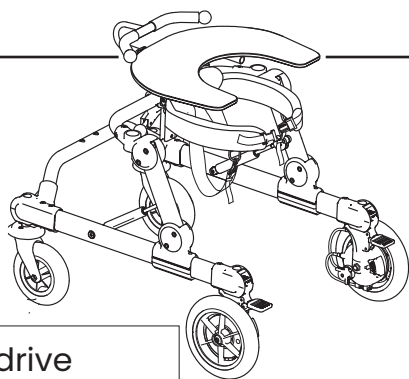


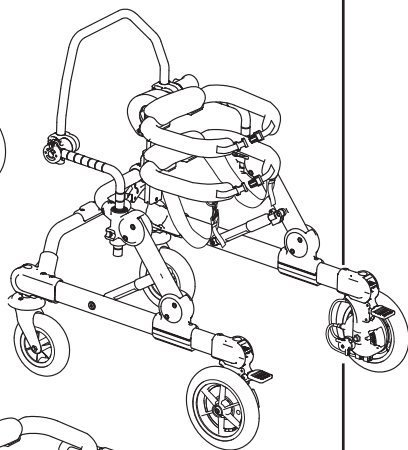


front drive and rear drive
gait trainer size mini

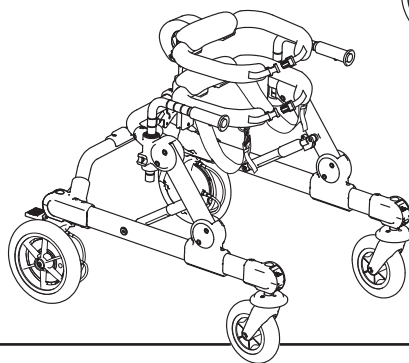
USA - cod. 220195 29-05-25



front drive
gait trainer



rear drive
gait trainer



USE AND MAINTENANCE HANDBOOK

ORMESA®

• MADE IN ITALY SINCE 1980 •



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

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

ORMESA s.r.l. recommends that you read this manual carefully to fully understand its contents. In addition to help you become familiar with the device quickly, it also contains practical tips for making the best use of it safely and keeping it in good working order.

If, after reading it, you still have questions, contact your retailer, who will be happy to help you, or call AMYLOR directly at T 1 450 424-0288 | 1 888 453-0311 or send an email to info@amylor.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 mini can be only used by people who have well read the instructions specified in this handbook.**
- **Training for the use of GRILLO mini 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".**
- **Always ask for original spare parts, if not the warranty expires**
- **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 mini 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 mini.



- **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 49, 50, 51, 52, 53, 54, 55, 56, 57 58.**



GRILLO mini IS A MECHANICAL MEDICAL DEVICE:



THE USER has to perform **REGULAR MAINTENANCE** and **CLEANING** following the instructions shown in the "Maintenance" chapter on pages 49, 50, 51, 52, 53, 54, 55, 56, 57 58. 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 **CE** marking will lapse



PRODUCT REPAIRS other than the regular **maintenance** shown on pages 9, 50, 51, 52, 53, 54, 55, 56, 57 58 of the manual must be **ONLY MADE** by a **SPECIALIZED SERVICE CENTER** in the maintenance of mechanical aids for disables, otherwise warranty and **CE** 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 WITHOUT ORIGINAL PARTS OR COMPONENTS** **ARE NOT AUTHORIZED**. **REFER ONLY TO ORMESA**, otherwise warranty and **CE** 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.

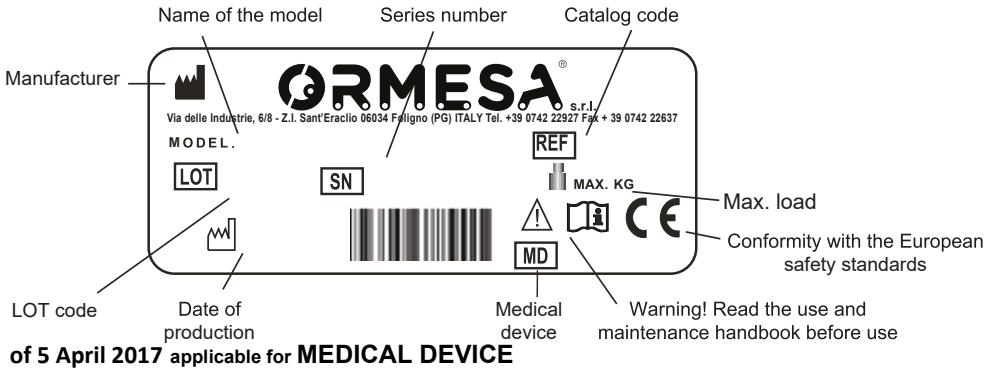


WHAT NOT TO DO WITH THE PRODUCT

- GRILLO mini 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 mini 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 mini ON UNEVEN GROUND, STEEP SLOPES OR STAIRS
- NEVER ALLOW UNKNOWN PEOPLE TO USE GRILLO mini.
- NEVER LEAVE THE USER UNATTENDED WHILE USING GRILLO mini.
- NEVER LEAVE GRILLO mini 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 mini 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 EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 applicable for MEDICAL DEVICE



This Medical Device is identified by a UDI (Unique Device Identifier), in compliance with Regulation (EU) 2017/745 and Code of Federal Regulations (CFR, US) Title 21. The UDI is a standardized code that allows the traceability and unique identification of the device throughout its life cycle.



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 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 49, 50, 51, 52, 53, 54, 55, 56, 57 58 and the warnings  on page 55.



WHAT GRILLO mini IS AND WHAT IT IS FOR

GRILLO mini 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 spathic/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 mini 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 ;
- 1) to develop physical self-sufficiency and psychological independence by experimenting the possibility of acting alone.

Grillo must be prescribed by a specialistic doctor. Further, it must be configured and regulated by a healthcare professional, who must provide the family with explanations on proper use, warnings, maintenance.

HOW GRILLO mini WORKS

GRILLO mini 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.

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

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 mini.

WHEN THESE OPERATIONS ARE COMPLETED, GRILLO mini 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 mini freely so that he can try the different ways of using it.

For "fearful" children who are afraid to use GRILLO mini (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 mini 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.

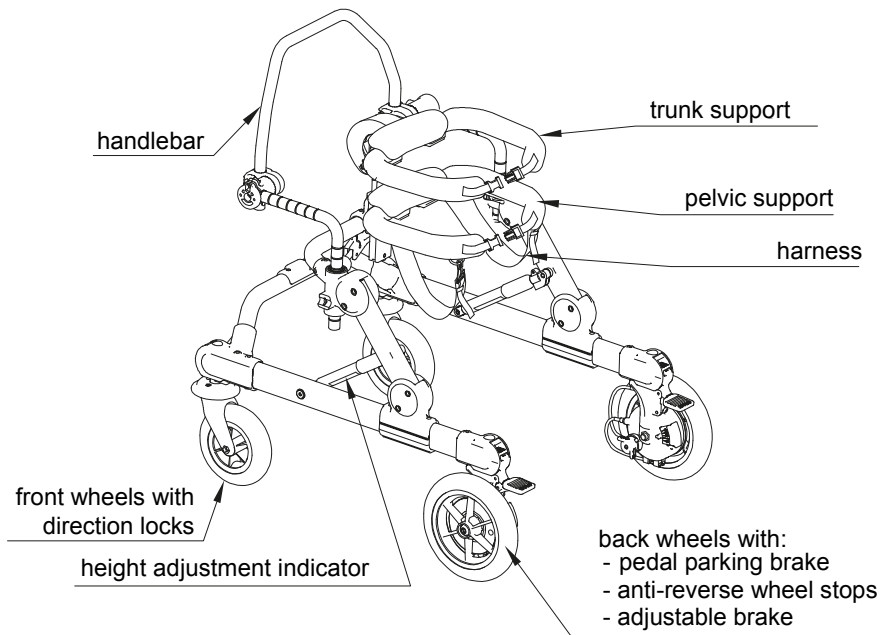
We suggest to follow well defined paths specifically designed to help orientate both "rash" and "fearful" Users.

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.

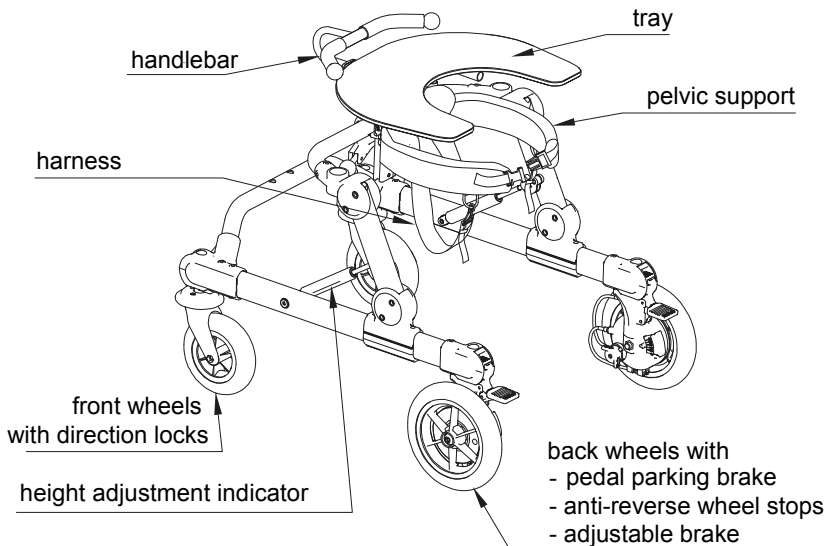


HOW GRILLO mini IS COMPOSED

FRONT-DRIVE PT FRAME

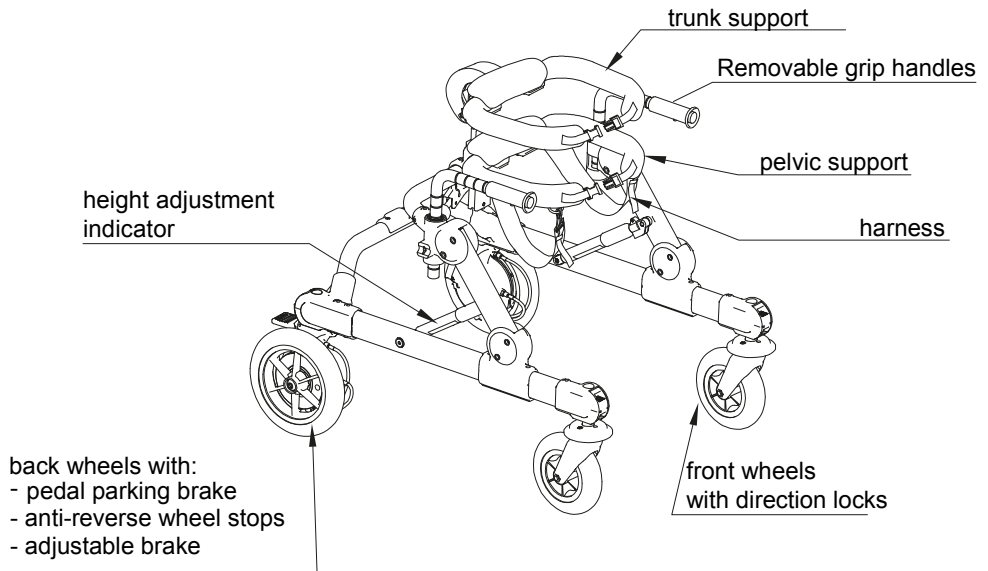


FRONT-DRIVE PTM FRAME





REAR DRIVE PT FRAME

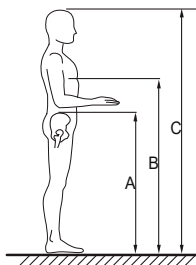




TECHNICAL SPECIFICATIONS

- **GRILLO mini** gait-trainer is available in two models: **the Front drive and the rear drive versions**
- **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.
- Adjustable **HANDLES**.
- **TRAY** removable and adjustable in height, tilt and back-forward positions.
- **HANDLEBARS (front-drive PT and front-drive PTM versions)** removable and adjustable in height, tilt and back-forward positions, it is used as a reference and as an armrest.
- **WHEELS**, light and puncture-proof: 2 fronts swiveling, Ø15 and 2 rear solid, Ø20 cm, for indoor and outside use
- **DIRECTIONAL LOCKS** on front wheels.
- **ADJUSTABLE BRAKES**.
- **ANTIREVERSE DEVICE**.
- **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**
- **REMOVABLE GRIP HANDLES** (for the REAR DRIVE version)

User dimensions



USER HEIGHT (C): from 75 to 95 cm (29,5"-37,4")

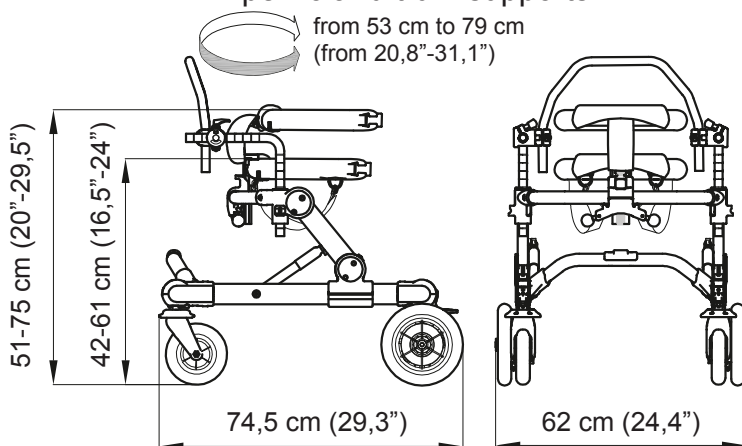
IMPORTANT:

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



DIMENSIONS in cm an Inches - Weights in Kilos and Pounds

Inner circumference of the adjustable
pelvic and trunk supports

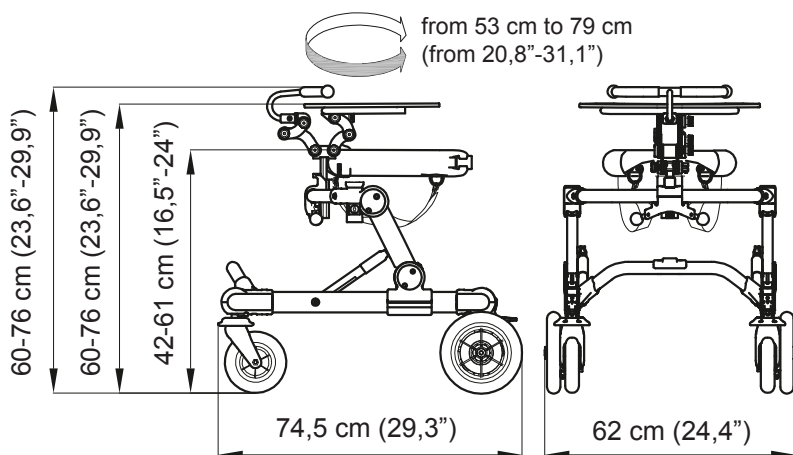


FRONT-DRIVE PT

WEIGHT 15 kg (33 Lb)

MAX. LOAD kg 35 (77,1 Lb)

Inner circumference of the adjustable
pelvic and trunk supports



FRONT-DRIVE PTM

WEIGHT 15,4 kg (33,9Lb)

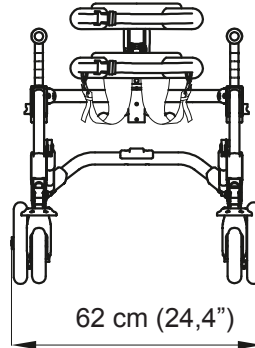
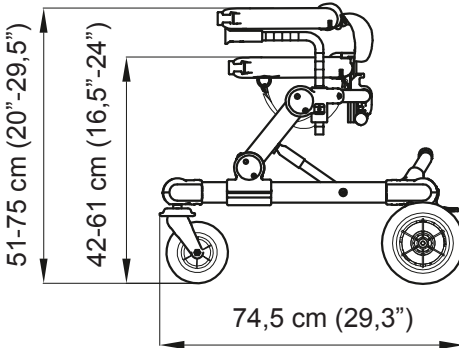
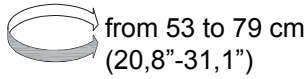
MAX. LOAD kg 35 (77,1Lb)

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



DIMENSIONS in cm an Inches - Weights in Kilos and Pounds

Inner circumference of the adjustable
pelvic and trunk supports



REAR DRIVE PT

WEIGHT 15 Kg (33 Lb)

MAX. LOAD 35 Kg (77,1 Lb)

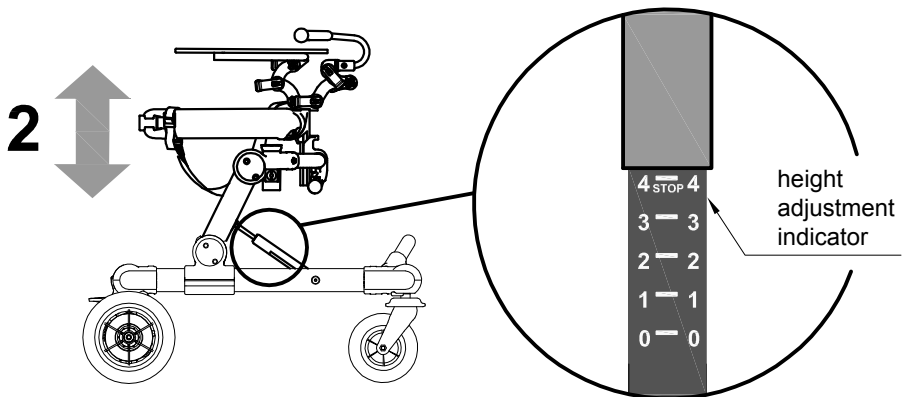
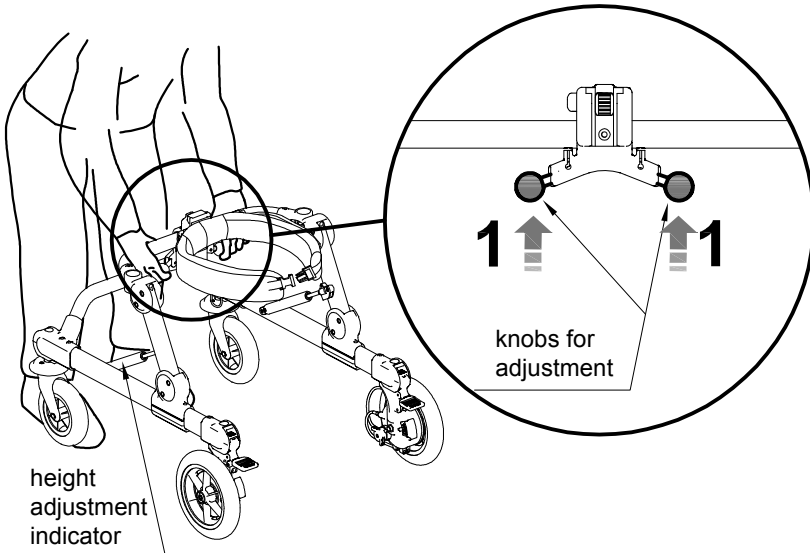
HYPHEN-SEPARATED NUMBERS INDICATE THE MINIMUM AND MAXIMUM RANGE OF ADJUSTMENT



HOW TO USE GRILLO mini

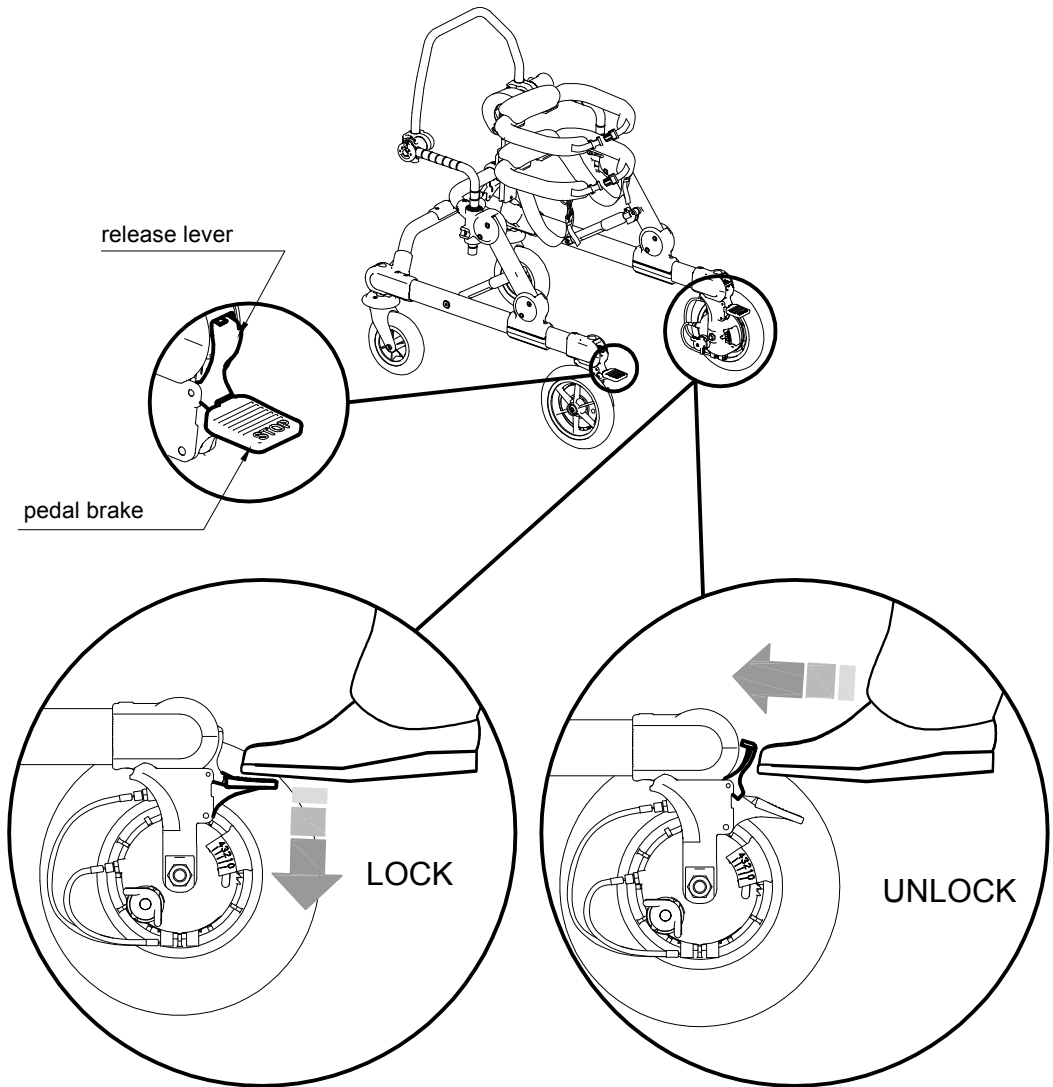
FRAME:HEIGHT ADJUSTMENT

- 1- OPERATE THE ADJUSTMENT KNOBS WITH BOTH HANDS
- 2- ADJUST THE HEIGHT OF GRILLO mini (0)RELEASING THEADJUSTMENT KNOBS



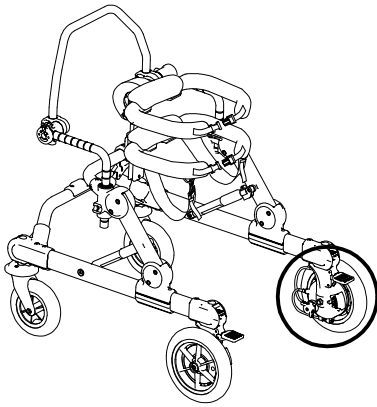


PARKING BRAKES

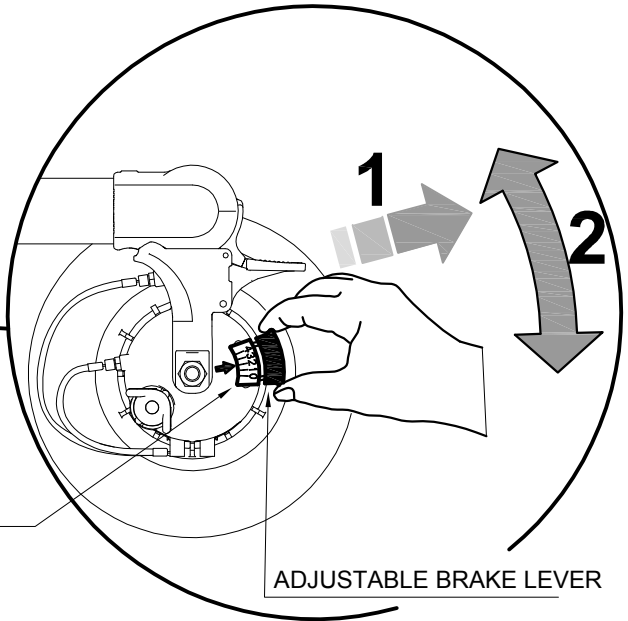




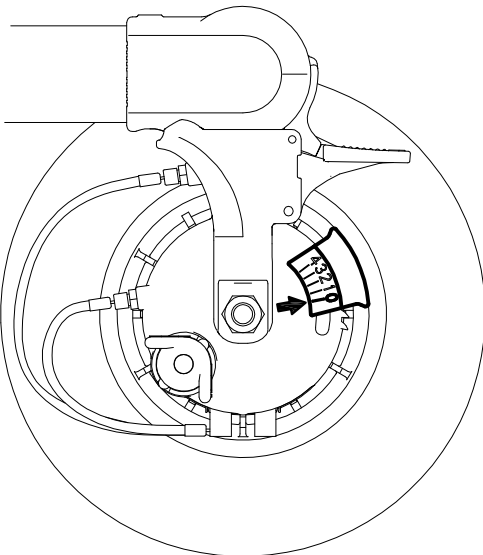
ADJUSTABLE BRAKE



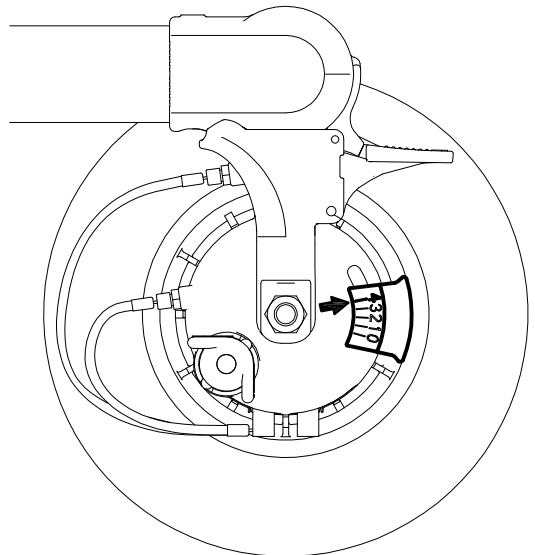
5 POSITIONS OF THE
ADJUSTABLE BRAKES



POSITION ZERO
FREE WHEEL



POSITION FOUR
WHEEL LOCKED



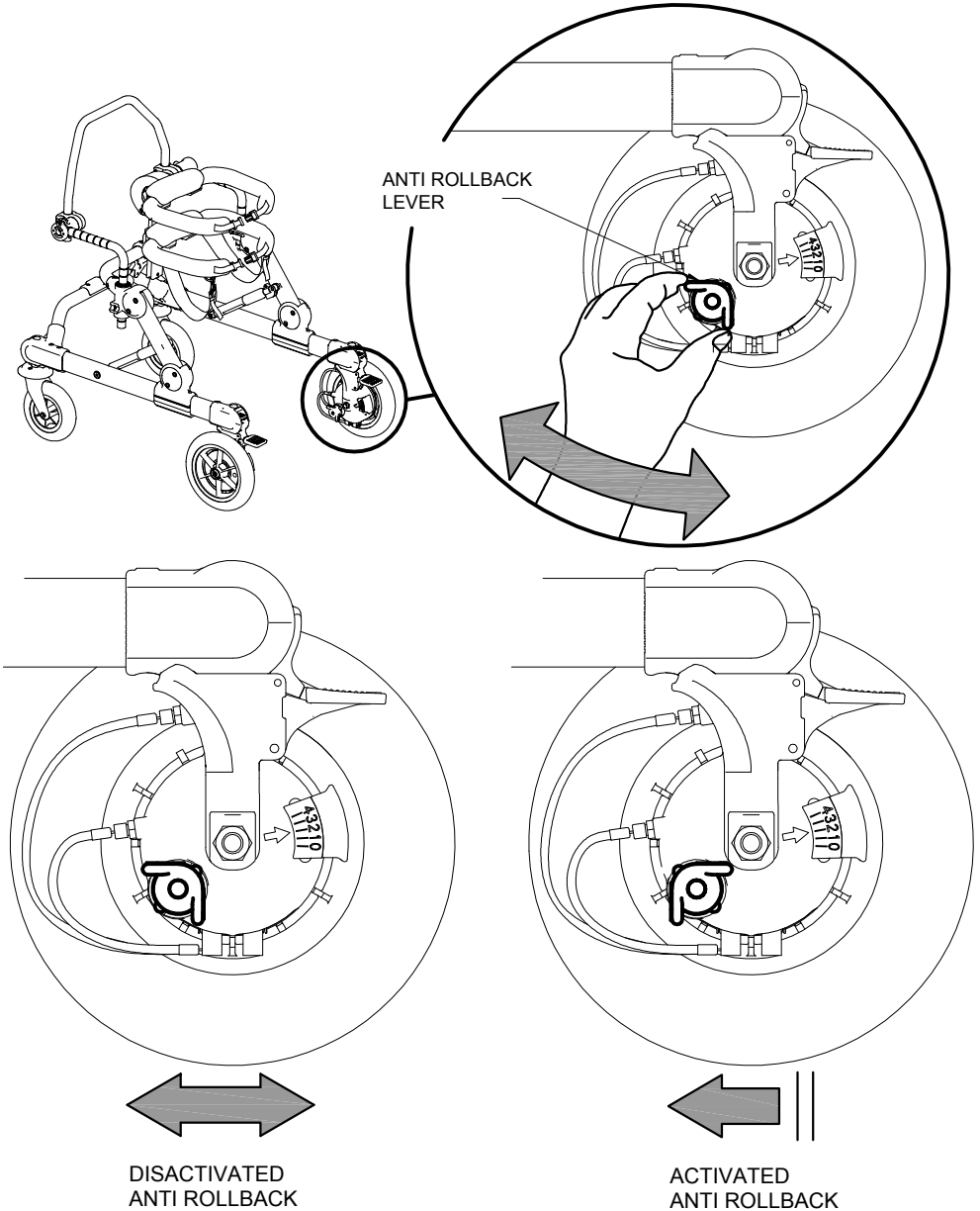


ANTI-REVERSE DEVICE



WARNINGS!

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





PELVIC SUPPORT: HEIGHT ADJUSTMENT

height
adjustment
indicator

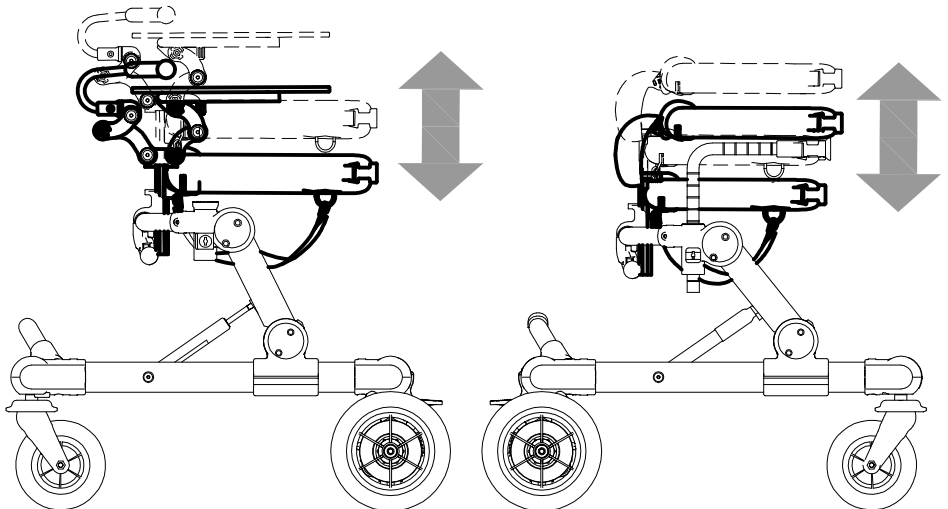
VIEW FROM ABOVE

unlock

lock

position of
the locking lever

locking lever

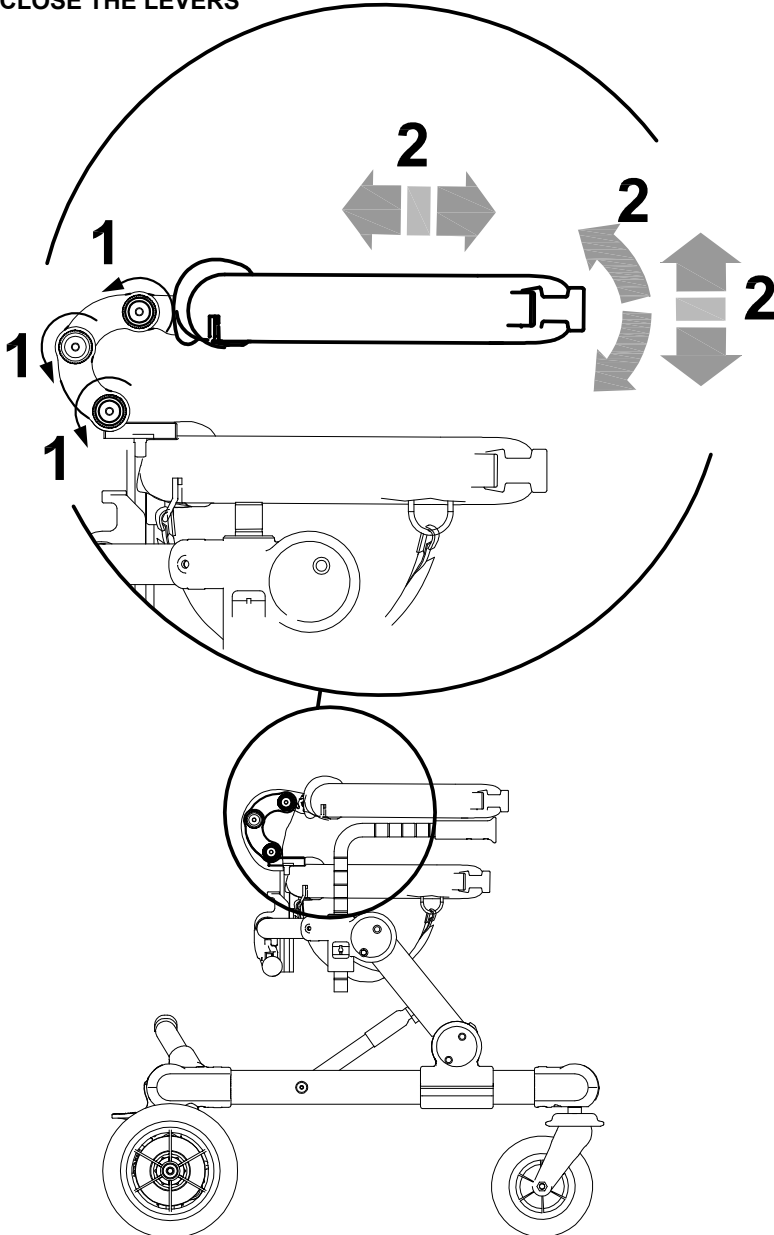




THORACIC SUPPORT: HEIGHT, TILT and BACK-FORWARD ADJUSTMENTS

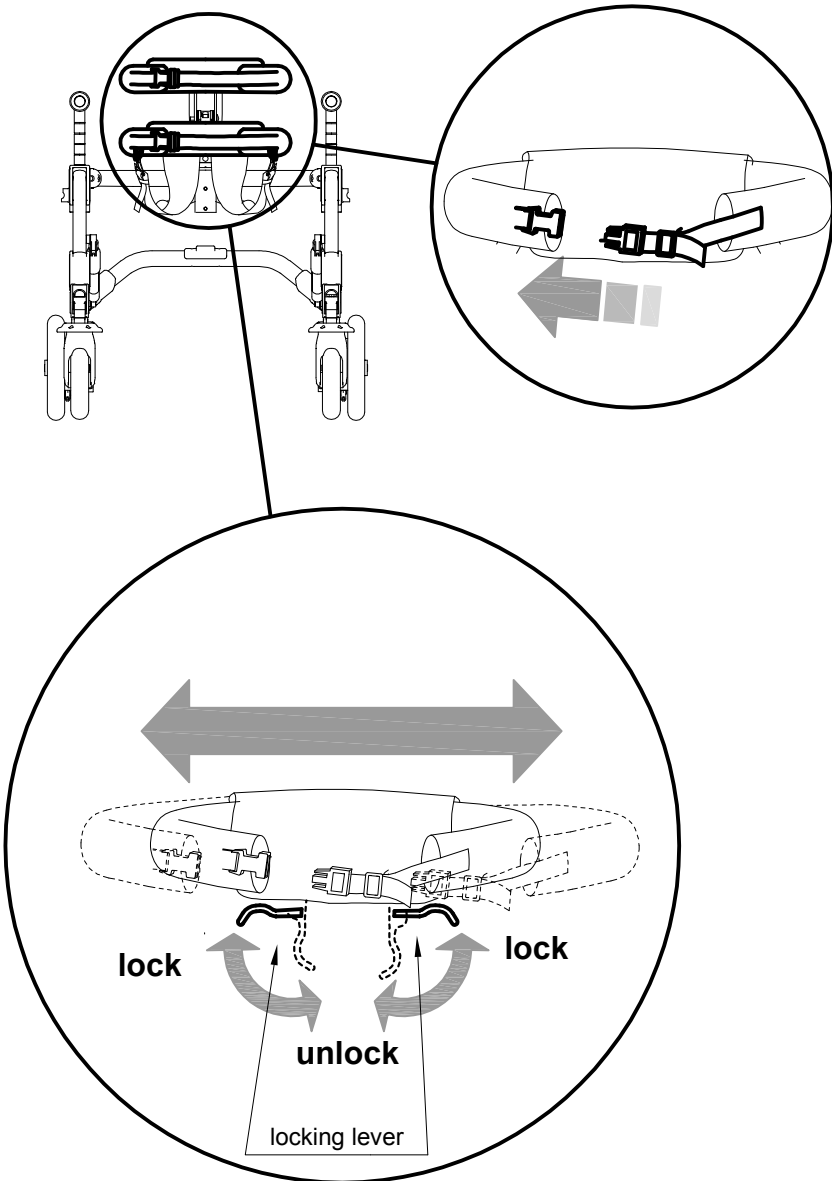
1 UNLOCK THE THREE GREEN LEVERS

2 ADJUST THE HEIGHT, THE TILT AND THE BACK-FORWARD POSITION OF THE TRUNK SUPPORT.
THEN CLOSE THE LEVERS



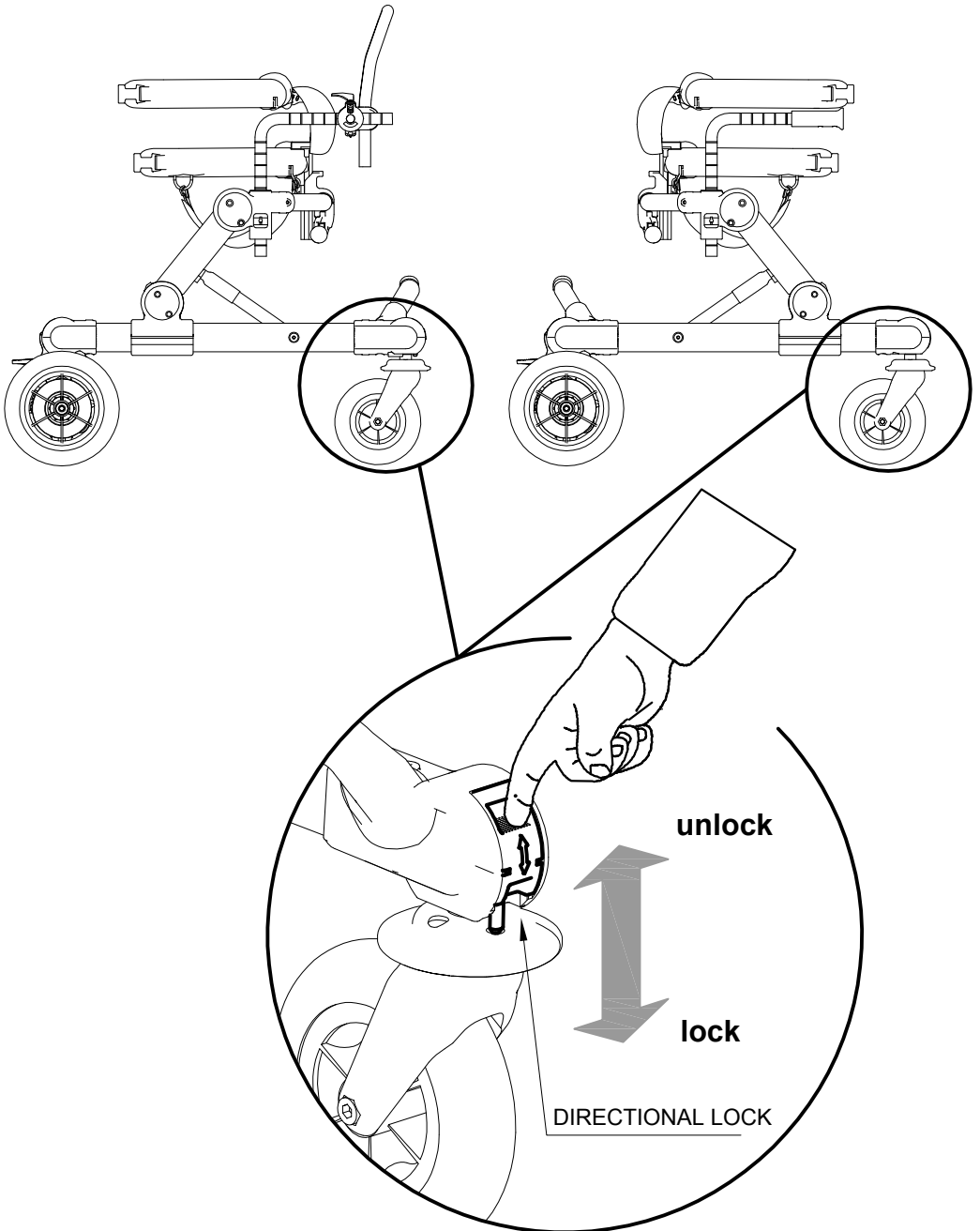


PELVIC AND THORACIC SUPPORTS: CIRCUMFERENCE ADJUSTMENT





DIRECTIONAL LOCKS





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

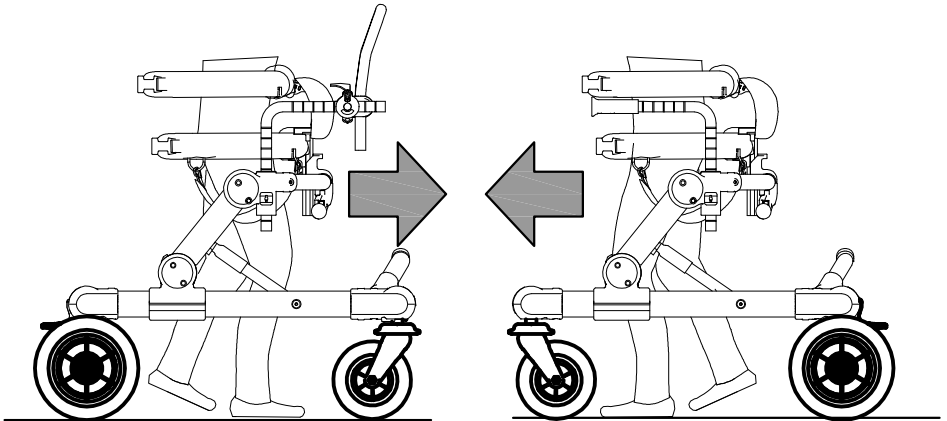
WARNINGS!

This operation must be done by qualified personnel only

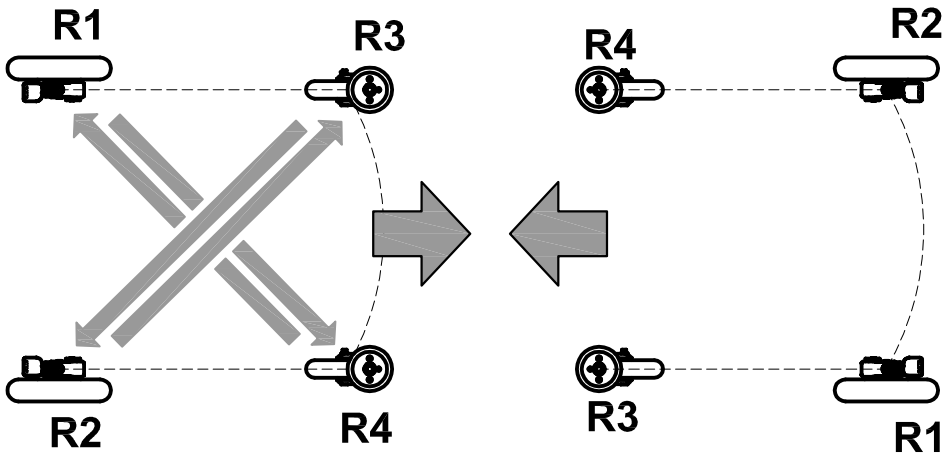
A WHEEL-ASSEMBLING AND DISASSEMBLING SCHEME

FRONT DRIVE GRILLO mini

REAR DRIVE GRILLO mini



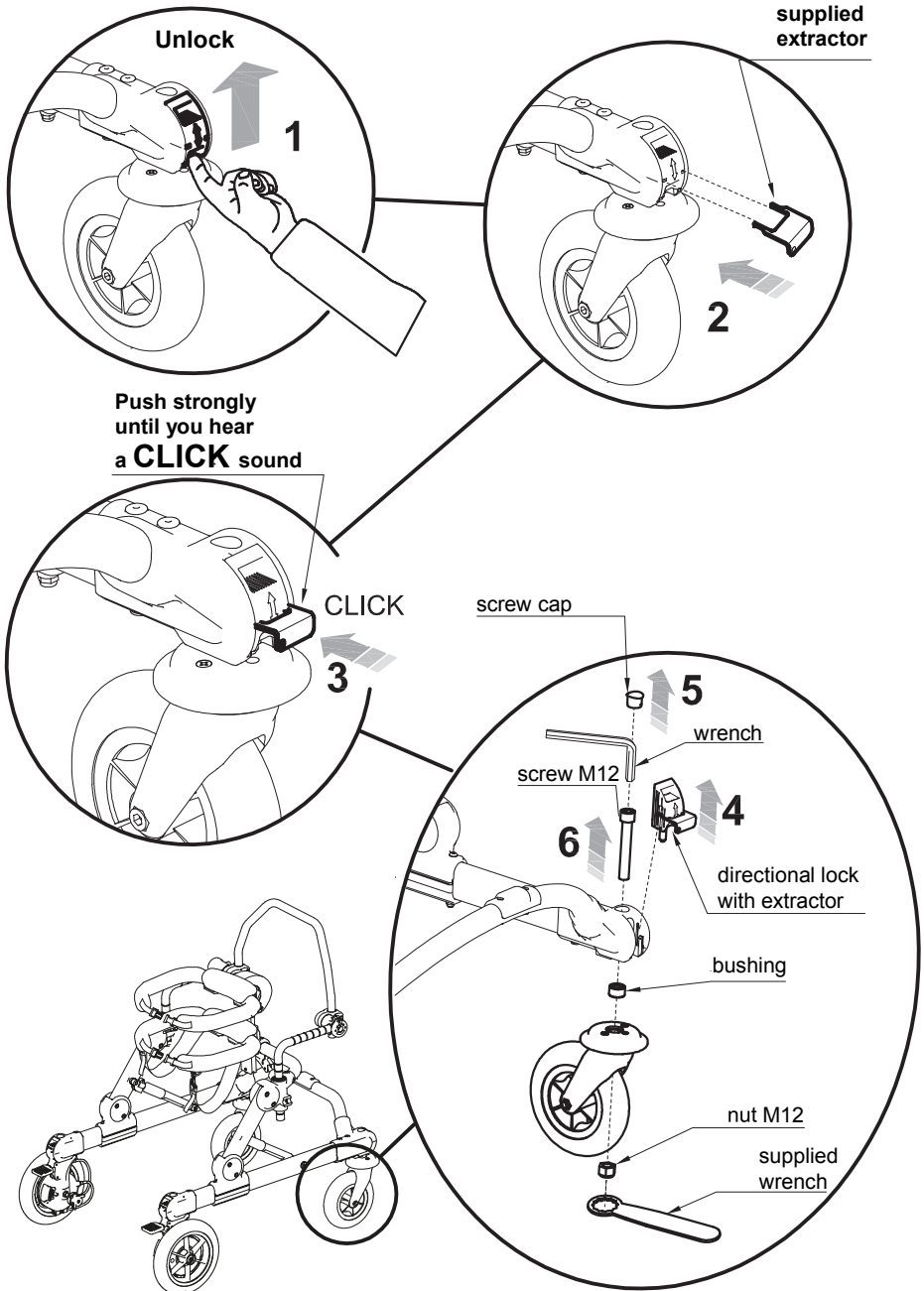
VIEW FROM ABOVE





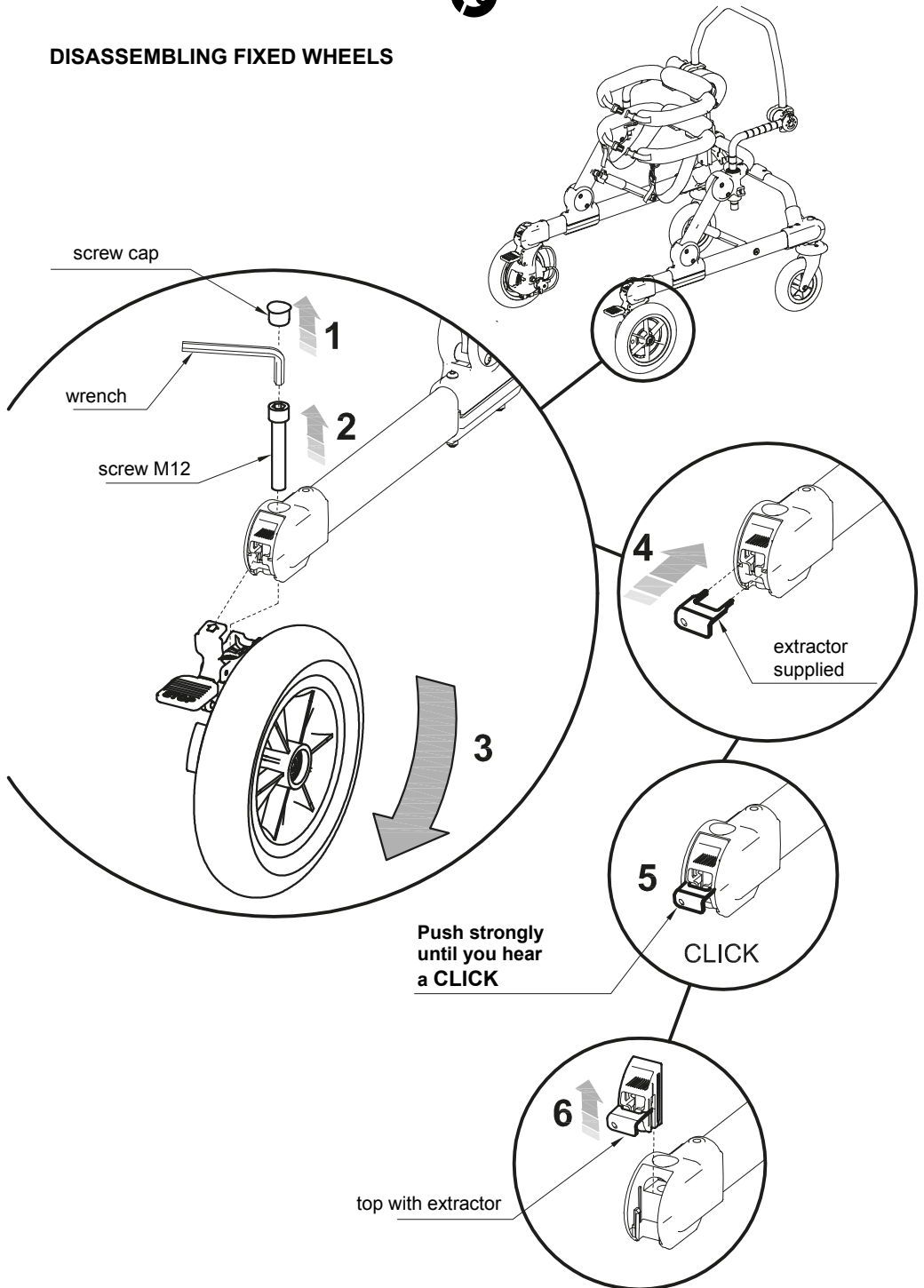
B FRONT-DRIVE GRILLO mini

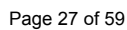
DISASSEMBLING THE WHEELS OF THE FRONT-DRIVE GRILLO mini





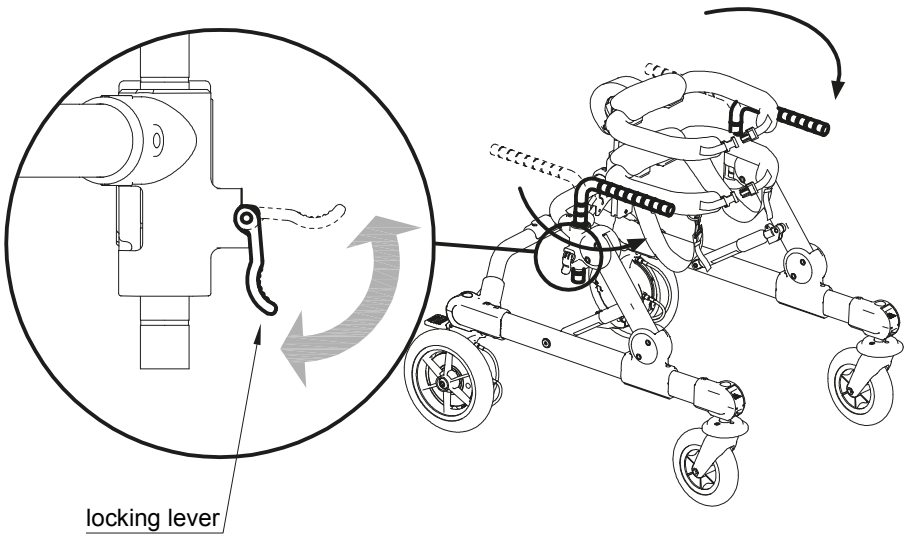
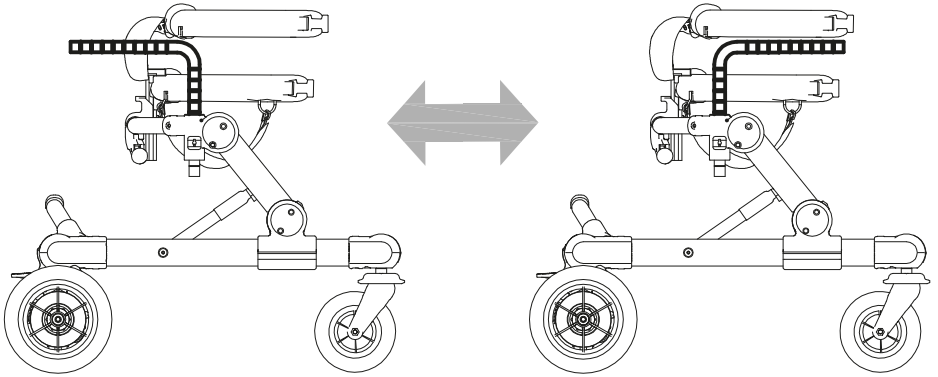
DISASSEMBLING FIXED WHEELS







D TURNING THE HANDLES

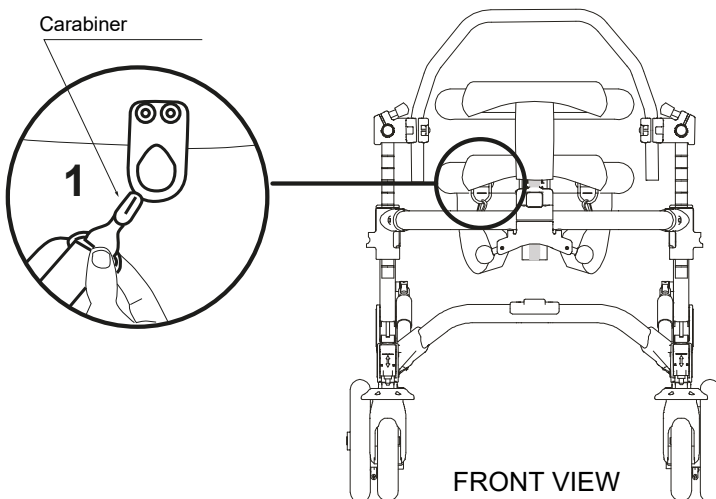
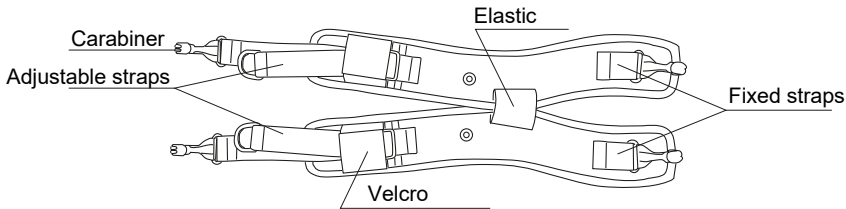




PELVIC HARNESS: ASSEMBLY AND ADJUSTMENT

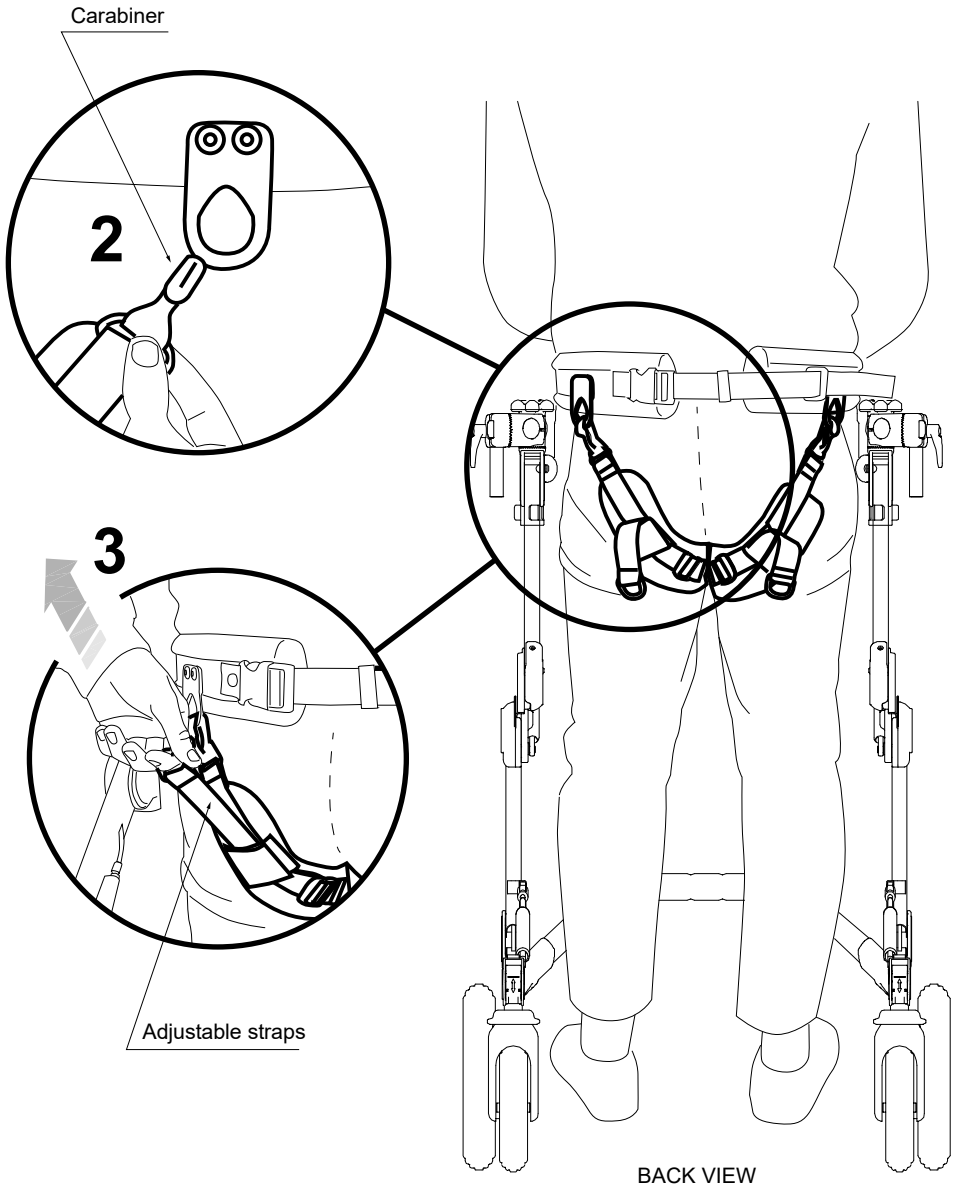
The procedure and harness position are the same, both on the front drive and rear drive models

- 1) ATTACH THE TWO FIXED STRAPS USING THE SNAP HOOKS INTO THE TWO HOOKS LOCATED ON THE FRONT OF THE PELVIC SUPPORT. THE ADJUSTABLE STRAPS REMAIN ON THE BACK SIDE OF THE USER TO FACILITATE TRACTION.
- 2) WITH THE WALKER SLIGHTLY LOWERED, ATTACH THE RIGHT ADJUSTABLE STRAP WITH THE SNAP HOOK AND THEN THE LEFT. RAISE THE WALKER UNTIL IT REACHES THE CORRECT HEIGHT FOR WALKING.





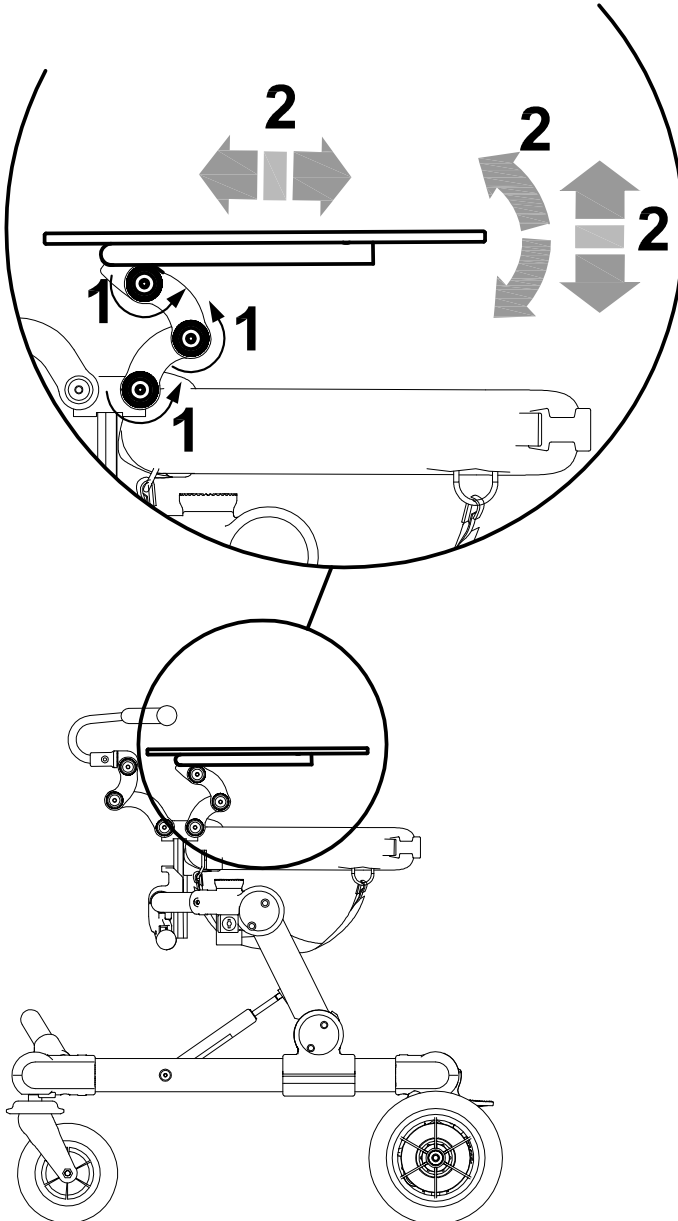
3) PULL THE ADJUSTABLE STRAPS UPWARDS TO TENSION THE PELVIC HARNESS





TRAY: HEIGHT, TILT and BACK-FORWARD ADJUSTMENTS (for Front-drive PTM Grillo mini)

- 1 UNLOCK THE THREE GREEN LEVERS
- 2 ADJUST THE HEIGHT, THE TILT AND THE BACK-FORWARD POSITION OF THE TRAY
THEN TIGHTEN THE LEVERS

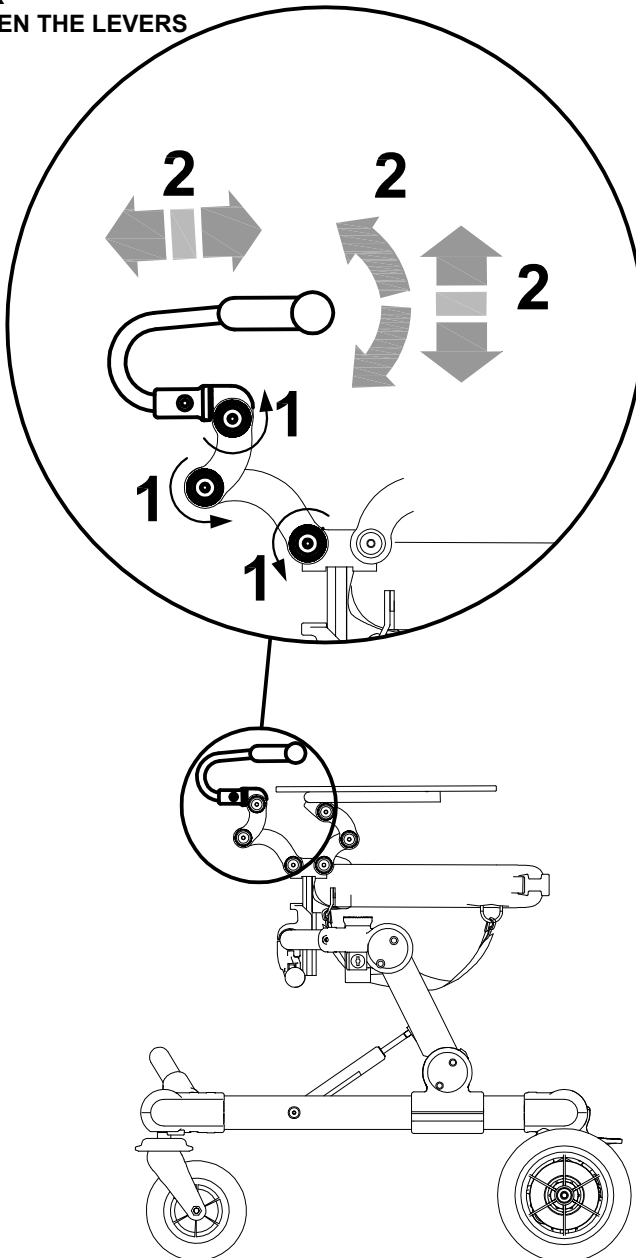




HANDLEBAR: HEIGHT, TILT and BACK-FORWARD ADJUSTMENTS (for Front-drive PTM Grillo mini)

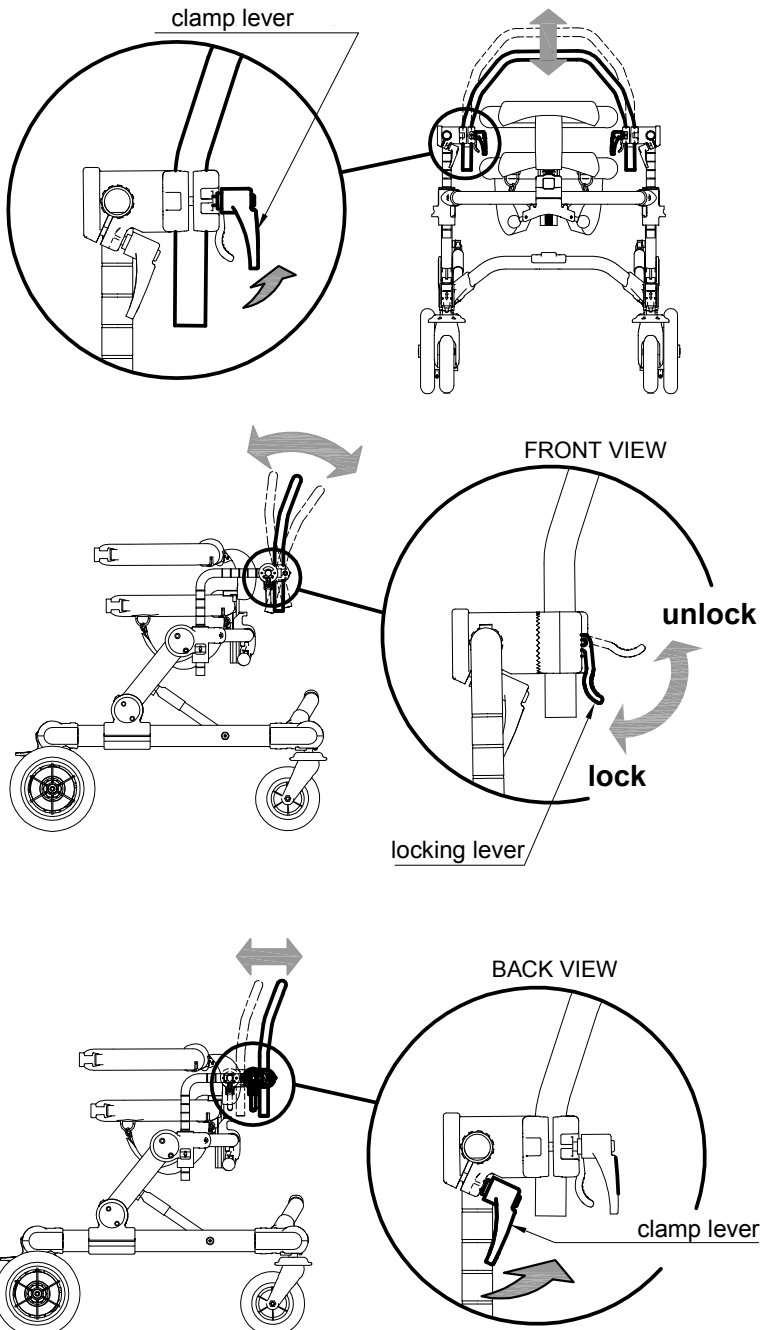
1 UNLOCK THE THREE GREEN LEVERS

**2-ADJUST THE HEIGHT, THE TILT AND THE BACK FORWARD POSITION OF THE
HANDLEBAR
THEN TIGHTEN THE LEVERS**



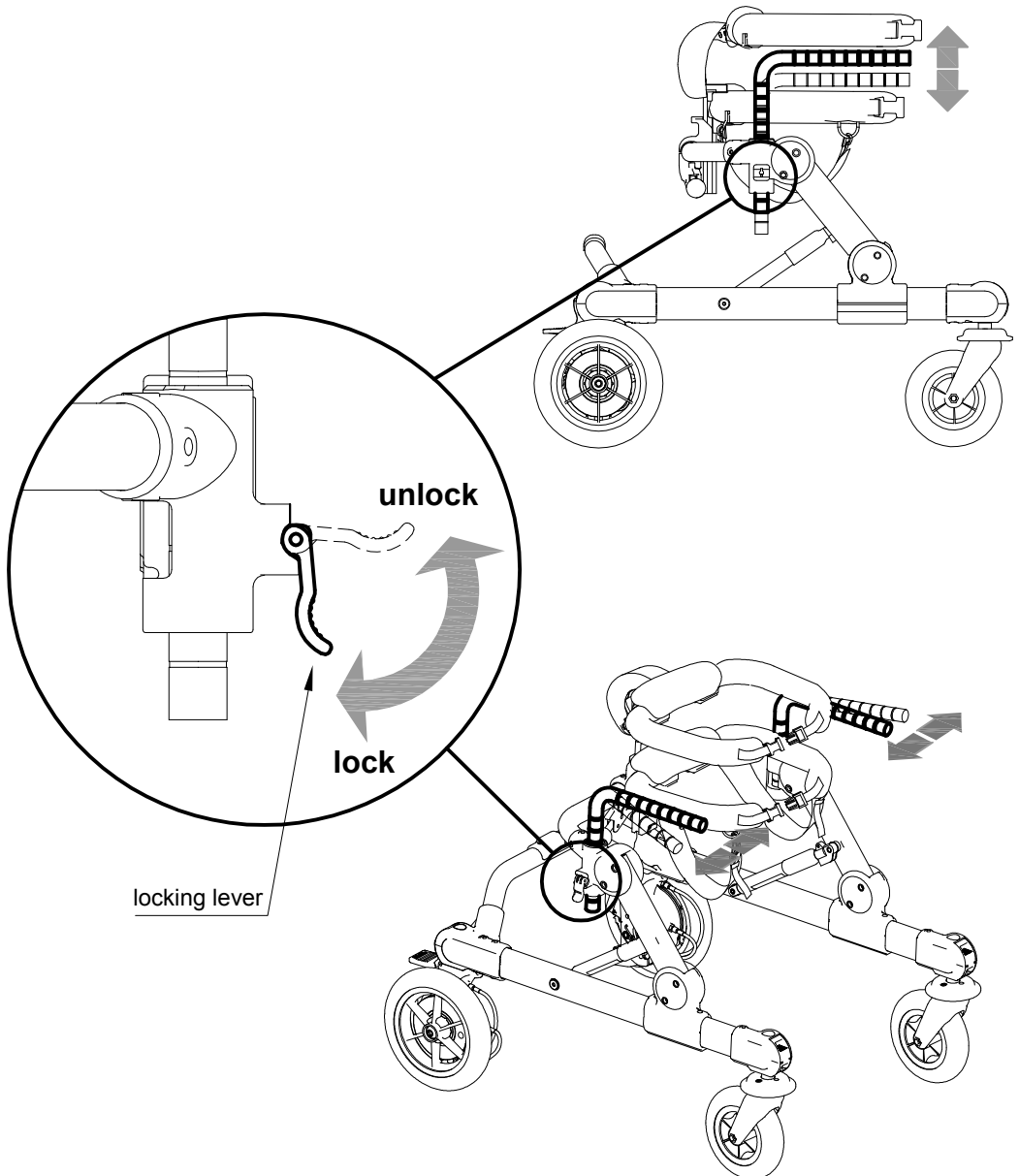


HANDLEBAR: HEIGHT, TILT and BACK-FORWARD ADJUSTMENTS (for Front-drive PT Grillo mini)





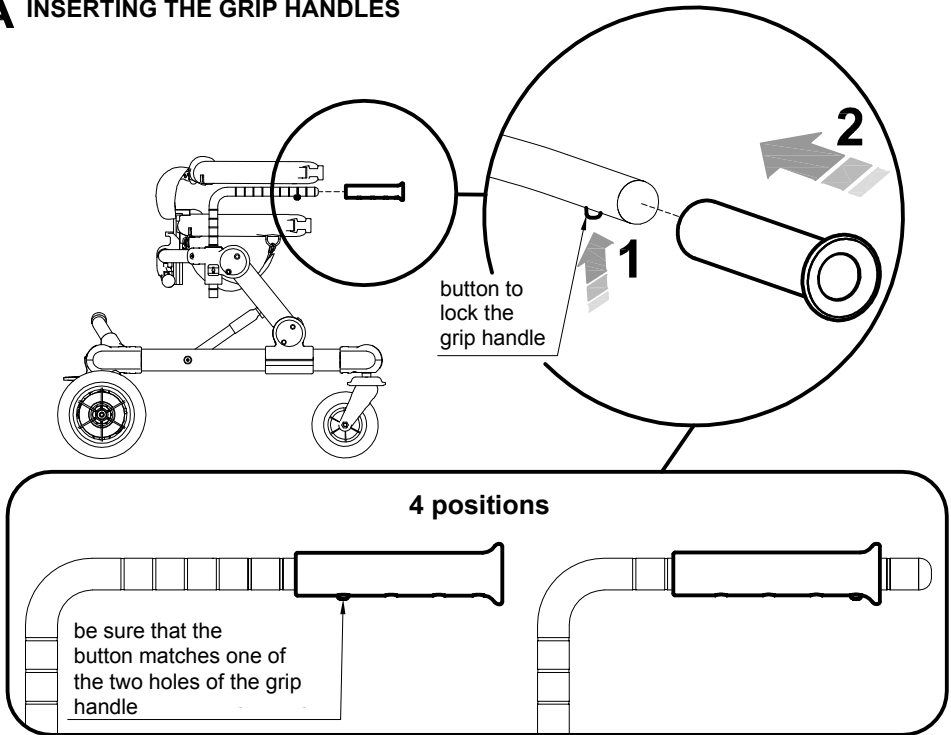
HANDLES: HEIGHT AND WIDTH ADJUSTMENTS (for Grillo mini front-drive PT and rear drive PT)



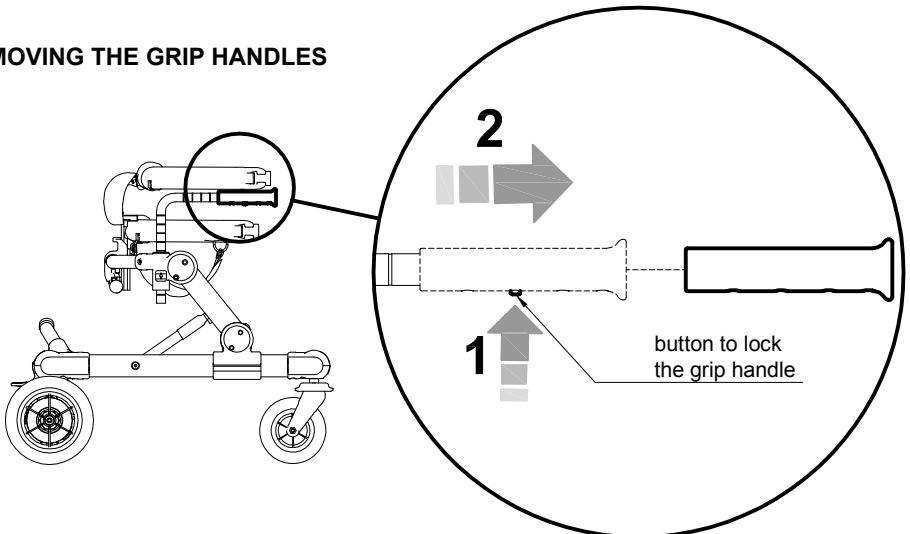


REMOVABLE GRIP HANDLES (for Rear drive PT Grillo mini)

A INSERTING THE GRIP HANDLES



B REMOVING THE GRIP HANDLES

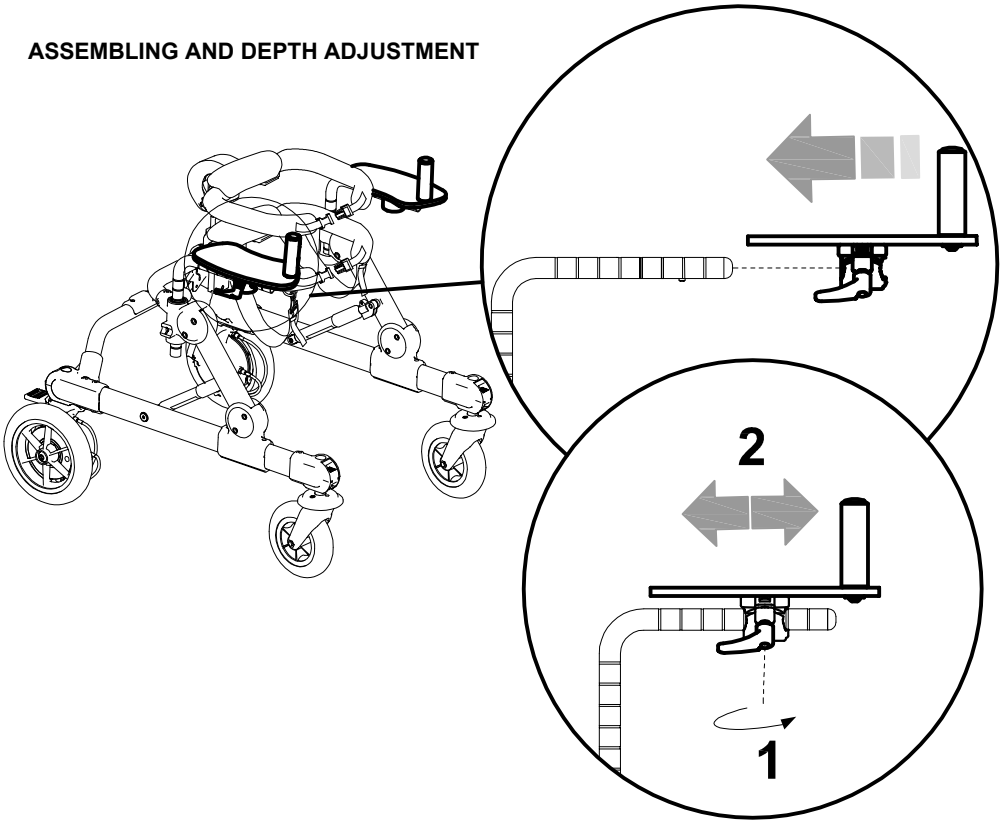




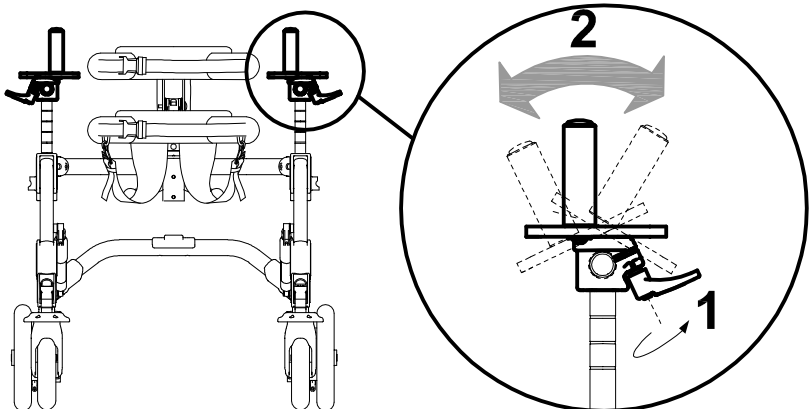
ASSEMBLING AND ADJUSTING THE COMPONENTS

ARM SUPPORTS

ASSEMBLING AND DEPTH ADJUSTMENT

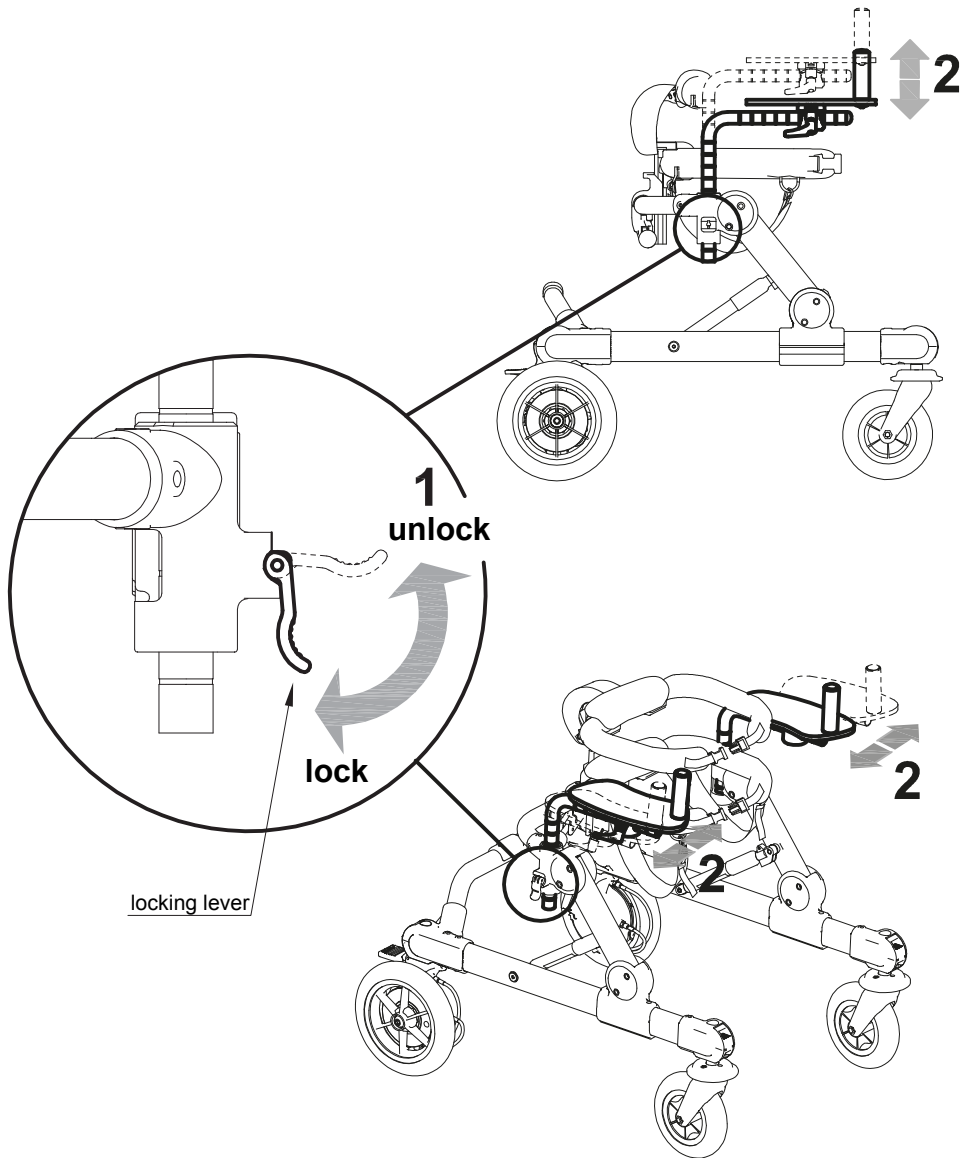


ROTATION ADJUSTMENT





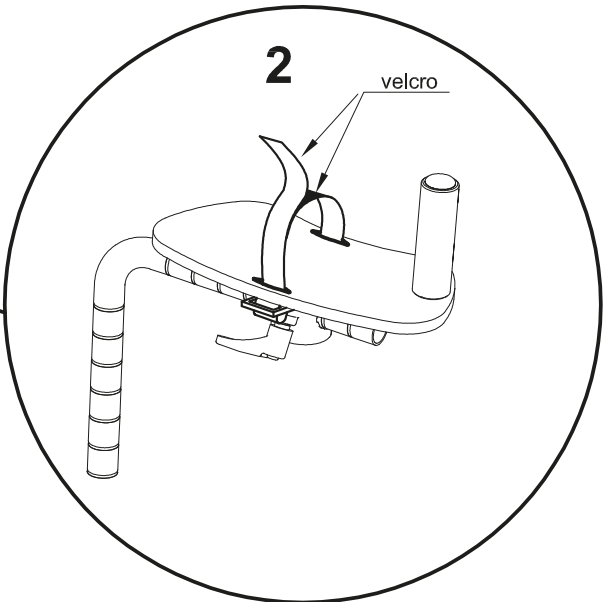
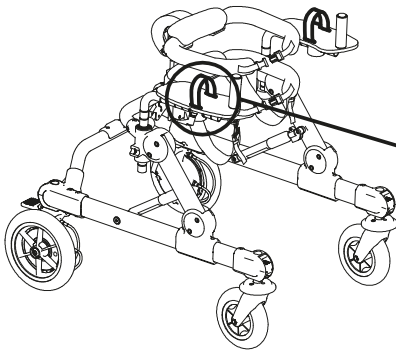
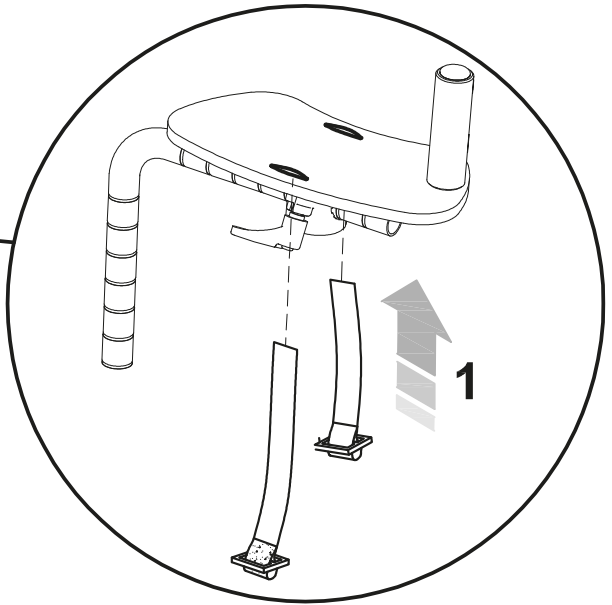
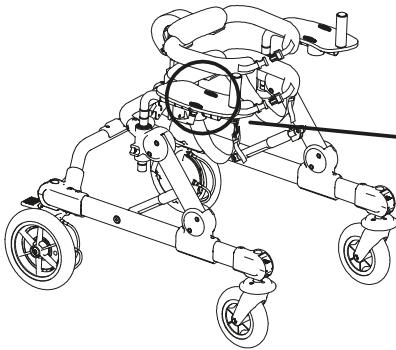
HEIGHT and WIDTH ADJUSTMENTS





ARM STRAPS

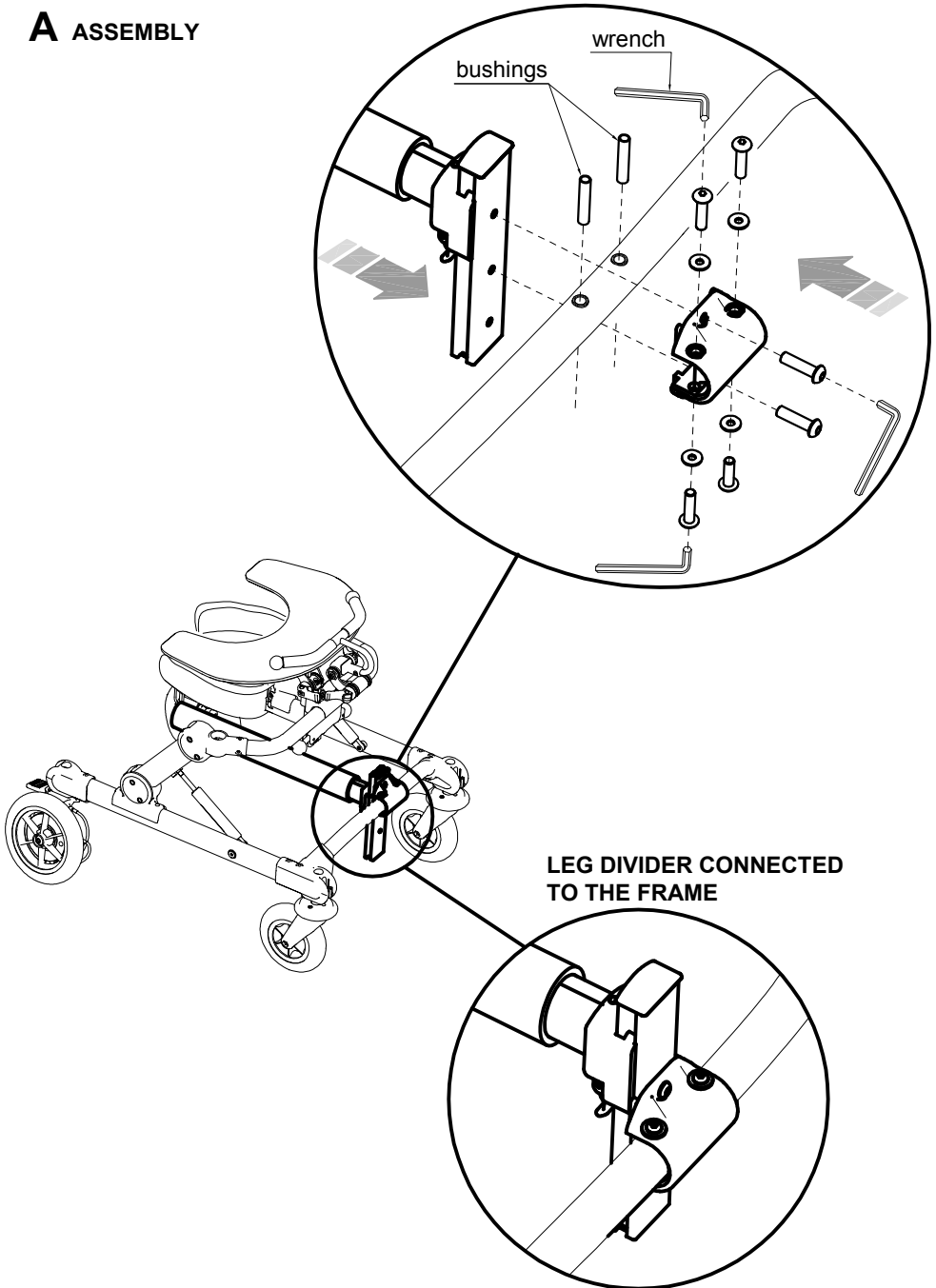
This accessory can only be mounted in presence of arm supports





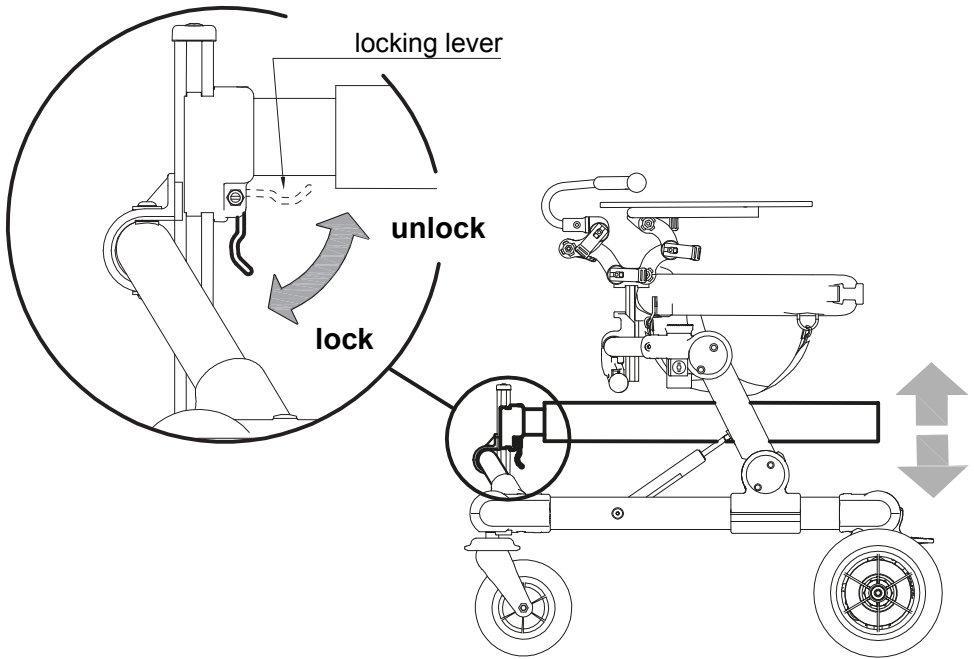
LEG DIVIDER GRILLO mini

A ASSEMBLY

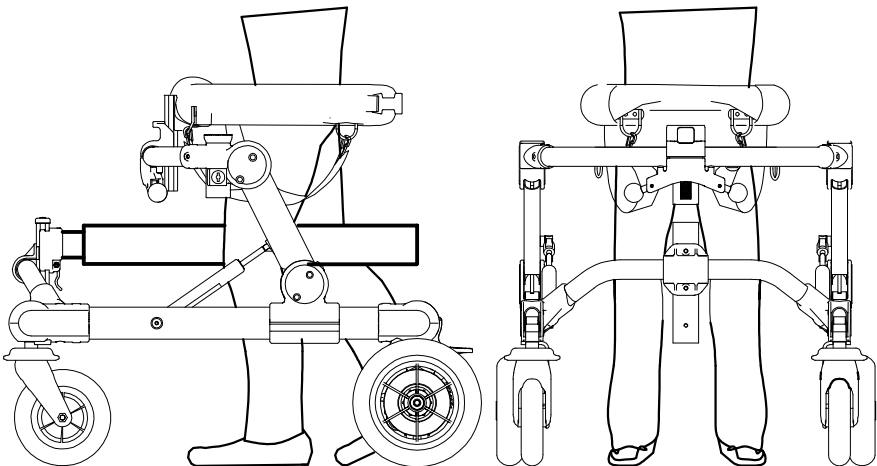




B ADJUSTMENT IN HEIGHT



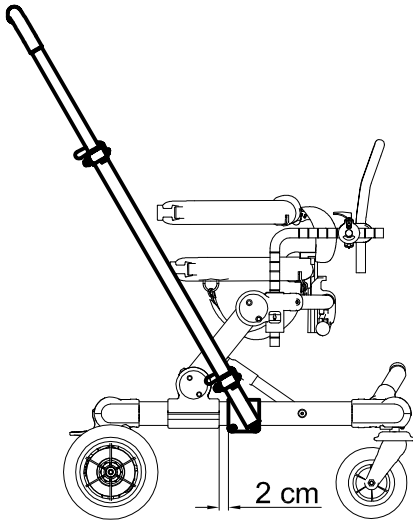
C ADJUSTING THE LEG DIVIDER ON GRILLO mini



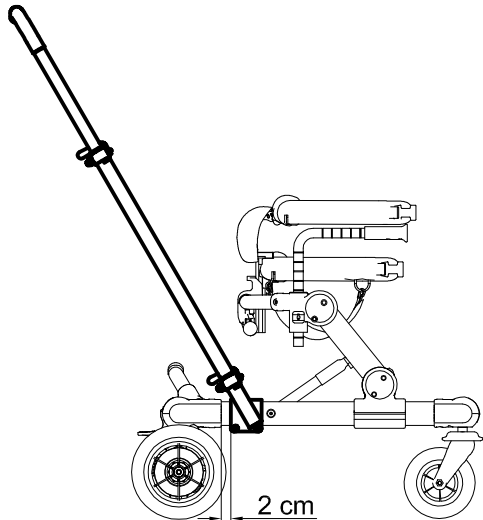


PUSH HANDLE for THE ASSISTANT

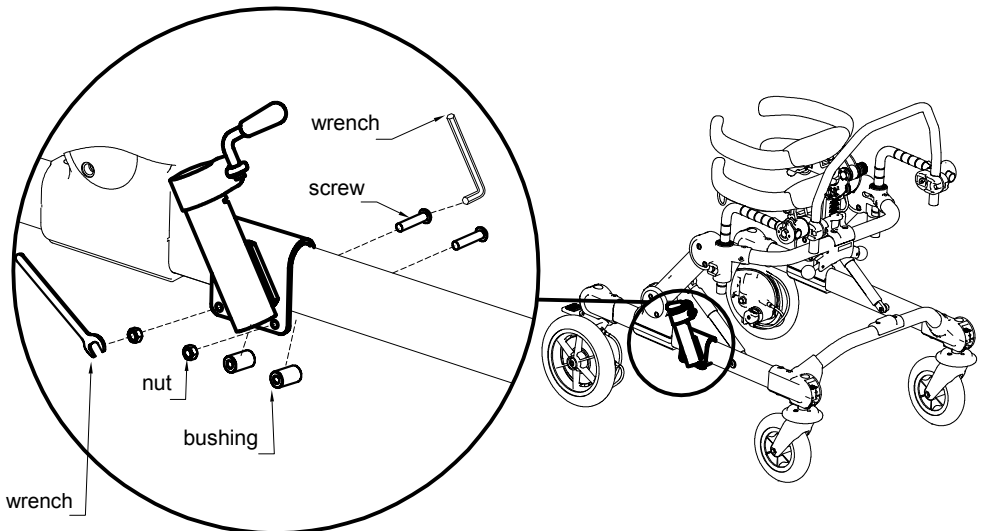
POSITION ON FRONT-DRIVE GRILLO mini



POSITION ON POSTERIOR GRILLO mini

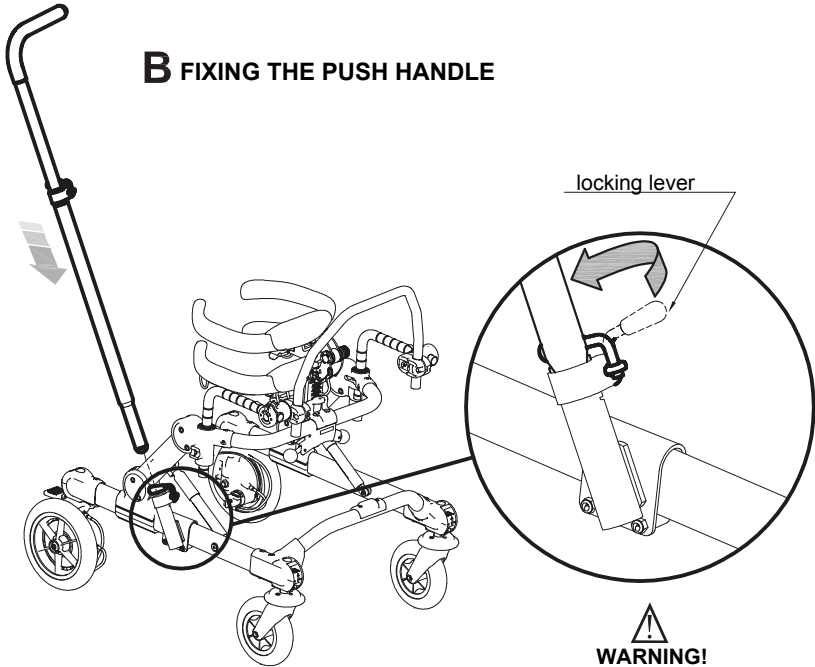


A ASSEMBLY OF THE HANDLE FORK



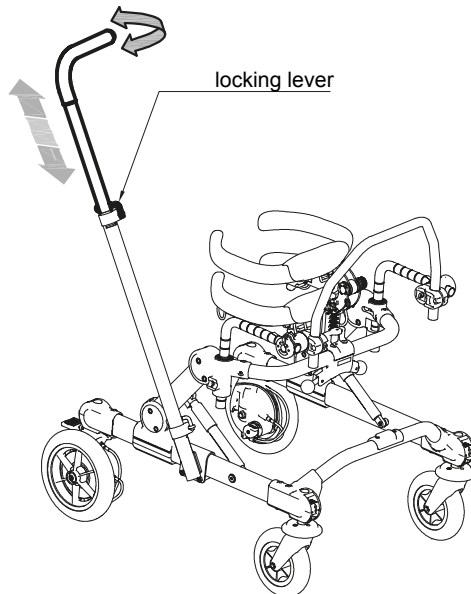


B FIXING THE PUSH HANDLE



WARNING!
THE PUSHING HANDLEBAR MUST
BE COMPLETELY INSERTED INSIDE
THE SUPPORT

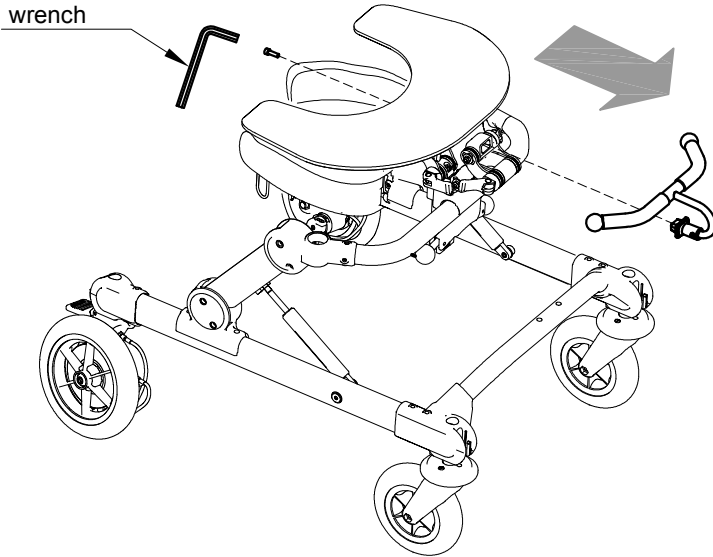
C HEIGHT AND ROTATION ADJUSTMENT



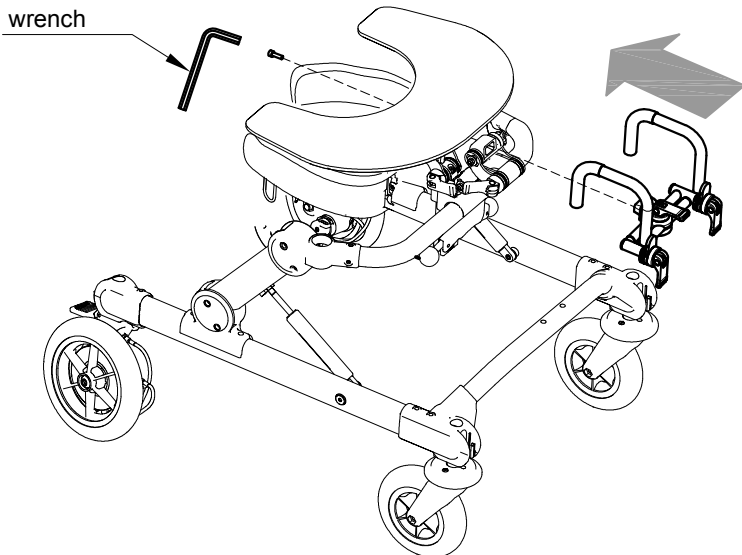


GRIP HANDLES (for front-drive PTM Grillo mini)

A REMOVE THE HANDLEBAR



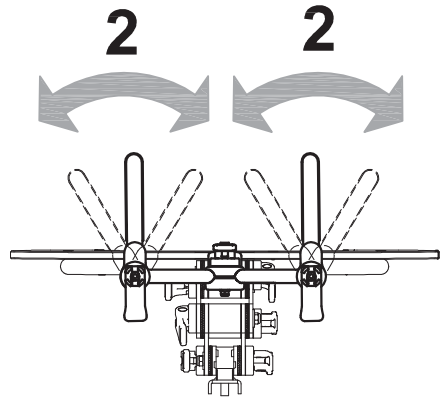
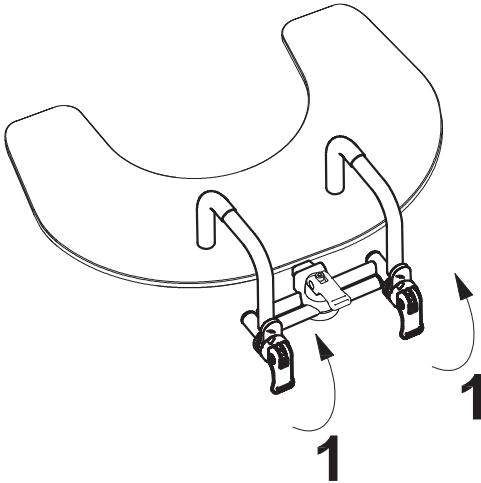
B FIX THE GRIP HANDLES



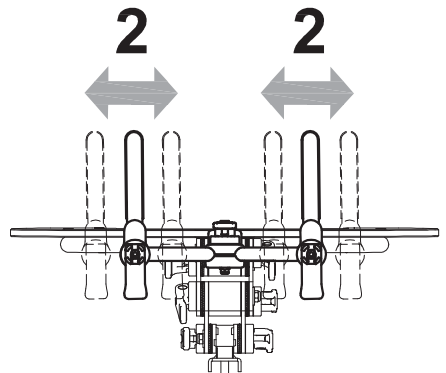
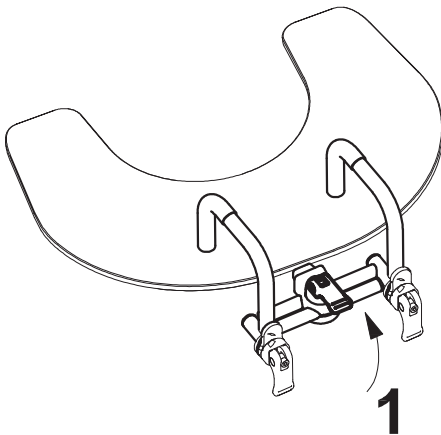


C ADJUST THE GRIP HANDLES in WIDTH AND ROTATING

1. UNLOCK THE TWO GREEN LEVERS
2. ADJUST IN ROTATION THE GRIP HANDLES. THEN LOCK THE LEVERS

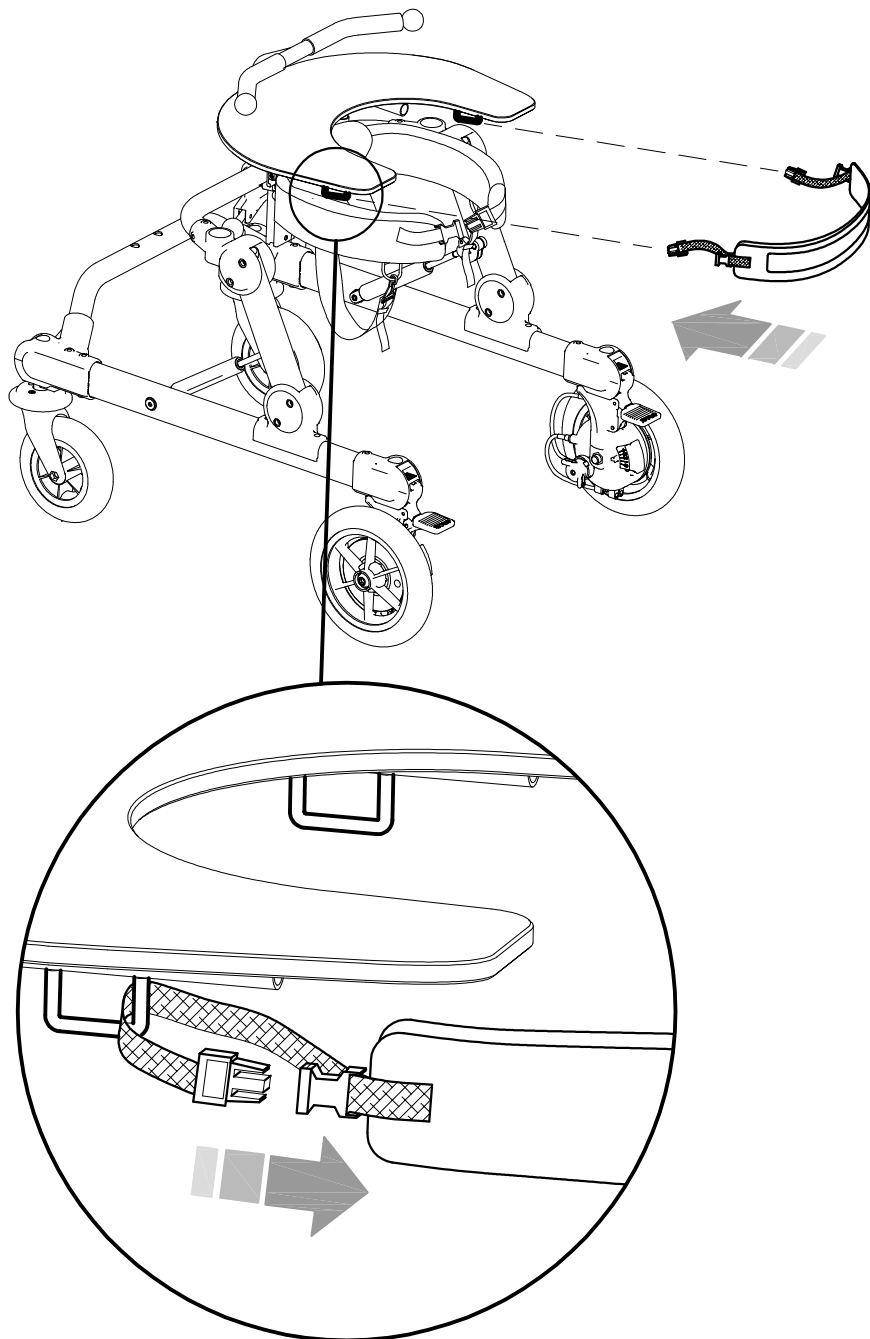


3. UNLOCK THE GREEN CENTRAL LEVER
4. ADJUST THE WIDTH OF THE GRIP HANDLES. THEN LOCK THE LEVER



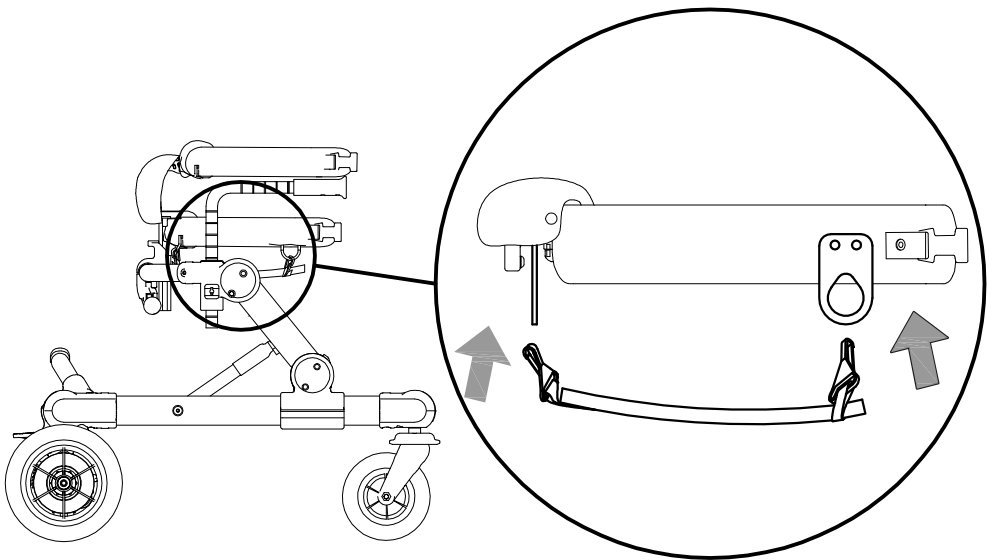
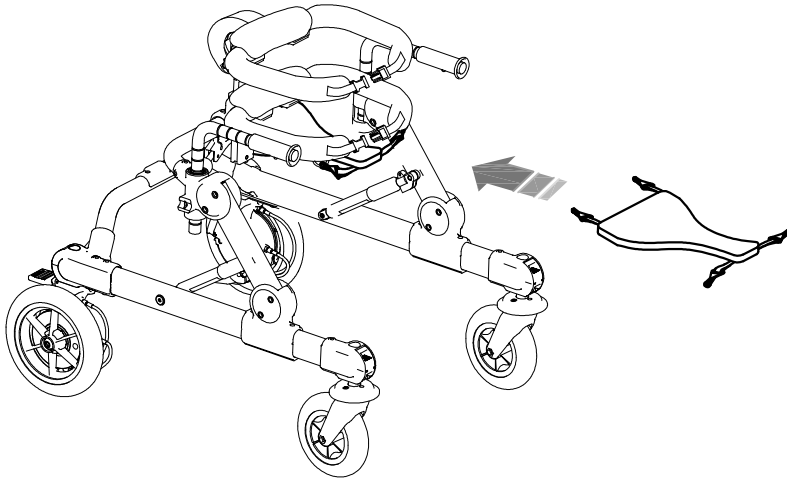


TRAY BELT (for Grillo mini Front-Drive PTM)





ERGONOMIC SADDLE

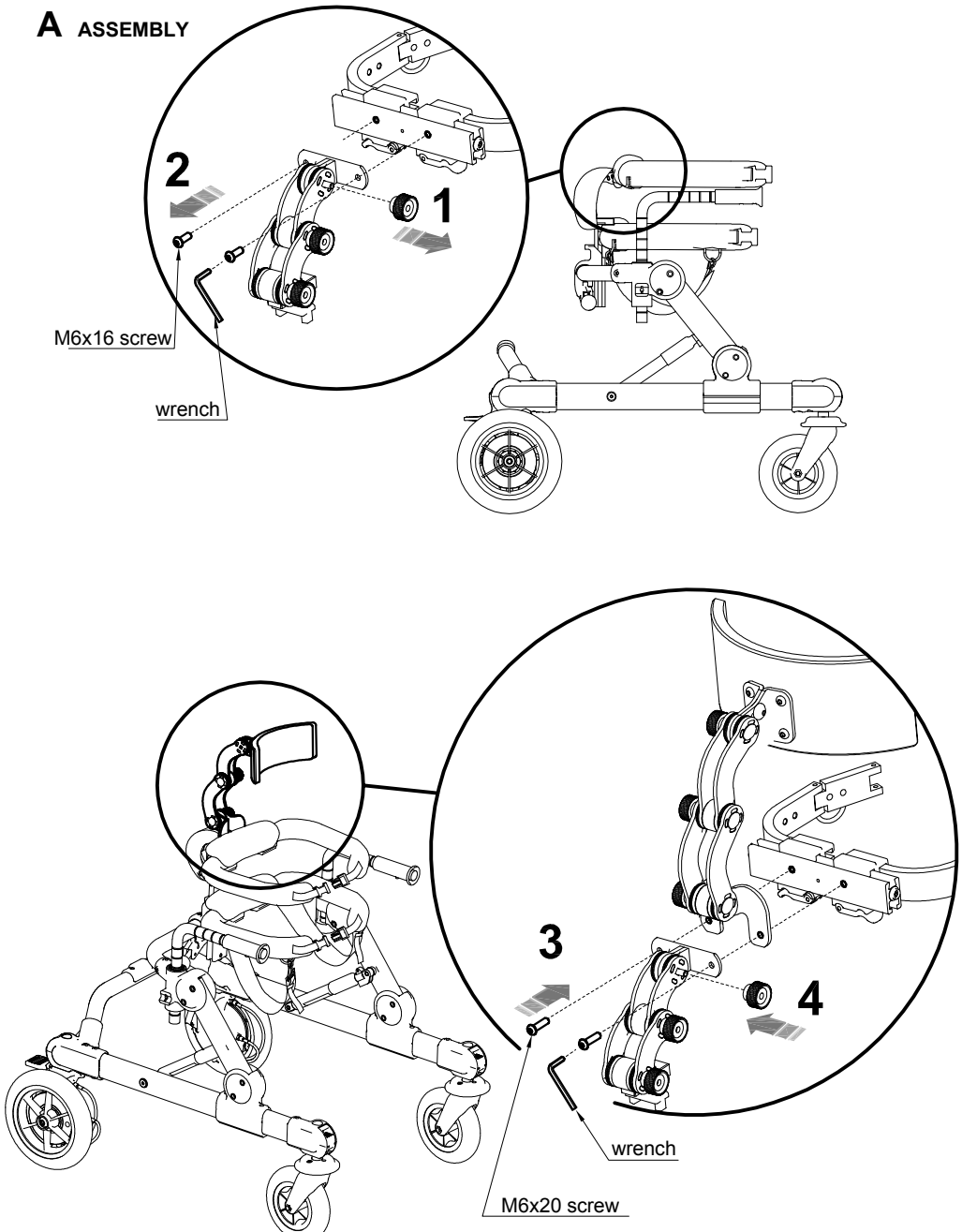


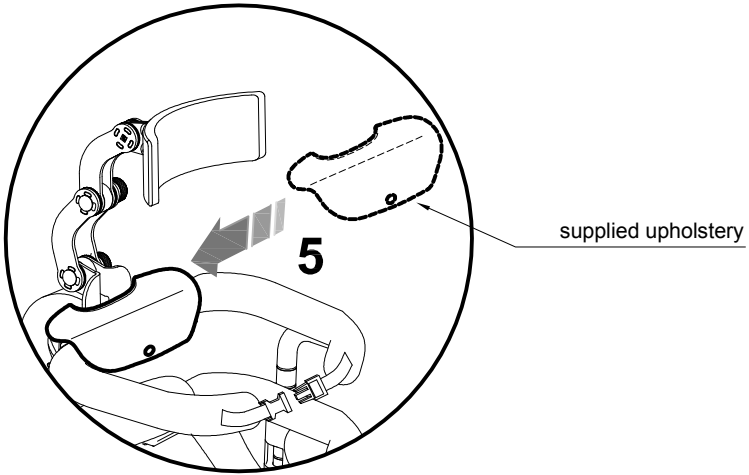


MULTI ADJUSTABLE HEADREST

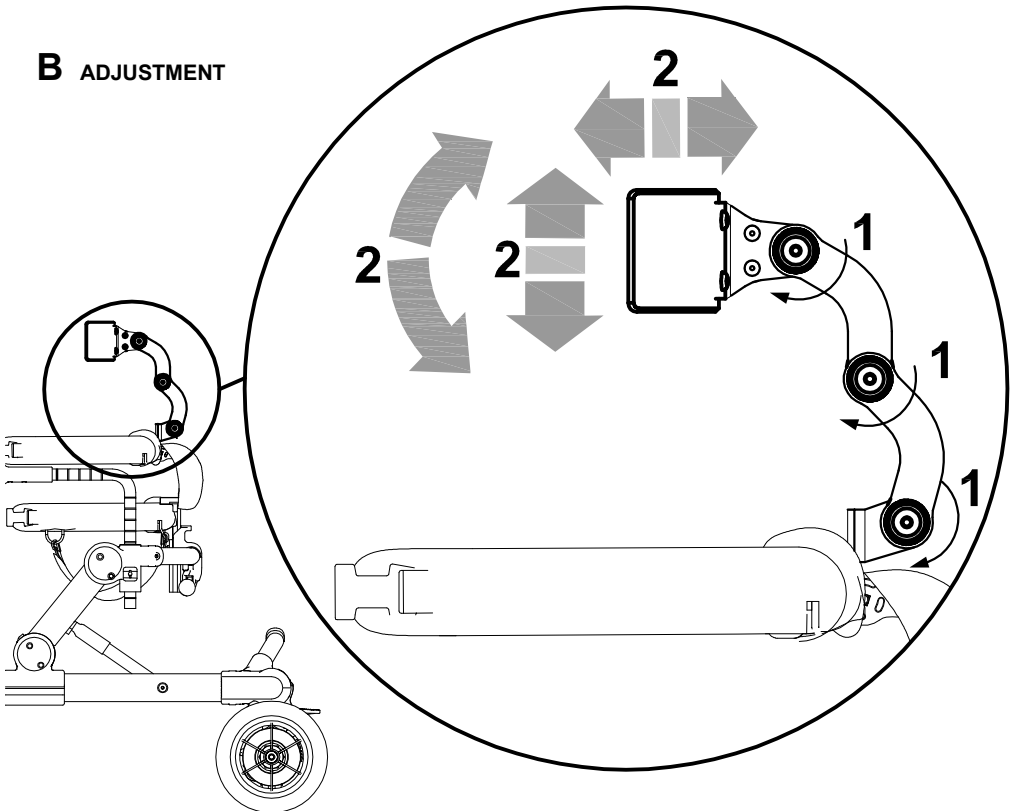
Available only for rear drive version with Trunk support

A ASSEMBLY





B ADJUSTMENT





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)

GRILLO is a mechanical device and as such must be kept efficiently to maintain a high level of performance. This is possible with regular maintenance, including cleaning, lubrication and inspection. Routine periodic checks and maintenance should be carried out by a person with good technical competence; otherwise contact the health professional who provided it, or company specializing in maintenance.

	Maintenance and replacement of parts or additional components must be carried out without the user sitting 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).
	Regular lubrication reduces friction between moving parts, preventing breakage or seizing and delays rust formation.

PART	DESCRIPTION/INTERVENTION	MODE
WHEELS	- Clean the WHEELS from dust and dirt, to keep them smooth - Check that the wheels turn freely In case of failure, please contact the Healthcare Professional who supplied the device or the distributor for the replacement with original component	functional test
BRAKES	Check the effectiveness of the wheel locking/unlocking mechanism according to the instructions of the user manual. In case of failure, please contact the Healthcare Professional who supplied the device or the distributor for the replacement with original component.	functional and visual test
BOLTS/SCREWS	Check the tightening of all bolts and screws Tighten them if loose.	functional test/tools



ADJUSTMENT AND LOCKING MECHANISM	• Check the smoothness of the MOVING PARTS and keep them clean from dust and dirt, to avoid friction that could compromise the correct functioning. In case of failure, lubricate them with commercial dry silicone oil following the instructions on the container label. After lubrication, dry the treated parts well with a soft cloth to remove excess residual grease. • Check that the adjustment mechanisms are held in place. In case of failure, please contact the Healthcare Professional who supplied the device or the distributor for the replacement with original component. If 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 as shown in § 1.1 SETTING OF CONTROL LOCKING LEVERS.	functional test
HEIGHT ADJUSTMENT SYSTEM	• Check the functioning of gas springs and their cables. In case of failure, please contact the Healthcare Professional who supplied the device or the distributor for the replacement with original component	functional test
UPHOLSTERIES	• Check the state of wear of the Upholsteries. In case of needs, please contact the Healthcare Professional who supplied the device or the distributor for the replacement with original component	visual test
PRODUCT INTEGRITY	• Check that all components described in the user manual are present. • Check that there are no oxidized parts, and the uniformity of coating on the support elements or frame fastenings. In case of failure, please contact the Healthcare Professional who supplied the device or the distributor for the replacement with original component	visual test/tools

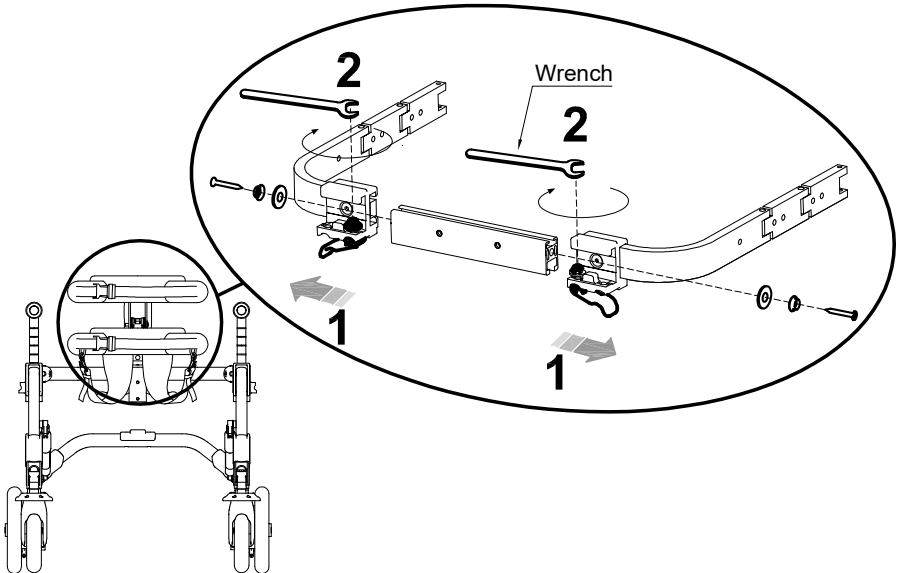


1.1 SETTING OF CONTROL LOCKING LEVERS

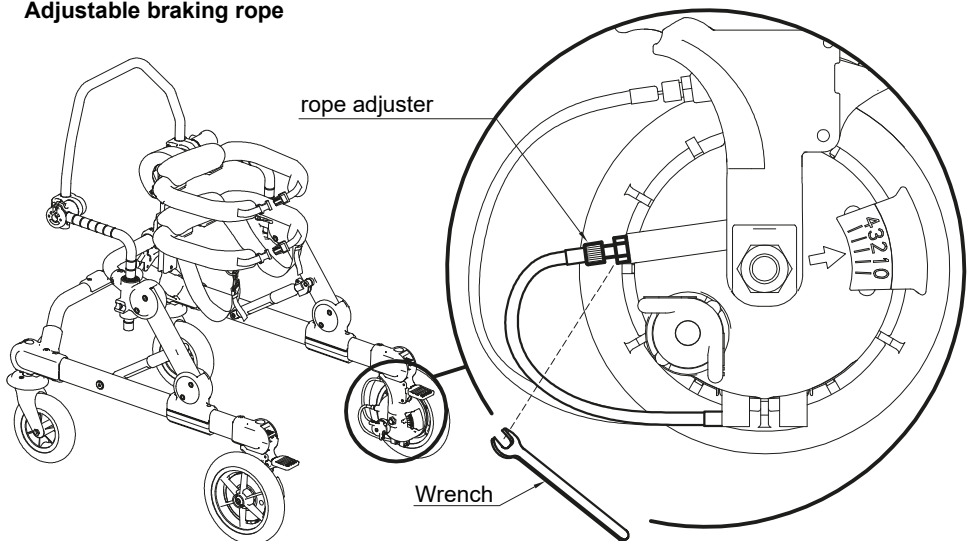


should you have noticed an INEFFICIENCY, even partially, on the LOCKING of the adjustment GREEN LEVERS of the PELVIC SUPPORT, of the TRUNK SUPPORT, of the HANDLEBAR, of the ARM SUPPORTS, please contact your ORTHOPAEDIC WORKSHOP to TIGHTEN THE NUT LITTLE BY LITTLE as shown below, UNTIL the PROPER LOCKING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

Width adjustment locking lever for pelvic and thoracic supports

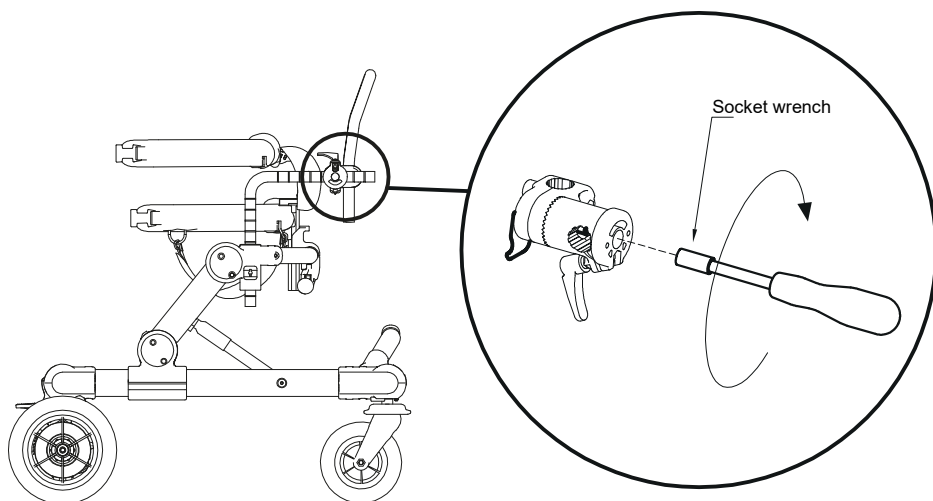


Adjustable braking rope

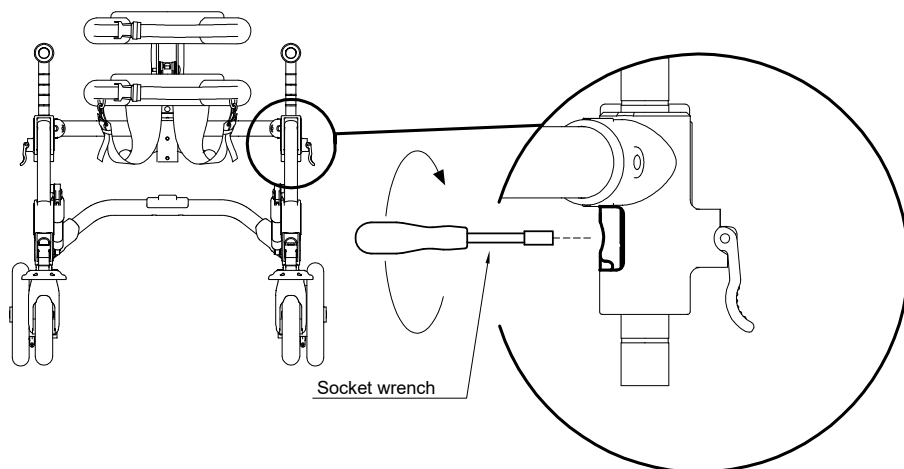




Levers of the handlebar joints



Height adjustment levers of the handles





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 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 components must never be done while the aid is being used.

2. **PREVENTIVE MAINTENANCE (biennial)**

ORMESA s.r.l. 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 must be carried out by the **MANUFACTURER**, the **DISTRIBUTOR** or by a **SPECIALISED SERVICE CENTER** in the maintenance of mechanical aids for people with disabilities and it 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

THE **MANUFACTURER** or the **AUTHORIZED SUBJECT** must release a **REPORT** which provides the 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 **MANUFACTURER**, the **DISTRIBUTOR** or **YOUR TRUSTED ORTHOPEDIC SHOP**

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

THE MANUFACTURER or the **AUTHORIZED SUBJECT** must release a **REPORT** which provides the evidence of 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 OF ACTION** indicated on the product **LABEL**.

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



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).



4.3 WASHING	Based on use	It is possible to wash the HARNESS and REMOVABLE UPHOLSTERIES, respecting the following indications  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.
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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.
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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 GRILLO mini 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.**
2. **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.**
3. **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 disable, or directly ORMESA.



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