

USE AND MAINTENANCE HANDBOOK



ORMBDB

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

GRILLO mini is a walking frame where the attention to its functionality is combined with the respect of ergonomic and safety principles.

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

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

Luigi Menichini

CEO

ORMEDS

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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.
- Λ
- 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.
- Λ
- Avoid areas near unprotected artificial or natural water basin and water courses.
 Always lock brakes when parking, even on flat ground, and before
- \triangle
 - making any adjustments

 Before each use always check that the accessories and the green
- Δ
- 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



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 45-46-47-48.

GRILLO mini IS A MECHANICAL MEDICAL DEVICE:

Perform REGULAR MAINTENANCE and CLEANING following the instructions shown in the "Maintenance" chapter on page 45,46,47,48 and HAVETHE 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



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PRODUCT REPAIRS other than the regular maintenance shown on pages 45,46,47,48 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 CHANGESin the product ARE NOT

AUTHORIZED REFER ONLY TO ORMESA,
otherwise warranty and C€ marking will be voided



The REPLACEMENT WITHOUT ORIGINAL
PARTS OR COMPONENTSARE NOT
AUTHORIZED.REFER ONLY TO ORMESA, otherwise
warranty and C marking will be voided



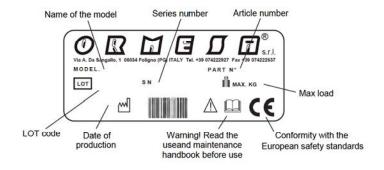
In case of DOUBT about the SAFETY of the product or DAMAGE to parts or components, you are urged to IMMEDIATELY DISCONTINUE USE and CONTACT a SPECIALIZED SERVICE CENTER in the maintenance of mechanical aids for disables, or directly ORMESA.

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SOME EXAMPLES OF 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



CE CONFORMITY DECLARATION

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

GRILLO mini

Front-drive 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 classI and has been designed in observance to the following standards:

CEI EN ISO 14971:2012	Medical Devices - Application of risk

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

requirements and test method

October 14, 2014the Legal Representative

Luigi Menichini

↑ 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 45,46,47,48 and the warnings ♠ on page 46.

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 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 mini is used:

- a) to generate and help the step pattern;
- b) to train in maintaining balance of the trunk and pelvis;
- to organize a wider structured vision of space, distance and the User's surroundings in the upright position;
- 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;
- to develop physical self-sufficiency and psychological independence by experimenting the possibility of acting alone.

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 offermaximum 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 trunk 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 optimalsetting 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 trunk support is usually adjusted according to the child's ability to control his trunk... If the User has a sufficient trunk control, the trunk support can 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.

By pushing the trunk support 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 $\overline{\mbox{AS}}$ 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

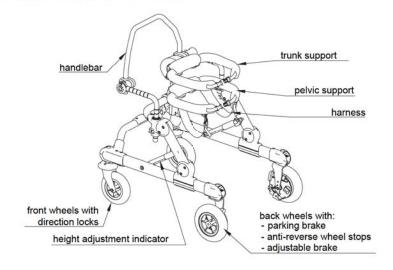
At first walking will be at a constant speed, then a change in step will be asked for so that speed will be faster or slower.

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

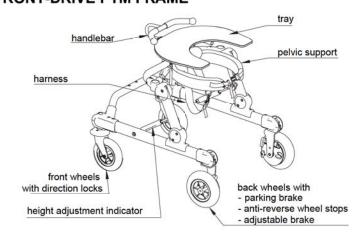
For those children who cannot easily walk, it is better to position the trunk support forwards respect to the pelvic support in order to get the flexion of the trunk. In this way it will be easier to start moving the lower limbs.

HOW GRILLO mini IS COMPOSED

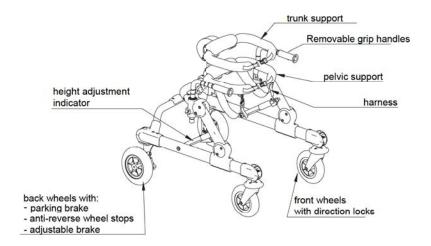
FRONT-DRIVE PT FRAME



FRONT-DRIVE PTM FRAME

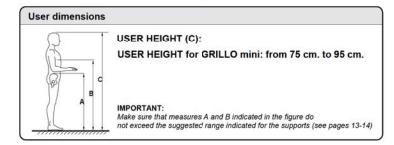


POSTERIOR PT FRAME



TECHNICAL SPECIFICATIONS

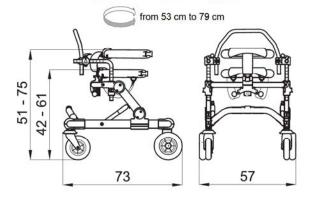
- GRILLO mini gait-trainer is available in two models: the Front drive and the Posterior one.
- ALUMINIUM FRAME, foldable for easy transportation and with PATENTED HEIGHT-ADJUSTMENT SYSTEM.
- PELVIC SUPPORT and TRUNK SUPPORT, padded, independently adjustable in height, width and circumference; allow 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. The TRUNK SUPPORT can be also adjusted in tilt and backwards-forwards.
- . 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 front swiveling, Ø15 and 2 rear solid, Ø cm 17,5, for indoor and outside use
- . DIRECTIONAL LOCKS on front wheels.
- · ADJUSTABLE BRAKES.
- . ANTIREVERSE DEVICE.
- PARKING BRAKE
- SEMI-ELASTIC BUFFERSon front wheelsto protect against bumps.
- LEG DIVIDER avoids adduction and helps to follow the right gait pattern.
- . PUSH HANDLE FOR THE ASSISTANT
- PEDALS for PARKING BRAKES
- REMOVABLE GRIP HANDLES (for the posterior version)



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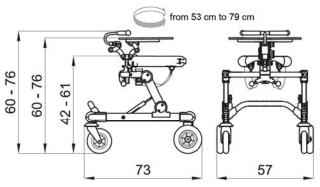
DIMENSIONS in cm

Inner circumference of the adjustable pelvic and trunk supports



FRONT-DRIVE PT GRILLO size mini WEIGHT 14 kg MAX. LOAD kg 35

Inner circumference of the adjustable pelvic and trunk supports



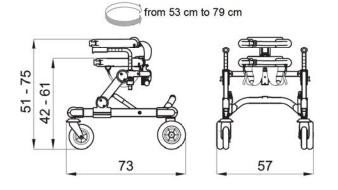
FRONT-DRIVE PTM GRILLO size mini WEIGHT 13,5 kg MAX LOAD kg 35

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

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DIMENSIONS in cm

Inner circumference of the adjustable pelvic and trunk supports



POSTERIOR PT GRILLO size mini WEIGHT 13,5 kg MAX. LOAD kg 35

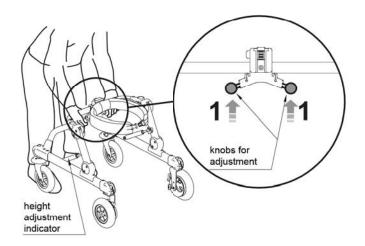
HYPHEN-SEPARATED NUMBERS INDICATE THE MINIMUM AND MAXIMUM RANGE OF ADJUSTMENT

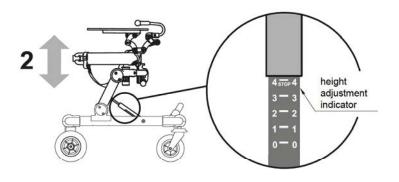
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HOW TO USE GRILLO mini

FRAME:HEIGHT ADJUSTMENT

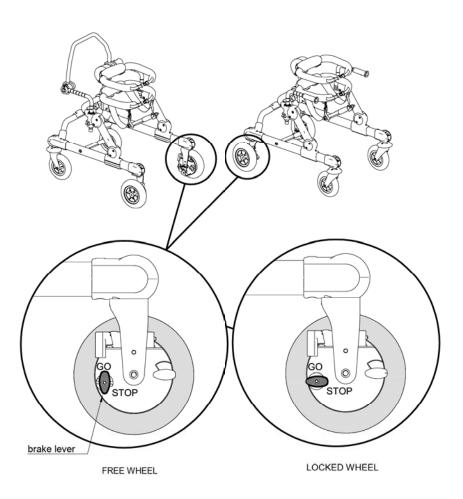
- 1- OPERATE THE ADJUSTMENT KNOBS WITH BOTH HANDS2- ADJUST THE HEIGHT OF GRILLO mini RELEASING THE ADJUSTMENT KNOBS



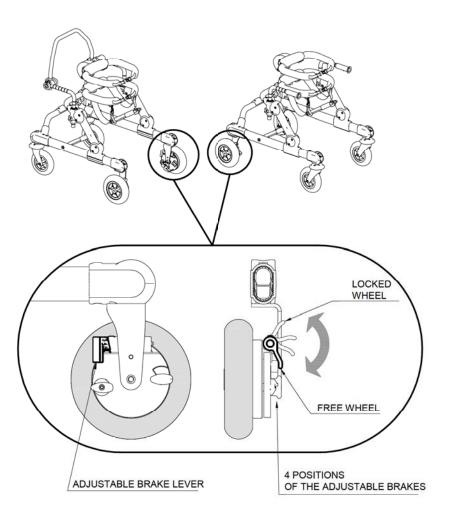


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PARKING BRAKES



ADJUSTABLE BRAKE

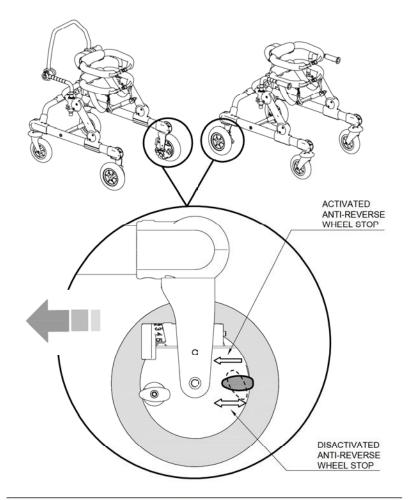


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ANTI-REVERSE DEVICE

WARNINGS!

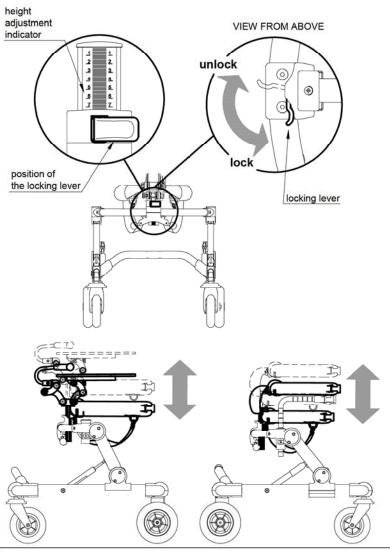
The anti-reverse device reduces the maneuverability of the gait trainer



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PELVIC SUPPORT: HEIGHT ADJUSTMENT

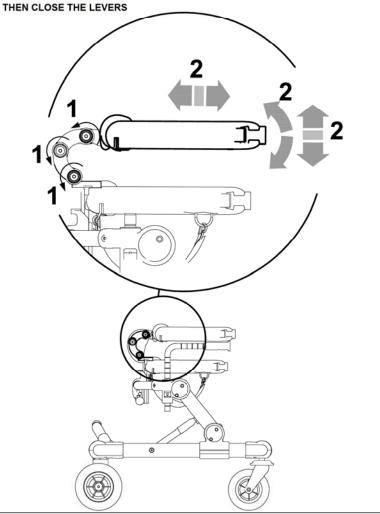


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ORMBDD

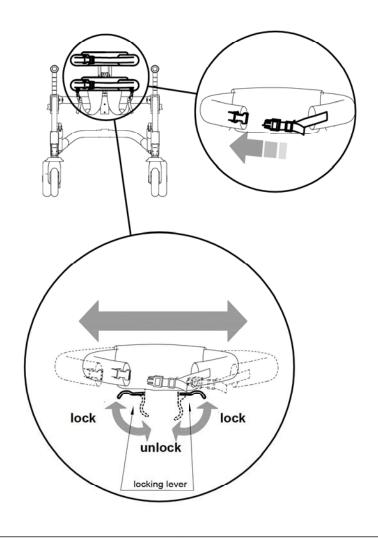
TRUNK SUPPORT: HEIGHT, TILT and BACK-FORWARD ADJUSTMENTS

- 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



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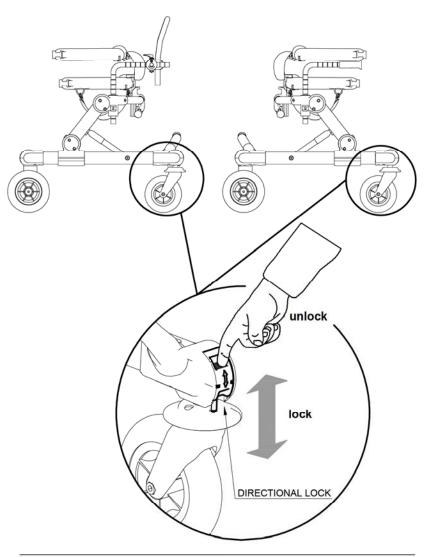
PELVIC AND TRUNK SUPPORTS: CIRCUMFERENCE ADJUSTMENT



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DIRECTIONAL LOCKS



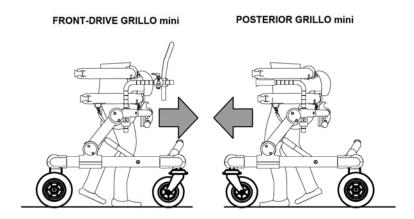
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CHANGE GRILLO mini from FRONT-DRIVE to POSTERIOR and VICE VERSA

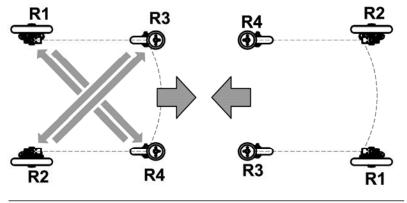
WARNINGS!

This operation must be done by qualified personnel only

A WHEEL-ASSEMBLING AND DISASSEMBLING SCHEME



VIEW FROM ABOVE

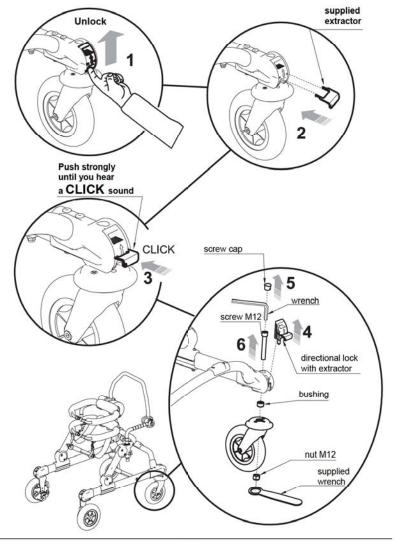


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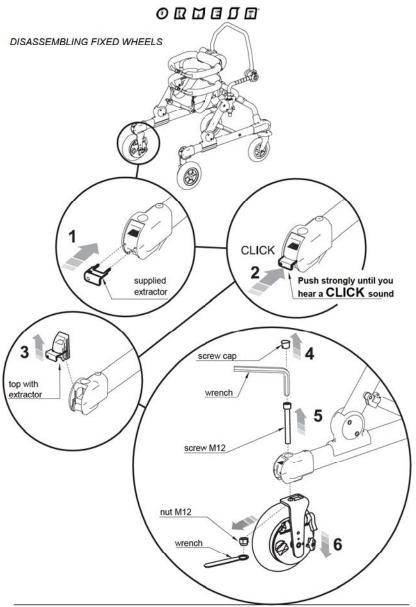
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B FRONT-DRIVE GRILLO mini

DISASSEMBLING THE WHEELS OF THE FRONT-DRIVE GRILLO mini



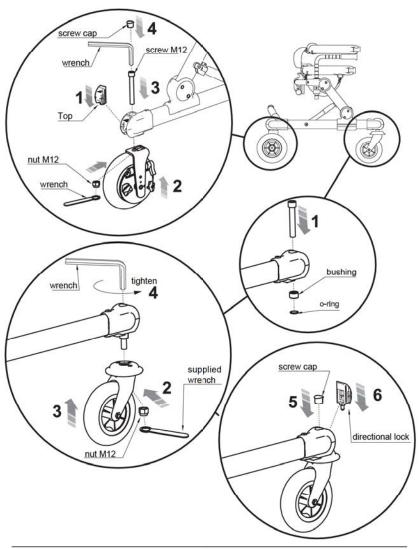
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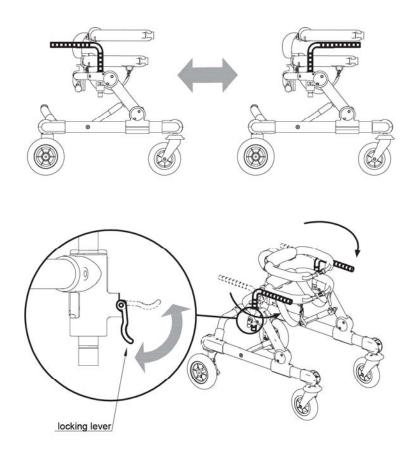
C POSTERIOR GRILLO mini: ASSEMBLING THE WHEELS



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ORMBDD

D TURNING THE HANDLES



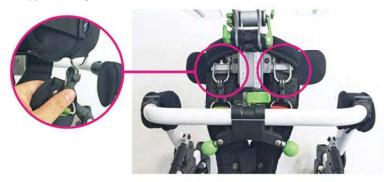
PELVIC HARNESS: ASSEMBLY AND ADJUSTMENT



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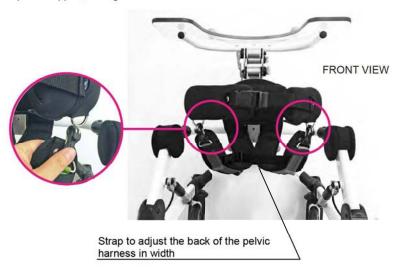
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Attach the **two fixed carabiners** on the two hooks on the **front** of the pelvic support, see figure.



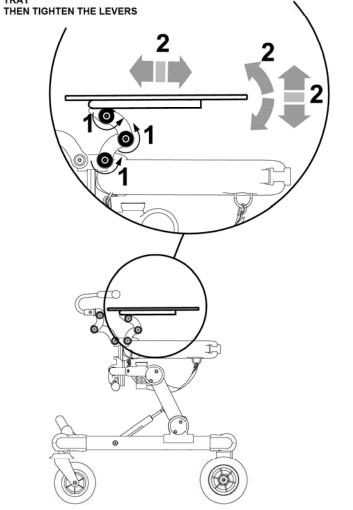
FRONT VIEW

Attach the two adjustable carabiners on the two hooks on the back of the pelvic support, see figure.



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

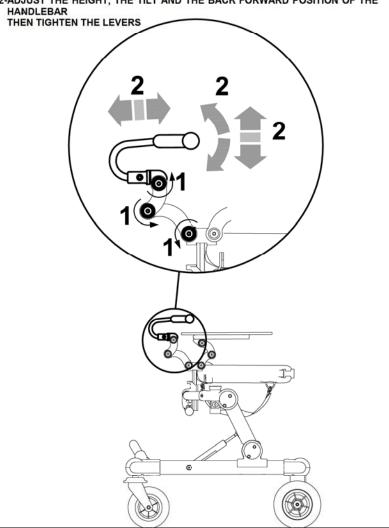
- 1 UNLOCK THE THREE GREEN LEVERS
 2 ADJUST THE HEIGHT, THE TILT AND THE BACK-FORWARD POSITION OF THE TRAY



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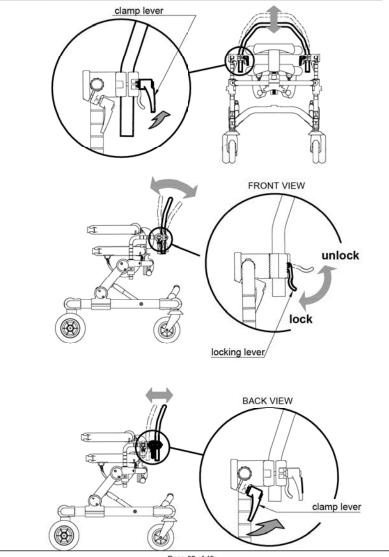
HANDLEBAR: HEIGHT, TILT and BACK-FORWARD ADJUSTMENTS (for Front-drive PTM Grillo mini)

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



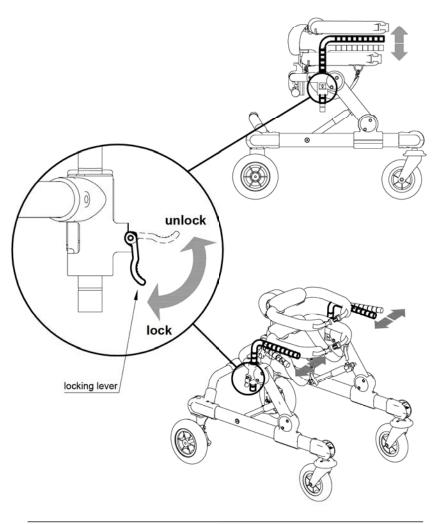
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HANDLEBAR: HEIGHT, TILT and BACK-FORWARD ADJUSTMENTS (for Front-drive PT Grillo mini)



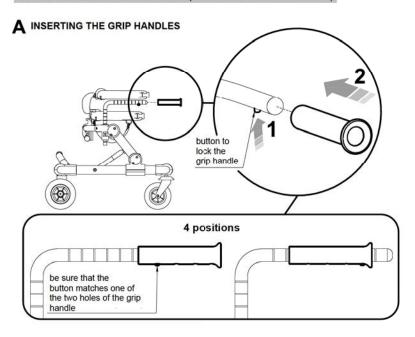
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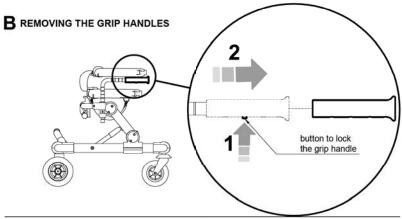
HANDLES: HEIGHT AND WIDTH ADJUSTMENTS (for front-drive PT and posterior PT Grillo mini)



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REMOVABLE GRIP HANDLES (for Posterior PT Grillo mini)

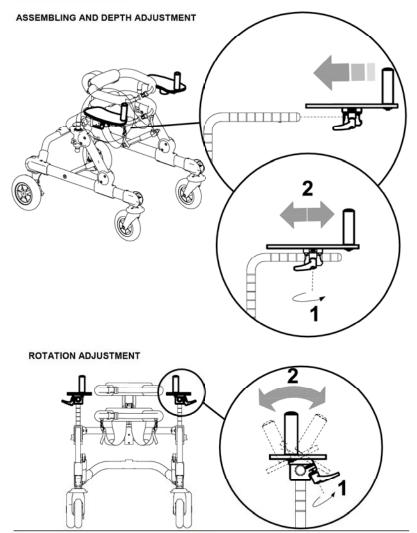




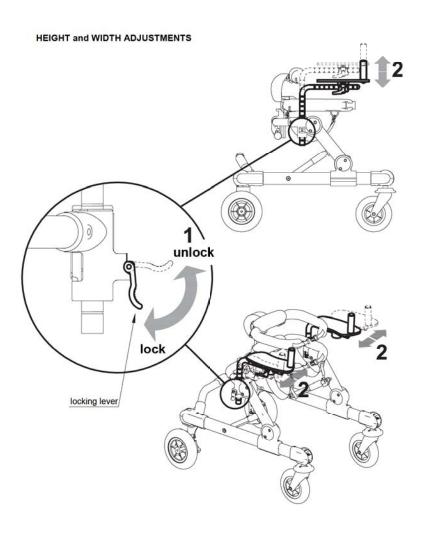
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ASSEMBLING AND ADJUSTING THE COMPONENTS

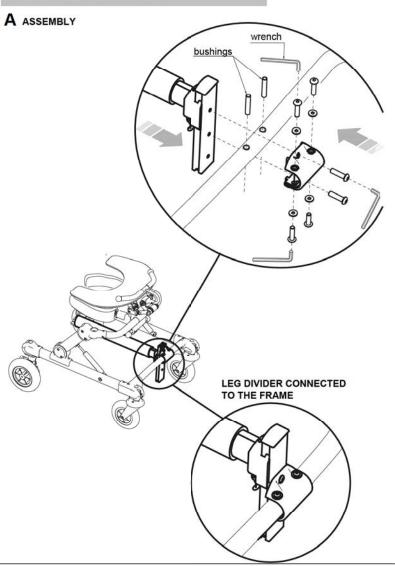
ARM SUPPORTS



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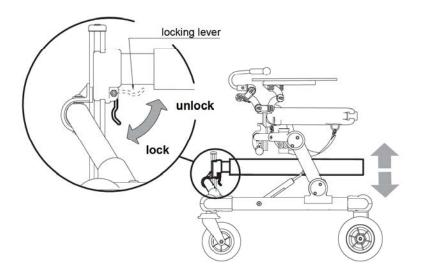


LEG DIVIDER GRILLO mini

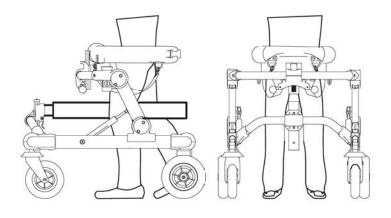


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B ADJUSTMENT IN HEIGHT



C ADJUSTING THE LEG DIVIDER ON GRILLO mini

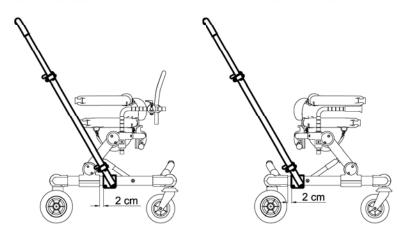


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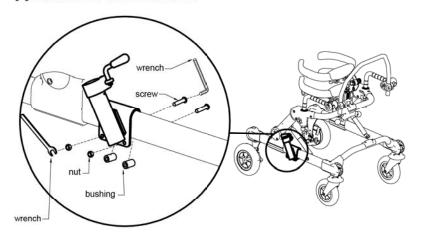
PUSH HANDLE for THE ASSISTANT

POSITION ON FRONT-DRIVE GRILLO mini

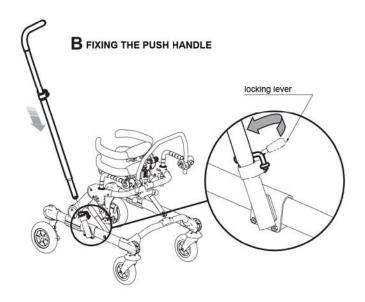
POSITION ON POSTERIOR GRILLO mini



A ASSEMBLY OF THE HANDLE FORK



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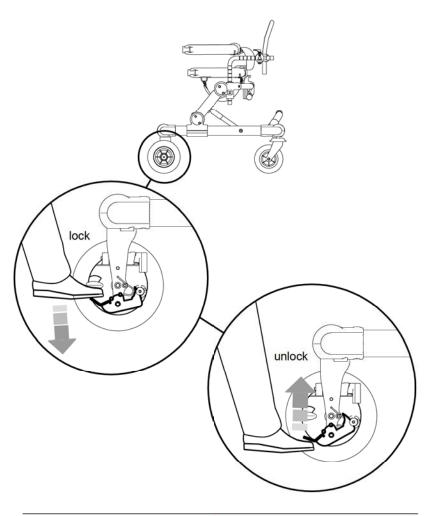


C HEIGHT AND ROTATION ADJUSTMENT



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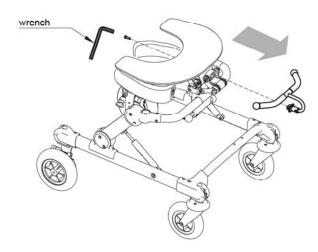
PEDALS for PARKING BRAKES



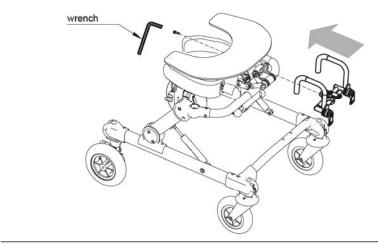
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GRIP HANDLES (for front-drive PTM Grillo mini)

A REMOVE THE HANDLEBAR



B FIX THE GRIP HANDLES

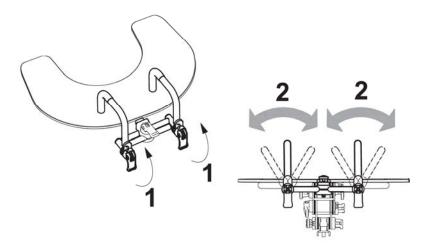


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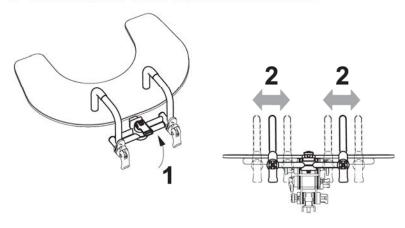
ORMIJO

C ADJUST THE GRIP HANDLES in WIDTH AND ROTATING

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

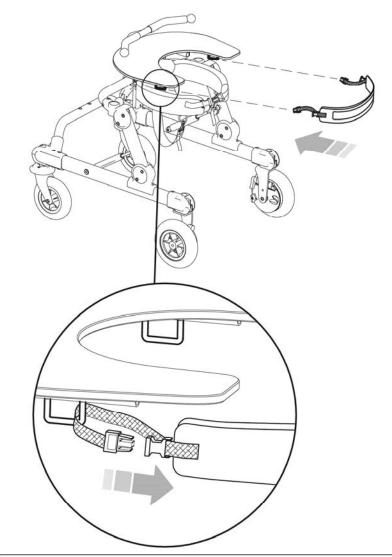


- UNLOCK THE GREEN CENTRAL LEVER
 ADJUST THE WIDTH OF THE GRIP HANDLES. THEN LOCK THE LEVER



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TRAY BELT (for Front-Drive PTM Grillo mini)



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MAINTENANCE, CLEANING AND DISINFECTION OF GRILLO mini

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 HEREIN SPECIFIED, THE RESPONSIBILITY OF KEEPING THE MAIN REQUIREMENTS OF THE WALKING FRAME (ENCL. 1 EEA/93/42 STANDARD) IS UP TO THE MANUFACTURER. FURTHERMORE THE MANUFACTURER RECOMMENDS A COMPLETE REVISION/SERVICE 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

CLEANING THE VARNISHED AND CHROMIUM-PLATED FRAME

Clean the varnished and chromium-plated parts of the aid with a soft cloth moistened with alcohol prior diluted in water.

CLEANING THE UPHOLSTERIES

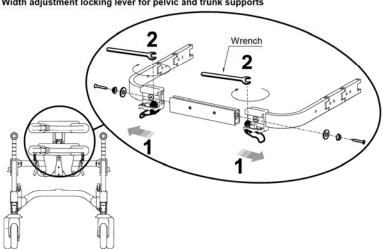
- Clean the padded covers with a soft cloth dipped in water and neutral detergent and well squeezed
- Wash the harness respecting the following symbols:

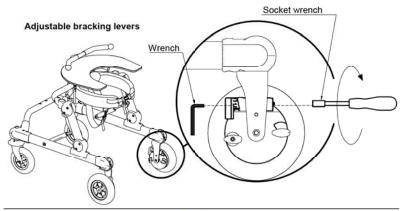


SETTING OF CONTROL LOCKING LEVERS

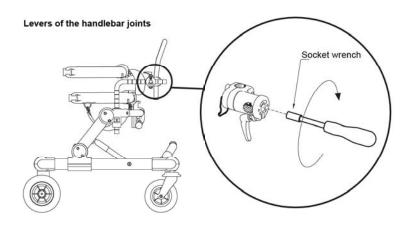
should you have noticed an INEFFICIENCY, even partially, on the LOCKING of the adjustment GREEN LEVERS of the PELVIC SUPPORT, of the HANDLEBAR, please contact your ORTHOPAEDIC WORKSHOP to TIGHTEN THE NUT LITTLE BY LITTLE as shown below, UNTIL the PROPER LOCKING IS REACHED.

Width adjustment locking lever for pelvic and trunk supports

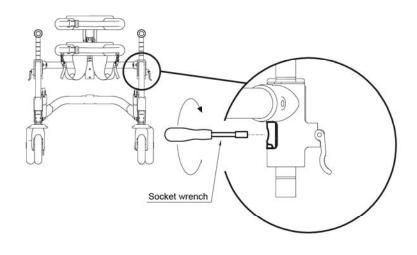




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Height adjustment levers of the handles



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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, 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 partsexposed 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.

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.



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

ASSISTANCE AND SPARE PARTS OF GRILLO mini

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

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 9001, there is adequate confidence thatthe 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:

- 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.
- 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.





COMPANY WITH QUALITY
MANAGEMENT SYSTEM
CERTIFIED BY
= ISO 9001=



FDA REGISTERED - USA

Authorized	

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