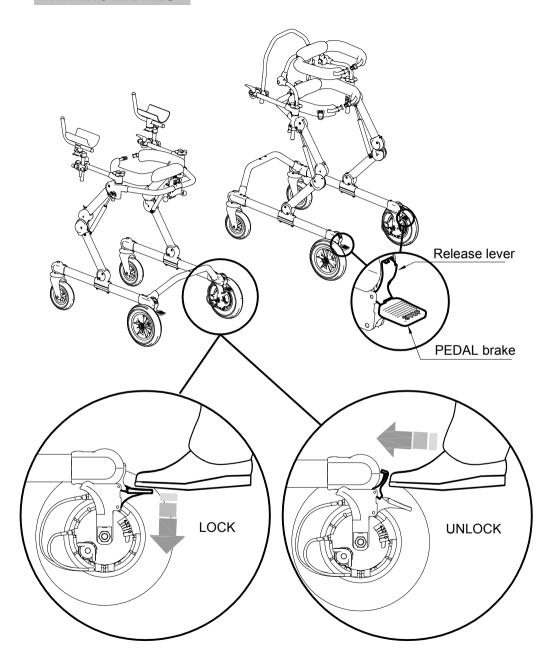
- 1- OPERATE THE ADJUSTMENT KNOBS WITH BOTH HANDS
- 2- ADJUST THE HEIGHT OF GRILLO RELEASING THE ADJUSTMENT KNOBS



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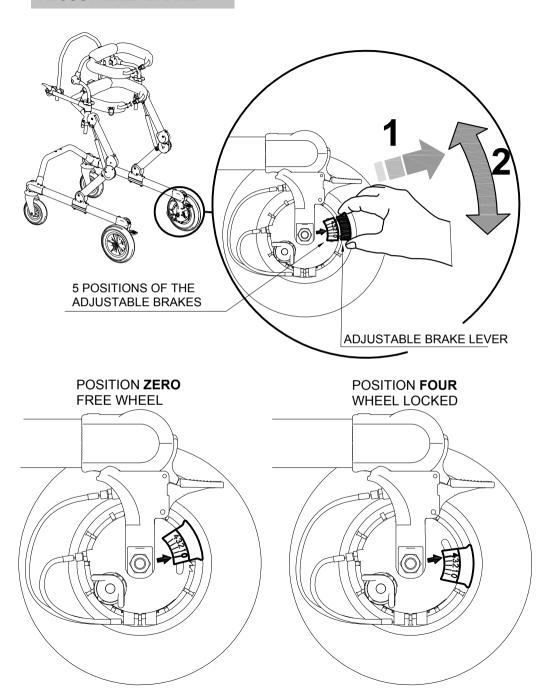


PARKING BRAKES





ADJUSTABLE BRAKE



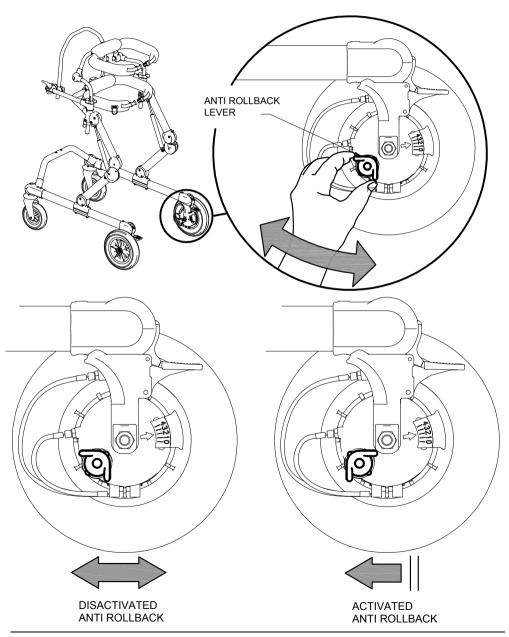


ANTI ROLLBACK DEVICE

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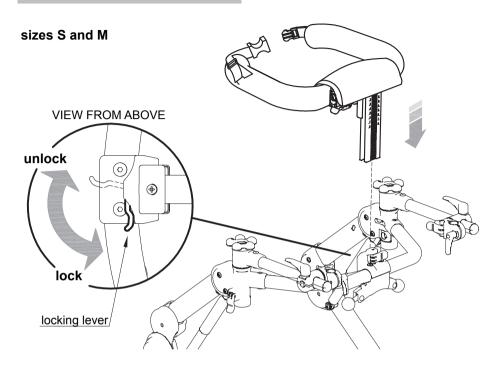
WARNINGS!

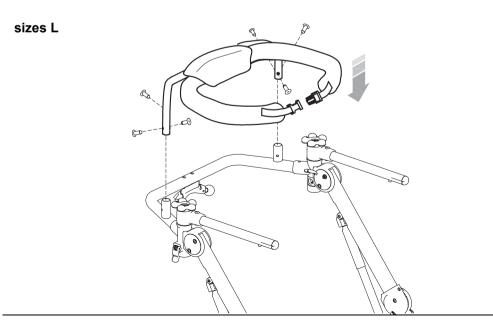
The anti-reverse device reduces the maneuverability of the gait trainer





PELVIC SUPPORT ASSEMBLY

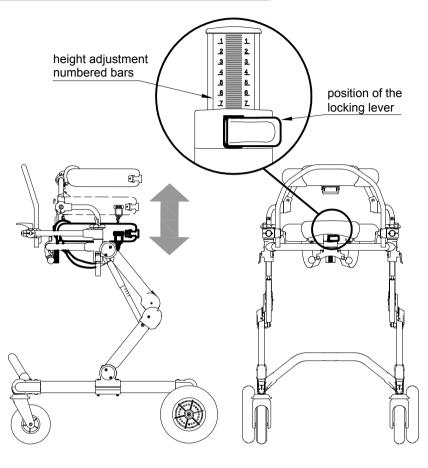


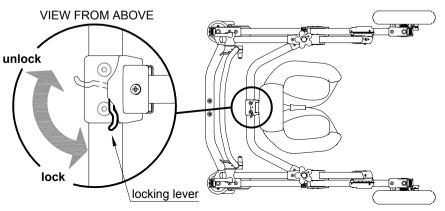


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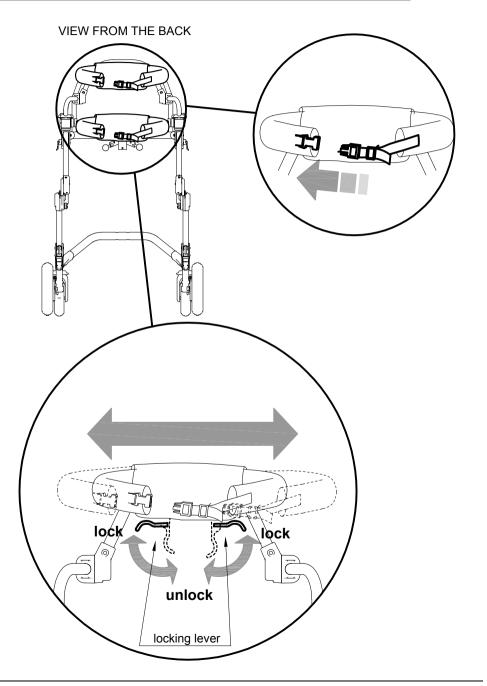
PELVIC SUPPORT: HEIGHT ADJUSTMENT [sizes S and M]





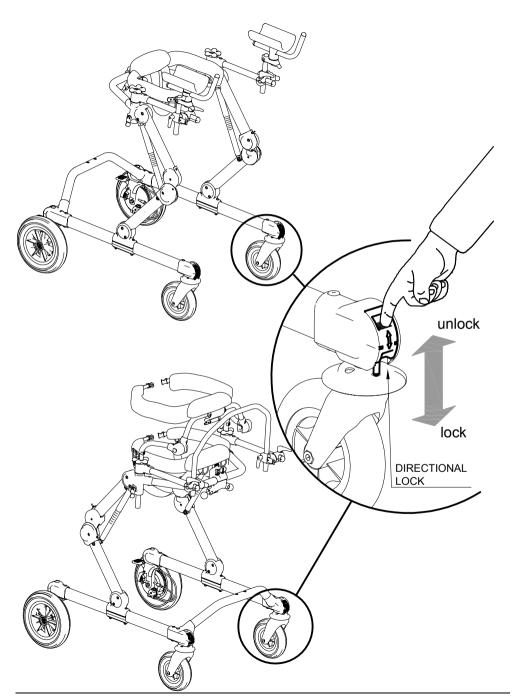


PELVIC AND THORACIC SUPPORTS: CIRCUMFERENCE ADJUSTMENT





DIRECTIONAL LOCKS



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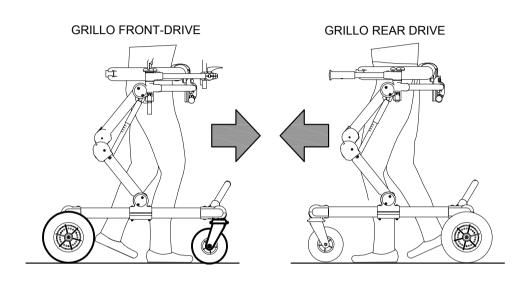


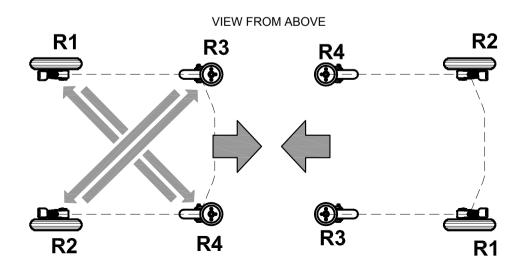
CHANGE GRILLO from REAR DRIVE to FRONT-DRIVE GAIT TRAINER and VICE VERSA

WARNINGS!

This operation must be done by qualified personnel only

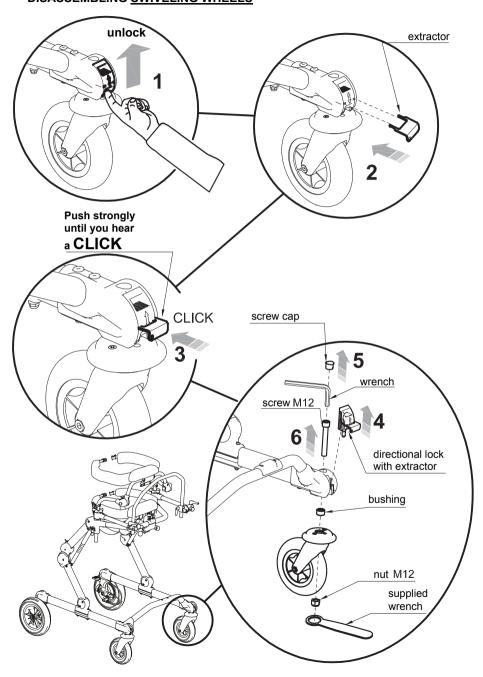
A WHEEL-ASSEMBLING AND DISASSEMBLING SCHEME



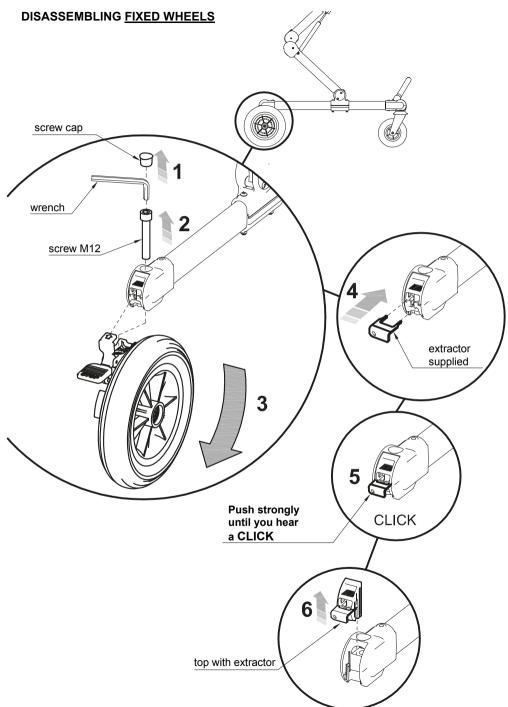




B GRILLO FRONT-DRIVE GAIT TRAINER DISASSEMBLING SWIVELING WHEELS







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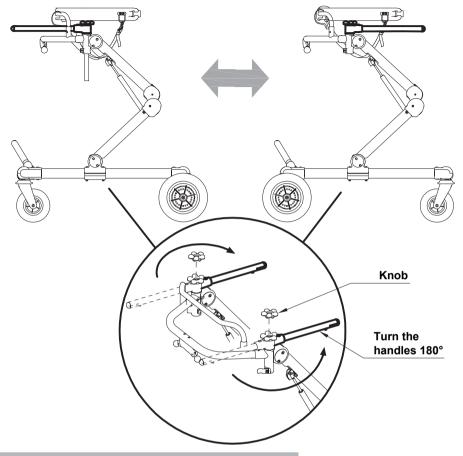


C GRILLO REAR DRIVE GAIT TRAINER: ASSEMBLING THE WHEELS screw cap Wrench M12 screw Tighten Wrench bushing o-ring Wrench screw cap M12 nut directional lock

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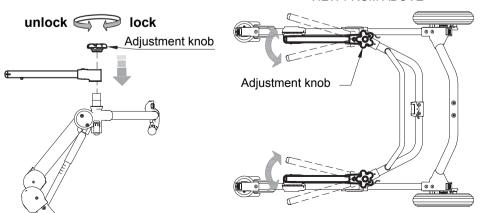
TURNING OF THE HANDLES





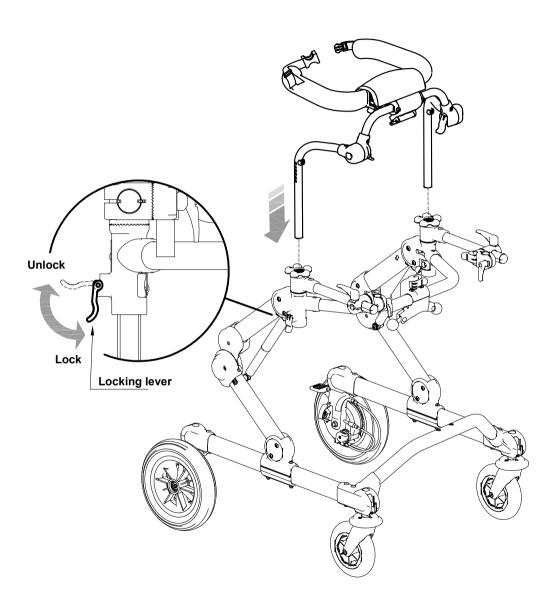
HANDLES: ADJUSTMENTS in WIDTH

VIEW FROM ABOVE



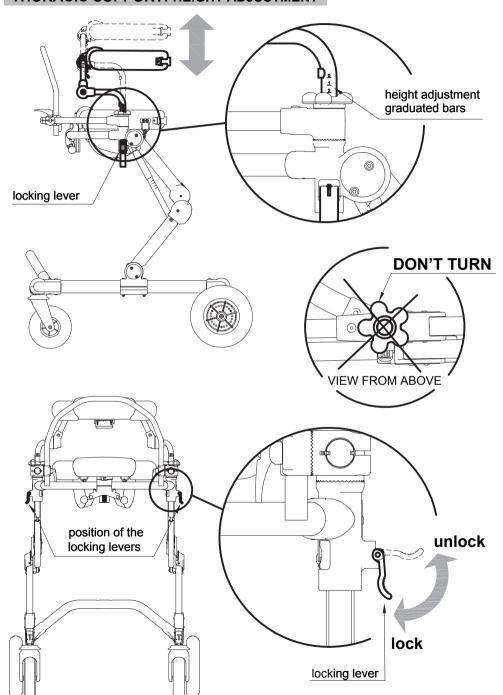


THORACIC SUPPORT ASSEMBLY





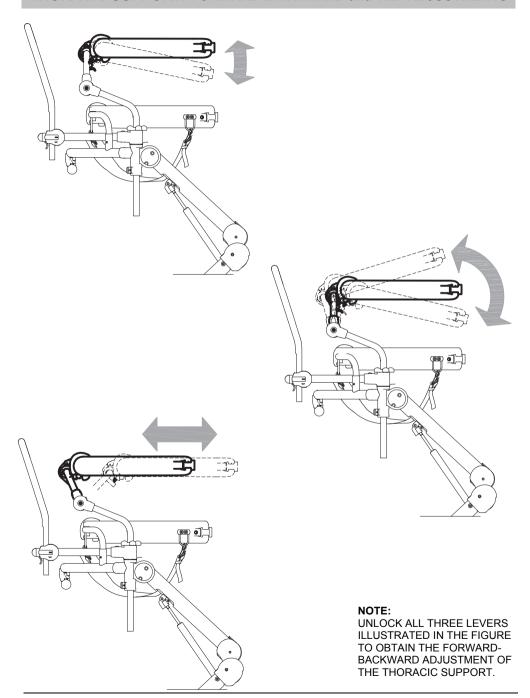
THORACIC SUPPORT: HEIGHT ADJUSTMENT



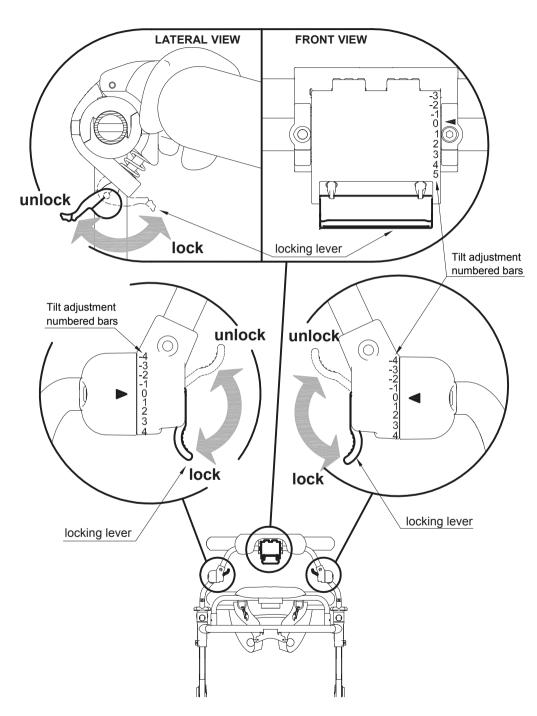
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THORACIC SUPPORT: FORWARD-BACKWARD and TILT ADJUSTMENTS



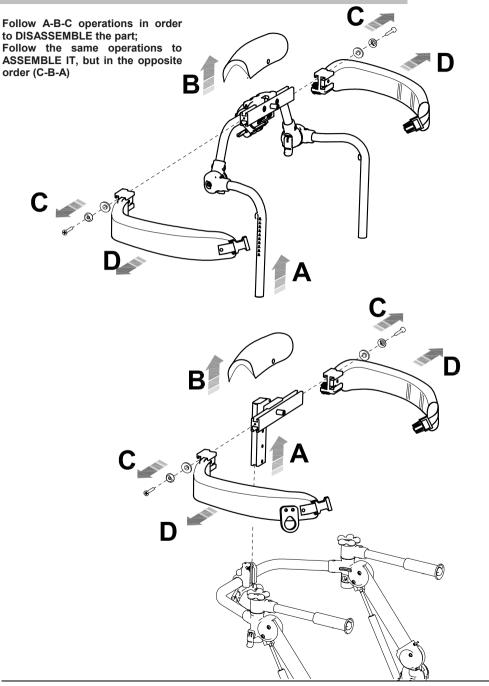




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CHANGING size M PELVIC and TRUNK SUPPORTS WITH size S AND size L WITH size M



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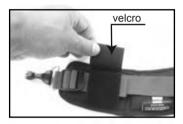


ADJUSTMENTS FOR GRILLO FRONT-DRIVE GAIT TRAINER

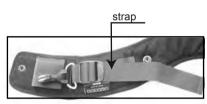
PELVIC HARNESS: ADJUSTMENT sizes M and L



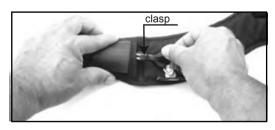
The harness can be reduced as indicated in the following figures:



1- remove Velcro



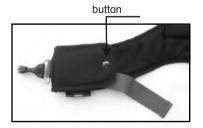
2- shorten the strap



3- insert the clasp in the hole



4- fold the end point of the harness



5- button up



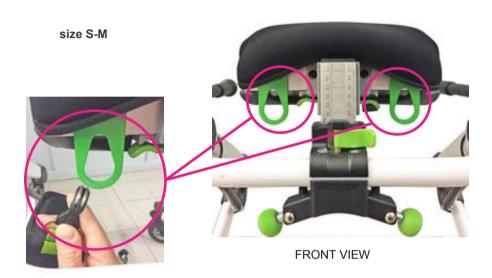
6- reduced harness



PELVIC HARNESS: ASSEMBLY sizes S, M and L

The procedure and harness position are the same, both on the front drive and rear drive models

1) Attach the **two fixed carabiners** on the two hooks on the **front** of the pelvic support, see figure.









2) Keeping the frame of the walker slightly lowered, fix the right inguinal belt with the hook and then proceed with the left one.
Lift the frame of the walker until the correct height for walking is reached.

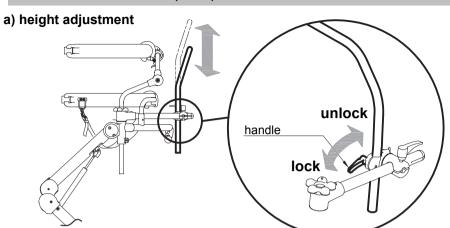


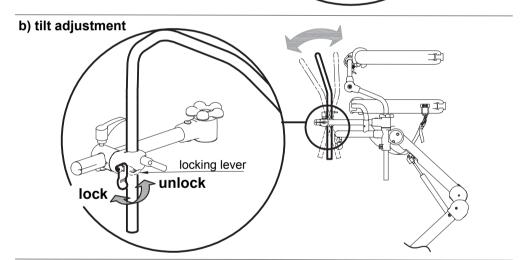
3) Pull the straps until the inguinal belts are tightened.

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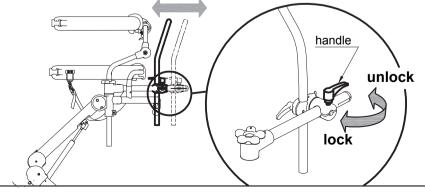


HANDLEBAR: HEIGHT, TILT, FORWARD-BACKWARD ADJUSTMENTS





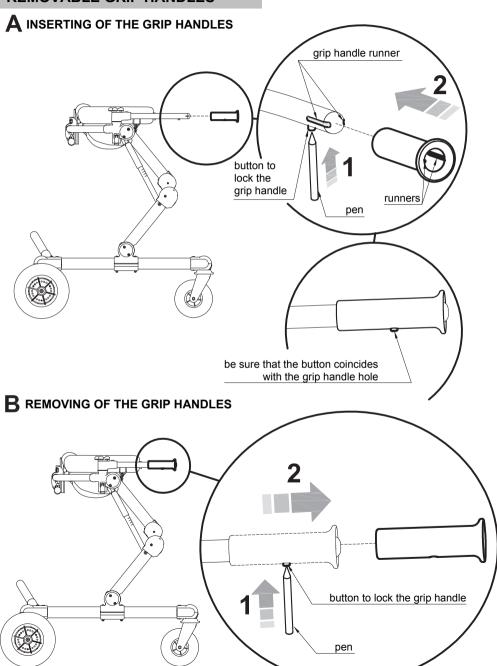
c) forward-backward adjustment





ADJUSTMENTS for GRILLO REAR DRIVE GAIT TRAINER

REMOVABLE GRIP HANDLES



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PELVIC HARNESS: ASSEMBLY AND ADJUSTMENT

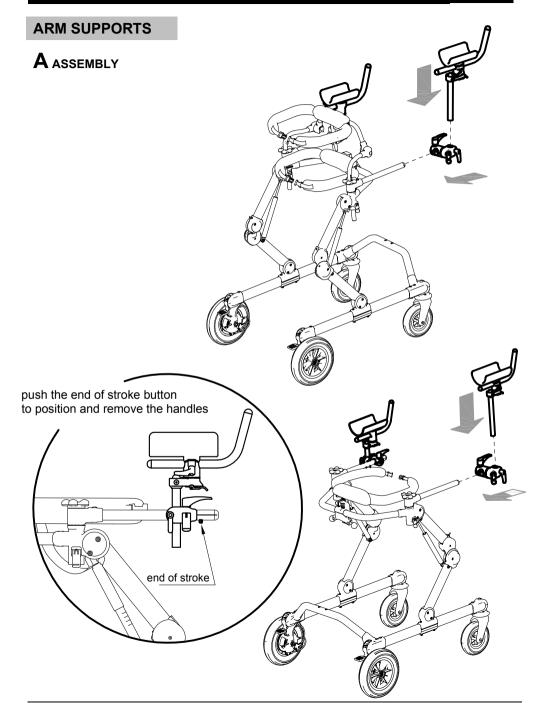
Follow the instructions on p. 34, 35, and 36 to mount the pelvic harness



Pull the straps until the inguinal belts are tightened.



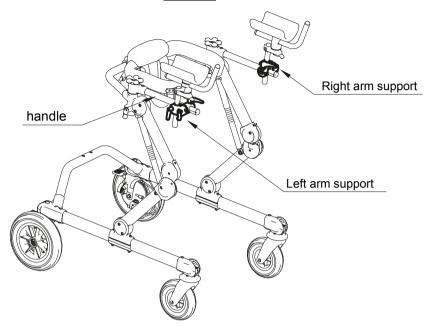
ASSEMBLING AND ADJUSTING THE ADDITIONAL COMPONENTS



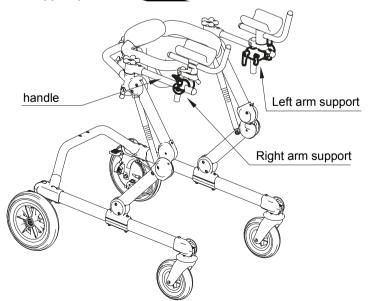


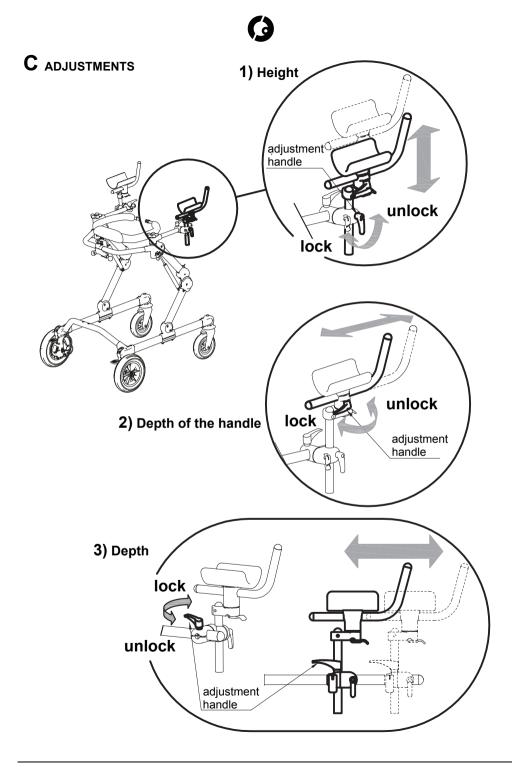
B POSITIONING

1) Arm support positioned outside the handle

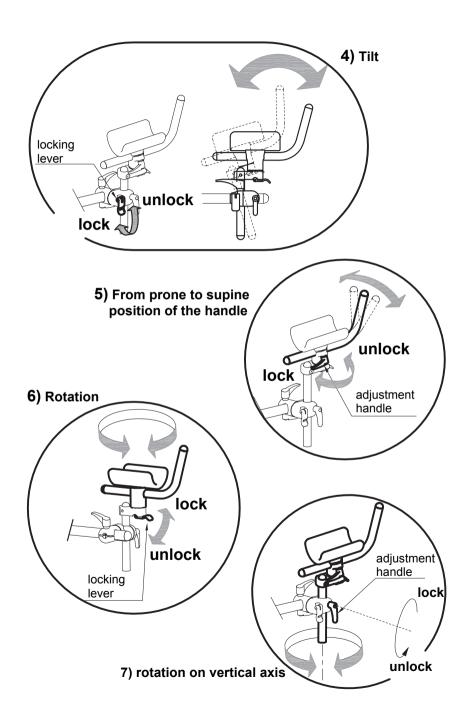


2) Arm support positioned inside the handle





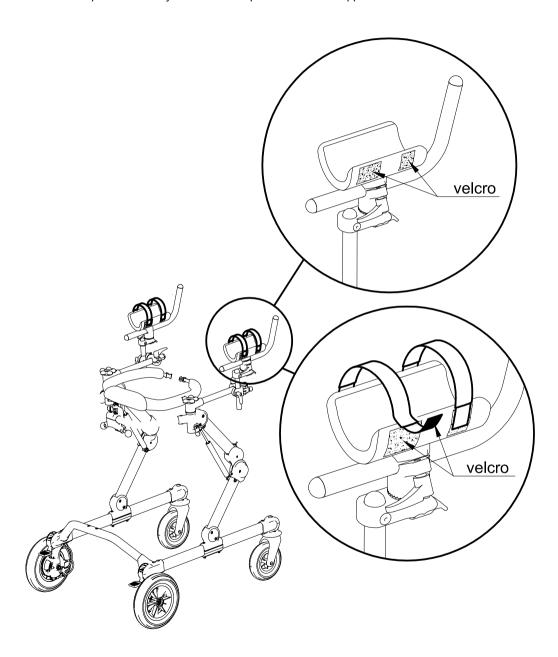






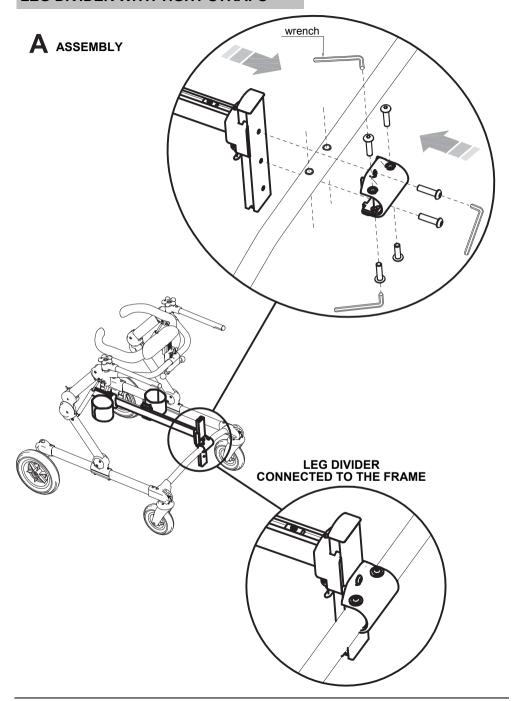
ARM STRAPS

This component can only be mounted in presence of arm supports

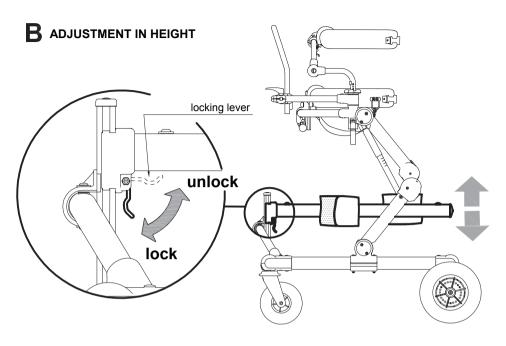




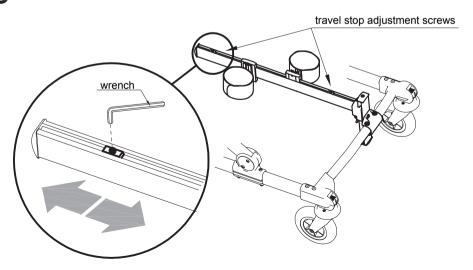
LEG DIVIDER WITH TIGHT STRAPS





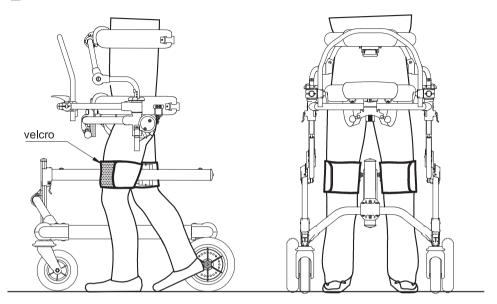


C ADJUSTING THE TRAVEL STOP

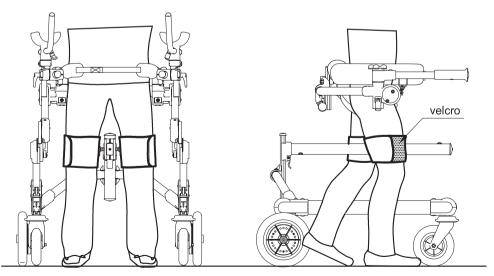




D POSITIONING THE LEGS DIVIDER GRILLO IN THE FRONT-DRIVE GAIT-TRAINER

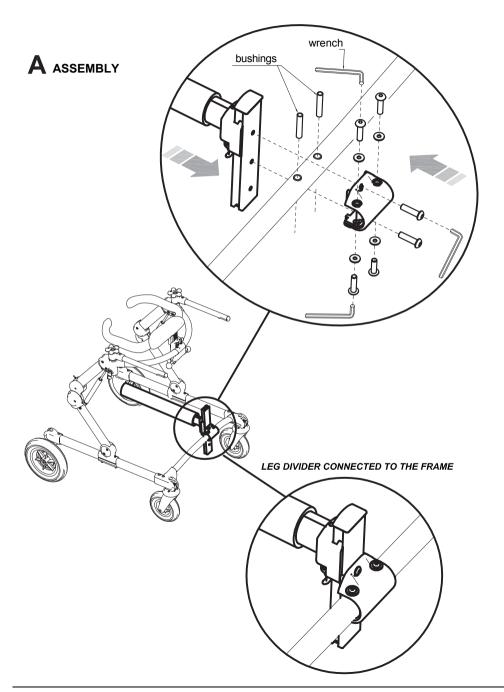


POSITIONING THE LEGS DIVIDER GRILLO IN THE REAR DRIVE GAIT TRAINER

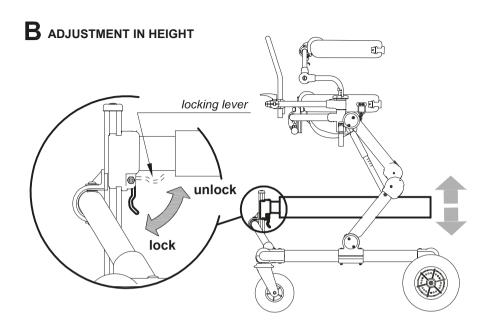




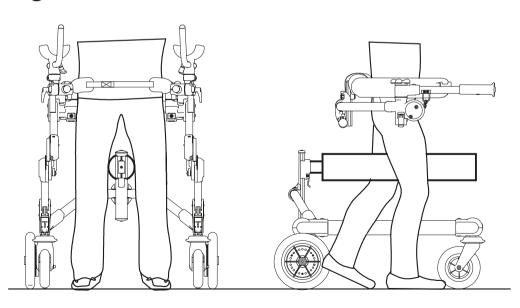
DISTAL ABDUCTOR





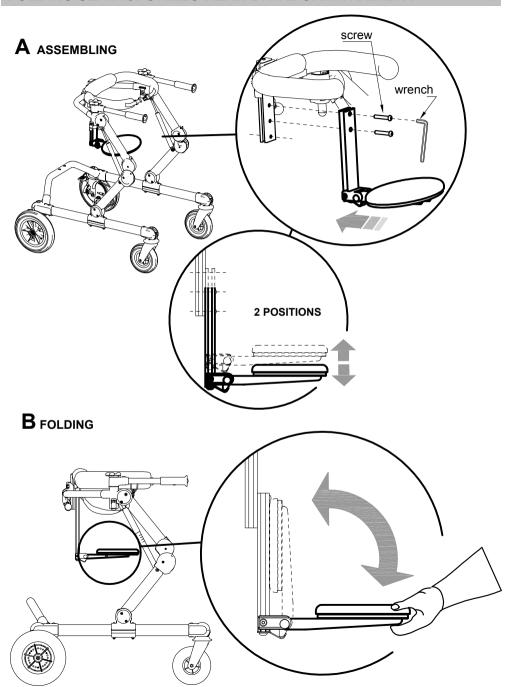


C POSITIONING THE DISTAL ABDUCTOR GRILLO





FOLDING SEAT for GRILLO REAR DRIVE GAIT TRAINER [sizes S and M]

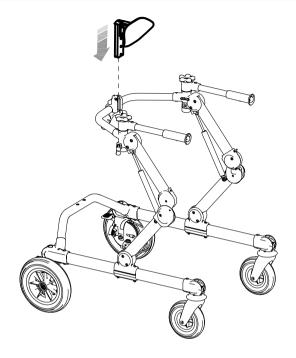


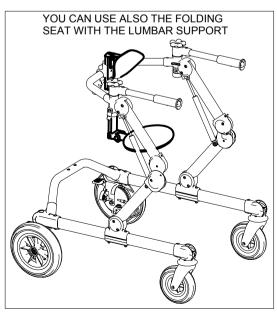
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LUMBAR SUPPORT for GRILLO REAR DRIVE GAIT TRAINER [sizes S and M]

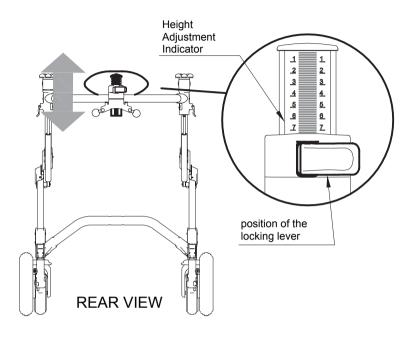
A ASSEMBLY

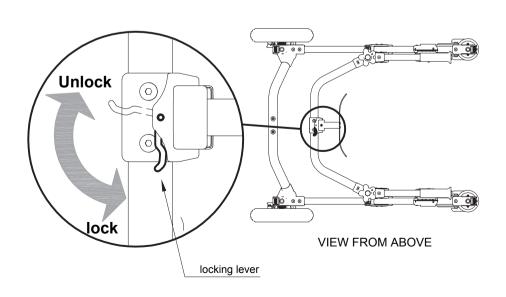






B HEIGHT ADJUSTMENT



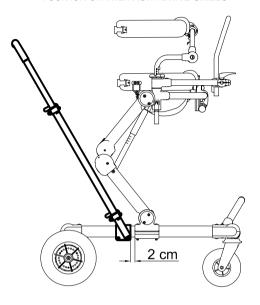


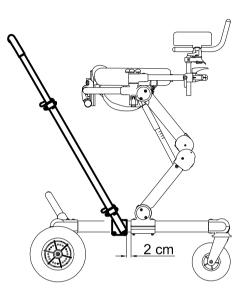


PUSH HANDLE for THE ASSISTANT [sizes S and M]

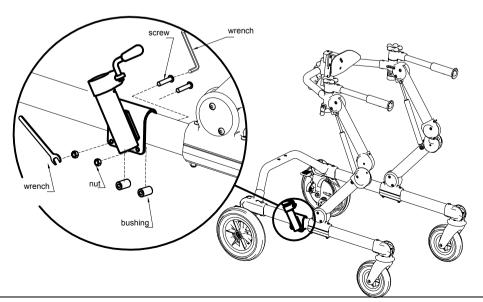
POSITION ON THE FRONT DRIVE GRILLO



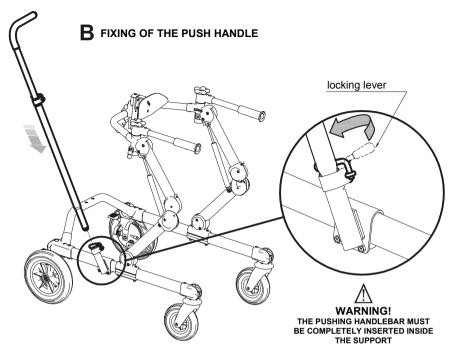




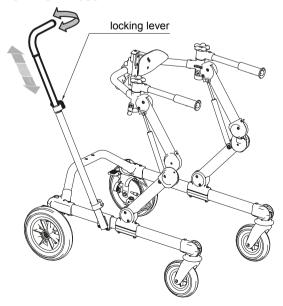
A ASSEMBLY OF THE HANDLE FORK







C HEIGHT AND ROTATION ADJUSTMENT





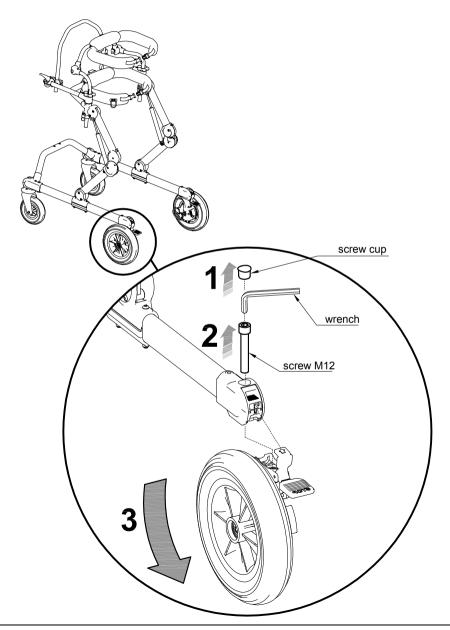
WEIGHT BARS

FIXED ON **REAR DRIVE** GRILLO FIXED ON FRONT DRIVE GRILLO wrench wrench nut screw



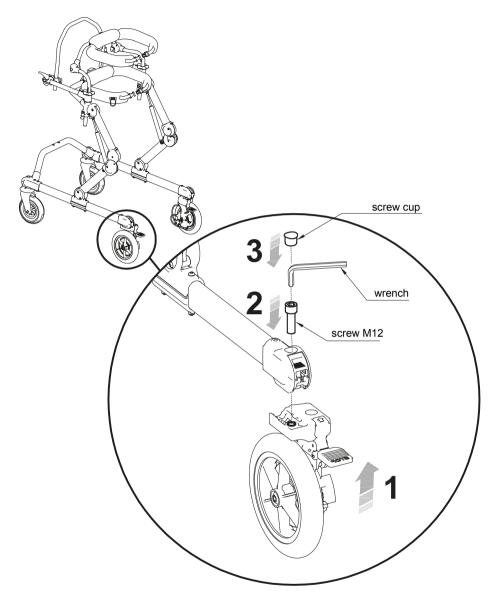
PAIR of WHEELS for NARROW BASE with PARKING BRAKES PEDALS only for INDOOR USE [sizes M and L]

A DISASSEMBLY WHEELS OF THE STANDARD BASE





B ASSEMBLY WHEELS FOR THE NARROW BASE

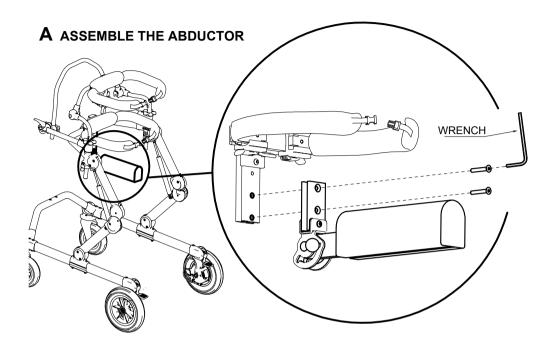


${f C}$ braking, adjustable braking, anti rollback system

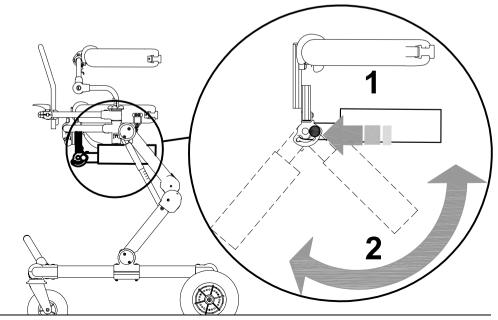
See pages 17,18,19



PROXIMALE ABDUCTOR [sizes S and M]

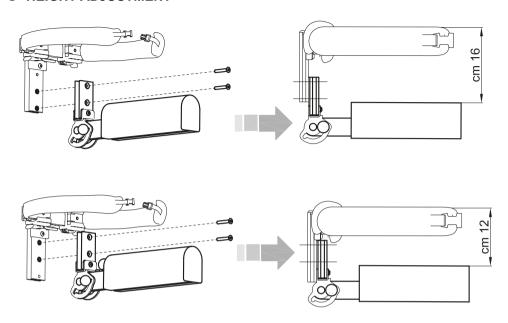


B HOW TO ROTATE THE ABDUCTOR TO NOT USE IT

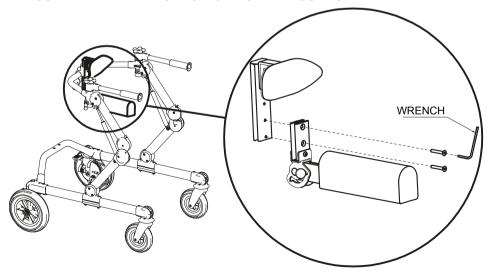




C HEIGHT ADJUSTMENT

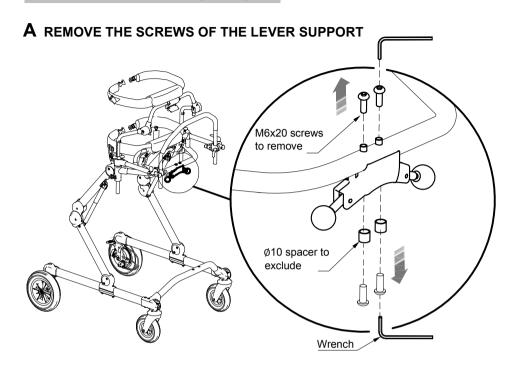


D ASSEMBLE THE ABDUCTOR ON LUMBAR SUPPORT

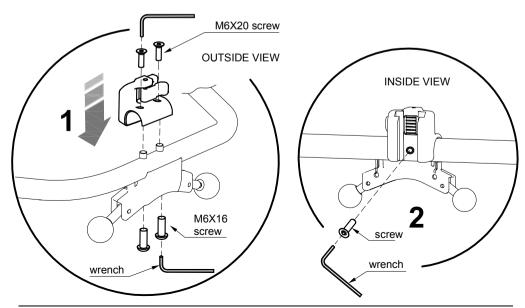




PROXIMAL ABDUCTOR [sizes L]

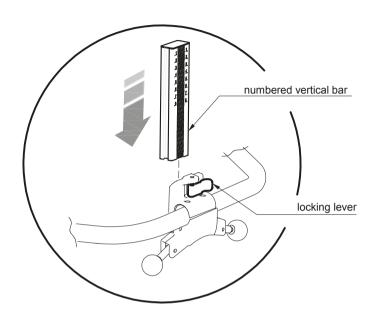


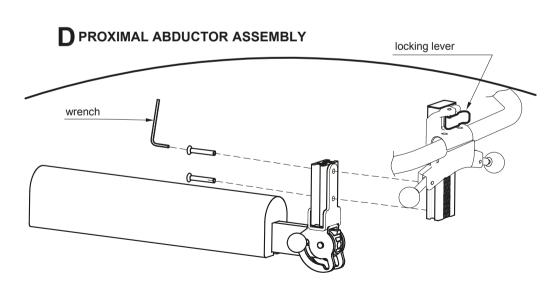
B FIX THE UPPER LOCKING





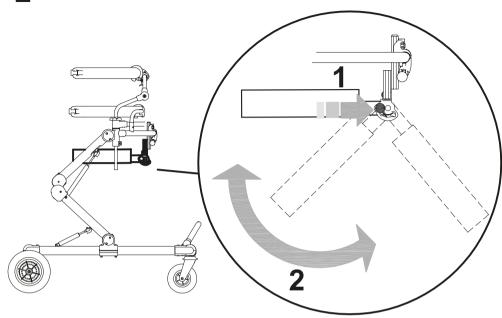
C FIXING THE NUMBERED VERTICAL BAR



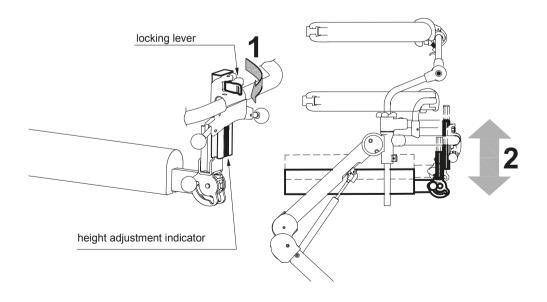




E HOW TO ROTATE THE ABDUCTOR NOT TO USE IT

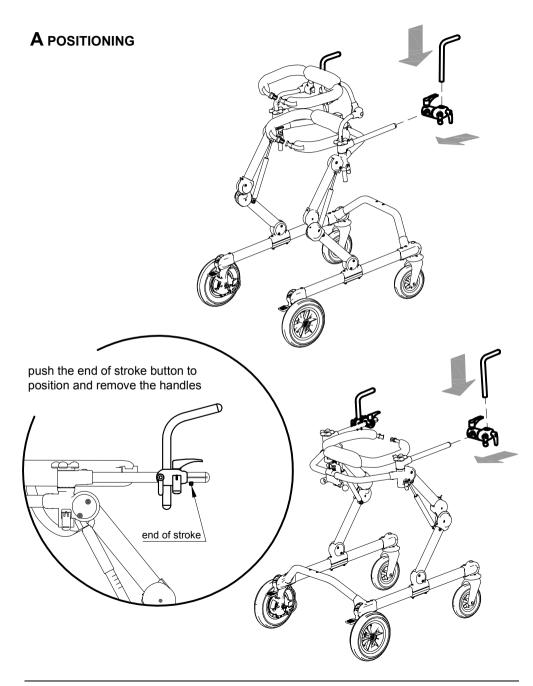


F HOW TO ADJUST IN HEIGHT



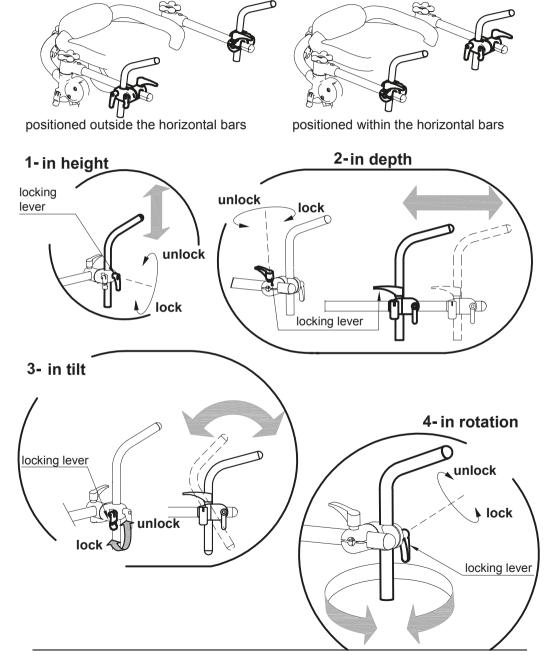


ERGONOMIC HANDLES of GRILLO





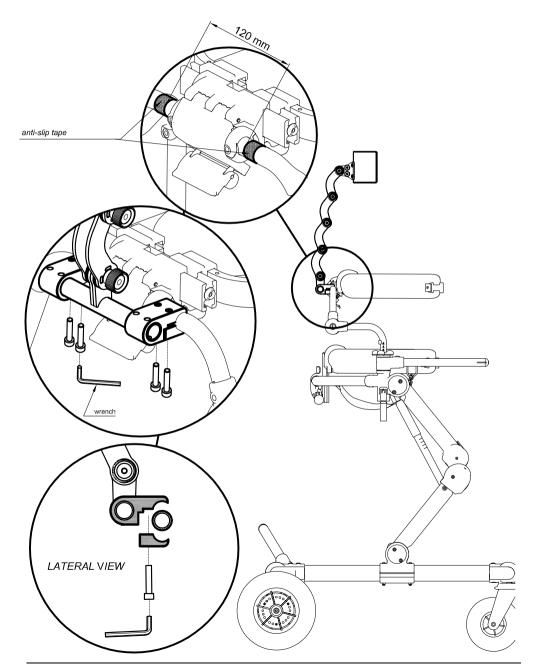
B POSITIONING and ADJUSTMENT





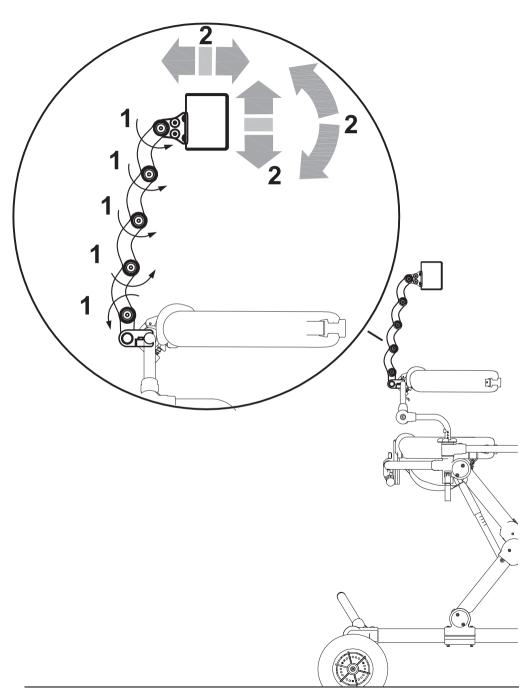
MULTI ADJUSTABLE HEADREST

Available only for rear drive version with Trunk support



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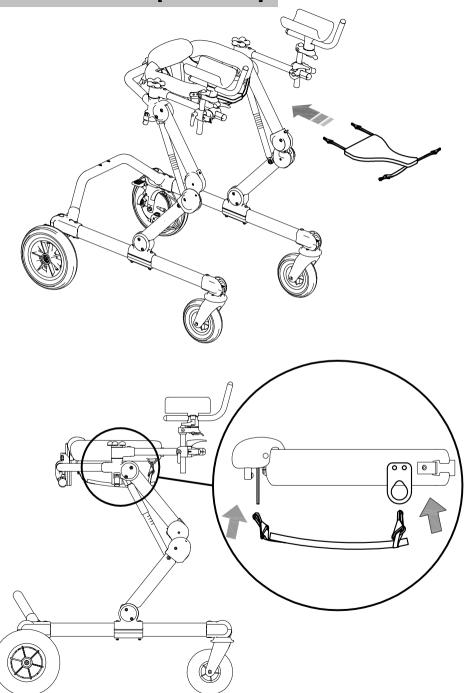




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ERGONOMIC SADDLE [sizes S and M]



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MAINTENANCE

The execution of all maintenance operations is necessary to maintain the correct functionality and safety of the device.

Only if these operations are carried out in the times and in the manner described, the responsibility for maintaining the essential requirements of the device rests with the manufacturer.

If in doubt about the safety or damage of the product, discontinue use and contact ORMESA.

1. ORDINARY MAINTENANCE (monthly)

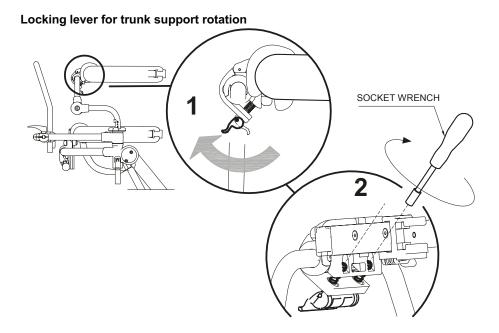
- 1.1 Clean the WHEELS from dust and dirt to maintain the smoothness and efficiency of the braking
- 1.2 check the smoothness of the MOVABLE PARTS and keep them clean from dust and dirt, in order to avoid friction that could compromise the correct operation:
- circumference and width adjustment of the pelvic support
- circumference and width adjustment of the thoracic support

if necessary, lubricate the MOVING PARTS with commercial silicone dry oil with the precautions indicated on the container.



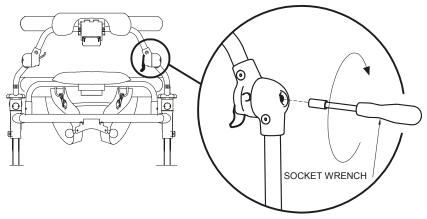
1.1 SETTING OF CONTROL LOCKING LEVERS

should you have noticed an INEFFICIENCY, even partially, on the LOCKING of the adjustment GREEN LEVERS of the PELVIC SUPPORT, of the TRUNK SUPPORT, of the HANDLEBAR, of the ARM SUPPORTS, please contact your ORTHOPAEDIC WORKSHOP to TIGHTEN THE NUT LITTLE BY LITTLE as shown below, UNTIL the PROPER LOCKING IS REACHED.

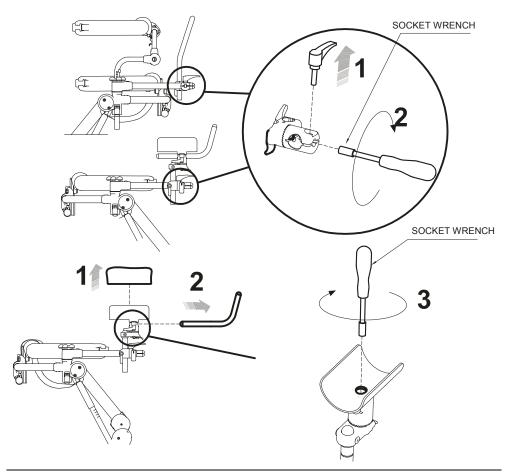




Locking levers for trunk support joints

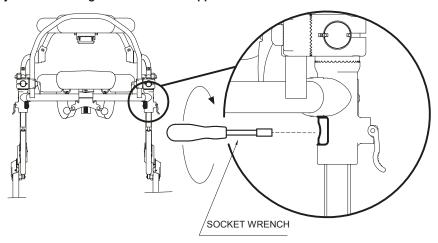


Locking levers for handlebar/arm supports joints

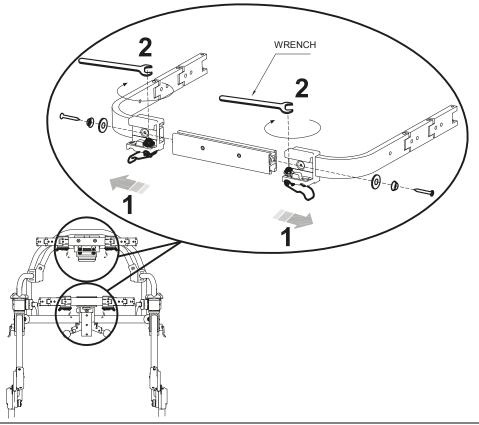


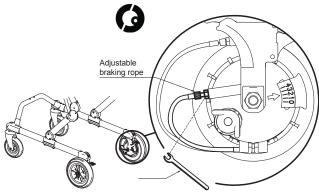


Height adjustment locking levers for trunk support



Width adjustment locking lever for pelvic and trunk supports





1.2 CLEANING THE WHEELS

Clean the wheels at least once a month keeping them free from waste (thread, hair etc...) which can stick to them



If you verify an INEFFICIENCY, even if just partial, of the BRAKES, contact the Dealer who sold you the product immediately. He will evaluate their possible reparation/change in order to avoid dangerous situations that could cause accidents.



Do NOT perform maintenance or replace parts or components when the user is in the device.



Intensify all checks in marine environments, clean more often, anoint the parts exposed to salt corrosion (such as chrome, bolts and screws).



Maintenance and replacement of parts or components must never be done while the aid is being used.

2. PREVENTIVE MAINTENANCE (biennial)

The Manufacturer recommends a COMPLETE REVIEW of the device, in order to verify it according to the specific use and to maintain the initial performances for all its lifetime.

This activity can be carried out by the Dealer who supplied the product or by an SERVICE CENTER, specialized in the maintenance of mechanical aids for people with disabilities and includes:

- 1) The general verification of the product, the integrity of the components and the locking of the mechanical parts, the smoothness of the moving parts
- 2) Performance verifications
- 3) The possible interventions aimed to restore the correct functionality
- 4) Mechanical control (in case of mechanical repairs)
- 5) Sanitization

Always ask for a REPORT that provides evidence of the interventions PERFORMED (VERIFICATIONS, REPAIRS, CONTROLS, SANITIZATIONS)



3. EXTRAORDINARY MAINTENANCE (or corrective)

EXTRAORDINARY MAINTENANCE are all operations done on the device other than regular or preventive maintenance (mentioned above).

Extraordinary maintenance must be carried out by the Dealer who supplied the product or by another subject indicated by the Manufacturer or the Distributor of the ORMESA products in the country of destination.

The interventions must be performed with ORIGINAL REPLACEMENTS PARTS of the manufacturer

Modifications of the product ARE NOT ALLOWED, except for those of possible configurations provided on the brochure

For each maintenance work, the following must be performed:

- 1. The general verification of the product, the integrity of the components and the locking of the mechanical parts, the smoothness of the moving parts
- 2. Performance verifications
- 3. Mechanical control (in case of mechanical repairs)
- 4. Sanitization

Always ask for a REPORT that provides evidence of the the interventions PERFORMED (VERIFICATIONS, REPAIRS, CONTROLS, SANITIZATIONS)



CLEANING, DISINFECTION, SANITIZATION

INFORMATION

SANIFICATION is the complex of cleaning and / or disinfection procedures and operations The **CLEANING** is a physical and mechanical process (i.e., rubbing) with which a large part of potential pathogenic microorganisms (bacteria, fungus, or virus), further to the visible dirt, is removed from the surface

The combination of mechanical action with other factors such as the use of detergents (chemical action), temperature and duration can efficiently and sufficiently reduce the microbial load of the device.

DISINFECTION, after cleaning and cleansing, further reduces the number of microorganisms on a surface and it eliminates pathogenic microorganisms, ie bacteria causing disease and viruses. Products that on the label bear the authorization / registration Number of the Ministry of Health or other competent authority of an EU member State. are "disinfectants". Each disinfection action must always be preceded by a cleaning and cleansing operation, since dirt reduces the activity of the disinfectant. DRYING is essential because microbial growth can occur in the residual aqueous film.

CHEMICAL PRODUCTS WITH VIRUCIDAL-GERMICIDAL-FUNGICIDAL EFFICACY are available on the market for hospital equipment. These products are effective in cold conditions, able to perform cleaning (elimination of dirt) and disinfection (elimination of pathogenic microorganisms, i.e. bacteria causing disease) in a single operation. and viruses).

Removable **UPHOLSTERIES** are washable respecting the symbols on the label. Washing is an extraordinary sanitation measure. Replace them when worn / difficult to sanitize.

WARNINGS

Read the TECHNICAL SHEET of the chemical product to verify that it is suited to be used on chrome plated/varnished surfaces and on plastic components in PVC, PA, PP and to test on a small surface to ensure that it does not damage the aid.

For an effective operation, it is important to RESPECT THE POSOLOGY and TIMES OFACTION indicated on the product LABEL.

Use the PPE (gloves, FFP mask, visor, etc...) required on the product LABELP



The operations of sanitization must be performed without the user inside the device. Do not use compressed air, which can cause aerosol and contamination of possible virus and bacteria in the environment and on his own person.



During the Covid-19 epidemic, the contaminated PPE (gloves, gowns, glasses, masks, caps, etc...) must be **thrown away in the general waste bin**, unless otherwise indications by the belonging municipality



PROCEDURE

Activities	Cadence	Description	
4.1 CLEANING and CLEANSING	daily or weekly based on intensity of use and biological risk (patient with particular sweating, salivation; pandemic or endemic emergency period eg Covid-19) Before disinfection	Soak a sponge or a clean disposable cloth with neutral detergent previously diluted in water. Rub upholstery, frame, accessories and finally wheels. Remove any traces of product by wiping with a clean damp sponge or cloth. Dry with a clean soft cloth. Proceed with any disinfection	
4.2 DISINFECTION	Before Re-using the product with a new user	Spray a virucidal / germicidal / fungicidal chemical product for hospital equipment that is effective cold on a clean disposable cloth. Rub the upholstery, the frame and the clean accessories (4.2), until complete evaporation.	
		WARNING! to clean / disinfect the pelvic / thoracic padding do not use ethyl alcohol or detergents containing, even if in small quantities, acetone, trichlorethylene and ammonia (solvents in general).	



		19		
4.3 WASHING	Besed on use		ble to wash the HARNESS and BLE UPHOLSTERIES, respecting the ndications Machine wash with neutral soap .Max. temperature. 40°. Delicate cycle Do not bleach Do not iron Do not tumble dry Dry horizontally. PADDED UPHOLSTERIES require	
			EFFECTIVE DRYING IN A VENTILATED or HEATED ENVIRONMENT for at least 6-10 hours	
		For an ANTIVIRAL DISINFECTANT action, a SPECIFIC CHEMICAL PRODUCT can be added to the normal washing cycle; washing at a high temperature (60 ° C) is possible as long as occasionally, as the upholstery may wear out. WARNING! The metal carabiners attached to the ergonomic harness could damage the washing machine drum if it comes fast cycle centrifuge used. Use the short (gentle) cycle as indicated in the table.		



4.4 SANITIZATION WITH PERCARBONATE	Based on use	The percarbonate is a natural product of mineral origin that is commercially available; when dissolved in water, it releases active oxygen already at 30 ° with disinfectant, antibiotic and antibacterial action.
		For a sanitizing action during the cleaning of the frame and the washing of the harness and removable upholsteries, you can add 1 teaspoon of percarbonate > 30% to the detergent: - In the washing machine: add 1 teaspoon of percarbonate in the drum together with the
		detergent By hand/ for the frame cleaning: dissolve 1 teaspoon of percarbonate in the bowl together with the detergent, proceed with the washing, and cleansing.
		WARNING! When washing / cleaning the fabric it is recommended not to mix sodium percarbonate with acids (for example: Vinegar, Lemon), as it could create chemical reactions that could damage it.

ASSISTANCE AND SPARE PARTS OF GRILLO



Should you need assistance or spare parts, contact the Dealer who sold you the product.

DISPOSAL



If the aid must be scrapped, dispose of the parts according to the legal requirements in force in your Country.



CONDITIONS FOR DURABILITY, REUSE AND REASSIGNMENT TO A NEW USER

Granted that Ormesa products should be selected, evaluated and ordered for the needs of an individual user, reuse is however possible with the respect the following conditions.

Based on the experience of other similar sold models, on technological progress, on the guarantees of the Quality Management System certificated in 1998 according to ISO 13485, there is adequate confidence that the average lifespan of the GRILLO is about 5 years, on condition that it is used according to the directions given in the user manual.

Only when the conditions for storage and transport of chapter HOW TO STORE AND TRANSPORT THE MEDICAL DEVICE" are followed, the periods in which the product is stored at the dealer should not be considered in that time period.

Factors unrelated to the product such as the development of the user, its diseases, the use and the surrounding environment can make significantly lower the duration of life of the product; on the contrary, if the indications on the use and maintenance are properly observed, the reliability of the product can extend well beyond the lifetime average above.

Prior to recycling or reassignment an already used Ormesa product, it is required that:

- A doctor or therapist verifies that the aid is appropriate and adequate to meet the dimensional, functional and postural needs of the new user, and if all its components are suitable / appropriate for him. You should also consider that the CE marking and the manufacturer's responsibility for safety requirements for the product remain only if the original product still has not changed and only original components or spare parts have been applied.
- 2. Qualified technical personnel of a company specialized in the maintenance of technical aids for people with disabilities performs a detailed technical inspection to verify its condition and wear, the absence of any damage and failure of all components / adjustments, the presence of the user's manual, of the label with the date and serial number. A copy of the manual and maintenance may be always requested to the retailer that supplied the product or directly to Ormesa.
- The product has been thoroughly cleaned and disinfected following the directions given in the "MAINTENANCE, CLEANING AND DISINFECTION" Chapter.

We recommend you keep written records on all inspections performed on the product before any assignment to the new user.



In case of doubt about the safety of the product or damage to parts or components, you are urged to immediately discontinue use and contact the Dealer who supplied you with the product; the Distributor or the Manufacturer are at your disposal for any further doubt or assistance.



Via A. Da Sangallo, 1 Paciana 06034 FOLIGNO PG ITALY

COMPANY WITH QUALITY SYSTEM CERTIFIED BY DNV GL = ISO 13485 =



Authorized Dealer	

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