

USE AND MAINTENANCE HANDBOOK



| ORMESA thanks you for the confidence placed in choosing our GRILLO gait trainer. |
|--|
| GRILLO is a walking frame where the attention to its functionality is combined with the respect of ergonomic and safety principles. |
| ODMECA there are greate you to good this handbook your coverible. It will halp you |

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.

If, after reading it, you still have questions, contact your retailer, who will be happy to help you, or call **INNOVATION IN MOTION** directly at 1.260.665.2769, send a fax to 1.260.665.3047 or send an e-mail to iim@mobility-usa.com

Luigi Menichini CEO



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- 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".
- 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 accessories 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 72, 73, 74, 75, 76, 77.

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 72, 73, 74, 75, 76, 77 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



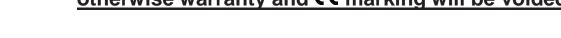
PRODUCT REPAIRS other than the regular maintenance shown on page 72, 73, 74, 75, 76, 77 of the manual must be ONLY MADE by a SPECIALIZED SERVICE CENTER in the maintenance of mechanical aids for disables, otherwise warranty and (marking will be voided



Any CHANGES in the product ARE NOT

AUTHORIZED. REFER ONLY TO ORMESA,

otherwise warranty and C€ marking will be voided





The REPLACEMENT <u>WITHOUT ORIGINAL</u>

PARTS OR COMPONENTS ARE NOT

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

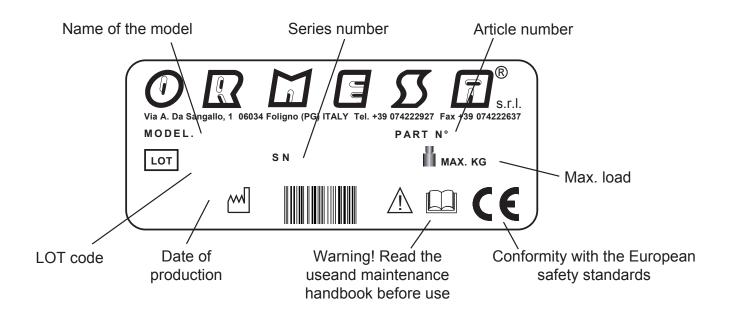
warranty and € marking will be voided



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.

- 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 ACCESSORIES 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



C€ CONFORMITY DECLARATION

ORMESA S.r.I. GUARANTEES AND DECLARES, under its own exclusive responsibility, that the following medical device, technical aid for rehabilitation:

GRILLO

Anterior/Posterior Gait Trainer

Which this declaration refers to, conforms with the general requirements provided in the Directive **93/42/EEC** and subsequent amendments and additions, concerning the medical devices, according to which this aid belongs to the **risk class I** and has been **designed in observance to the following standards:**

management to medical

EN 12182:2012 technical aids for disabled persons - general

requirements and test methods

EN 980:2009 Graphical symbols for use in the labelling of

medical devices

EN 1041:2009 Information supplied by the manufacture with

medical devices

ISO 9999:2011 Technical aids for persons with disabilities -

Classification and terminology

EN 1985 :2001 Walking aids. General requirements and test

methods

EN ISO ISO 11199-3:2005 Walking aids manipulated by both arms -

Requirements and test methods – Part 3:

Walking tables

EN UNI EN ISO11199-2:2005 Walking aids manipulated by both arms.

Requirements and test methods. Rollators

October 14, 2014 the Legal Representative

Luigi Menichini

⚠ GUARANTEE

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

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

- use by an unsuitable person;
- incorrect assembly of parts or accessories;
- 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 72,73,74,75,76, 77 and the warnings ♠ on page 76

WHAT GRILLO IS AND WHAT IT IS FOR

GRILLO is a walking aid, that's to say a product that was designed to help and make the independent moving of a User easier. It is for spasthic/distonic users, for users who have little brawn or for users who start to walk.

It was designed and made for the user to:

- walk without help when independent walking is impossible;
- 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 simply the movement of a body in an upright position from one point in space to another and it is possible by:

- the step pattern (alternate bending and stretching of each leg);
- maintaining the balance of the trunk and pelvis, first on both feet and then on one only during the moving;
- awareness of space and distance.

GRILLO is used:

- a) to generate and help the step pattern;
- b) to train in maintaining balance of the trunk and pelvis;
- c) to organize a wider structured vision of space, distance and the User's surroundings in the upright position;
- d) 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 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 accessories 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.

The support of the pelvis and the weight on his feet can be increased or decreased by adjusting the harness 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. 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 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 difficult) 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.

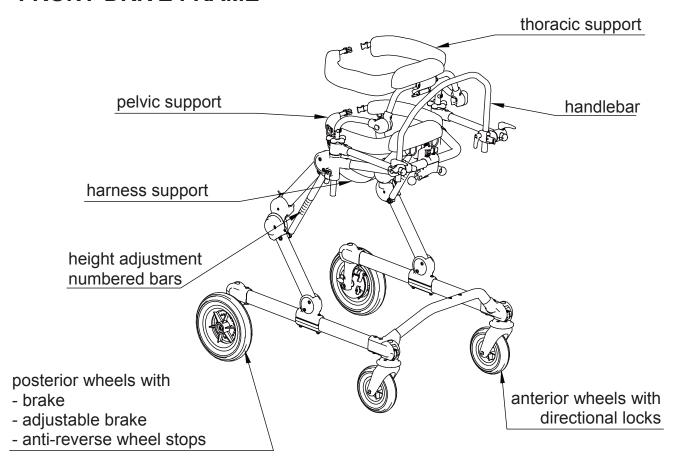
At first walking will be at a constant speed, then a change in step will be asked for so that speed will be faster or slower.

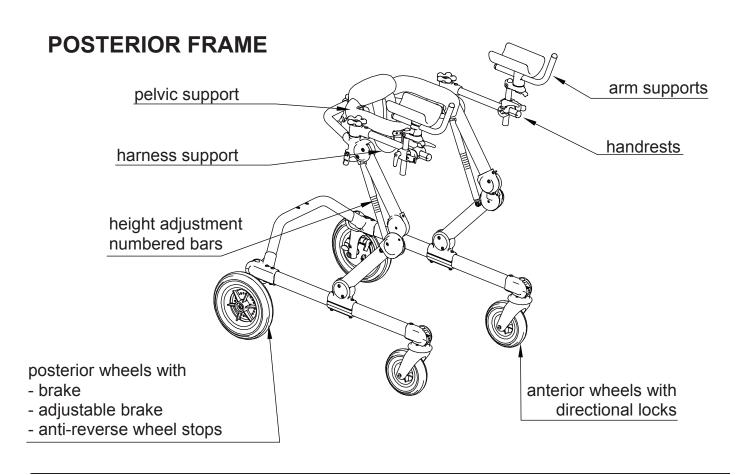
We suggest to follow well defined paths specifically designed to help orientate both "rash" and "fearful" Users.

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

FRONT-DRIVE FRAME

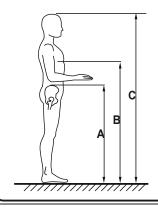




TECHNICAL SPECIFICATIONS - GRILLO GAIT

- Available in 3 SIZES S, M and L and 2 MODELS (GRILLO Front drive and Posterior 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.
- SADDLE, 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 S and Ø cm 25 size M and size L
- DIRECTIONAL LOCKS on front wheels.
- ADJUSTABLE BRAKES.
- ANTIREVERSE DEVICE.
- WHEEL STOP.
- UPHOLSTERIES breathable and removable for washing.
- **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
- PEDALS for PARKING BRAKES
 PAIR OF REAR WHEELS NARROW BASE for size M and L

User dimensions



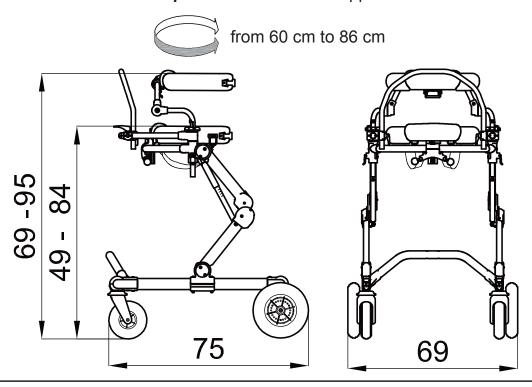
USER HEIGHT (C):

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)

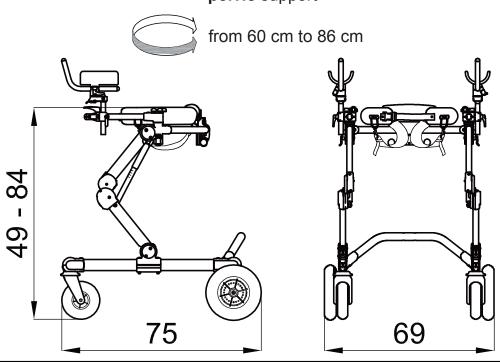
Inner circumference of the adjustable pelvic and thoracic supports



GRILLO FRONT-DRIVE WALKER size S

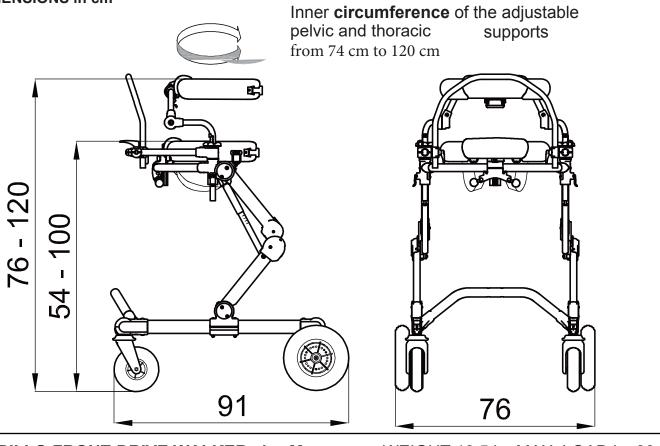
WEIGHT 16,2 kg MAX. LOAD kg 45

Inner **circumference** of the adjustable **pelvic** support



GRILLO POSTERIOR WALKER size S

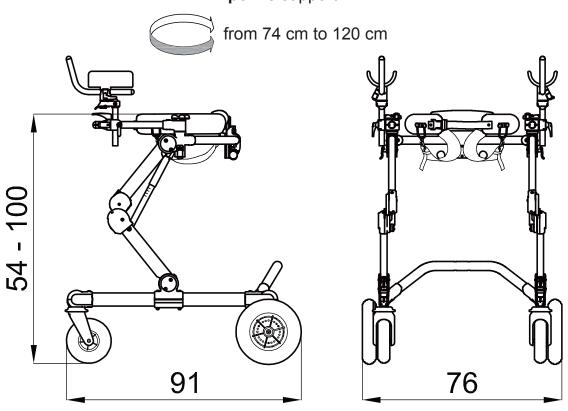
WEIGHT 15,7 kg MAX LOAD. kg 45



GRILLO FRONT-DRIVE WALKER size M

WEIGHT 19,5 kg MAX. LOAD kg 90

Inner **circumference** of the adjustable **pelvic** support

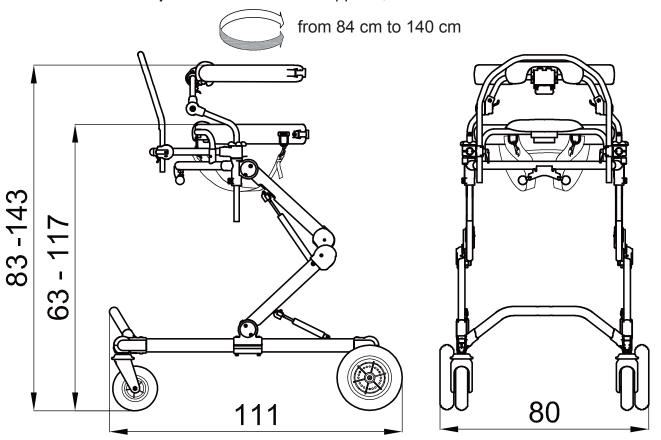


GRILLO POSTERIOR WALKER size M

WEIGHT 17,7kg MAX LOAD. kg 90

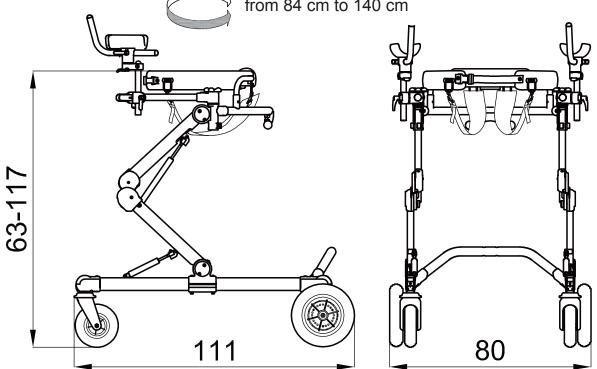
HYPHEN-SEPARATED NUMBERS INDICATE THE MINIMUM AND MAXIMUM RANGE OF ADJUSTMENT

Inner circumference of the adjustable pelvic and thoracic supports, from 84 cm to 140 cm



GRILLO FRONT-DRIVE WALKER size L WEIGHT 23 kg MAX. LOAD kg 110

Inner circumference of the adjustable pelvic support from 84 cm to 140 cm



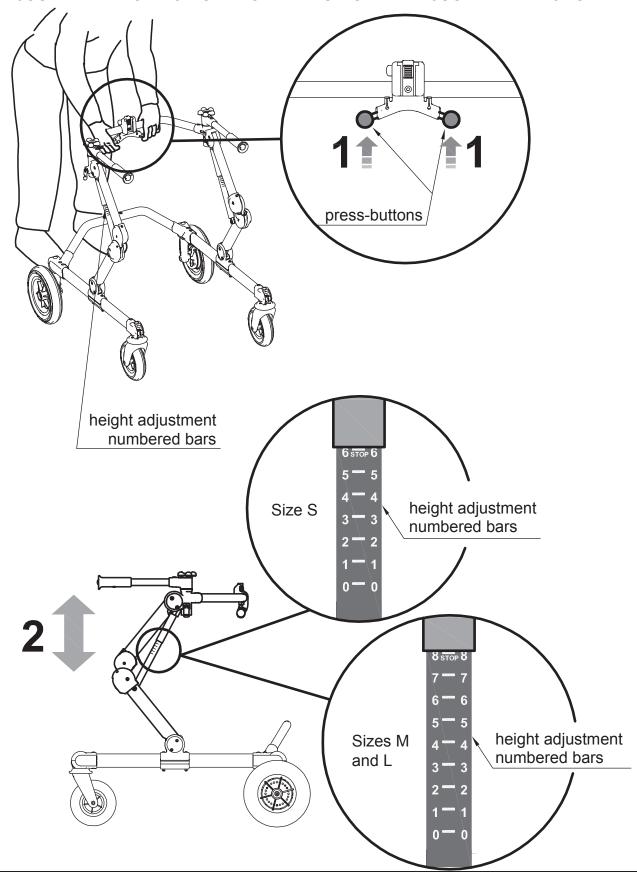
GRILLO POSTERIOR WALKER size L WEIGHT 22kg MAX LOAD. kg 110

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

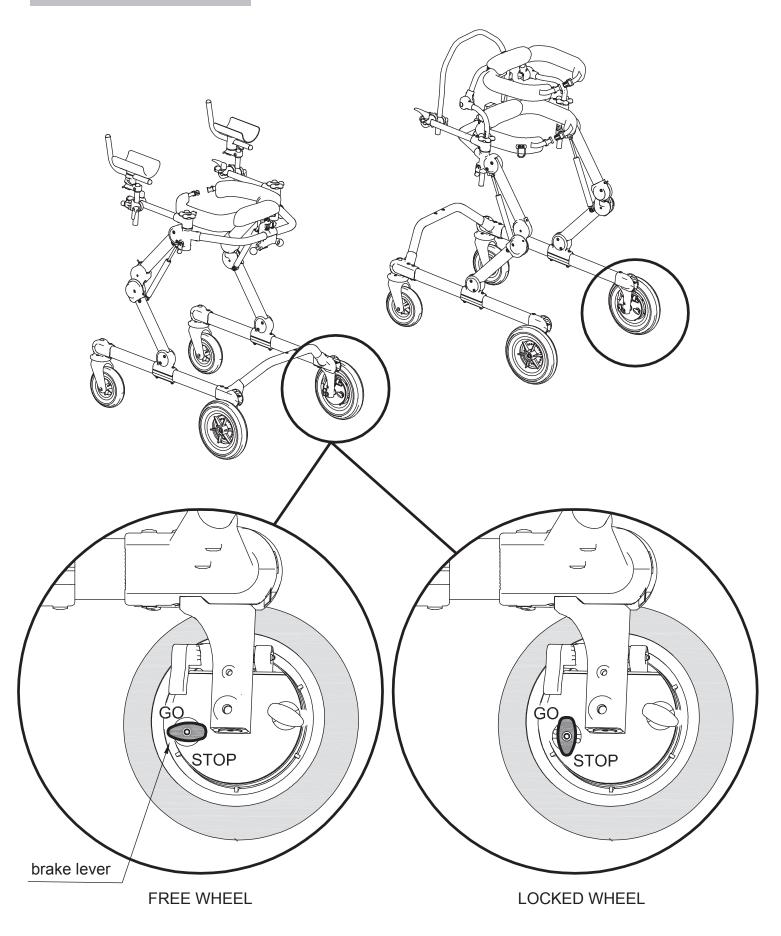
HOW TO USE GRILLO, FRONT DRIVE and POSTERIOR GAIT TRAINER

FRAME: HEIGHT ADJUSTMENT

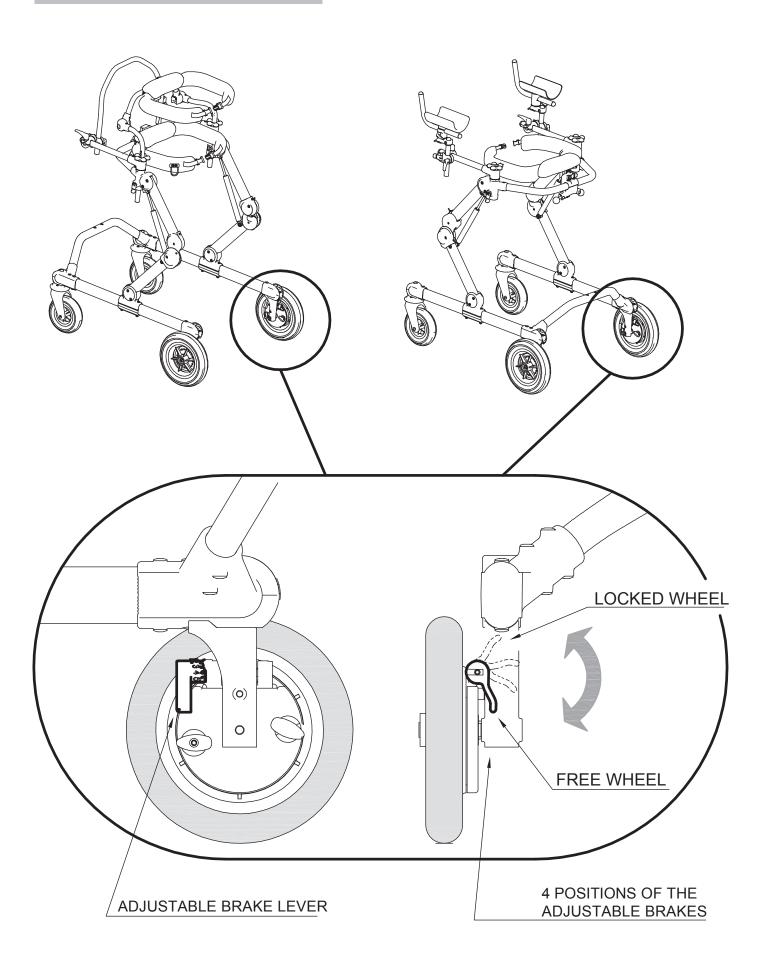
- 1- OPERATE THE ADJUSTMENT KNOBS WITH BOTH HANDS
- 2- ADJUST THE HEIGHT OF GRILLO RELEASING THE ADJUSTMENT KNOBS



PARKING BRAKES



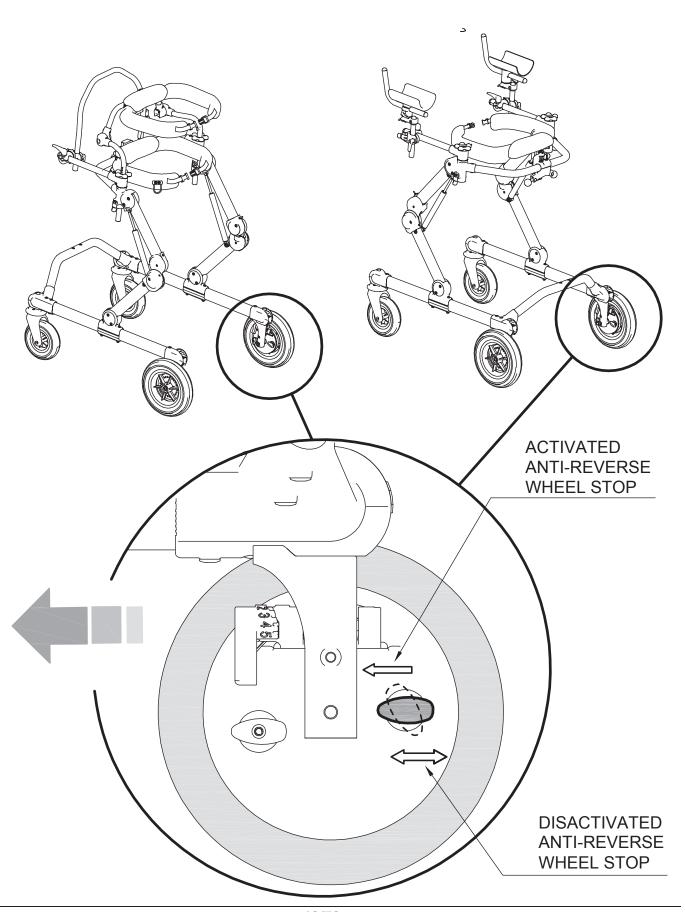
ADJUSTABLE BRAKE



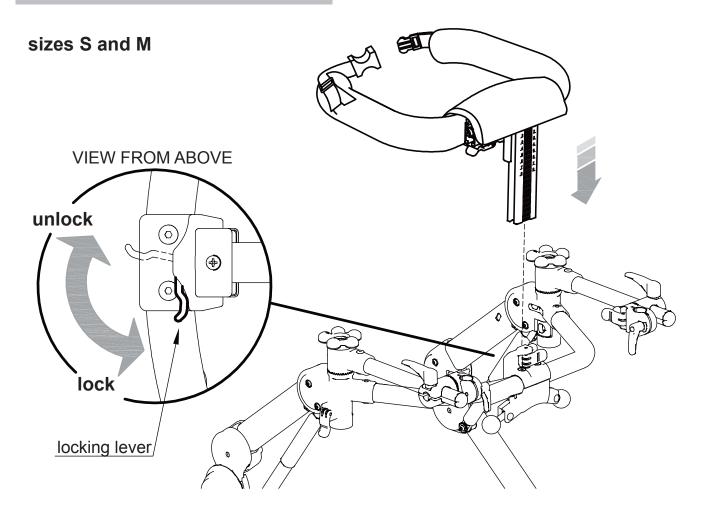
ANTI-REVERSE DEVICE

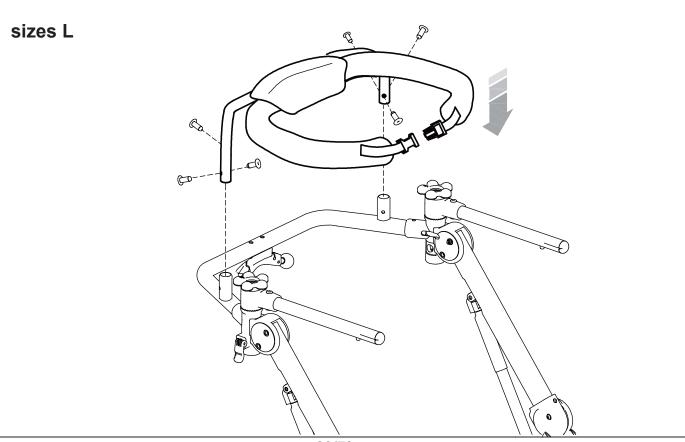


The anti-reverse device reduces the maneuverability of the gait trainer

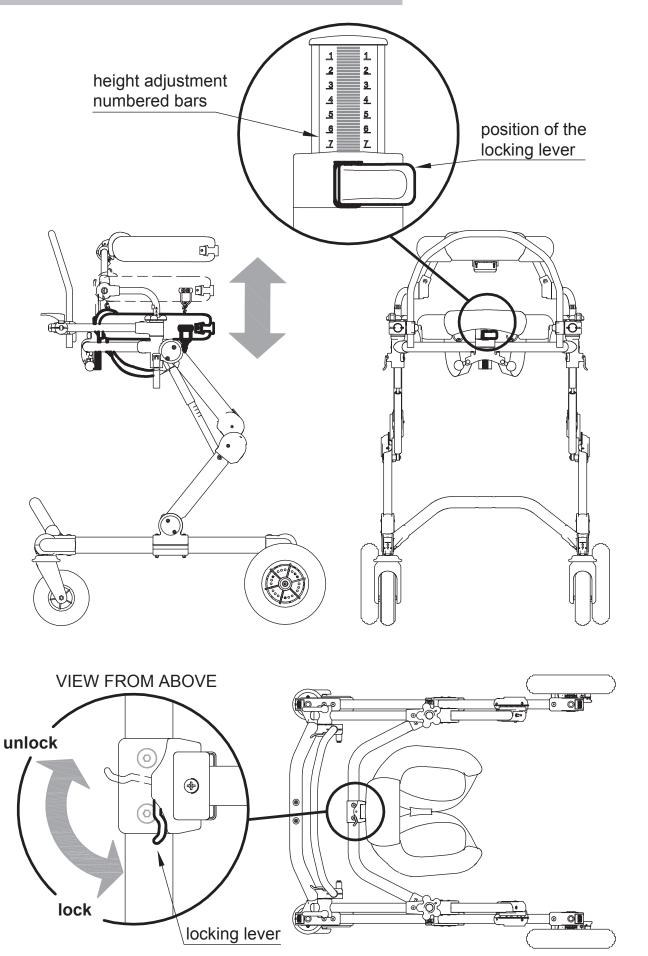


PELVIC SUPPORT ASSEMBLY

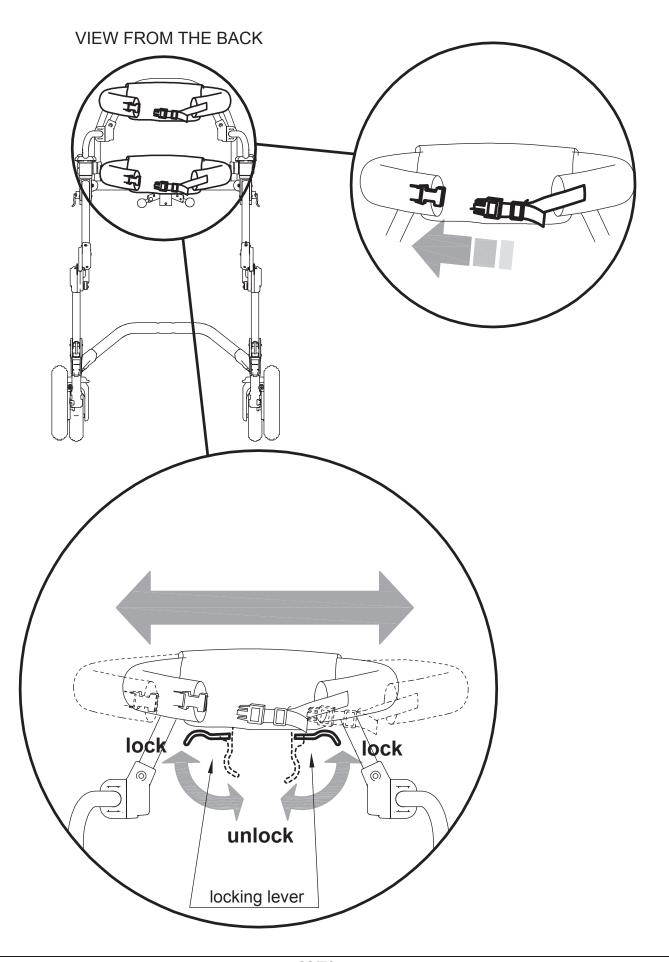


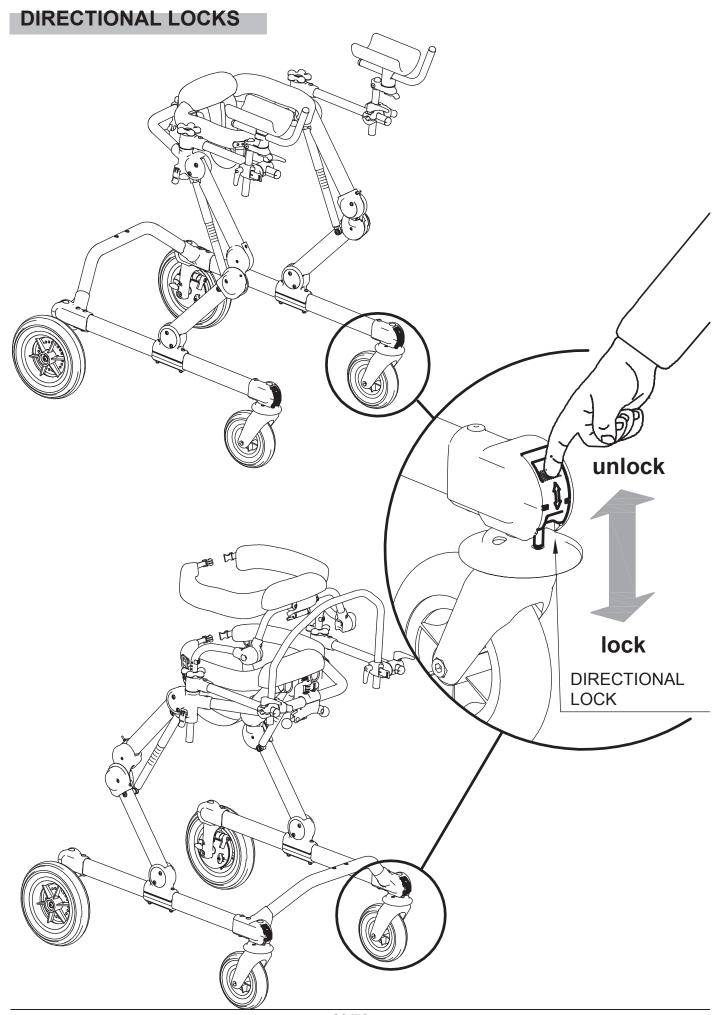


PELVIC SUPPORT: HEIGHT ADJUSTMENT sizes S and M



PELVIC AND THORACIC SUPPORTS: CIRCUMFERENCE ADJUSTMENT



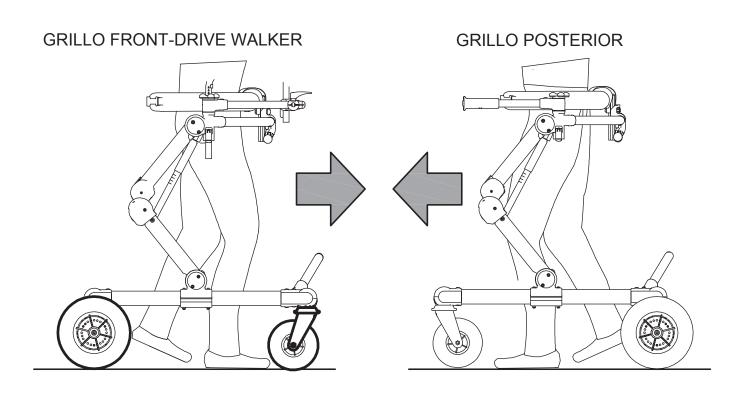


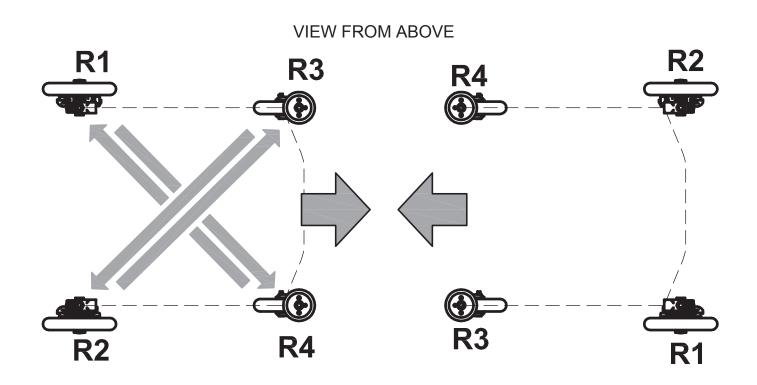
CHANGE GRILLO from POSTERIOR to FRONT-DRIVE GAIT TRAINER and VICE VERSA

WARNINGS!

This operation must be done by qualified personnel only

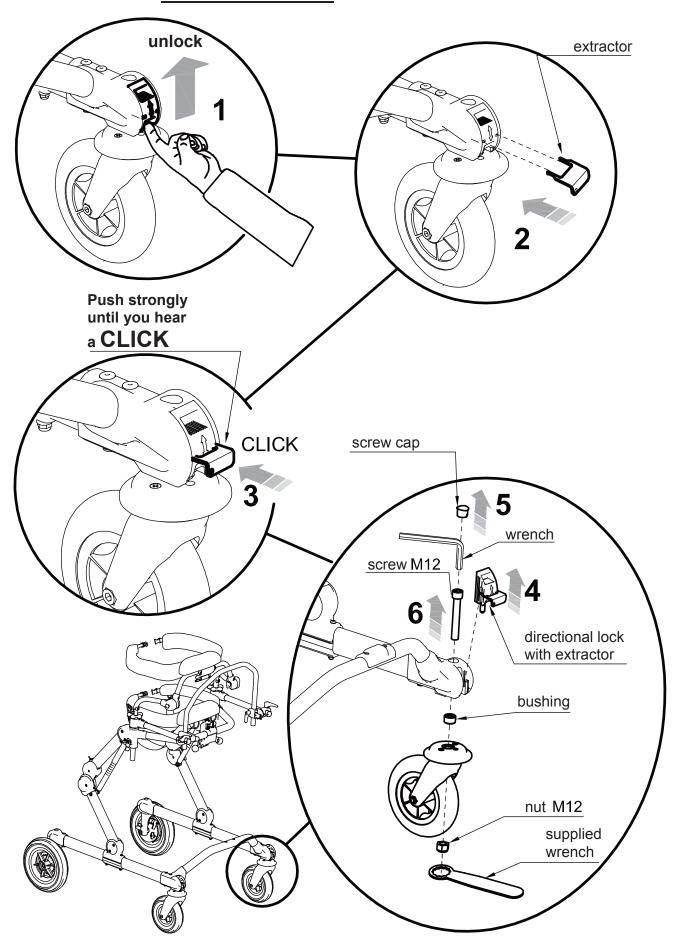
A WHEEL-ASSEMBLING AND DISASSEMBLING SCHEME

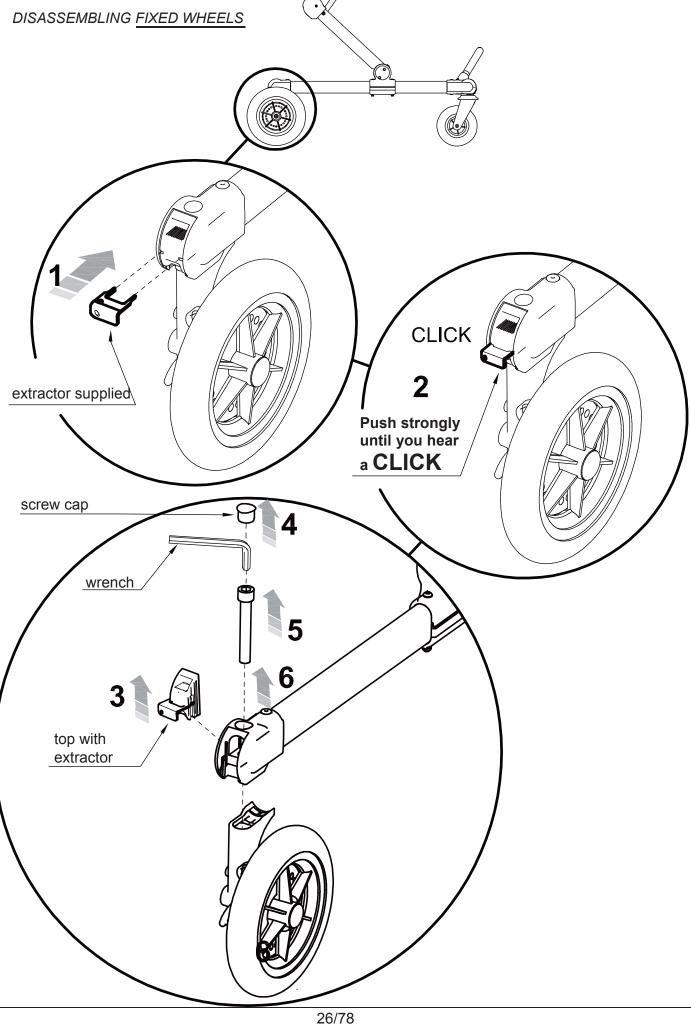


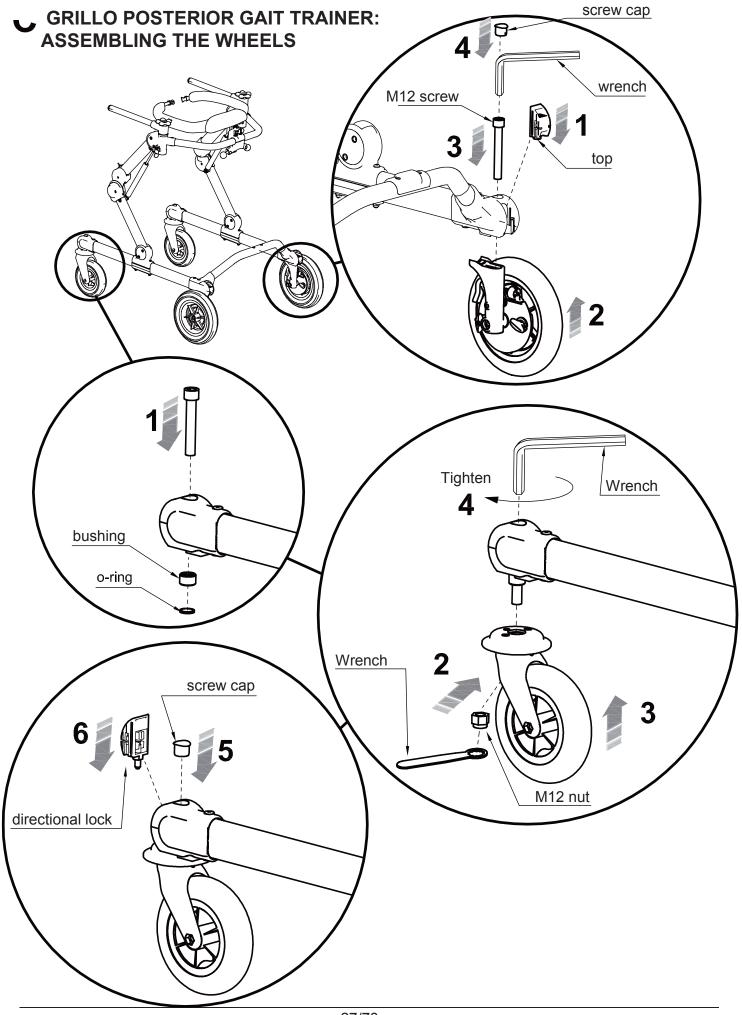


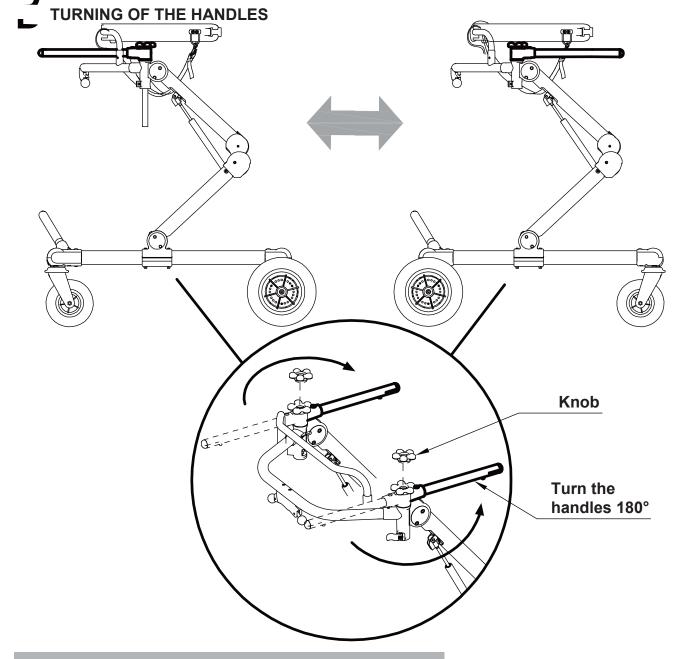
B GRILLO FRONT-DRIVE GAIT TRAINER

DISASSEMBLING SWIVELING WHEELS



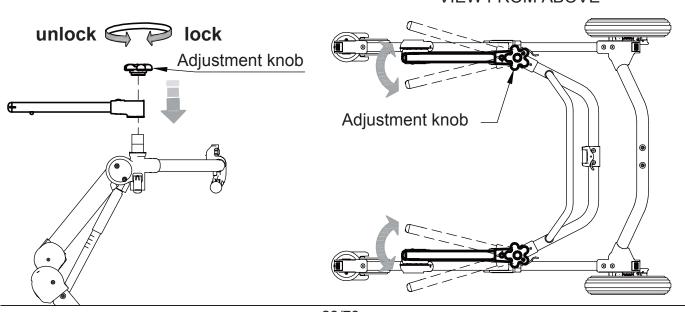




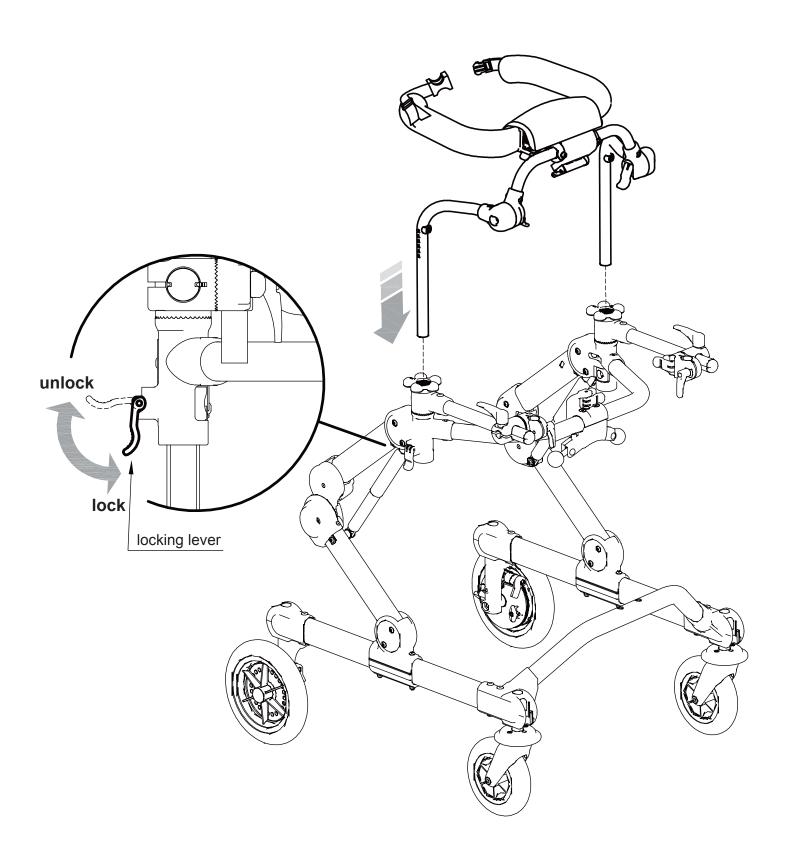


HANDLES: ADJUSTMENTS in WIDTH

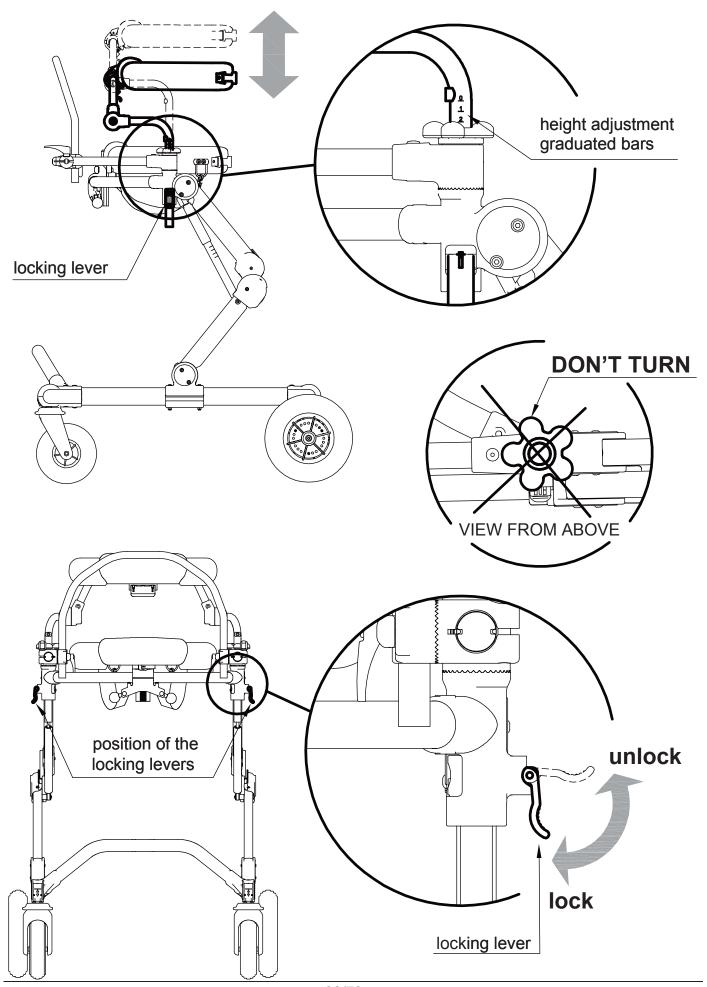
VIEW FROM ABOVE



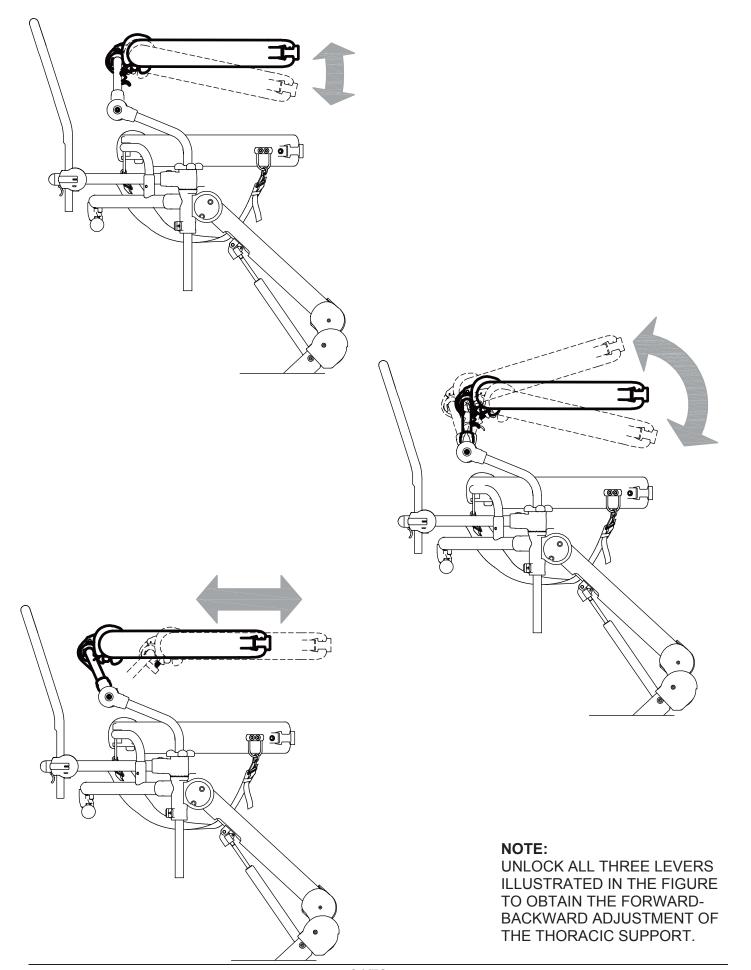
THORACIC SUPPORT ASSEMBLY

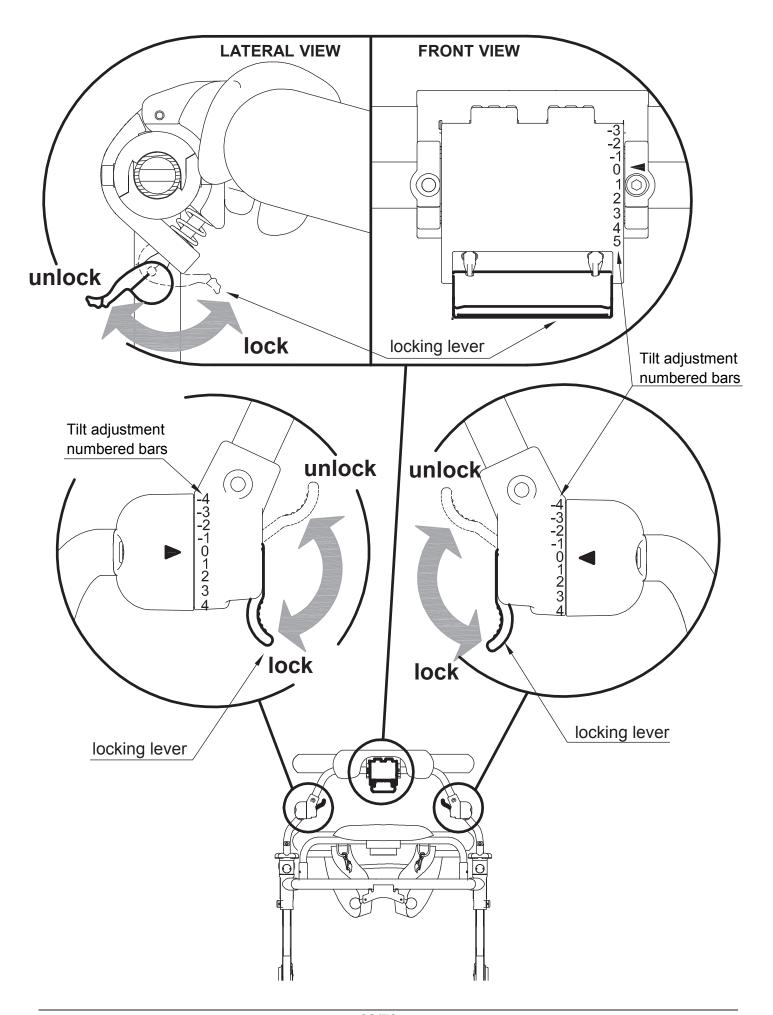


THORACIC SUPPORT: HEIGHT ADJUSTMENT

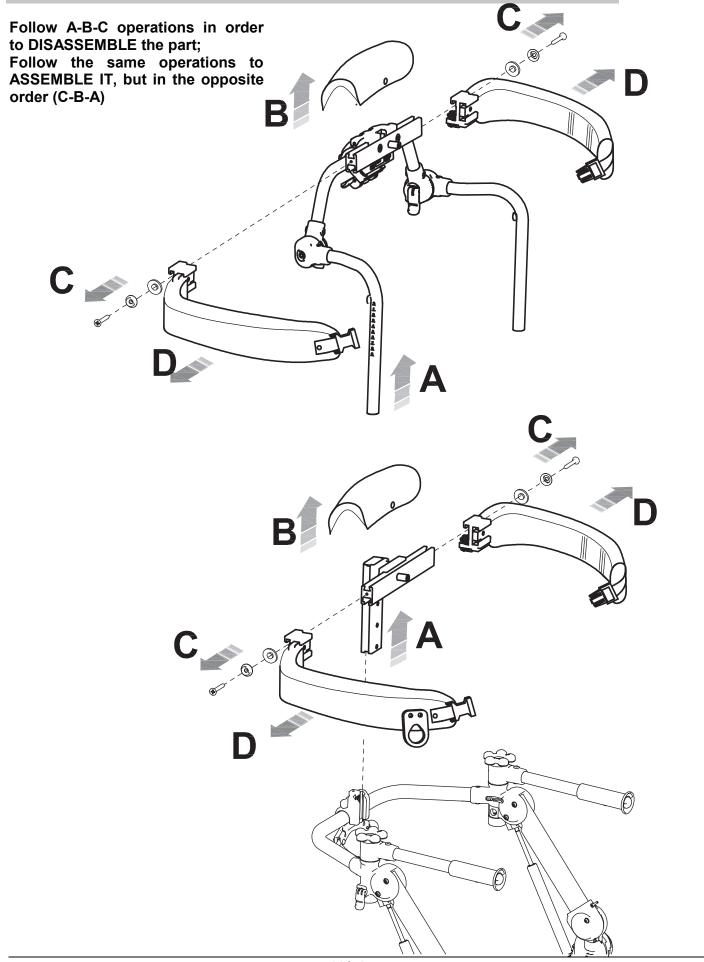


THORACIC SUPPORT: FORWARD-BACKWARD and TILT ADJUSTMENTS





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

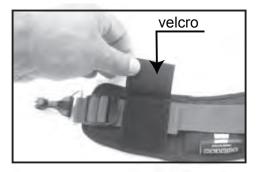


ADJUSTMENTS FOR GRILLO FRONT-DRIVE GAIT TRAINER

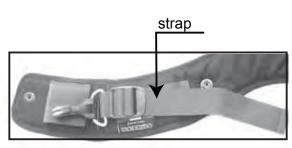
PELVIC HARNESS: ADJUSTMENT sizes M and L



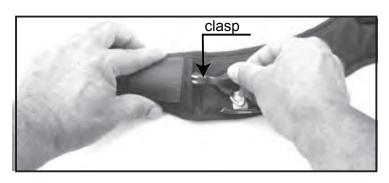
The harness can be reduced as indicated in the following figures:



1- remove Velcro



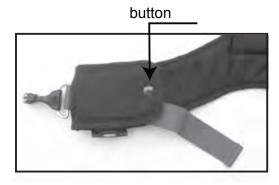
2- shorten the strap



3- insert the clasp in the hole



4- fold the end point of the harness



5- button up

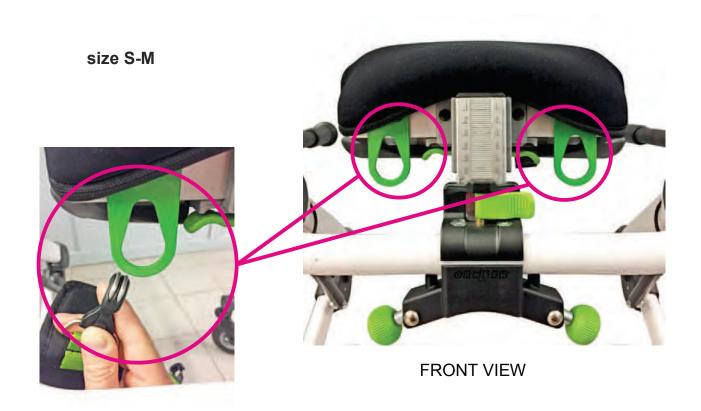


6- reduced harness

PELVIC HARNESS: ASSEMBLY sizes S, M and L

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

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





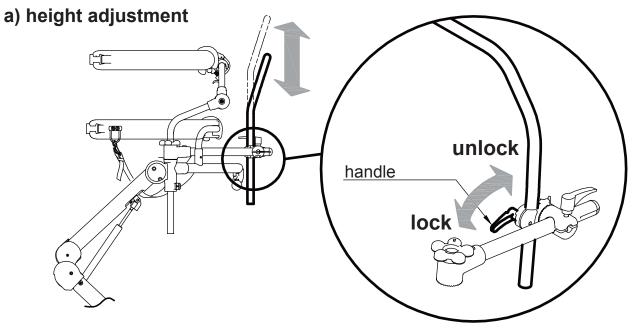


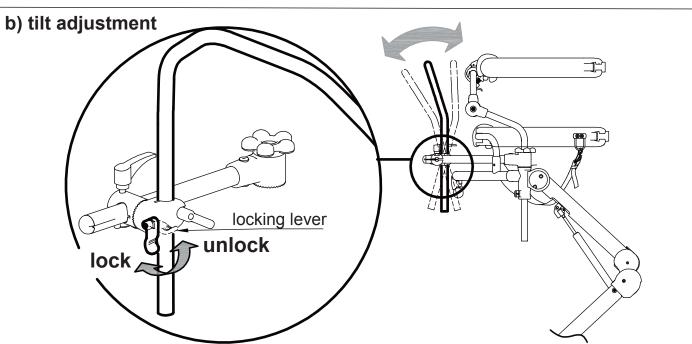
2) Keeping the frame of the walker slightly lowered, fix the right inguinal belt with the hook and then proceed with the left one. Lift the frame of the walker until the correct height for walking is reached.



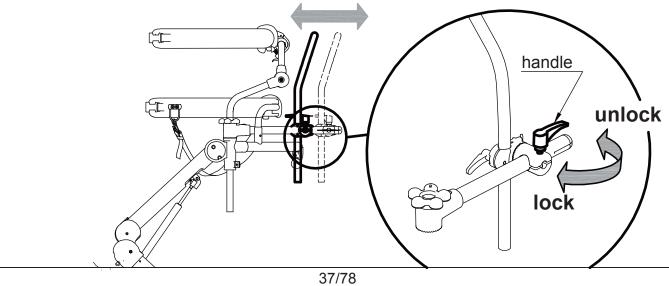
3) Pull the straps until the inguinal belts are tightened.

HANDLEBAR: HEIGHT, TILT, FORWARD-BACKWARD ADJUSTMENTS



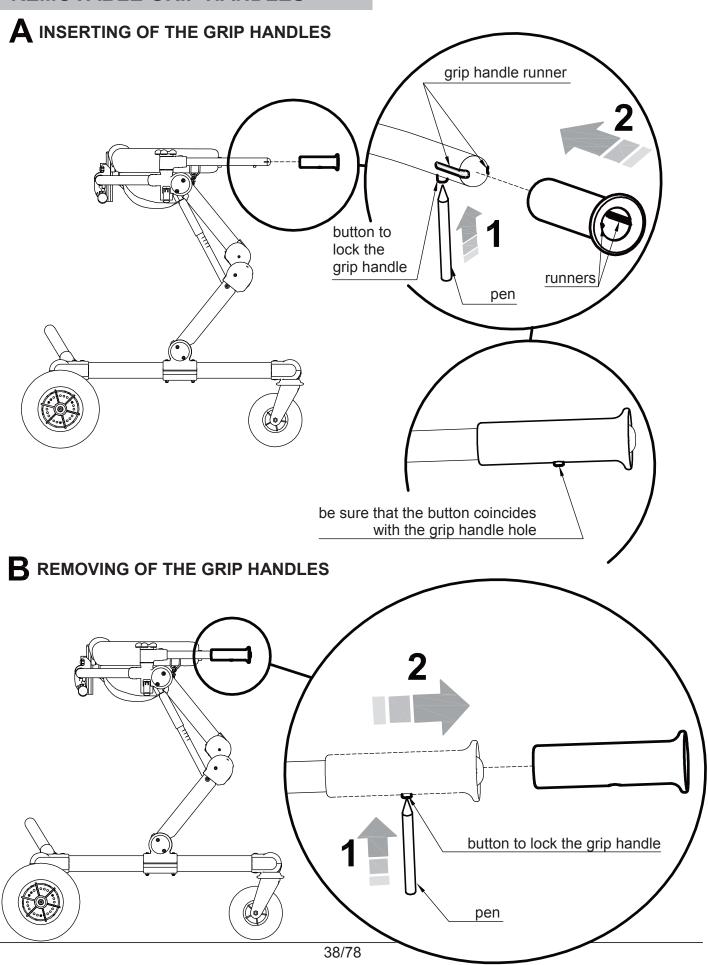


c) forward-backward adjustment



ADJUSTMENTS for GRILLO POSTERIOR GAIT TRAINER

REMOVABLE GRIP HANDLES



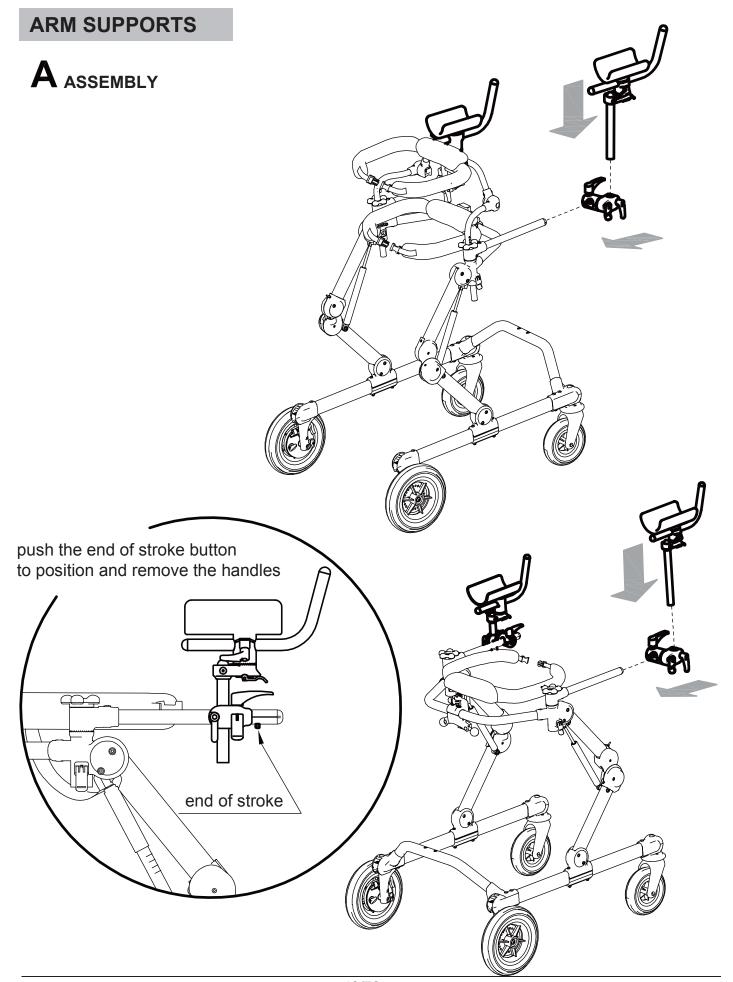
PELVIC HARNESS: ASSEMBLY AND ADJUSTMENT

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



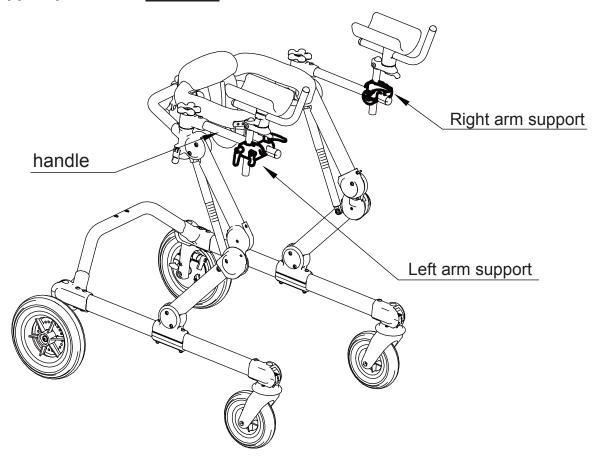
Pull the straps until the inguinal belts are tightened.

ASSEMBLING AND ADJUSTING THE COMPONENTS

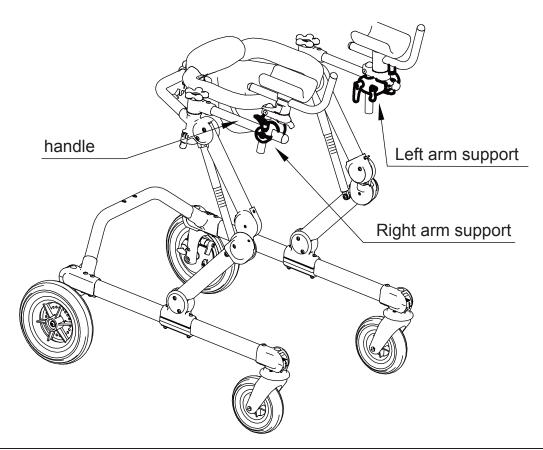


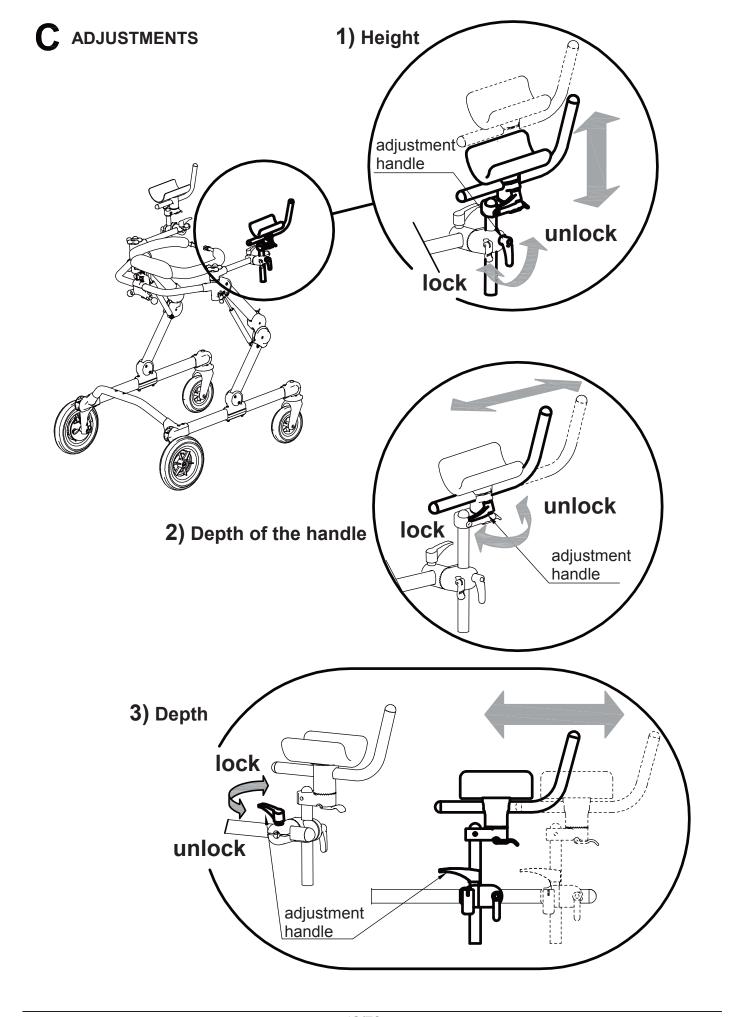
B POSITIONING

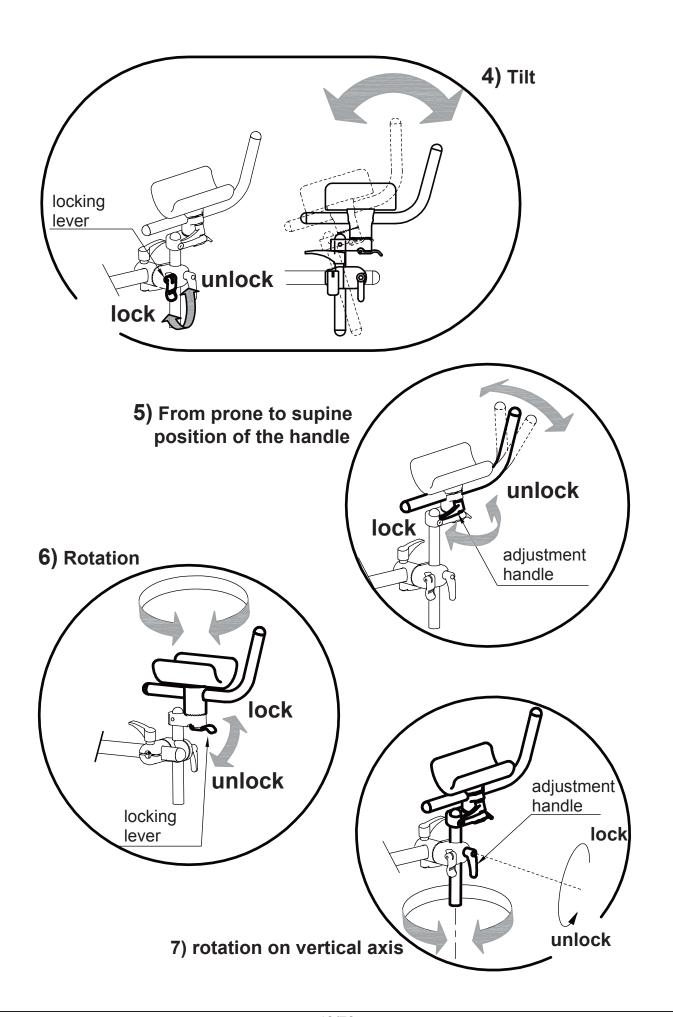
1) Arm support positioned <u>outside</u> the handle



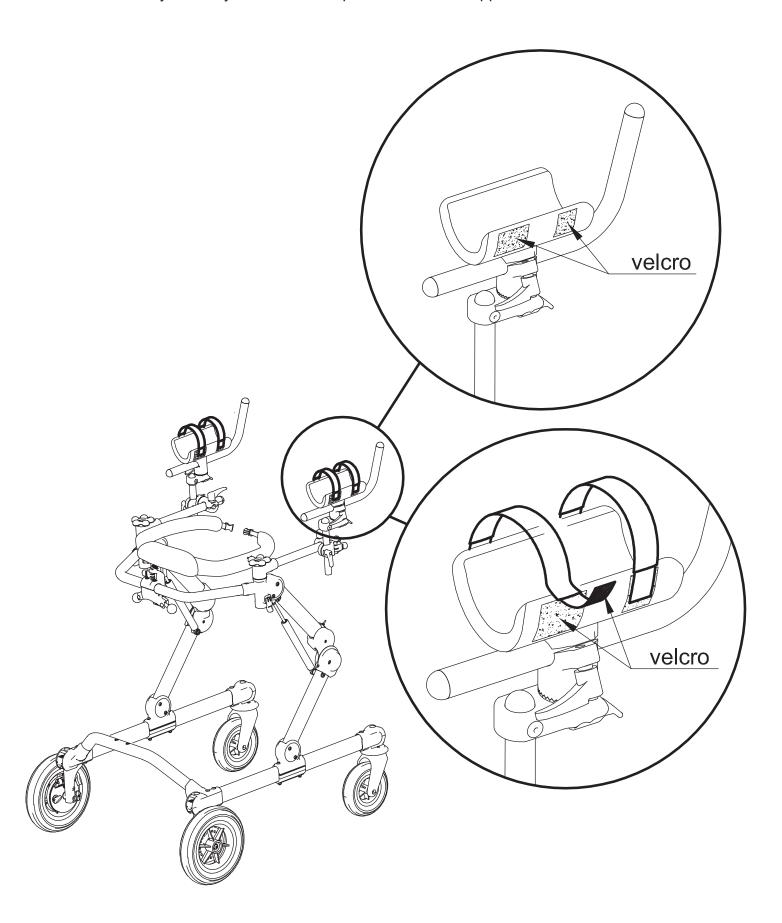
2) Arm support positioned <u>inside</u> the handle



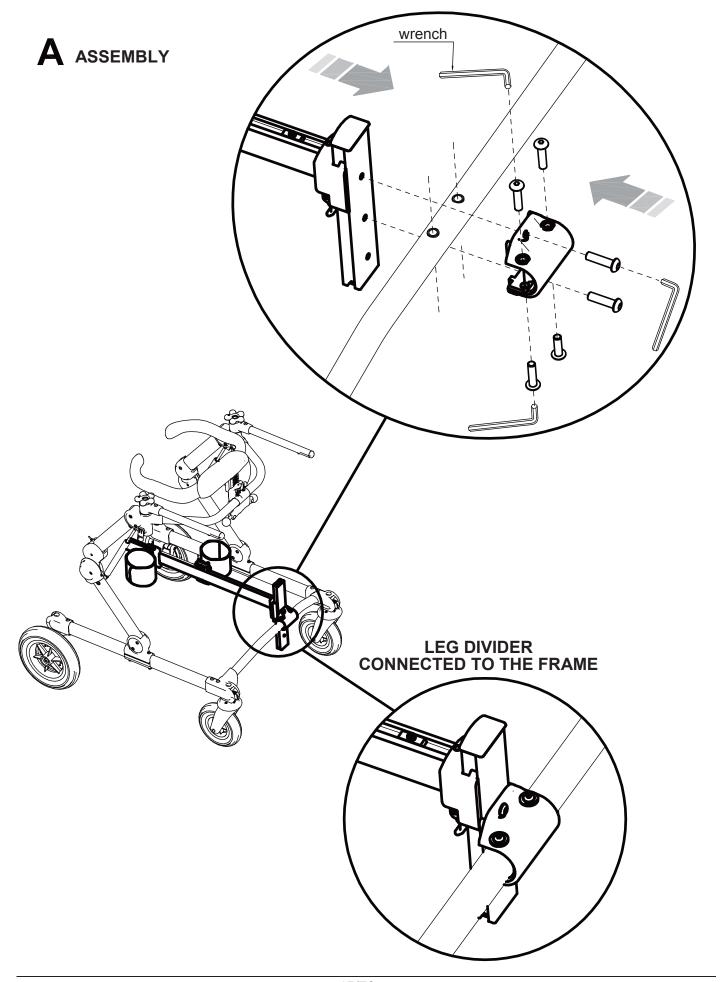


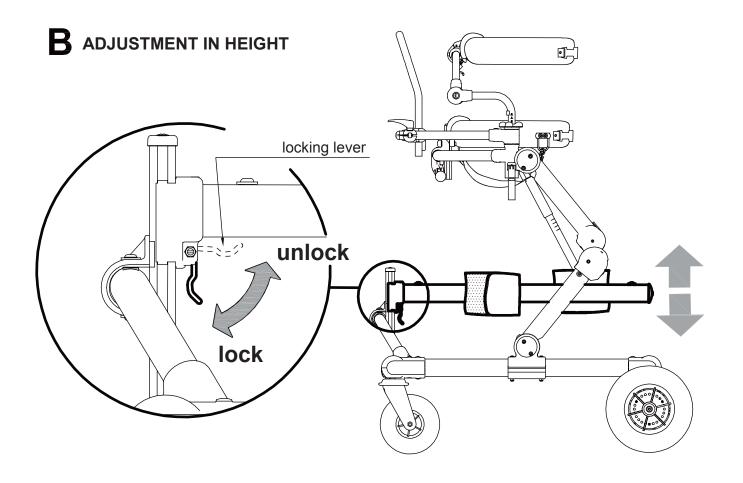


This accessory can only be mounted in presence of arm supports

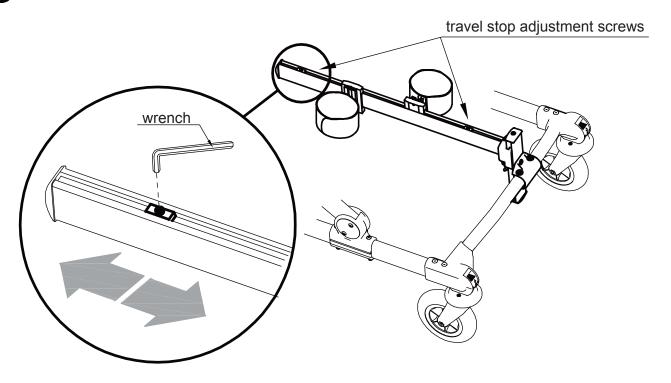


LEG DIVIDER WITH THIGH SUPPORTS

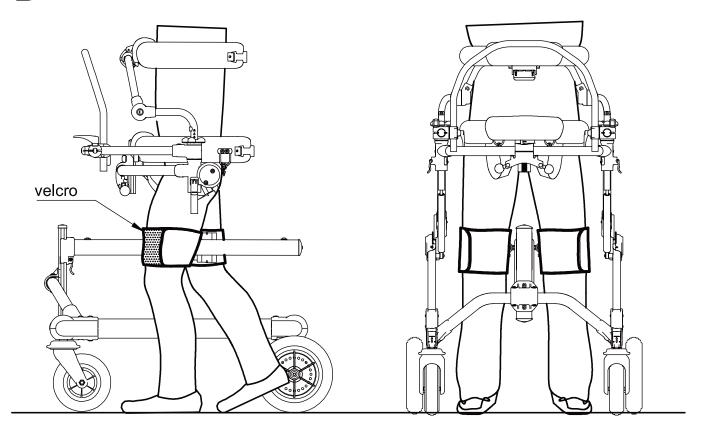




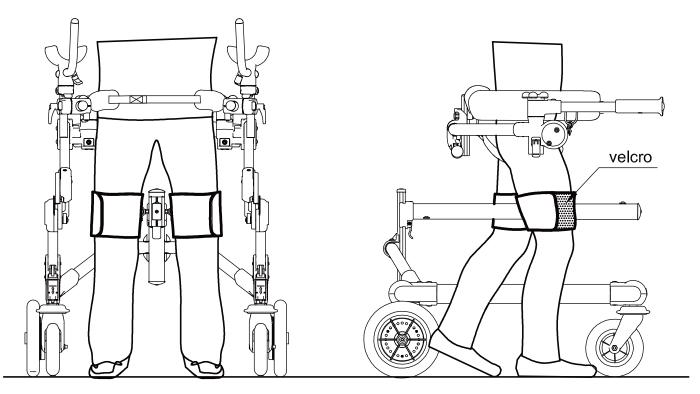
C ADJUSTING THE TRAVEL STOP

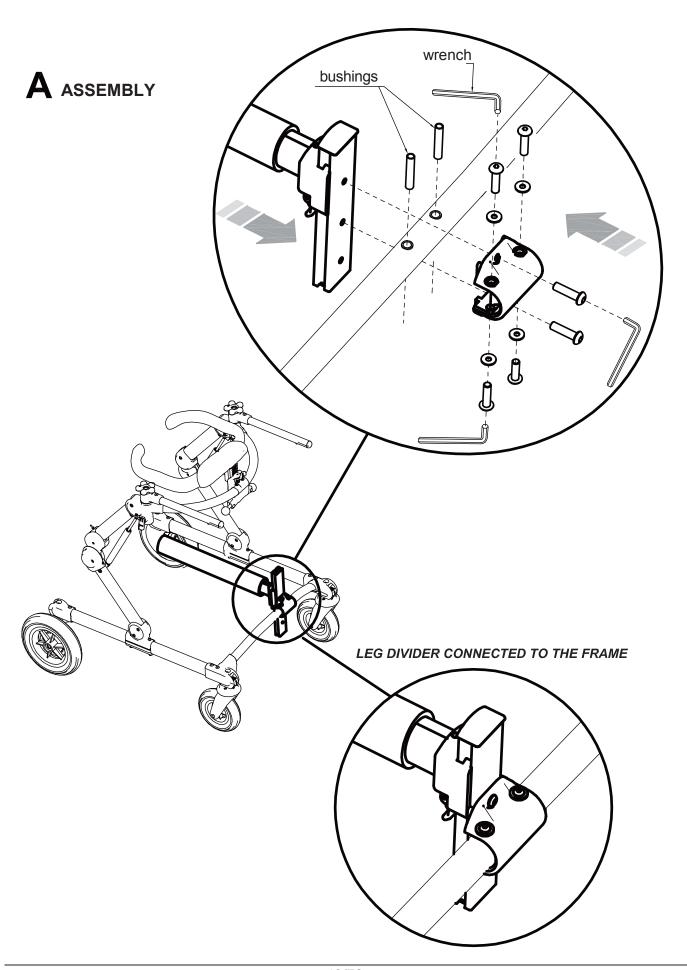


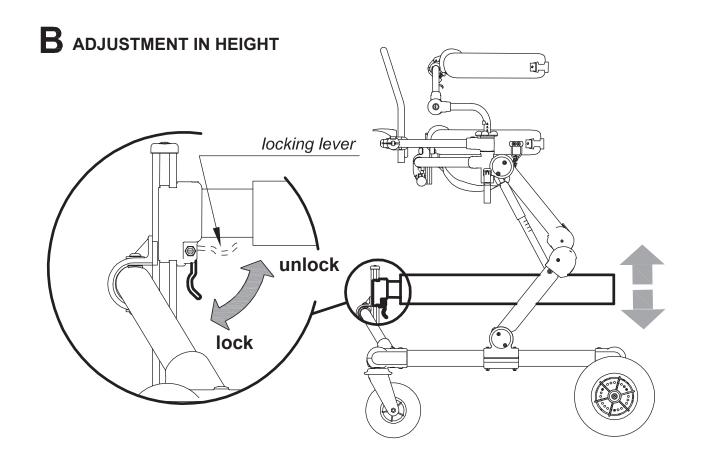
POSITIONING THE LEGS DIVIDER GRILLO IN THE FRONT-DRIVE GAIT-TRAINER



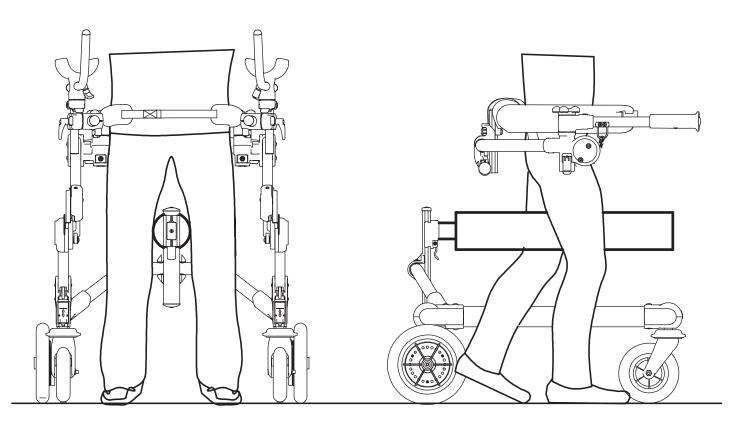
POSITIONING THE LEGS DIVIDER GRILLO IN THE POSTERIOR GAIT TRAINER





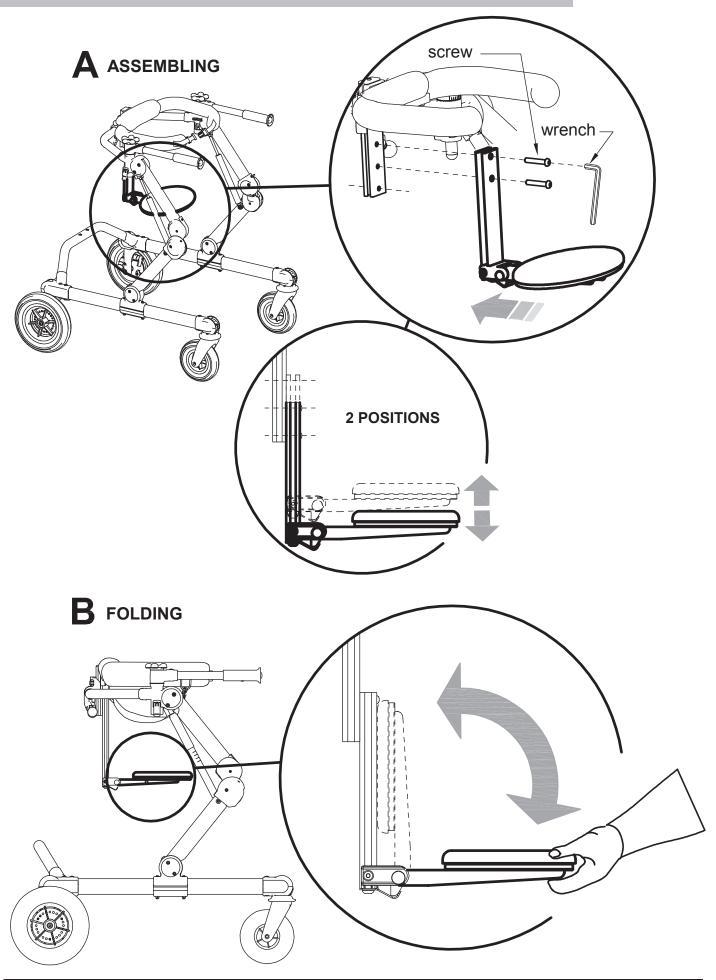


C POSITIONING THE LEGS DIVIDER GRILLO

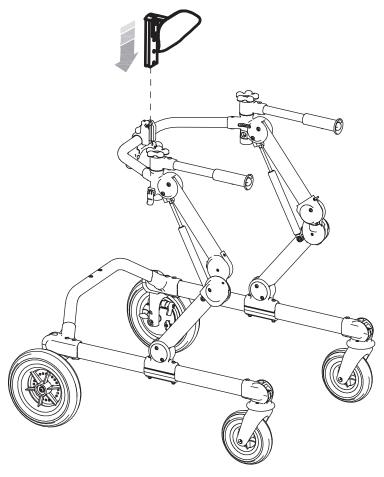


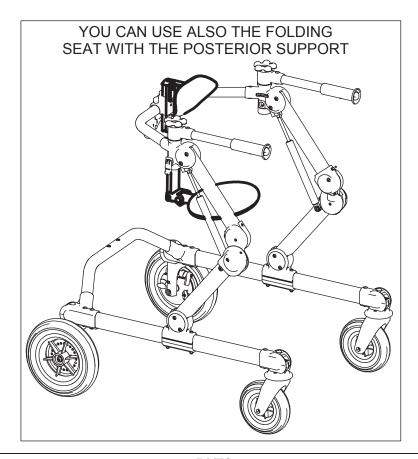
FOLDING SEAT for GRILLO POSTERIOR GAIT TRAINER

sizes S and M

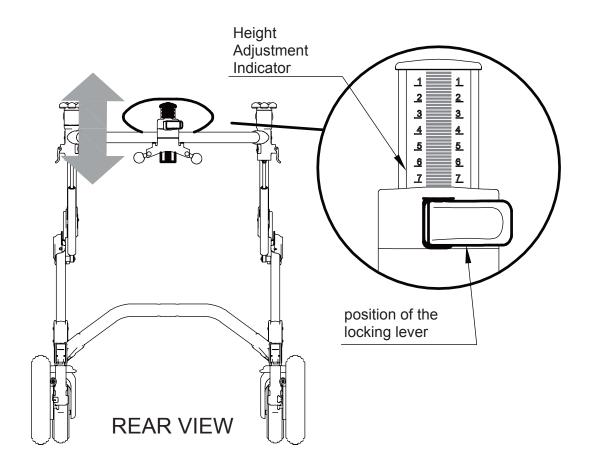


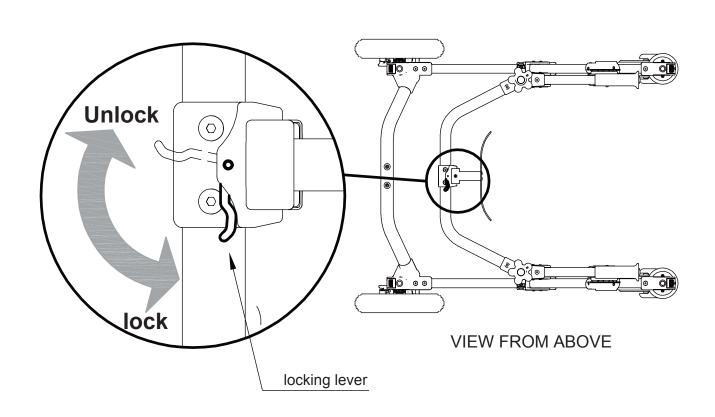






B HEIGHT ADJUSTMENT

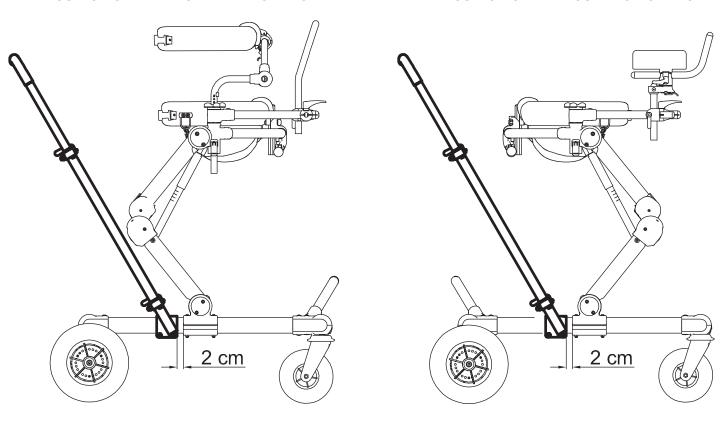




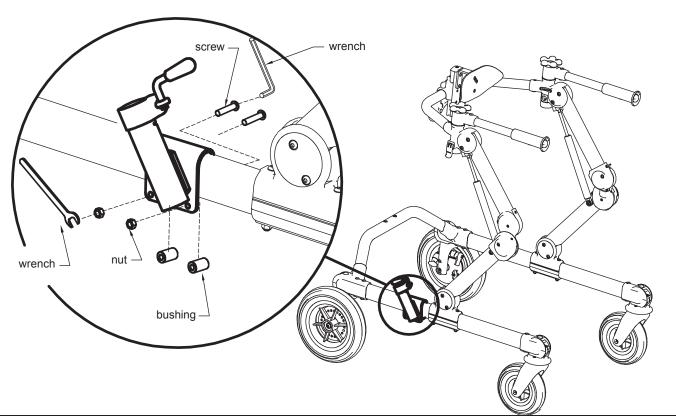
PUSH HANDLE for THE ASSISTANT sizes S and M

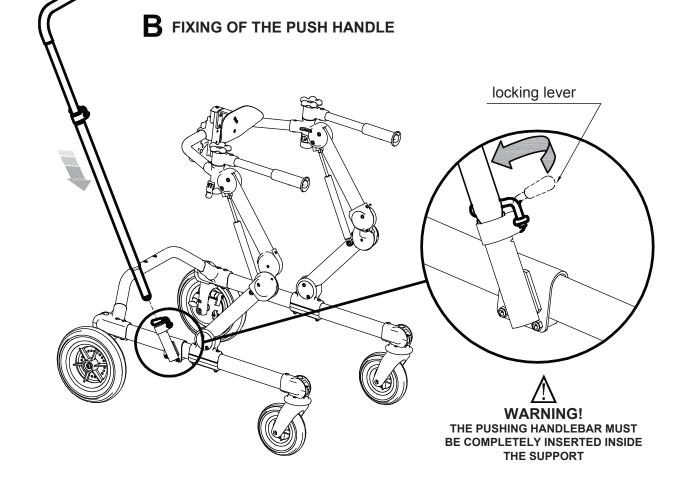
POSITION ON THE FRONT DRIVE GRILLO

POSITION ON THE POSTERIOR GRILLO

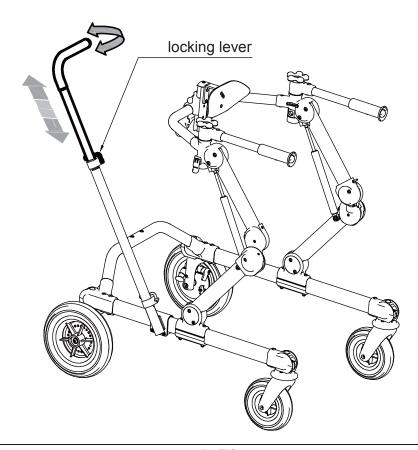


A ASSEMBLY OF THE HANDLE FORK



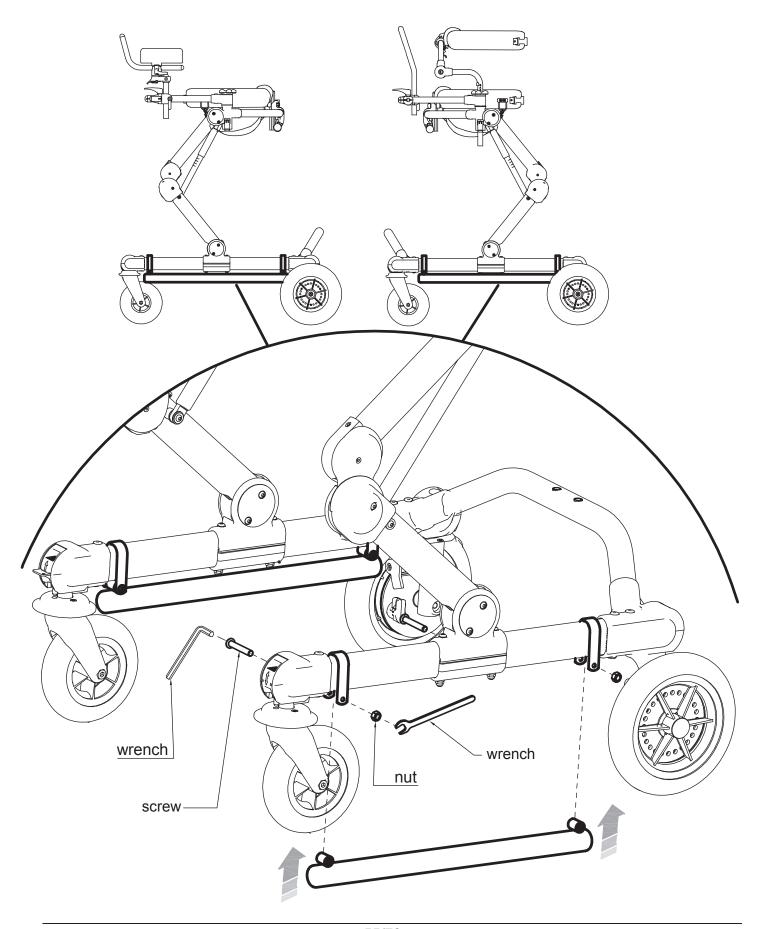


C HEIGHT AND ROTATION ADJUSTMENT

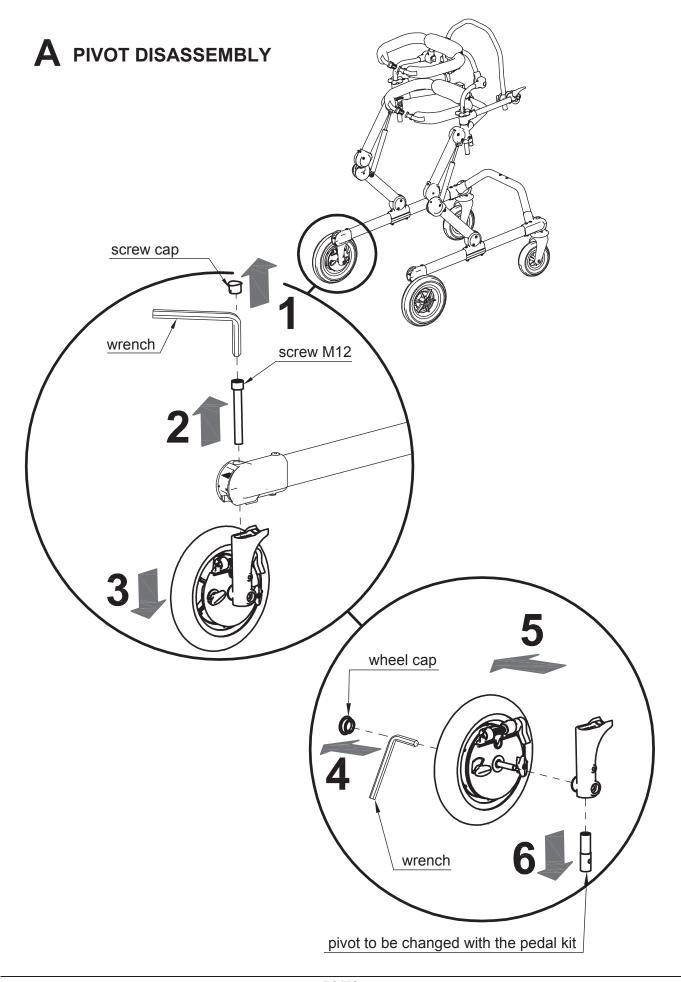


FIXED ON POSTERIOR GRILLO

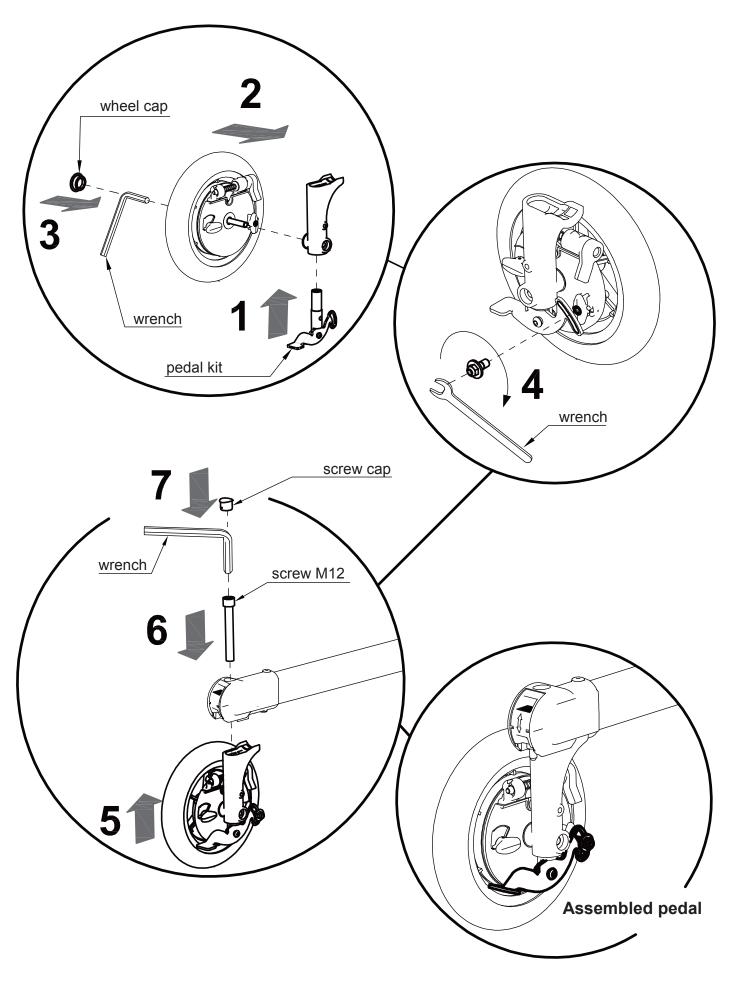
FIXED ON $\underline{\mathsf{FRONT}\text{-}\mathsf{DRIVE}}$ GRILLO

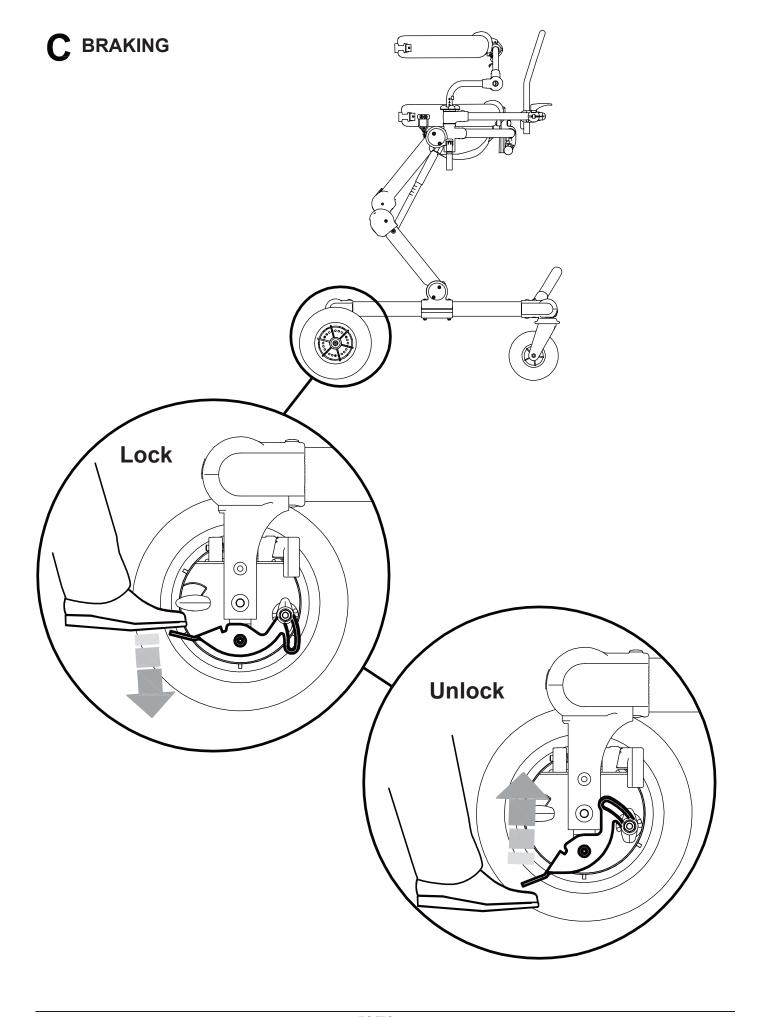


PEDALS for GRILLO PARKING BRAKES

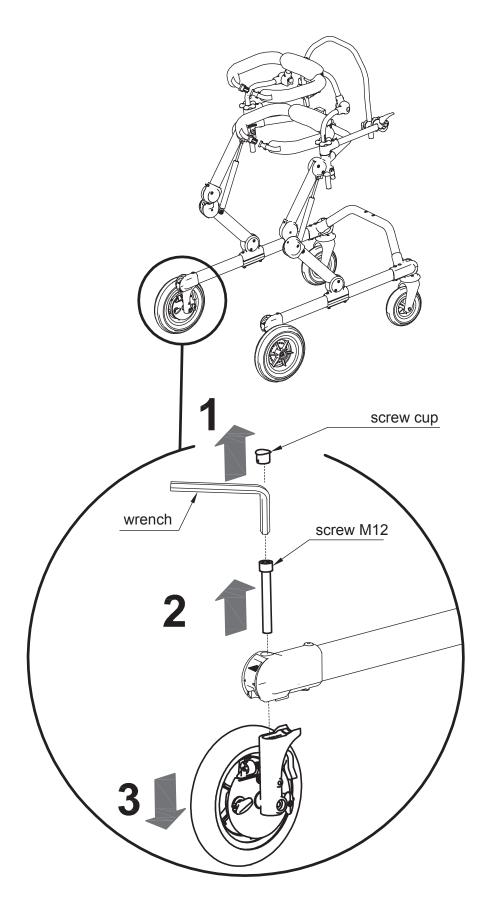


B PEDAL KIT ASSEMBLY

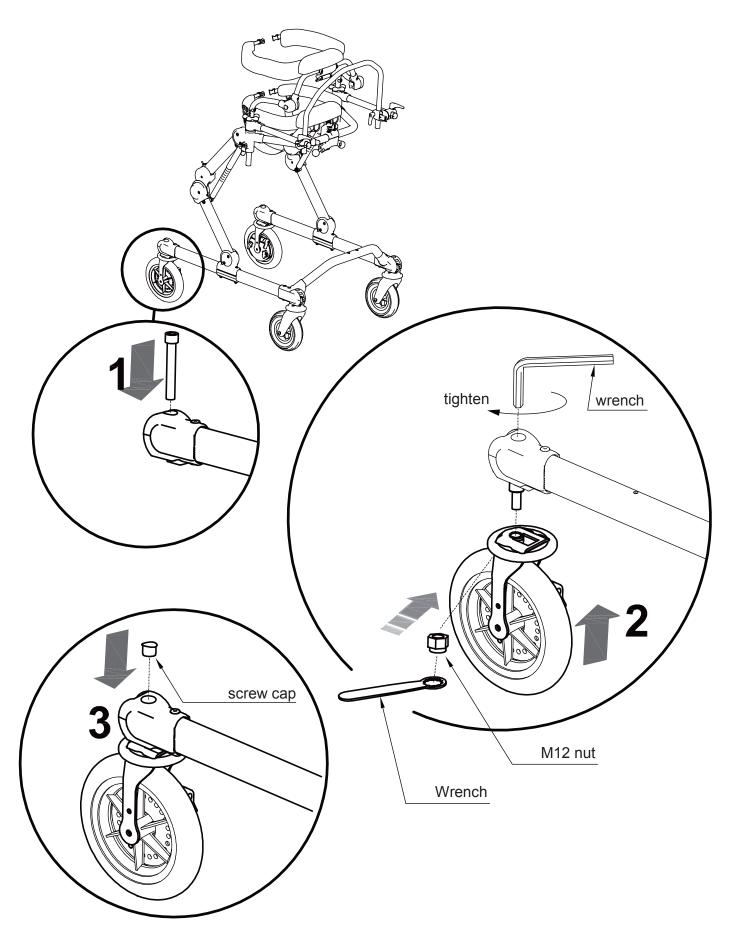


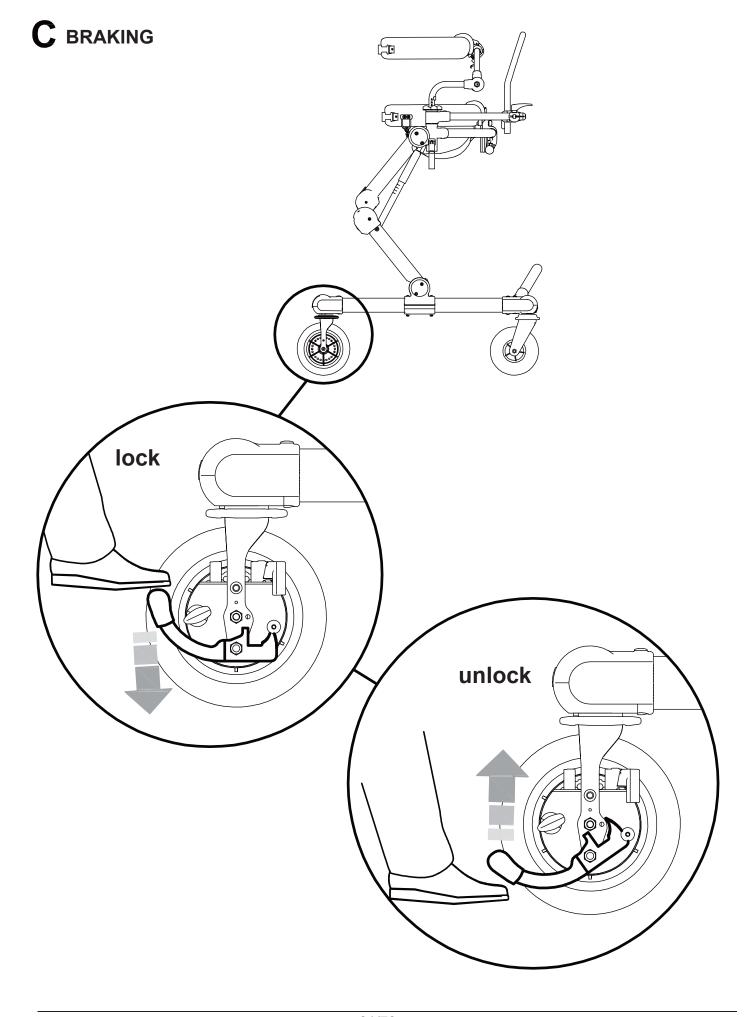


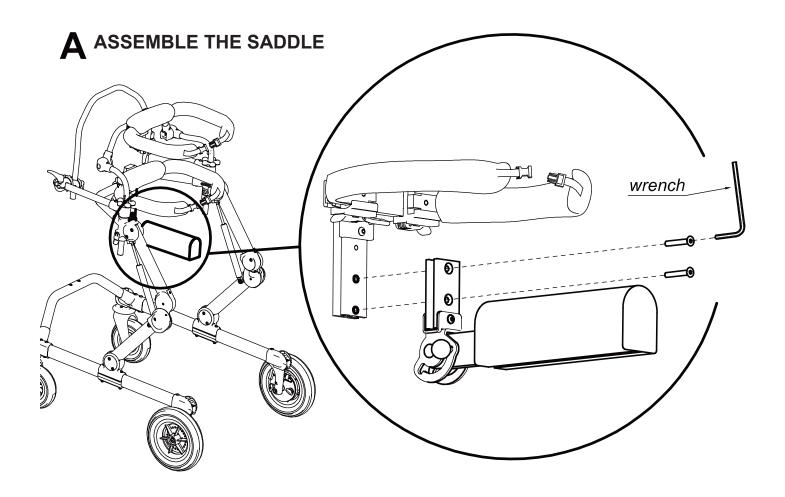
A DISASSEMBLY WHEELS OF THE STANDARD BASE

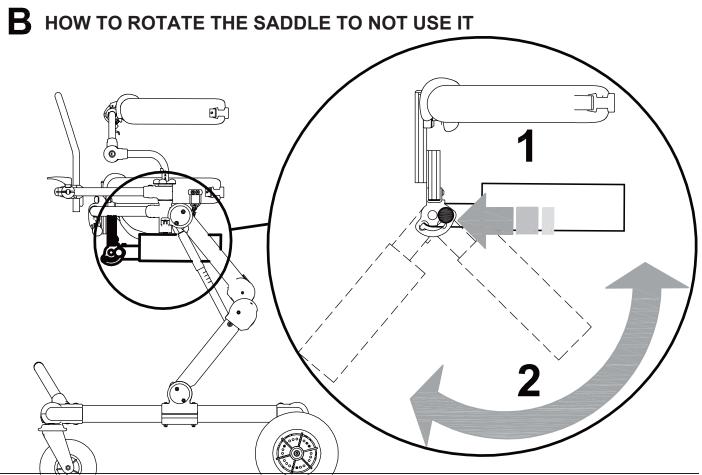


B ASSEMBLY WHEELS FOR THE NARROW BASE

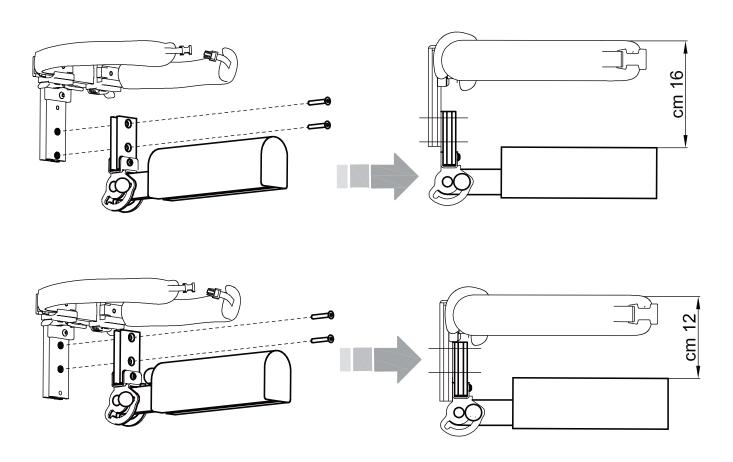




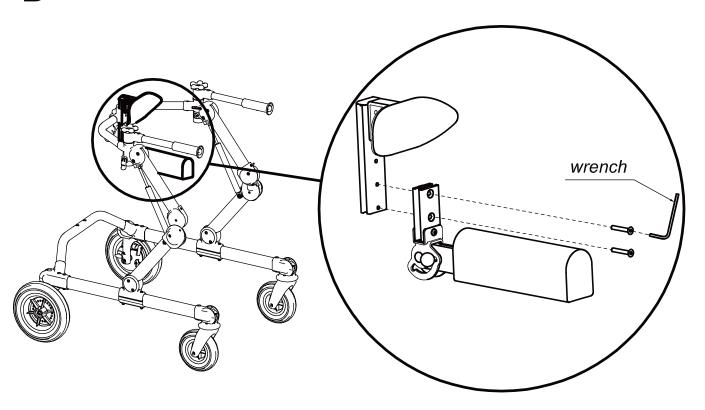




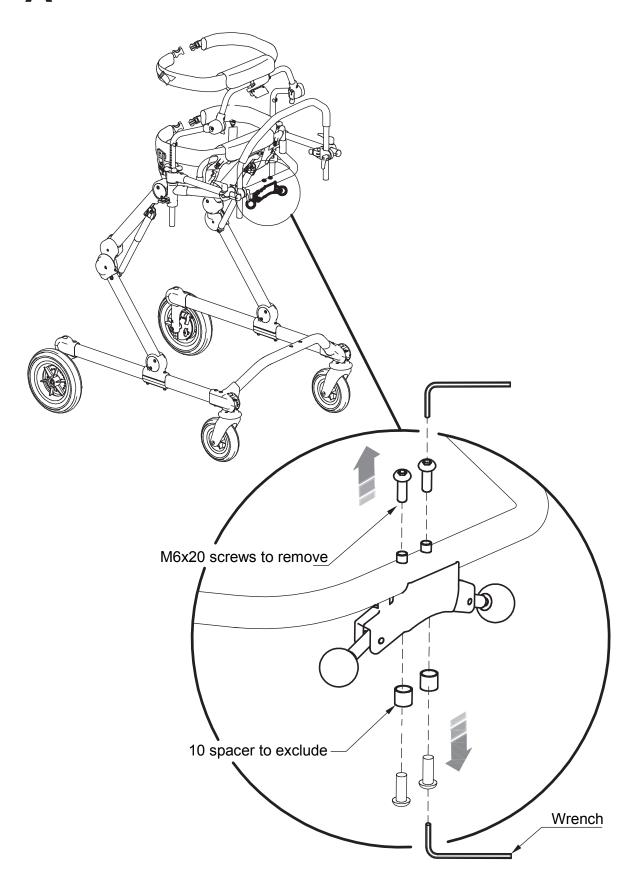
C HEIGHT ADJUSTMENT

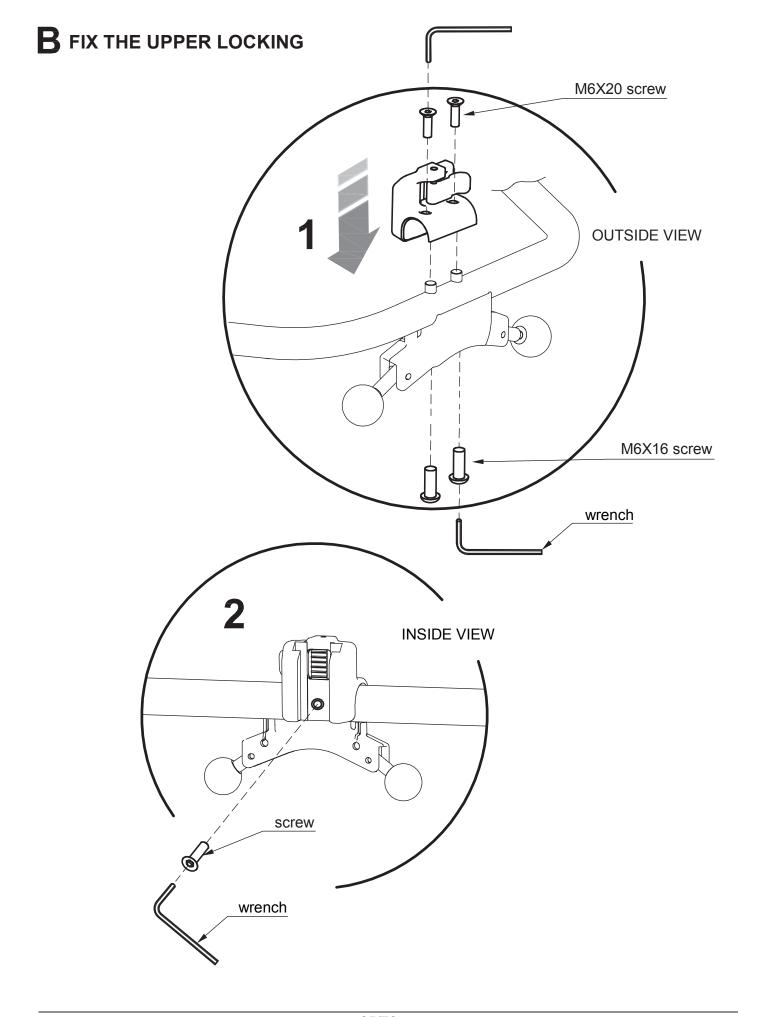


ASSEMBLE THE SADDLE ON LUMBAR SUPPORT

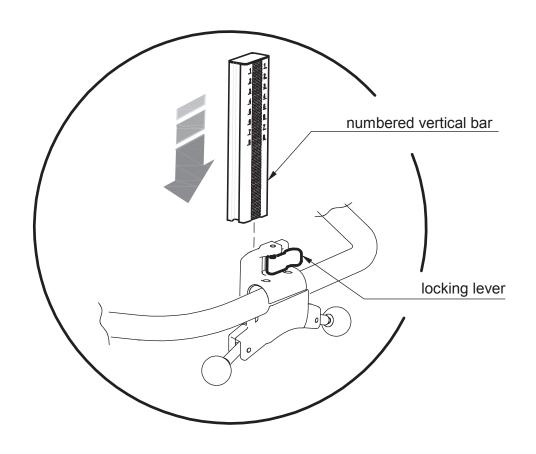


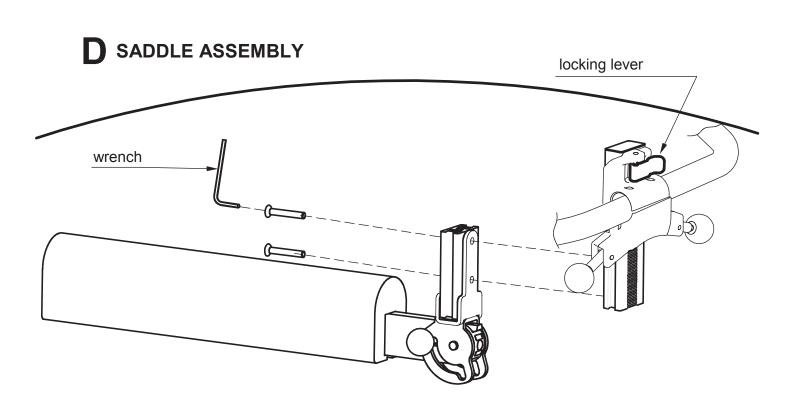
A REMOVE THE SCREWS OF THE LEVER SUPPORT



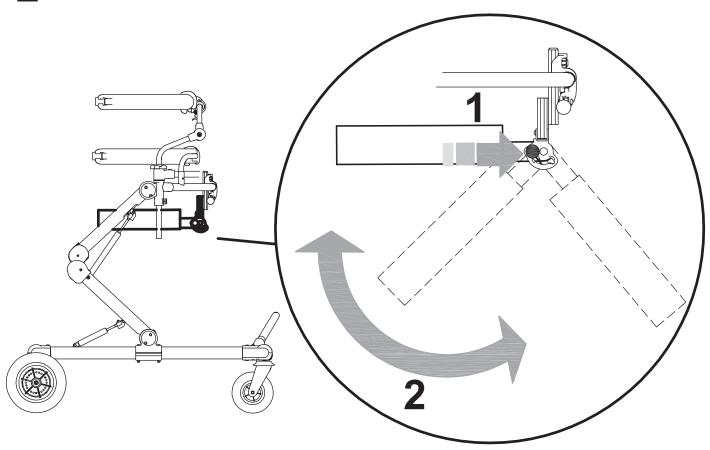


C FIXING THE NUMBERED VERTICAL BAR

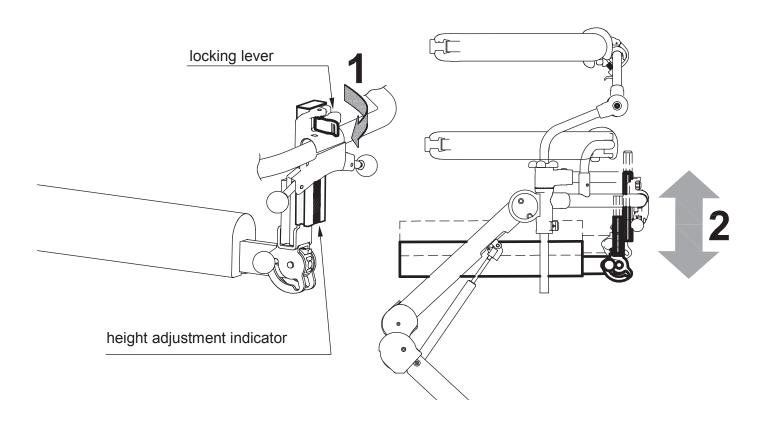


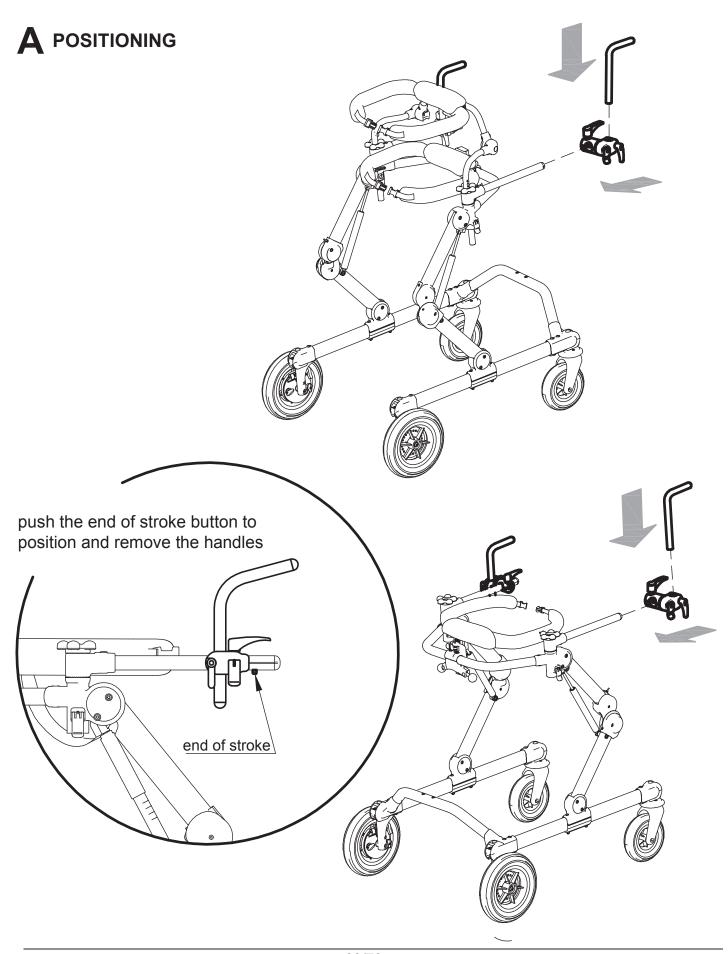


E HOW TO ROTATE THE SADDLE NOT TO USE IT

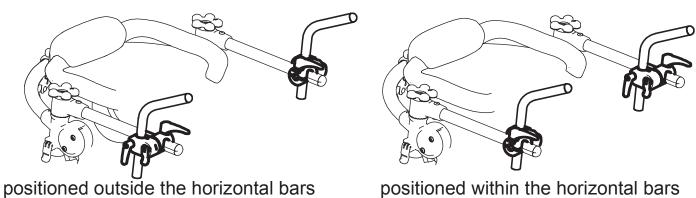


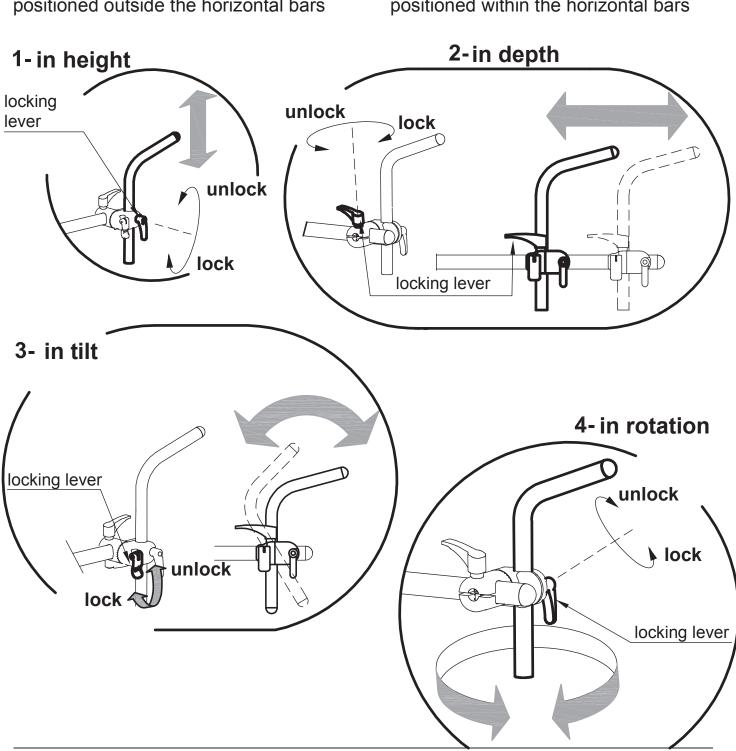
F HOW TO ADJUST IN HEIGHT



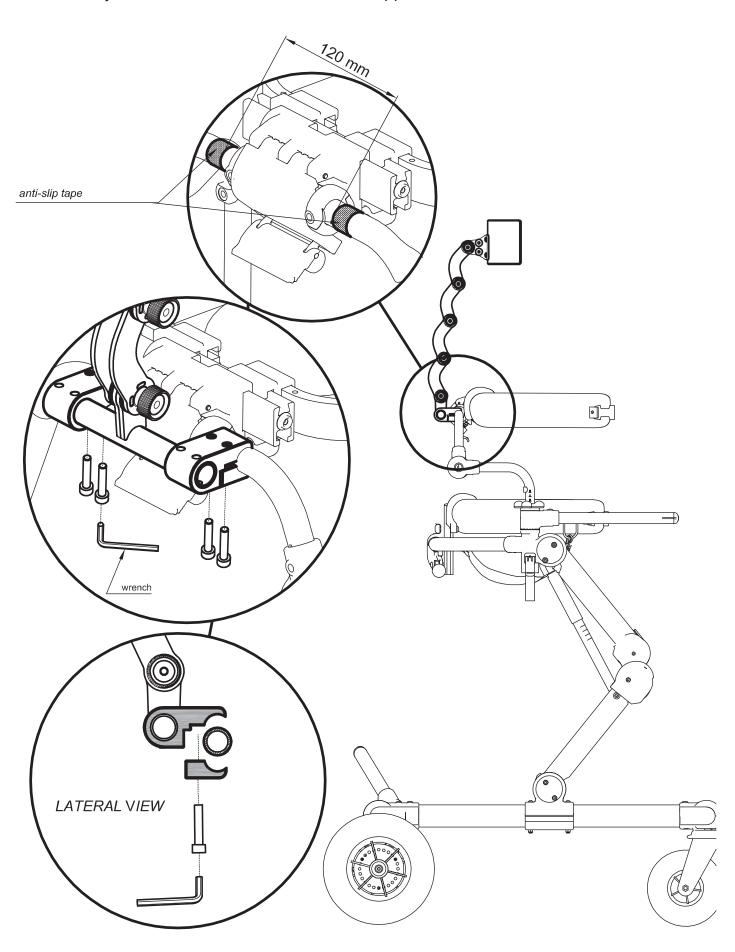


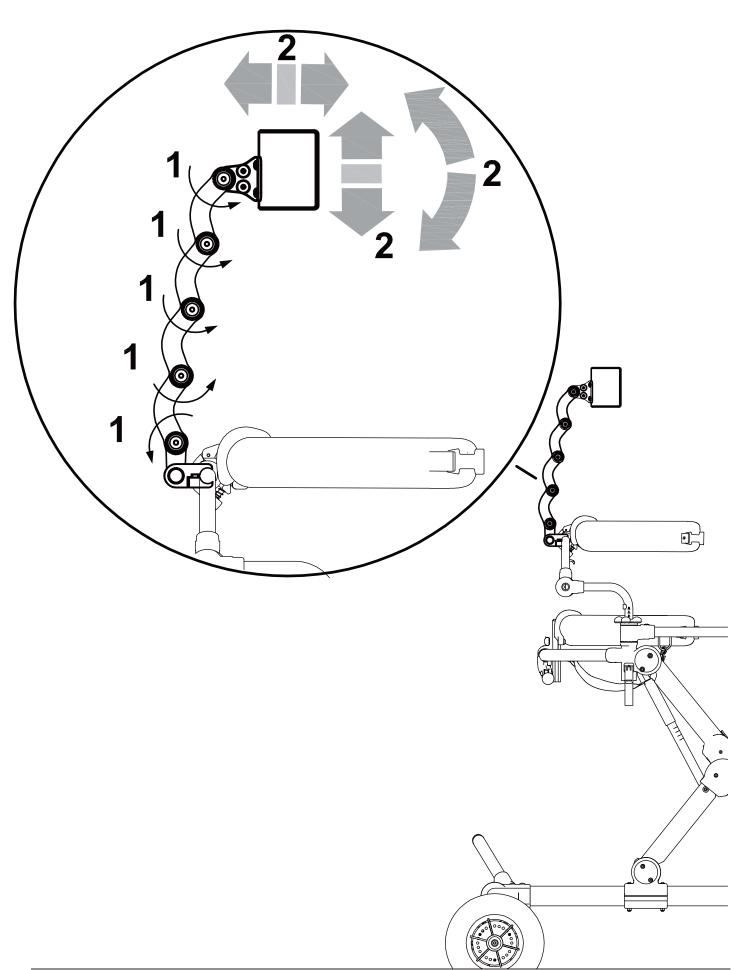
B POSITIONING and ADJUSTMENT





Available only for Posterior version with Trunk support





ORDINARY AND EXTRAORDINARY MAINTENANCE

1. ORDINARY MAINTENANCE (or preventive)

THE ORDINARY MAINTENANCE OF THE AID HAS TO BE DONE AT LEAST EVERY MONTH. ALL THE PERIODIC WORKS OF MAINTENANCE ARE NECESSARY TO ASSURE THE RIGHT USE OF THE AID AND ITS SAFETY. IT IS ALSO THE MAIN REQUIREMENT TO KEEP THE CE MARKING.

ONLY WHEN THESE INTERVENTIONS ARE COMPLETED IN THE TIME AND WAY SPECIFIED. THE RESPONSIBILITY OF **KEEPING** THE REQUIREMENTS OF THE WALKING FRAME (ENCL. 1 EEA/93/42 STANDARD) IS MANUFACTURER. THE **FURTHERMORE** THE MANUFACTURER **RECOMMENDS** COMPLETE REVISION/SERVICE Α ON THE FUNCTIONALITY/SAFETY OF THE AID BY THE SUPPLIER IN THE FOLLOWING **PERIODS:**

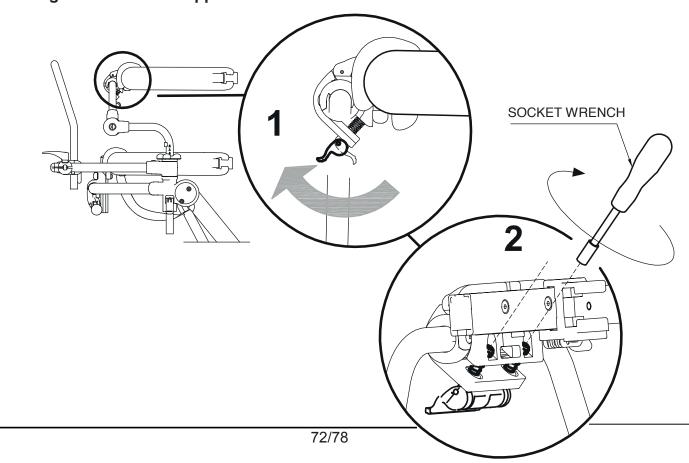
- 1) within 3 months from the purchase
- 2) within 6 months from the purchase
- 3) once in a year after the first year from purchase

1.1 SETTING OF CONTROL LOCKING LEVERS

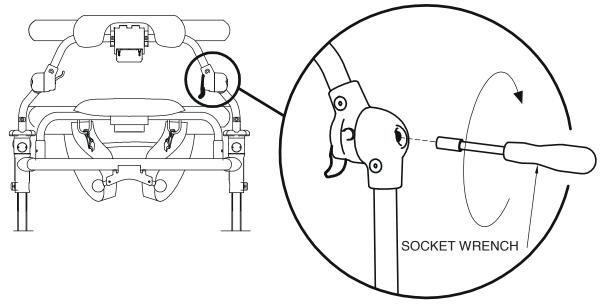


should you have noticed an INEFFICIENCY, even partially, on the LOCKING of the adjustment GREEN LEVERS of the PELVIC SUPPORT, of the TRUNK SUPPORT, of the HANDLEBAR, of the ARM SUPPORTS, please contact your ORTHOPAEDIC WORKSHOP to TIGHTEN THE NUT LITTLE BY LITTLE as shown below, UNTIL the PROPER LOCKING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

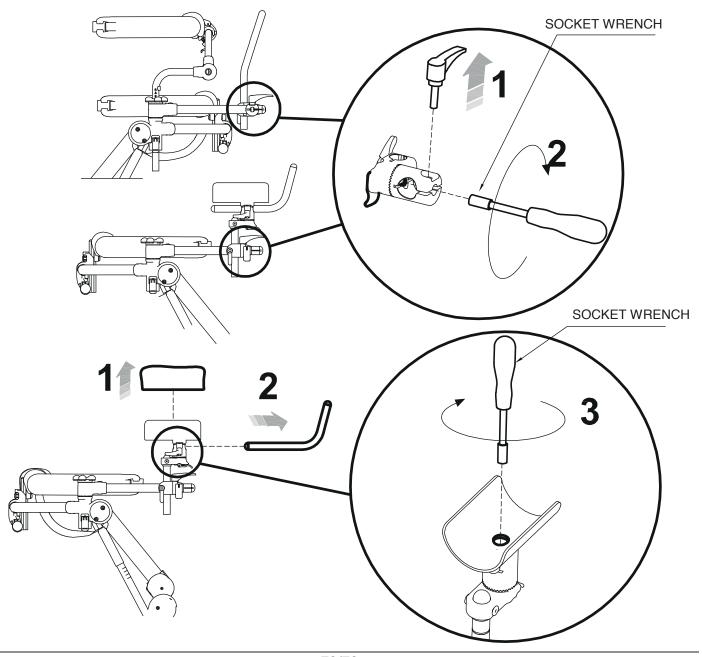
Locking lever for trunk support rotation



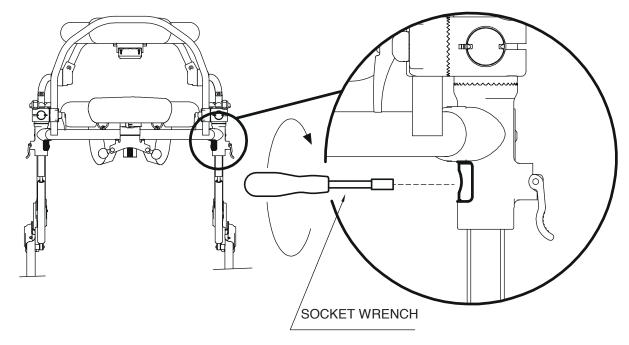
Locking levers for trunk support joints



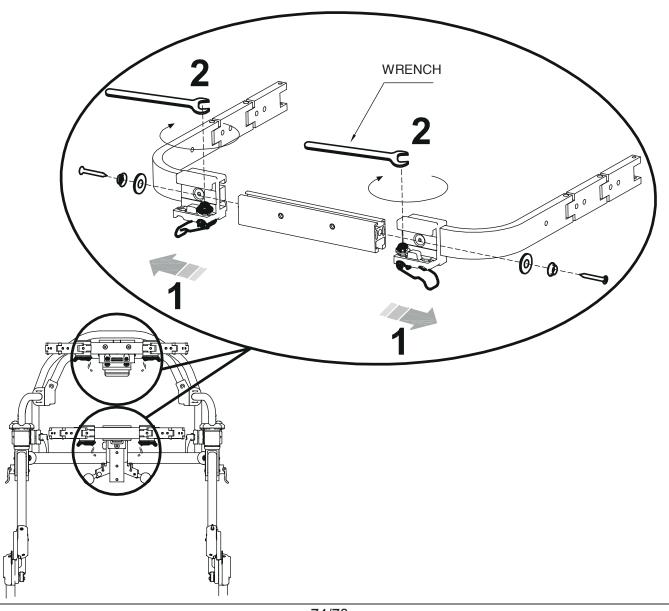
Locking levers for handlebar/arm supports joints

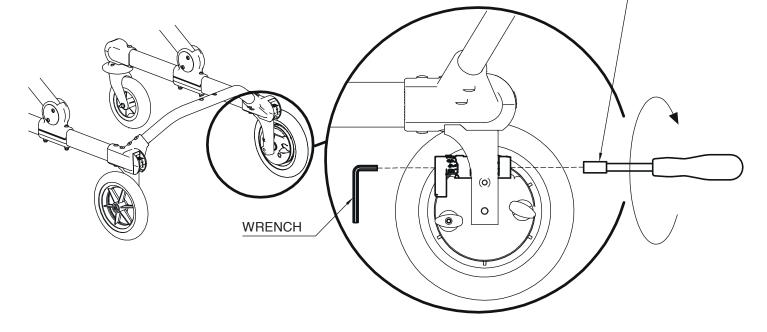


Height adjustment locking levers for trunk support



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 <u>INEFFICIENCY</u>, even if just partial, of the <u>BRAKES</u>, <u>contact</u> the <u>Dealer who sold you the product immediately</u>. 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 accessories 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 accessories must never be done while the aid is being used.

2. EXTRAORDINARY MAINTENANCE (or corrective)

EXTRAORDINARY MAINTENANCE MEANS ALL THOSE WORKS ON THE WALKING FRAME WHICH ARE DIFFERENT FROM THE ABOVE MENTIONED ONES.

WE ASK THE USER, DEALER AND ALL PUBLIC HEALTH SERVICES TO LET THE MANUFACTURER OR OTHER OFFICIALLY AUTHORIZED COMPANIES INTERVENE WITH EXTRAORDINARY MAINTENANCE WORKS.

ANY OTHER DIFFERENT ACTION MEANS THAT THE USER AND THE THIRD MAINTENANCE SERVICE ASSUME THEIR RESPONSIBILITY FOR THEIR DONE WORKS ON THE AID. THE MANUFACTURER WILL BE ONLY RESPONSIBLE FOR ANY POSSIBLE ORIGINAL DEFECT OF THE PRODUCT THAT MAY BE DECLARED TO THE MANUFACTURER.

CLEANING, DISINFECTION, SANITIZATION

1) **CLEANING AND CLEANSING**

0

With cleaning and cleansing, a large part of microorganisms, further to the visible dirt, is removed from the surface.

Clean regularly the varnished/chromium-plated frame, and the pelvic/trunk paddings and upholsteries as follow.

Dilute a teaspoon of neutral non-aggressive and no corrosive household detergent (e.g. Marseille soap), in a liter of warm water (max. 40°).

Moisten a sponge and, after squeezing it, pass it on the affected parts.

After cleaning, wipe only with a water-dampened cloth to remove any trace of detergent, and then dry.

When it is necessary a cleaning and a deeper cleansing of the removable upholsteries and the harness, it is possible to wash them following instructions as in point 3) WASHING.

1) **DISINFECTION**



Disinfection further decreases the number of microorganisms on a surface and it eliminates pathogenic microorganisms, i.e. bacteria that cause diseases and viruses. The products authorized by the Ministry of Health are "recognized disinfectants" and therefore defined as "medical surgical device".

For disinfection, when necessary or requested according to the use and needs of the specific user, it is possible to use germicidal and fungicidal products for hospital equipment, available in spray, which are efficient at cold temperature and without rinsing, respecting the time of action and the manufacturer's instructions available on the packaging or on the labeling

Any disinfection has to be always preceded by cleaning and cleansing, since dirt reduces the action of the disinfectant. Drying is essential because, microbial growth may occur in the residual water film.

It is recommended to read the technical sheet of the spray 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.

WARNING!

for the cleaning / disinfection of <u>pelvic/trunk supports paddings</u>, <u>do not use</u> ethyl alcohol or detergents containing, even if in small quantities, acetone, trichloroethylene and ammonia (solvents in general).

1) **WASHING**

It is possible to wash the HARNESS and REMOVABLE UPHOLSTERIES, respecting the following indications:











WARNING

The metal rings of the harness could damage the washing machine drum if the fast cycle of spin dry is used. Use the short cycle (soft) as indicated in the table.

2) SANITIZATION WITH PERCARBONATE



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.

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.

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 9001, 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:

- 1. 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 accessories or spare parts have been applied.
- Qualified technical personnel of a company specialized in the maintenance of technical aids for disabled people 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 a specialized service center in the maintenance of mechanical aids for disabile, or directly ORMESA.



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

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| Authorized Dealer | | | |
|-------------------|--|--|--|
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The technical Data and information given in this handbook are not binding. ORMESA reserves the right to carry out any necessary change without prior notice or replacements