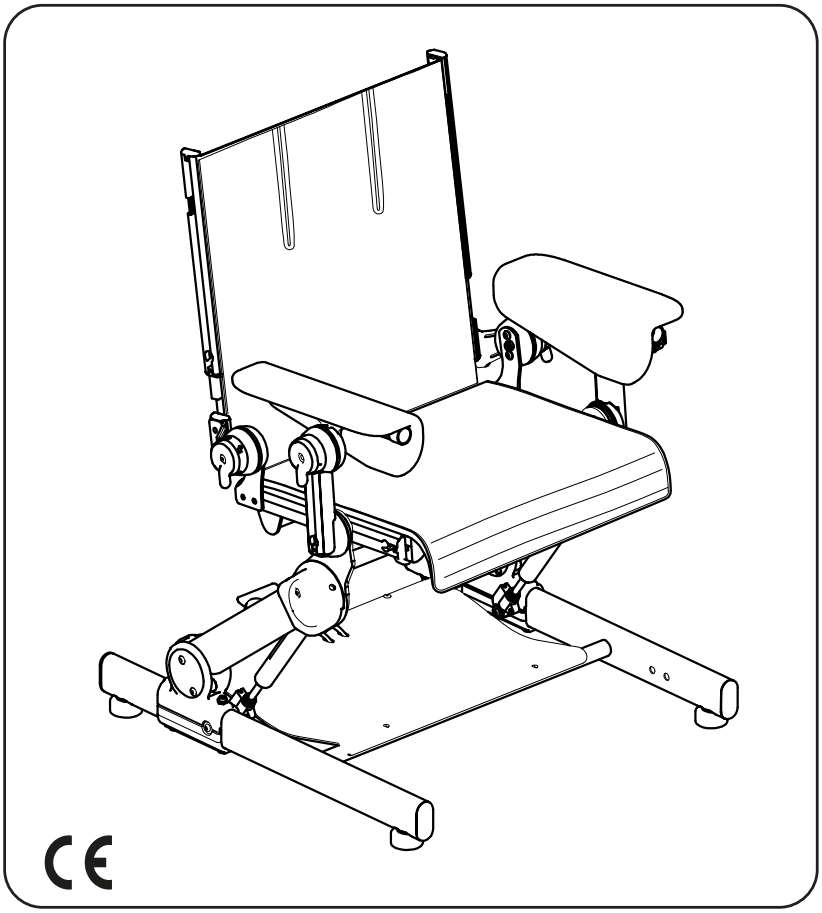
GRILLO chair

USA - Cod. 220681 -15-02-23



CE

USE AND MAINTENANCE HANDBOOK

ORMESA®

• MADE IN ITALY SINCE 1980 •

1. GENERAL INFORMATIONS

1.1 THANKS FOR CHOOSING THE MEDICAL DEVICE

ORMESA s.r.l. thanks you for your confidence in choosing **GRILLO Adaptive Seating**, a medical device designed and manufactured by ORMESA Srl, an **ISO 13485** certified company**.**

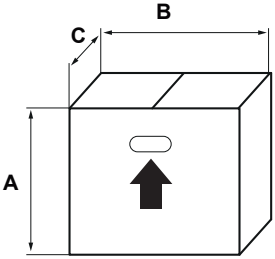
GRILLO CHAIR is an **ergonomic and adjustable chair** indicated for children with disabilities who need support while performing recreational, educational and daily activities.

ORMESA s.r.l. recommends that you read this manual very carefully and thoroughly understand its contents. It will help you familiarize yourself earlier and more effectively with **GRILLO CHAIR,** but not only that, because you will find several practical tips on how to use it in the best and safest way and how to keep it in perfect working order at all times..

1.2 CONTACT DETAILS FOR ASSISTANCE

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.

1.3 PACKAGING INFORMATION. UNPACKING INSTRUCTIONS AND SUPPLY COMPOSITION

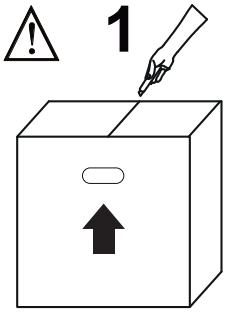


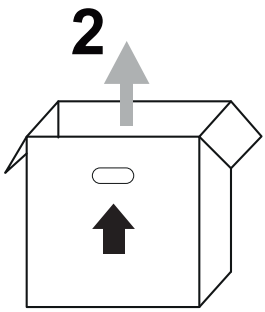
PACKAGING INFORMATION

SIZES	A cm	B cm	C cm	VOLUME m³	WEIGHT kg
Small	54	68	70	0,25704	15
Medium	54	68	70	0,25704	18

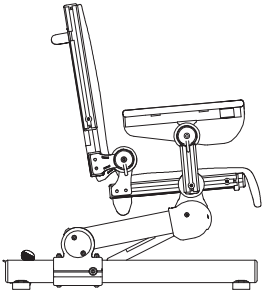
HOW TO TAKE GRILLO CHAIR OUT OF THE BOX

1) **CAUTION! CUT WITHOUT PRESSING TOOT HARD WITH THE BLADE SO AS NOT TO DAMAGE THE CONTENTS OF THE BOX**
2) **TAKE THE ACCESSORIES OUT OF THE BOX**
3) **TAKE GRILLO CHAIR OUT OF THE BOX**

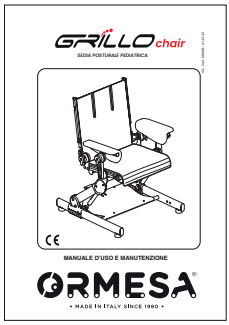




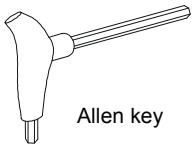
SUPPLY COMPOSITION



GRILLO CHAIR



Use and maintenance handbook

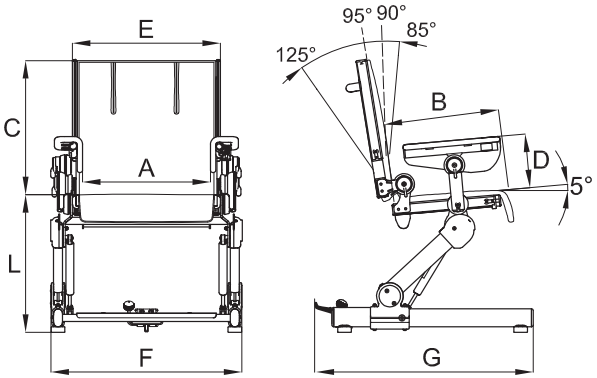


Allen key

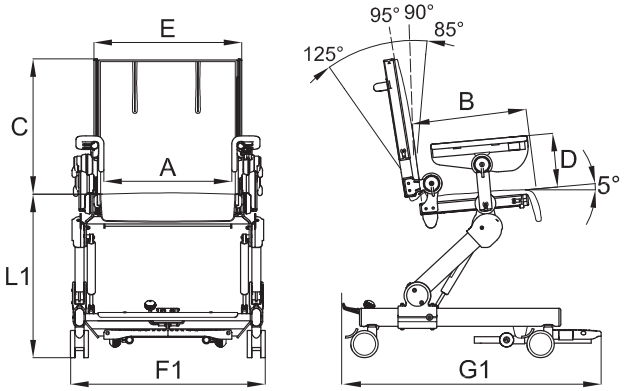
1.4 MECHANICAL AND DIMENSIONAL CHARACTERISTICS

Measures in cm, weight in kg

User height size S cm 90-120
User height size M cm 110-145



With **set of four wheels with footrest** (additional component 959)



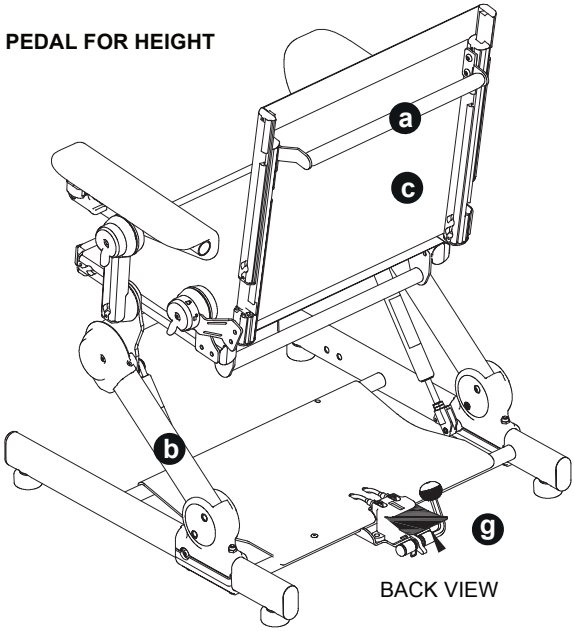
	A* (cm)	B (cm)	C (cm)	D (cm)	E (cm)	F (cm)	F1 (cm)	G (cm)	G1 (cm)	L (cm)	L1 (cm)	Peso ausilio (kg)	Portata max. (kg)
Small	30	20-30	30-45	15-18	36	48	50,5	50	52-64	20-31	28-39	10,7	35
Medium	35	28-43	35-55	16-20	41	52	54,5	56,5	62-73	25-40	33-48	13	45

*With additional component **multiadjustable pelvic side support 958R**: size Small 20-30 cm; Size Medium 25-35 cm.

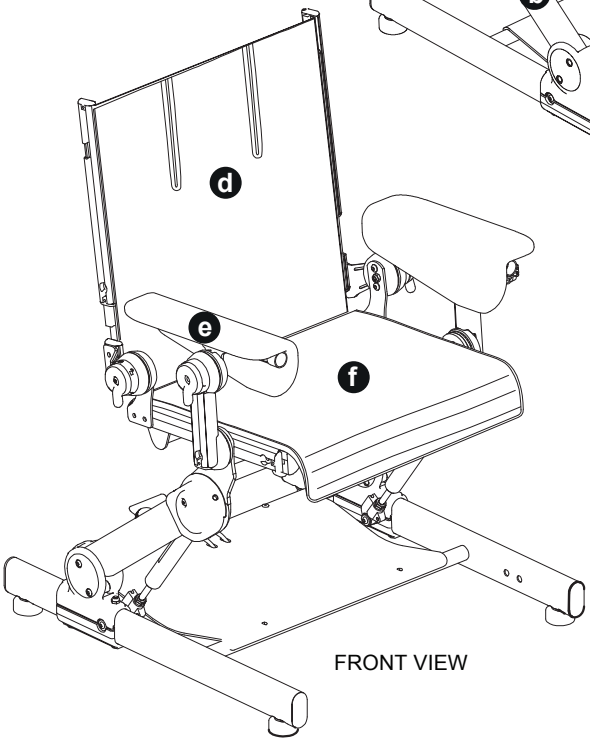
The numbers divided by the dash specify a minimum and a maximum adjustment

1.5 PRODUCT PARTS LEGEND

a) **HANDLE**
b) **FRAME**
c) **BACKREST**
d) **HARMRESTS**
e) **SEAT**
f) **RED SAFETY KNOB AND RED PEDAL FOR HEIGHT ADJUSTMENT**



BACK VIEW



FRONT VIEW

1.6 SYMBOLOGY USED IN THE MANUAL

Consult the use and maintenance handbook

European conformity mark.

Warning: Consult the instructions for use for important precautionary information such as warnings and precautions that, for a number of reasons, cannot be displayed on the medical device in question.

Do not disperse the product in the environment after use

Machine wash with neutral soap. Max. temperature 40°. Delicate cycle.

Do not bleach

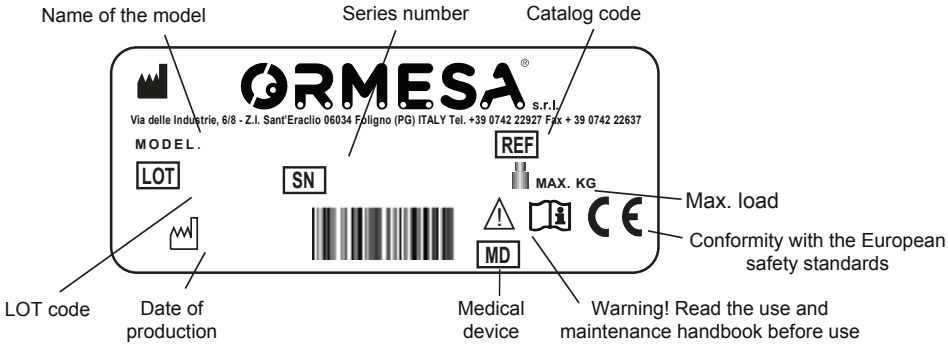
Do not iron

Do not tumble dry

Dry horizontally

1.7 IDENTIFICATION PLATE

THE CE MARKING CERTIFIES GRILLO CHAIR 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



2. LEGAL AND REGULATORY REFERENCES

2.1 LEGAL REFERENCES

Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices, repealing Council Directive 93/42/EEC, hereinafter also referred to as "Regulation (EU) 745/2017", or "RDM"

2.2 REGULATORY REFERENCES

HARMONIZED STANDARDS

UNI CEI EN ISO 13485:2016	Dispositivi medici - Sistemi di gestione per la qualità - Requisiti per scopi regolamentari. *Medical devices - Quality management systems - Requirements for regulatory purposes*
UNI CEI EN ISO 1497 1: 2012	Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici *Medical devices - Application of risk management to medical devices*
UNI CEI EN ISO 15223-1 : 2017	Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite - Parte 1: Requisiti generali. *Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements*
UNI EN 12183 : 2014	Prodotti destinati all'assistenza di persone con disabilità – Requisiti generali e metodi di prova. *Manual Wheelchairs - Requirements And Test Methods EN 12182:2012 Technical aids for disabled persons – general requirements and test methods*
UNI EN ISO 10993-3 : 2015	Valutazione biologica dei dispositivi medici. *Biological evaluation of medical devices*
UNI EN 1021-1:2014	Verifica accendibilità mobili imbottiti. Sorgente sigaretta *Assessment of the ignitability of upholstered furniture. Part 2: Ignitiori source match flame equivalent*
UNI EN 1021-2: 2014	Verifica accendibilità mobili imbottiti. Sorgente fiamma equivalente fiammifero *Assessment of the ignitability of upholstered furniture. Part 1: Ignition source smouldering cigarette*

INTERNAZIONAL STANDARDS

UNI CEI EN 1041 : 2013	Informazioni fornite dal fabbricante di dispositivi medici *Information provided by the medical device manufacturer*
UNI EN ISO 9999 : 2017	Prodotti d'assistenza per persone con disabilità - Classificazione e terminologia *Assistance products for people with disabilities - Classification and terminology*
UNI EN 12182 : 2012	Requisiti Generali *General Requirements*
UNI EN 1021-1 : 2014	Verifica accendibilità mobili imbottiti. Sorgente sigaretta *Assessment of the ignitability of upholstered furniture. Part 2: Ignition source match flameequivalent*
UNI EN 1021-2 : 2014	Verifica accendibilità mobili imbottiti. Sorgente fiamma equivalente fiammifero *Assessment of the ignitability of upholstered furniture. Part 1: Ignition source smouldering cigarette*
IEC 62366-1 : 2015	Dispositivi medici Applicazione dell'ingegneria dell'usabilità ai dispositivi medici *Medical devices Application of usability engineering to medical devices*
IEC/TR 62366-2 : 2016	Dispositivi medici - Guida all'applicazione dell'ingegneria dell'usabilità ai dispositivi medici . *Medical devices Guidance on the application of usability engineering to medical devices.*
ISO 7176-1 : 2014	Sedie a rotelle – parte 1. determinazione della stabilità statica. *Wheelchairs - part 1: determination of static stability*
ISO 7176-3 : 2014	Sedie a rotelle – parte 3. determinazione della efficacia dei freni *Wheelchairs - Part 3: Determination of effectiveness of brakes*
ISO 7176-8 : 2014	Sedie a rotelle – parte 8. requisiti e metodi di prova per la resistenza statica, di impatto e fatica. *Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths*
ISO 7176-11 : 2012	Sedie a rotelle – parte 11. manichini di prova *Wheelchairs - part 11: test dummies*
ISO 7176-15 : 1996	Sedie a rotelle – parte 15. requisiti per la diffusione delle informazioni, per la documentazione e la etichettatura. *Wheelchairs - part 15: requirements of information disclosure, documentation and labelling*
ISO 7176-22 : 2014	Sedie a rotelle – parte 22. Procedure *Wheelchairs - part 22: set-up procedures*

NATIONAL STANDARDS

UNI EN 1729-2 : 2016	Mobili-Sedie e tavoli per istituzioni scolastiche. Parte2: Requisiti di sicurezza e metodi di prova. *Furniture-chairs and tables for educational institutions. Part 2: Safety requirements and testmethods*
UNI EN 14988 : 2020	Seggioloni per bambini - Requisiti e metodi di prova *High chairs for children - Safety requirements and test methods*

2.3 WARRANTY CONDITIONS

ORMESA and INNOVATION IN MOTION warrant the product for 2 years: in case of problems, contact the supplier (health professional) where you purchased it. Always ask for original spare parts, otherwise the guarantee will decline.

ORMESA s.r.l. 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 ones shown in this use and maintenance handbook);*
- *damage caused by incorrect use and lack of regular maintenance, as shown in this user manual;*
- *exceptional events;*
- *failure to follow the instructions in this manual.*

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

3. SAFETY WARNINGS ⚠

3.1 MEDICAL DEVICE RISK CLASS ACCORDING TO ANNEX VIII OF REGULATION (EU) 745/2017

GRILLO CHAIR belongs to Risk Class I (Non-Invasive Device)

3.2 GENERAL WARNINGS

- **CAREFULLY READ AND UNDERSTAND THE INSTRUCTIONS IN THIS MANUAL BEFORE USING THE PRODUCT** because it has been written with the user's safety in mind and it will help the carer use the product safely and keep it in good working order. The Use and Maintenance Manual is an integral part of the product and must be carefully preserved for future reference.
- **THE USE AND MAINTENANCE HANDBOOK IS INTENDED FOR ALL USERS THE DEVICE: HEALTH PROFESSIONALS, CARERS (CARE GIVERS) PATIENTS;** It provides instructions for the correct use of the medical device.
- The manual reflects the technical state of the product at the time it was sold. **ORMESA S.R.L. RESERVES THE RIGHT TO MAKE ANY CHANGES TO THE PRODUCT OR MANUAL** suggested by experience, technical considerations or regulatory developments.
- **THE MEDICAL DEVICE MUST BE USED BY PEOPLE WHOSE BODY SIZE AND WEIGHT COMPLY WITH THE SPECIFICATIONS** in the § « MECHANICAL AND DIMENSIONAL CHARACTERISTICS », on pag. 5.
- **GRILLO CHAIR is a MECHANICAL MEDICAL DEVICE:**

THE USER has to perform REGULAR MAINTENANCE and CLEANING following the instructions shown in the "Maintenance" chapter on page 38-39-40-41-42-43 and HAVE THE PRODUCT 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 page 38-39-40-41-42-43 of the manual must be ONLY MADE by a SPECIALIZED SERVICE CENTER in the maintenance of mechanical aids for disables, otherwise warranty will fail and CE marking will lapse.

Any CHANGES in the product ARE NOT AUTHORIZED, 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 the HEALTH PROFESSIONAL WHO SUPPLIED IT, or directly ORMESA.

3.3 SPECIFIC WARNINGS

- **GRILLO CHAIR and its POSSIBLE ADDITIONAL COMPONENTS must be PRESCRIBED BY A SPECIALIST DOCTOR who also checks its use, and must be configured and adjusted for the user by a health professional authorized by the National Health System.**
- **L'impiego del GRILLO CHAIR e dei suoi aggiuntivi deve essere controllato dal medico**, in conformità alla legislazione, ai regolamenti e alle normative vigenti.
- **Nel caso in cui sia presente il componente aggiuntivo 959 (set di pedana e appoggiapiedi), PRIMA DI OGNI UTILIZZO verificate l'efficienza dei freni e l'usura delle ruote.**
- **Nel caso in cui sia presente il componente aggiuntivo 959 (set di pedana e appoggiapiedi), PRIMA DI EFFETTUARE QUALSIASI REGOLAZIONE e IN CASO DI SOSTA, anche su terreno piano, bloccate sempre i freni.**
- **DOPO AVER EFFETTUATO QUALSIASI REGOLAZIONE, accertatevi che gli elementi regolabili siano bloccati**

3.4 REASONABLY FORESEEABLE MISUSE

- **DO NOT USE THE MEDICAL DEVICE WITH SUBJECTS WITH DIMENSIONS GREATER THAN** those indicated on pag. 5.
- **NEVER LEAVE THE USER ALONE** in the medical device.
- **DO NOT USE THE MEDICAL DEVICE** outdoor unless it is a flat, paved and weather-protected surface.
- **DO NOT PLACE THE MEDICAL DEVICE IN PARK ON SLOPING GROUND.**
- **DO NOT USE THE MEDICAL DEVICE TO CLIMB OR DESCEND STAIRS:** its structure was not designed for this purpose.
- **DO NOT LIFT THE MEDICAL DEVICE WHEN IT IS IN USE WITH THE SUBJECT.**
- **DO NOT LIFT THE MEDICAL DEVICE BY THE FRAME.**
- **DO NOT ATTACH WEIGHTS TO THE HANDLE so as not to put at risk its stability during**

use.

- **DO NOT ALLOW OTHER CHILDREN TO USE THE MEDICAL DEVICE, EVEN FOR PLAY**
- **DO NOT PLACE EXCESSIVELY HOT LIQUID CONTAINERS OR OBJECTS ON THE TRAY SURFACE(additional component 824) THAT COULD CAUSE DAMAGE OR BURNS IF OVERTURNED.**
- **DO NOT USE THE MEDICAL DEVICE IF THERE ARE DAMAGED OR MISSING PARTS.**

3.5 CONTRAINDICATIONS AND SIDE EFFECTS

GRILLO Chair Grillo Adaptive Seating is generally not suitable for people with severe musculoskeletal deformities, who need postural seating units.

3.6 OPERATING ENVIRONMENTAL CONDITIONS

- **THE MEDICAL DEVICE IS NOT DESIGNED FOR USE IN OUTDOOR ENVIRONMENTS**, unless it is a flat, paved and weather-protected surface.
- **NEVER LEAVE THE STROLLER PARKED FOR A LONG TIME UNDER DIRECT SUNLIGHT OR NEAR SOURCES OF HEAT:** this will avoid overheating the device and discolouring the upholstery**.**

3.7 CONDITIONS OF TRANSPORT AND PACKAGING

- **THE MEDICAL DEVICE MUST BE STORED AND PACKED using the Ormesa original packaging materials, unless the guaranteed will be voided.**
- **Once unpacked, TRANSPORT must be done by ADEQUATELY ANCHORING IT to the vehicle.**
- **When travelling by plane, or in the car, DO NOT SUBJECT THE FOLDED FRAME TO LOADS THAT, especially with road bumps, COULD DAMAGE ITS STRUCTURE .**
- **THE MEDICAL DEVICE MUST BE PARKED/STORES IN CLOSED AND DRY PLACES.**
- **THE OPERATING ENVIRONMENT HAS NO PARTICULAR INFLUENCE ON THE PRODUCT 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 SLIDING PARTS. IN THIS CASE, WE RECOMMEND CAREFULLY CLEANING AND DRYING THE FRAME FOLLOWING THE INSTRUCTIONS SHOWN IN THE "MAINTENANCE, CLEANING AND DISINFECTION" CHAPTER ON PAGES 38-39-40-41-42-43 AND THE WARNINGS ⚠ ON PAGE 40.**

3.8 PRE-INSTALLATION/INSTALLATION AND COMMISSIONING

GRILLO CHAIR does not require installation.
For commissioning (including the possible insertion of postural components) **it requires configuration and adjustment exclusively by a health professional licensed** by the National Health System.

4. DEVICE DESCRIPTION

4.1 INTENDED USE OF THE MEDICAL DEVICE

GRILLO CHAIR is an ergonomic and adjustable chair suitable for children with disabilities who need support during the performance of recreational activities, education and everyday life.

It is **a seat with an ergonomic design** designed to ensure maximum comfort to the child that improving the sitting posture, is encouraged to develop motor skills and manual eye coordination, attention and therefore social inclusion.

The load-bearing upholstery, extremely breathable and durable, allows the child to live a rewarding and hassle-free sitting experience

GRILLO CHAIR, thanks to its **patented height adjustment system**, can be operated with the child sitting. Equipped with four swivel castors (additional component 959), it allows the approach to countertops and work with ease.

4.2 MAINS COMPONENTS/AVAILABLE VERSIONS

GRILLO CHAIR is available in three sizes and different configurations depending on the components chosen by the health care professional.

For a list of components, their assembly/adjustment by a health professional, and functionality, see § 5.2 on page 14.

4.3 DESCRIPTION OF THE MEDICAL DEVICE

Grillo Chair has a compact aluminum structure, painted with non-toxic epoxy powders.

The height adjustment system via gas spring, allows you to change the height of the chair even with the child sitting.

Grillo chair is the ideal solution for school and home: it can be combined with any surface for educational and playful activities or multifunctional tables such as the Ormesa multifunctional table

5. OPERATING INSTRUCTIONS

5.1 FIRST USE

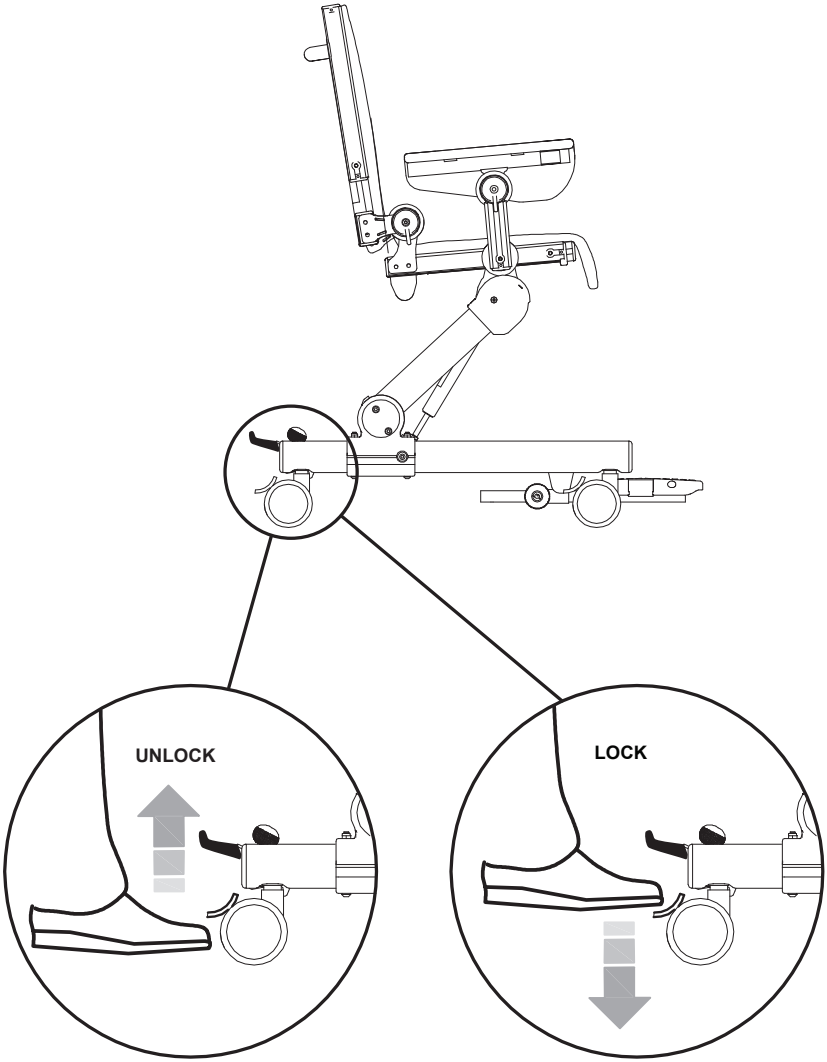
The medical device MUST BE CONFIGURED AND REGULATED BY A HEALTHCARE PROFESSIONAL, who must also provide the family with explanations on proper use, warnings, and maintenance, in accordance with this manual (§ 5.2 and 5.3)

5.2 ADJUSTMENT AND CONFIGURATION OF THE MEDICAL DEVICE by the health professional

BRAKING

BEWARE!
BEFORE PLACING OR REMOVING THE CHILD FROM GRILLO AS AND BEFORE ANY ADJUSTMENT, **IT IS NECESSARY O BRAKE THE AID.**

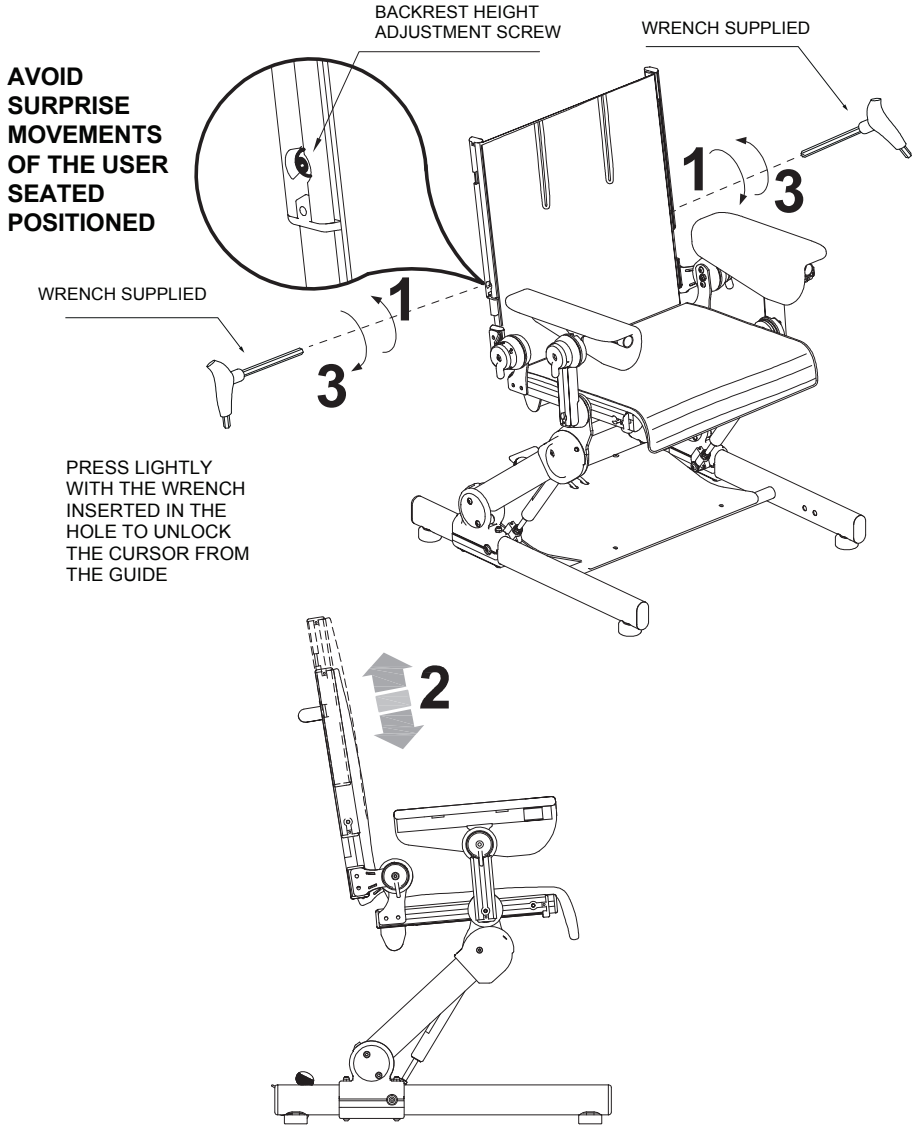
ONLY IN THE PRESENCE OF THE ADDITIONAL COMPONENT 959: SET OF 4 WHEELS WITH BRAKES AND FOOTRESTS.



BACKREST HEIGHT ADJUSTMENT

(video on the product page of the website www.ormesa.com)

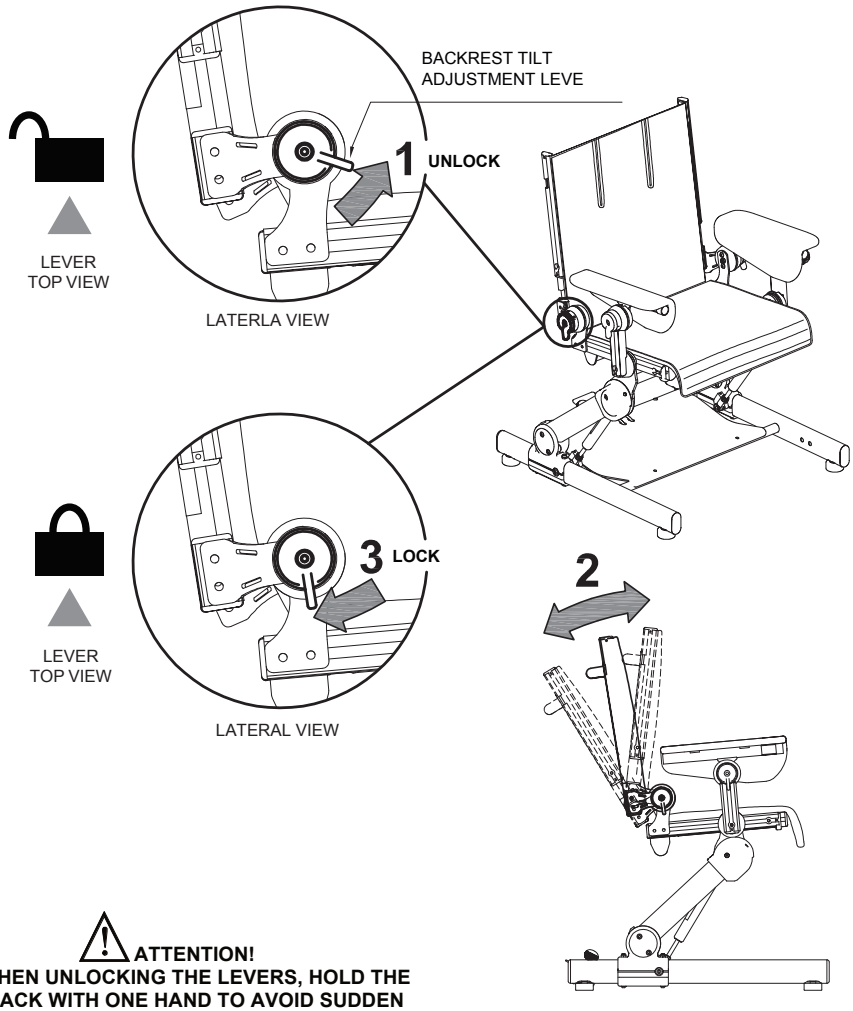
1) **LOOSEN THE SIDE SCREWS INDICATED**
2) **ADJUST THE HEIGHT OF THE BACKREST TO THE DESIRED POSITION**
3) **TIGHTEN THE SCREWS**



BACKREST INCLINATION ADJUSTMENT

(video on the product page of the website www.ormesa.com)

1) TURN THE TWO GREEN LEVERS COUNTERCLOCKWISE TO RELEASE THE BACKREST
2) ADJUST THE BACKREST IN INCLINATION
3) TURN THE TWO GREEN LEVERS CLOCKWISE TO LOCK IT

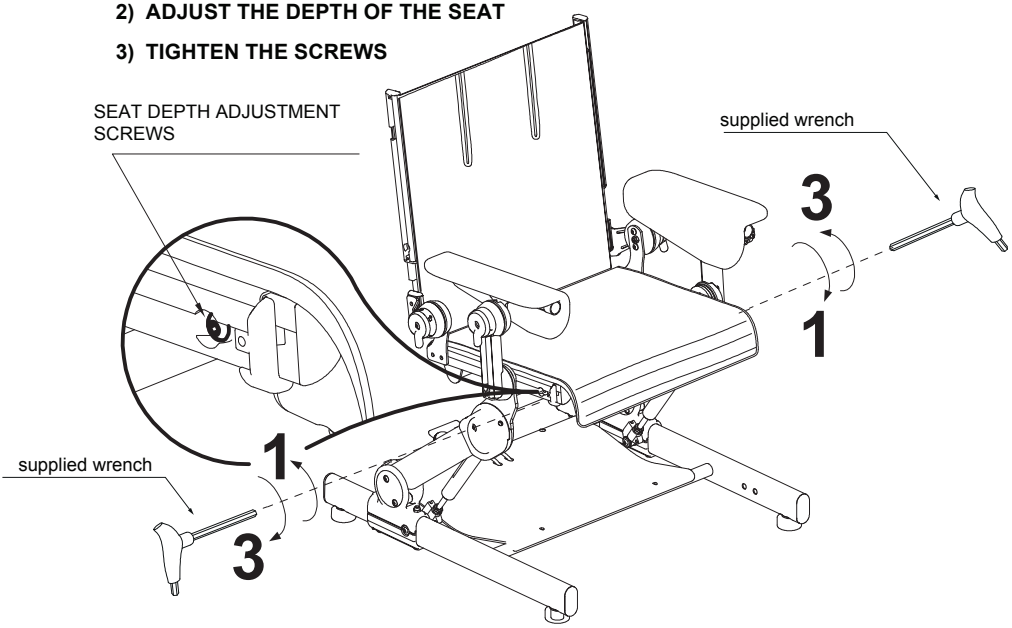


ATTENTION!
WHEN UNLOCKING THE LEVERS, HOLD THE BACK WITH ONE HAND TO AVOID SUDDEN MOVEMENTS TO THE USER

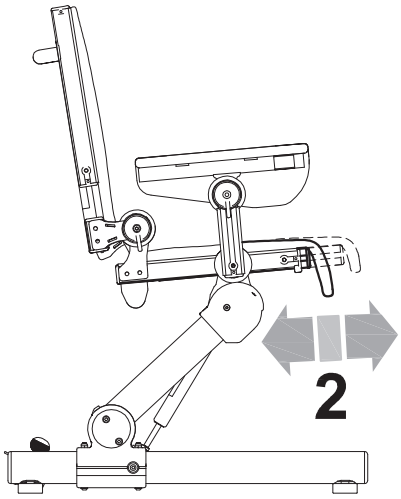
SEAT DEPTH ADJUSTMENT

(video on the product page of the website www.ormesa.com)

1) **LOOSEN THE INDICATED SCREW**
2) **ADJUST THE DEPTH OF THE SEAT**
3) **TIGHTEN THE SCREWS**



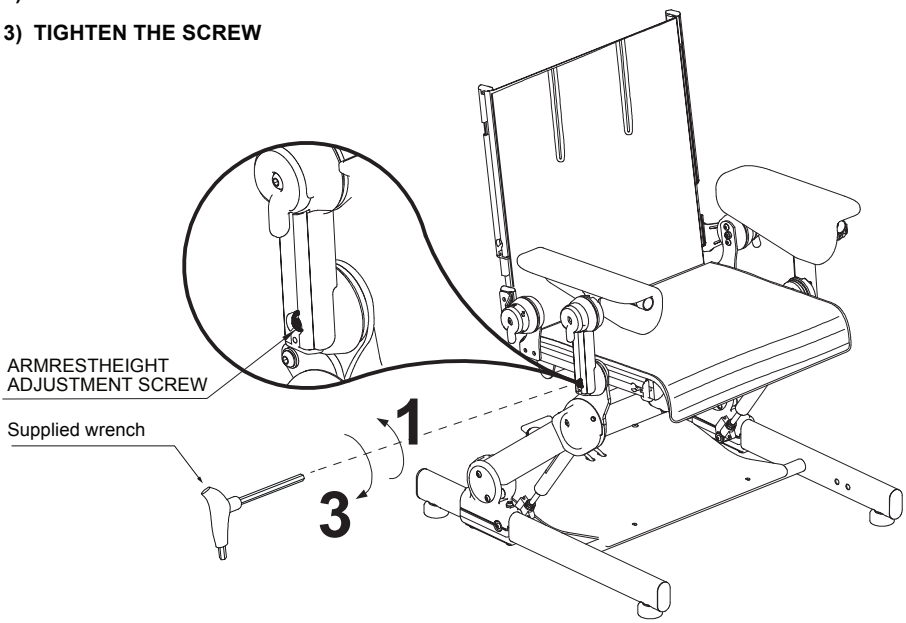
PRESS LIGHTLY WITH THE WRENCH INSERTED IN THE HOLE TO UNLOCK THE CURSOR FROM THE GUIDE



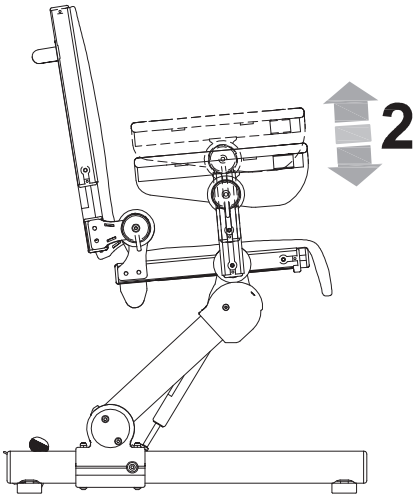
ARMREST ADJUSTMENT

A. HEIGHT ADJUSTMENT

1) LOOSEN THE SCREW
2) ADJUST THE HEIGHT OF THE ARMREST
3) TIGHTEN THE SCREW

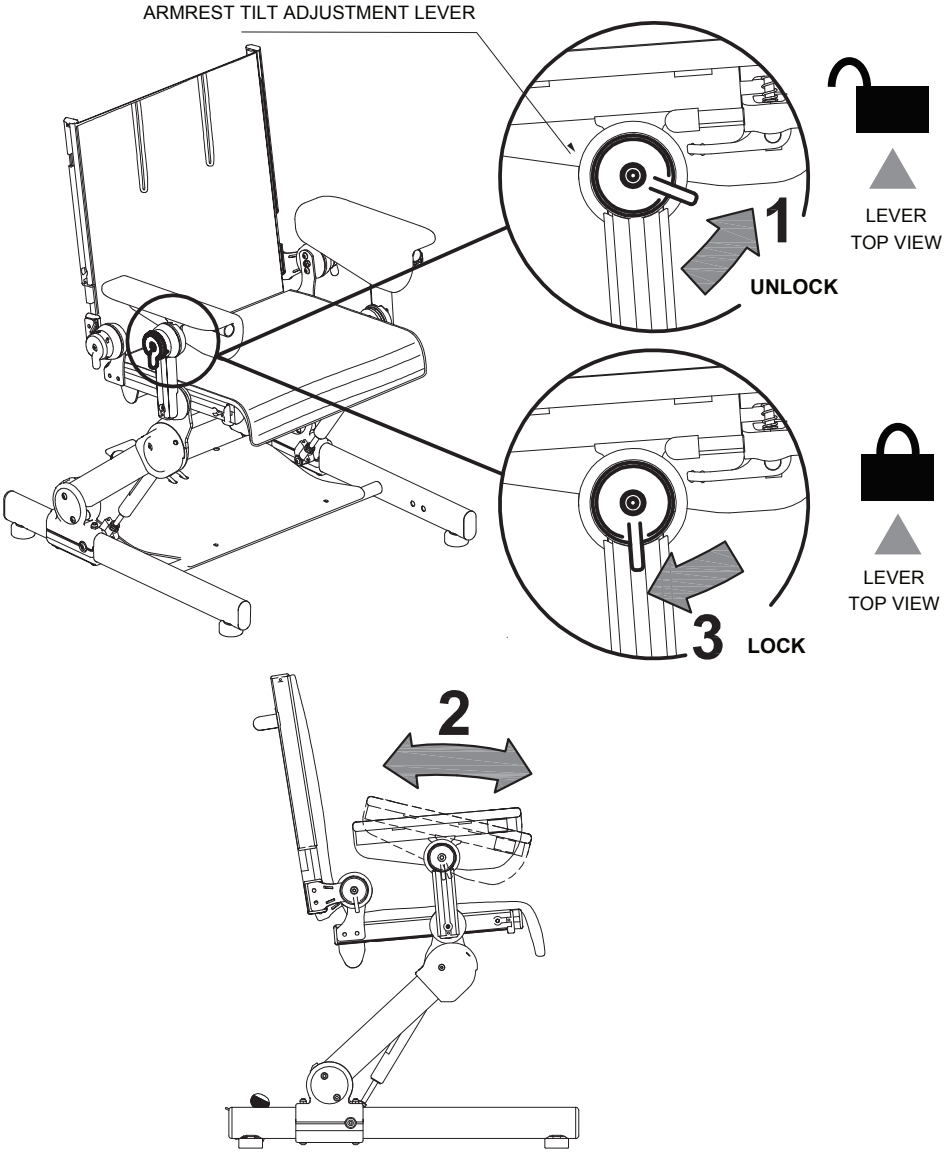


PRESS LIGHTLY WITH THE WRENCH INSERTED IN THE HOLE TO UNLOCK THE CURSOR FROM THE GUIDE



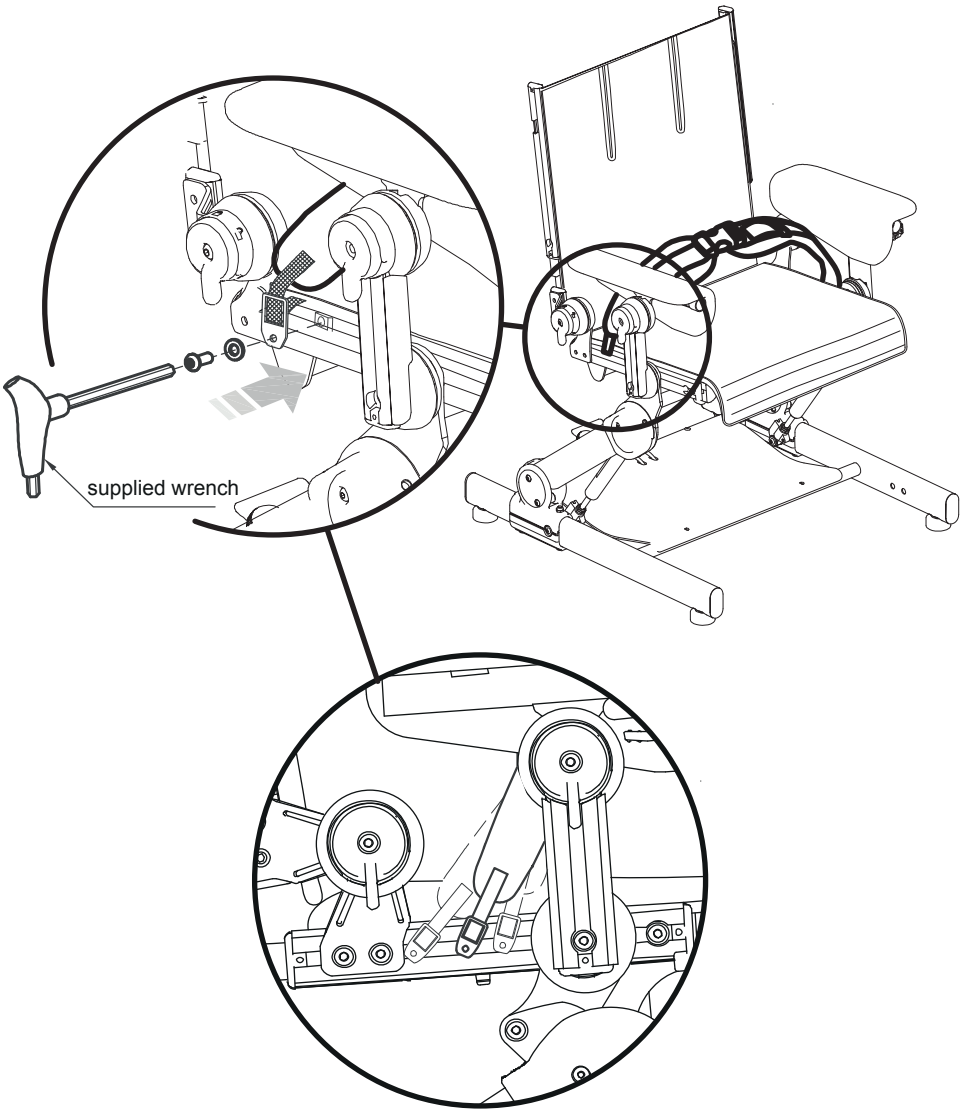
B. TILT ADJUSTMENT

1) TURN THE LEVER COUNTERCLOCKWISE TO RELEASE THE ARMREST
2) ADJUST THE ARMREST IN TILT
3) TURN THE LEVER CLOCKWISE TO LOCK IT

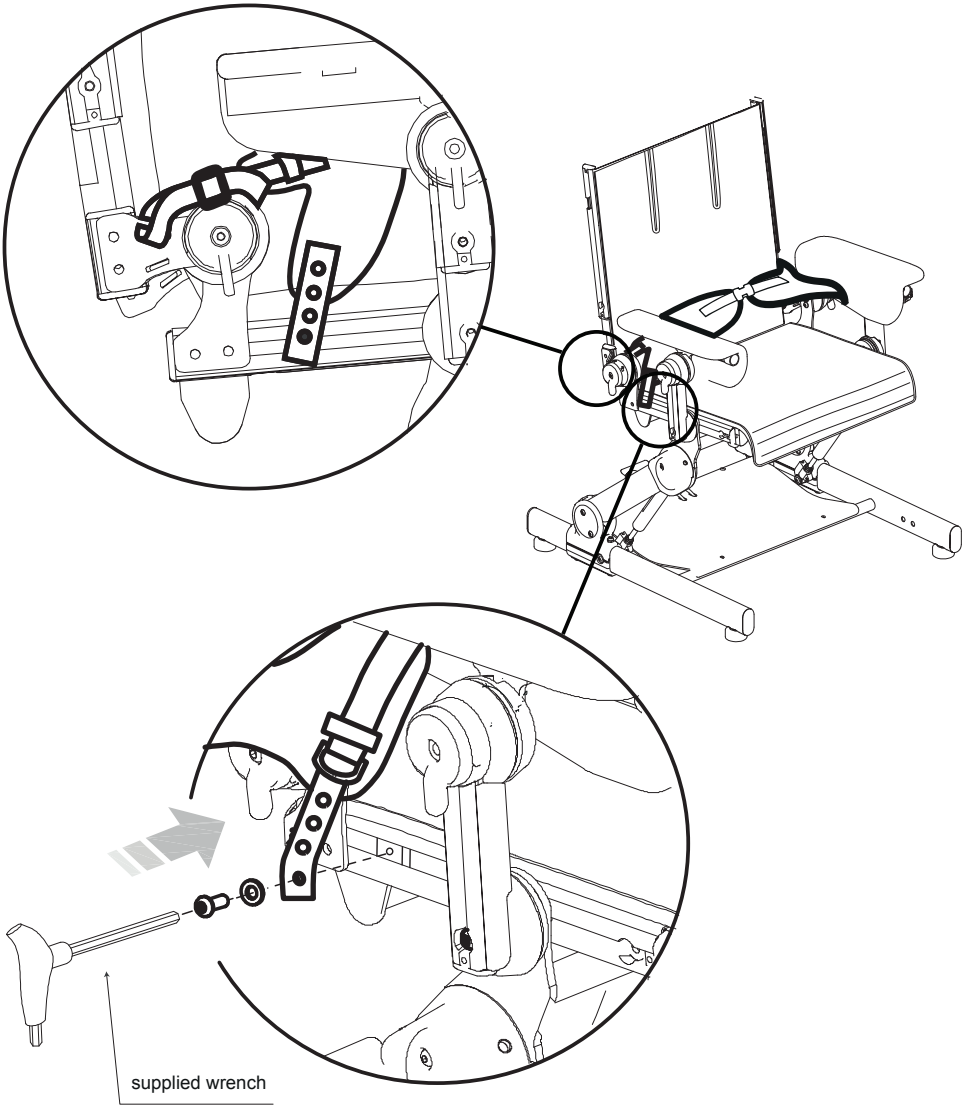


5.3 ADJUSTMENT AND CONFIGURATION OF THE ADDITIONAL COMPNENTS BY THE HEALTH PROFESSIONAL

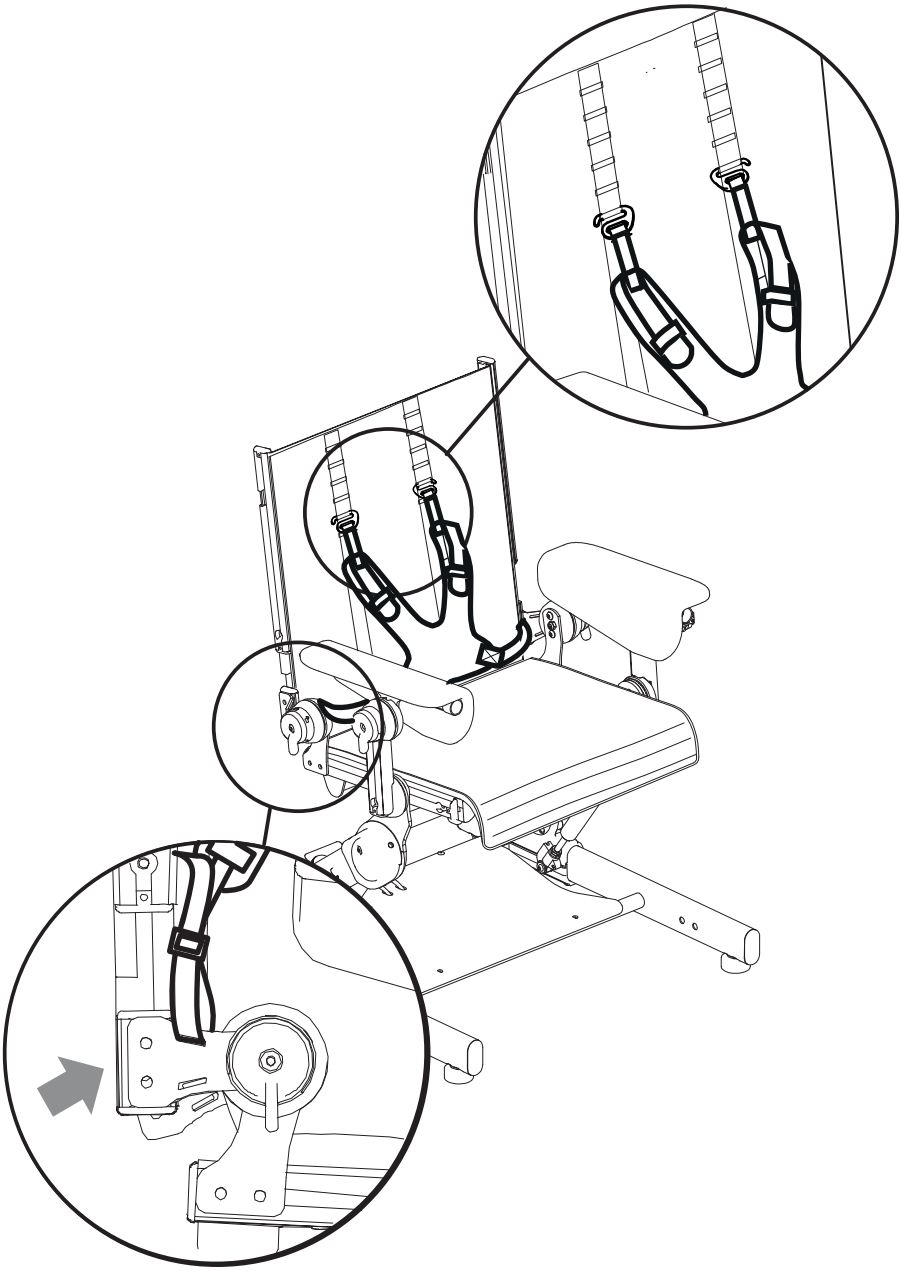
PELVIC BELT WITH VARIABLE ANGLE 947



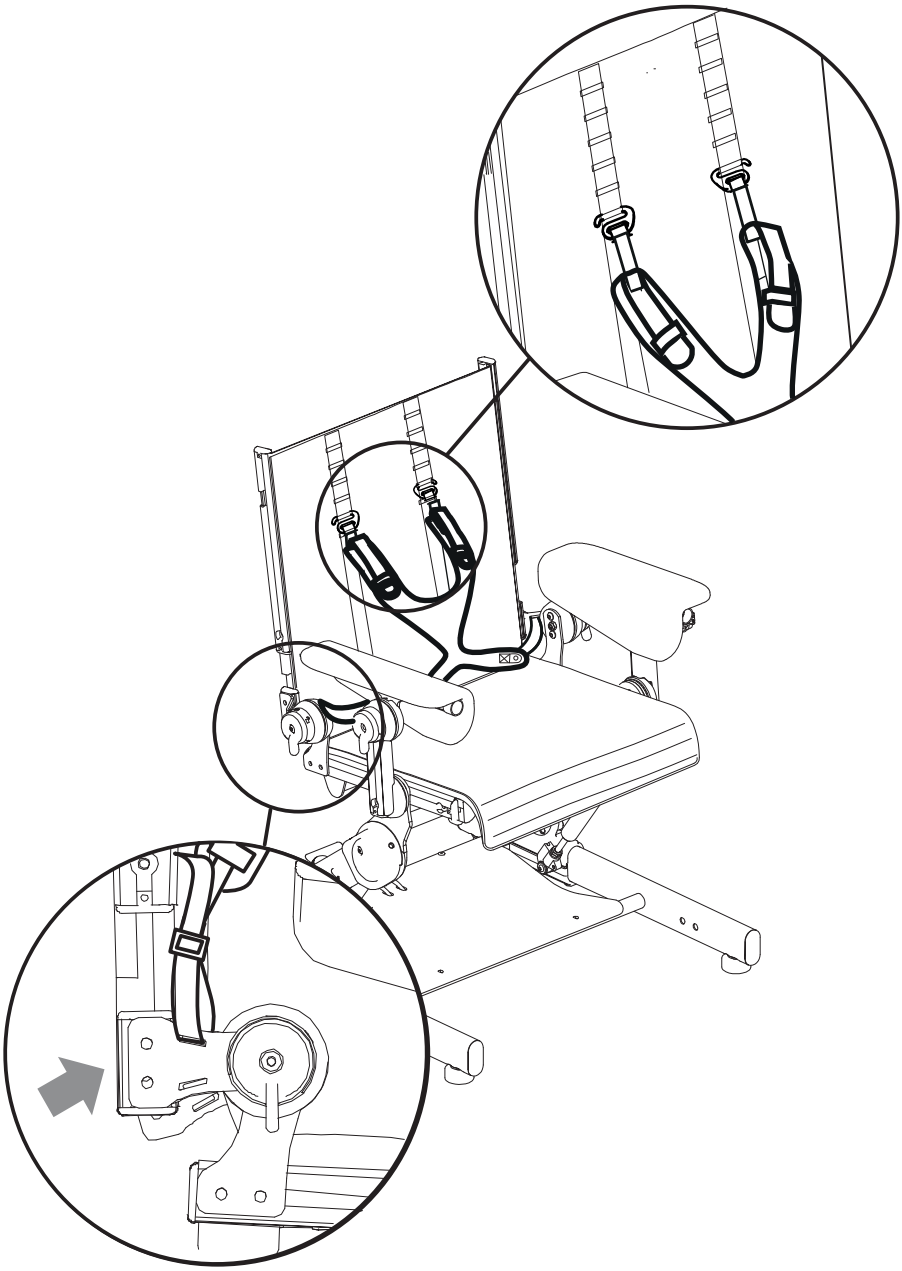
FOUR POINT PELVIC BELT 920



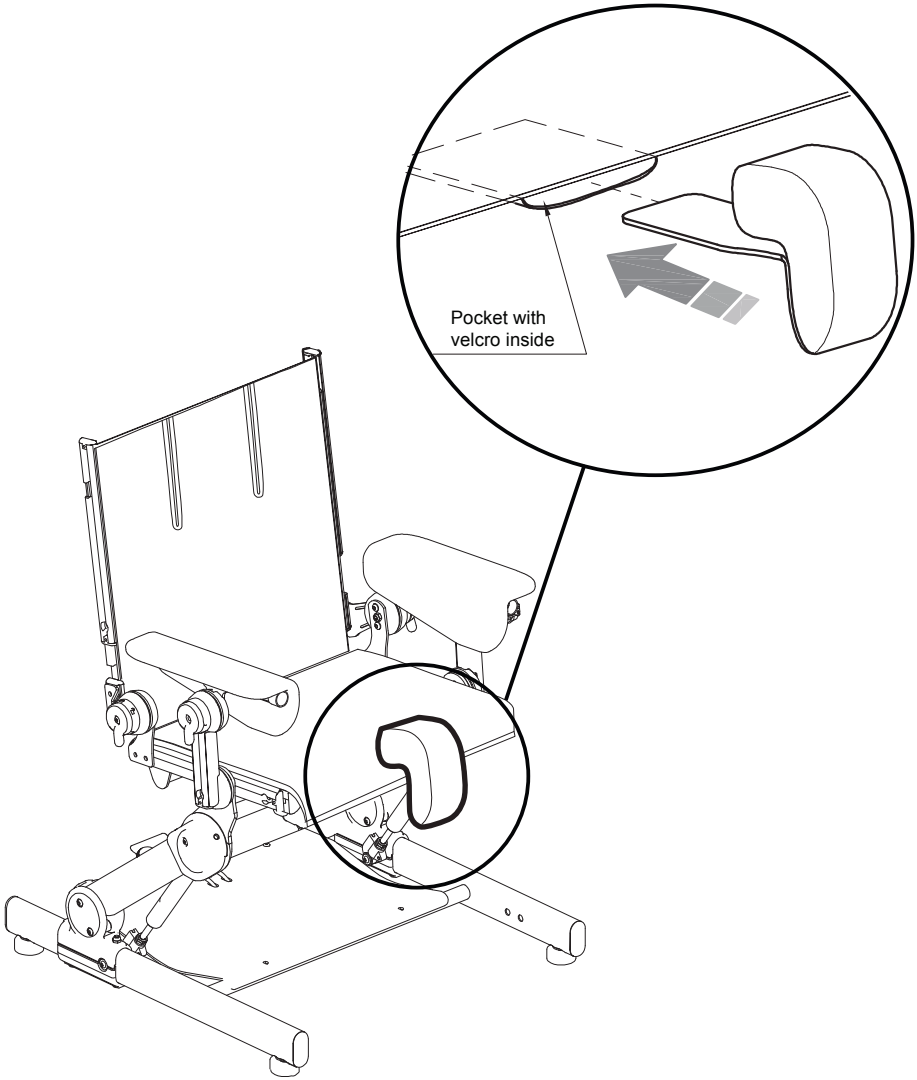
VEST HARNESS 853



SLIM FOUR POINT SHAPED HARNESS 853

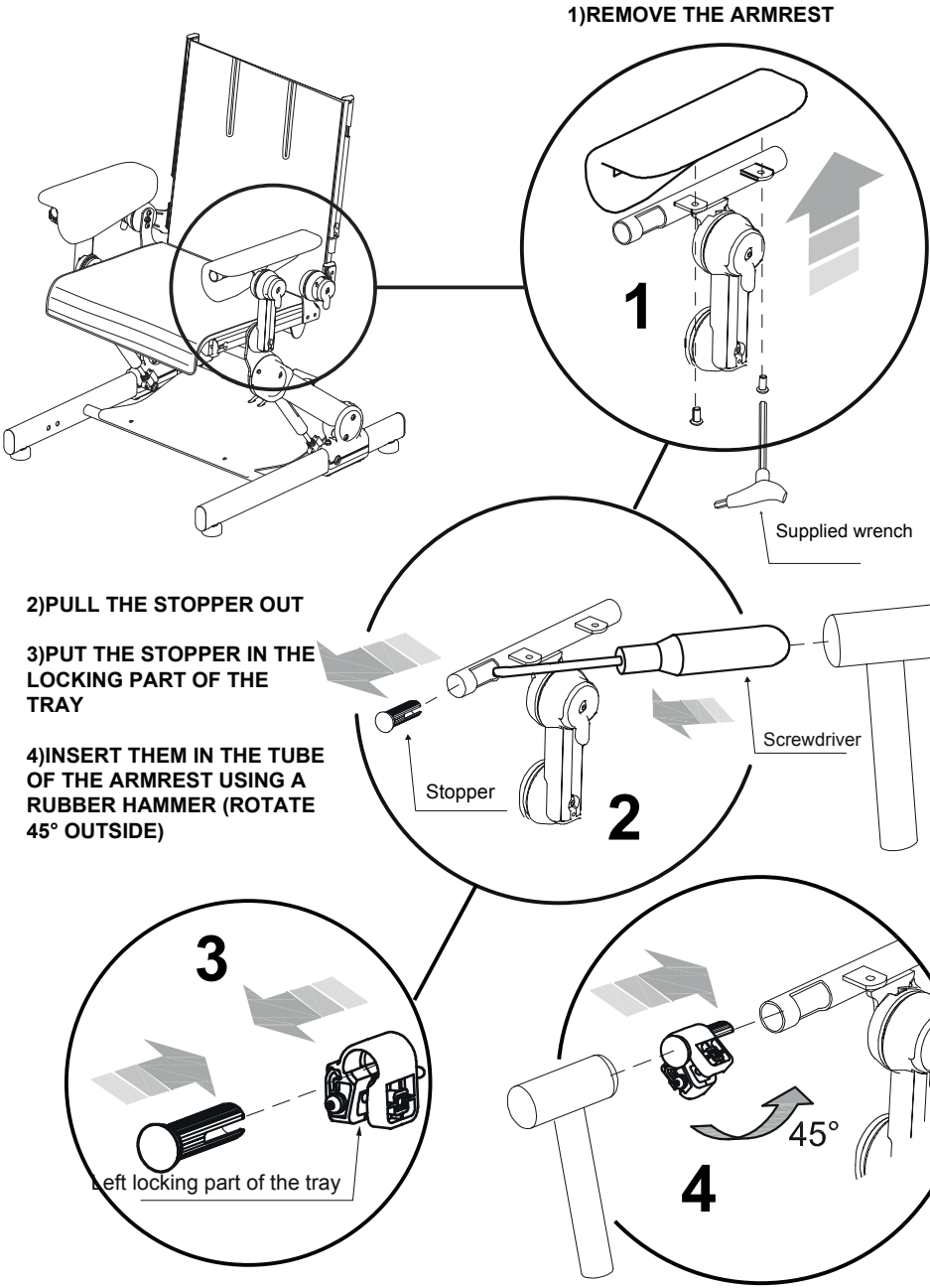


NARROW PADDED ABDUCTION BLOCK 834N



TRAY WITH WRAP-AROUND RECESS 824

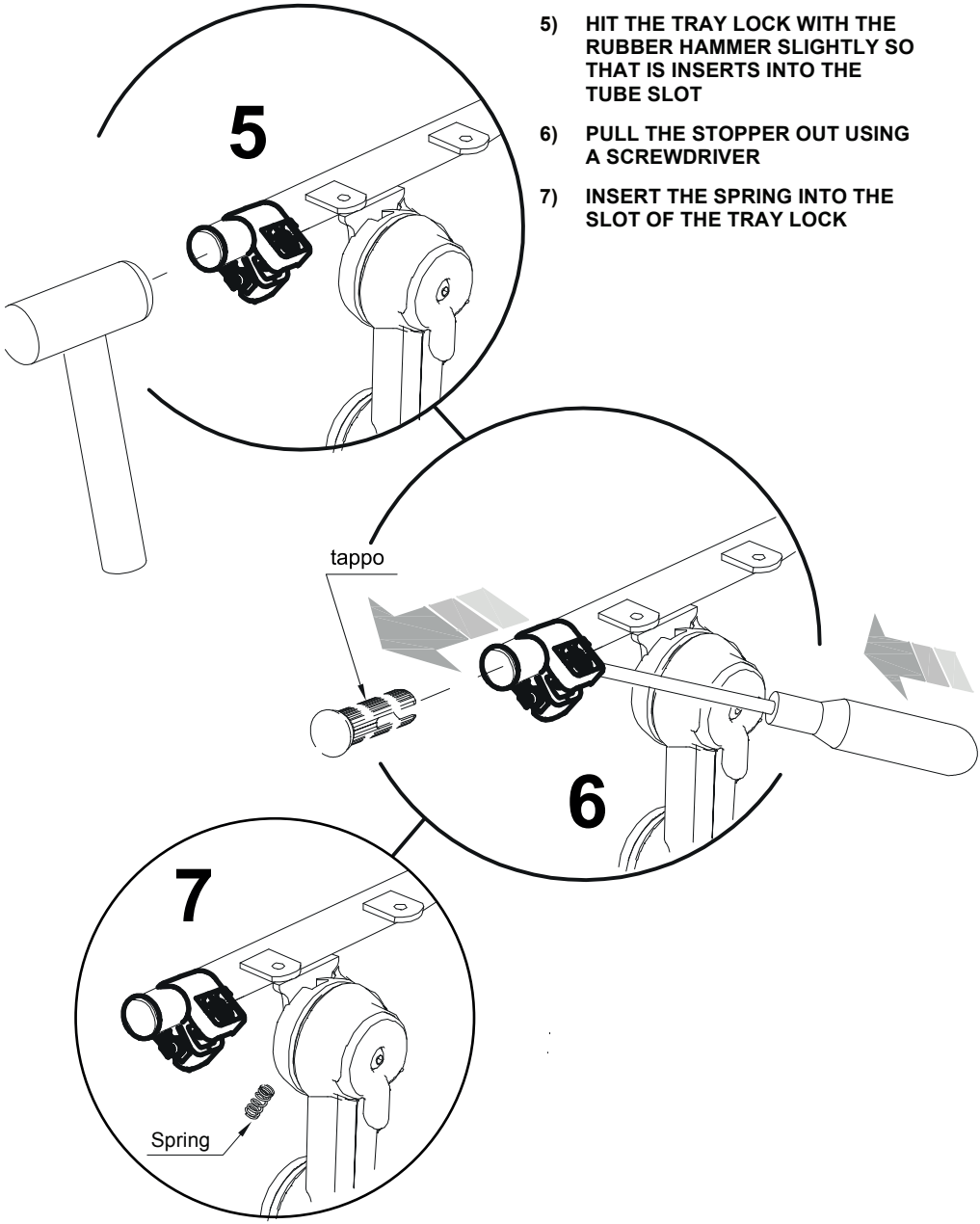
A. RIGHT AND LEFT MECHANISM

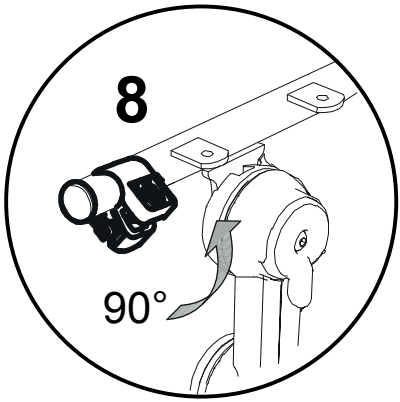


5) **HIT THE TRAY LOCK WITH THE RUBBER HAMMER SLIGHTLY SO THAT IS INSERTS INTO THE TUBE SLOT**

6) **PULL THE STOPPER OUT USING A SCREWDRIVER**

7) **INSERT THE SPRING INTO THE SLOT OF THE TRAY LOCK**

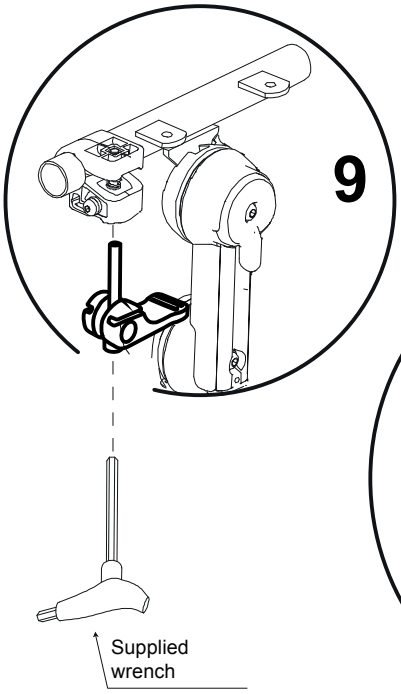


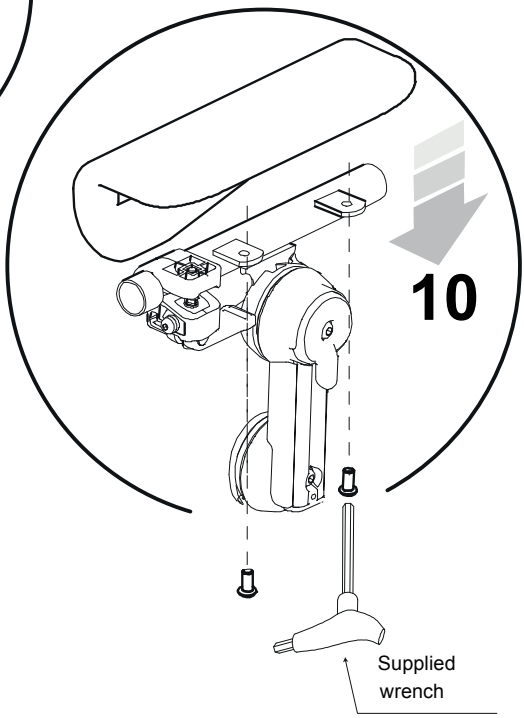


8) **TURN THE LOCKING PART OF THE TRY OUTWARDS**

9) **INSERT THE GREEN LEVER AND TIGHTEN THE SCREW**

10) **REASSEMBLE THE ARMREST**

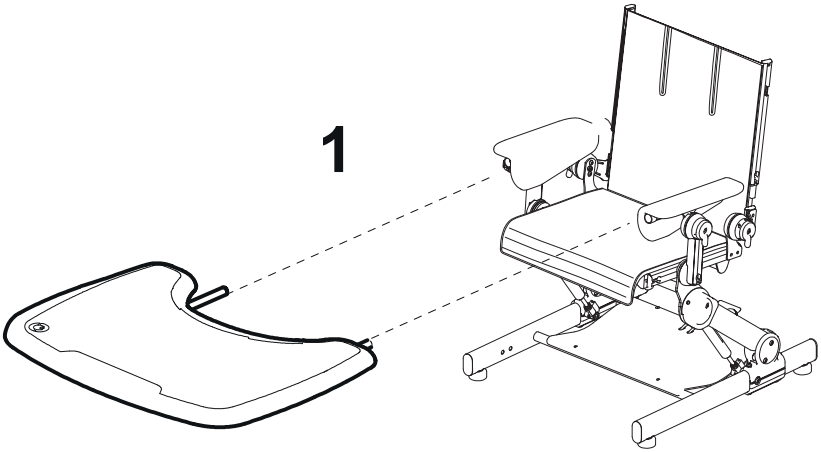


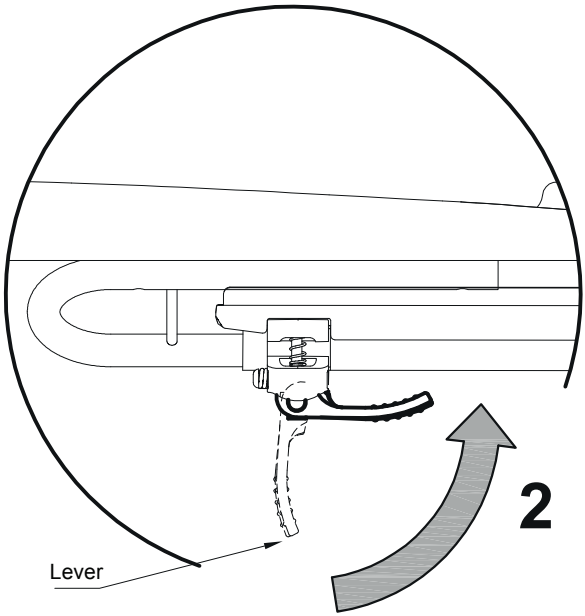


B. INSERTION AND FIXING

1) **INSERT THE TRY SO THAT THE TOP IS HORIZONTAL**

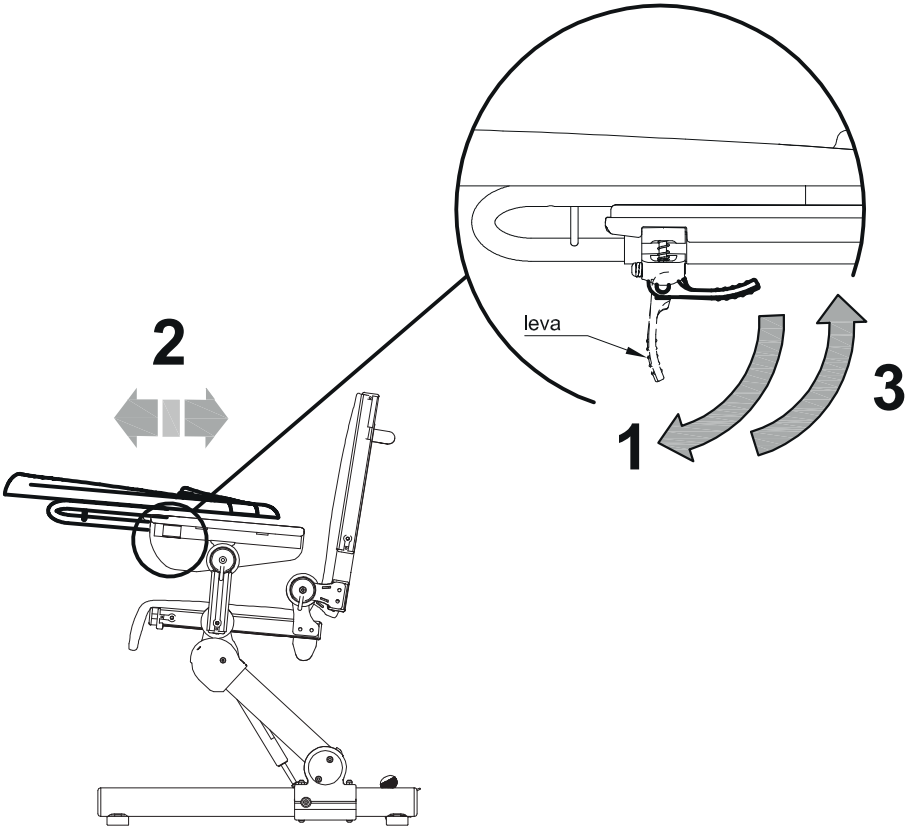
2) **LOCK THE INDICATED LEVER**





C. DEPTH ADJUSTMENT

1) **OPEN THE LEVER**
2) **ADJUST THE DEPTH OF THE TRAY**
3) **LOCK THE LEVER**



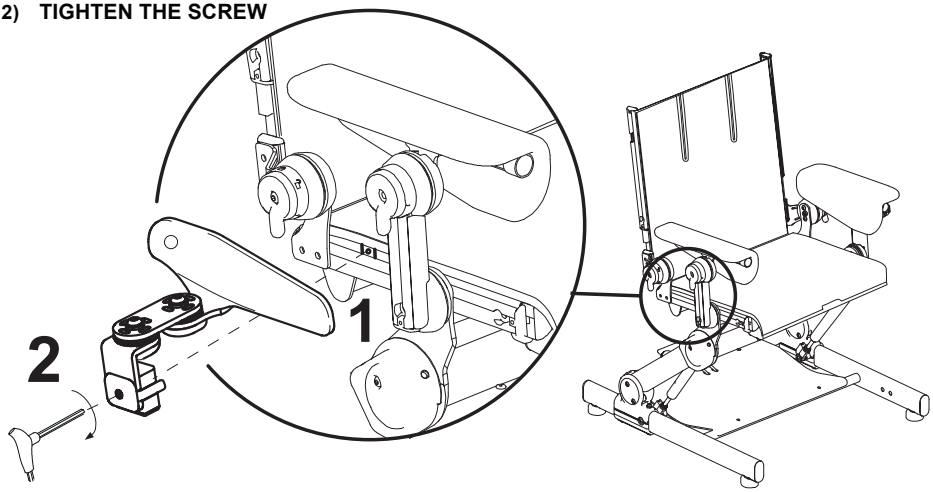
FOR **ADJUSTMENT LEVERS REGISTRATION** REFER TO THE CHAPTER ORDINARY MAINTENANCE

MULTIADJUSTABLE PELVIC SIDE SUPPORT 958R

PRESS LIGHTLY WITH THE WRENCH INSERTED IN THE HOLE TO UNLOCK THE CURSOR FROM THE GUIDE

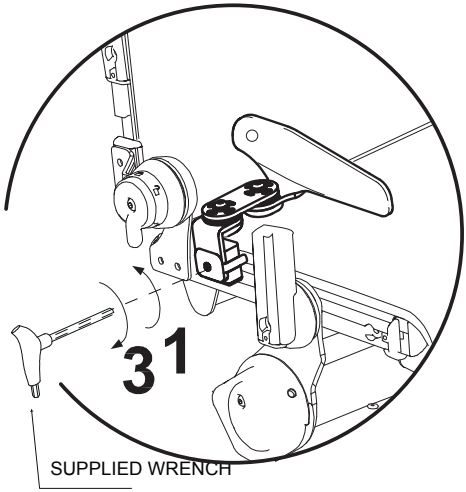
A. MOUNTING

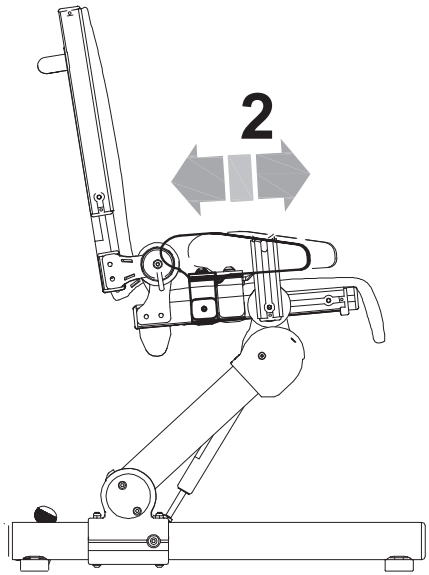
1) **INSERT THE SCREW IN THE CURSOR**
2) **TIGHTEN THE SCREW**



B. DEPTH ADJUSTMENT

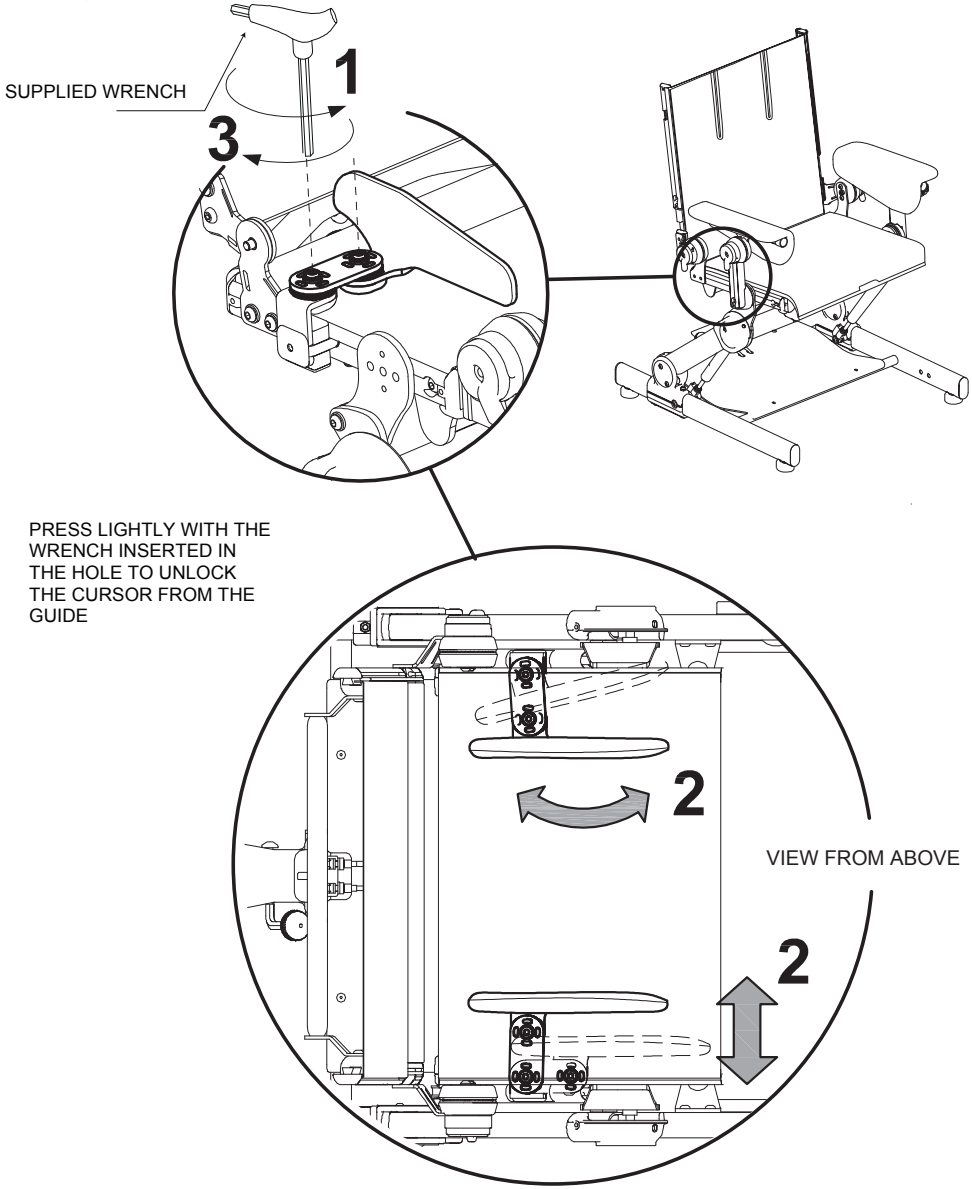
1) **LOOSEN THE SCREW**
2) **ADJUST THE PELOTTE IN DEPTH**
3) **TIGHTEN THE SCREW**





A. WIDTH AND ROTATION ADJUSTMENT

1) **LOOSEN THE SCREW**
2) **ADJUST THE PELOTTE IN WIDTH AND ROTATION**
3) **TIGHTEN THE SCREW**

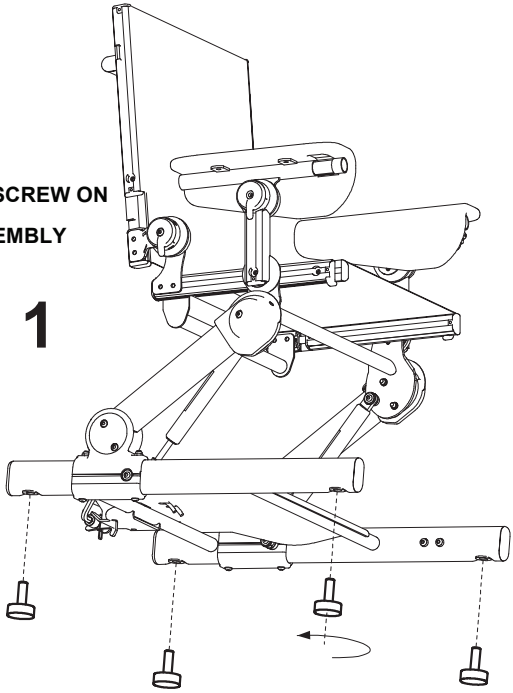


SET OF FOUR WHEELS WITH FOOTREST 959

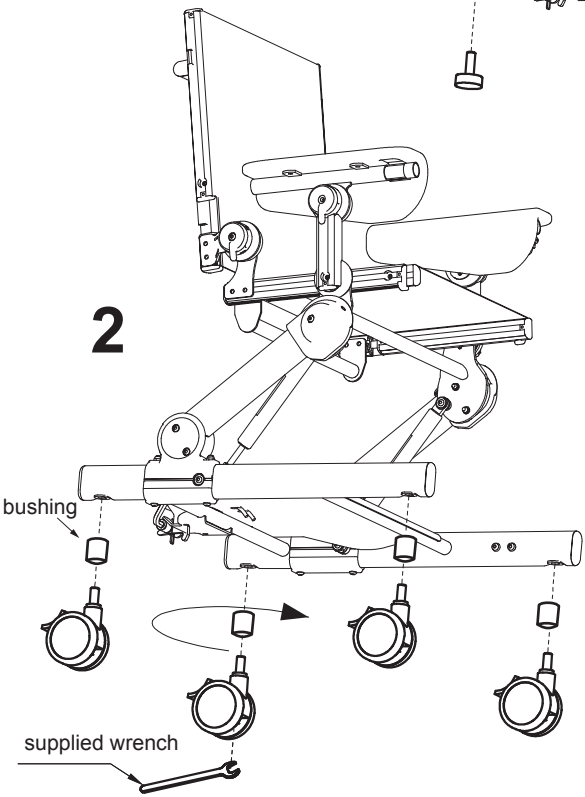
A. MOUNTING

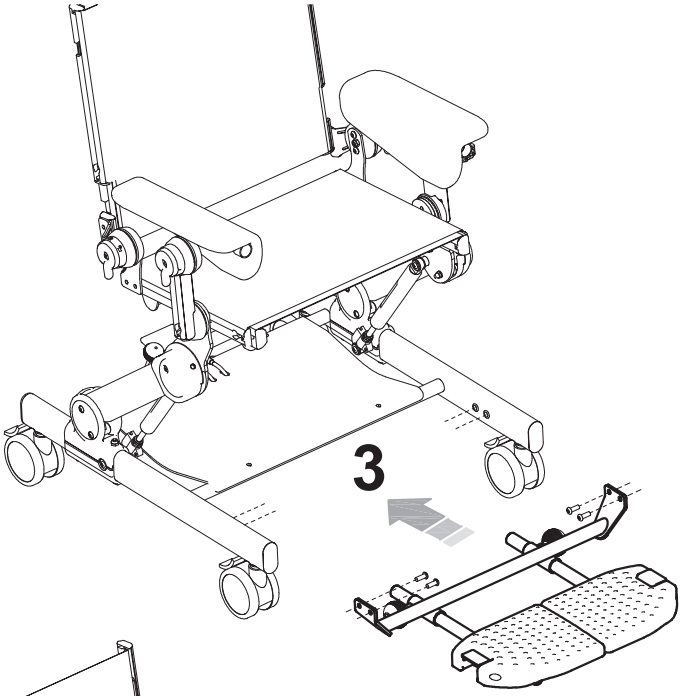
1) UNSCREW THE FEET
2) INSERT WHEELS AND BUSHING AND SCREW ON
3) 4) MOUNT THE RUNNING BOARD ASSEMBLY

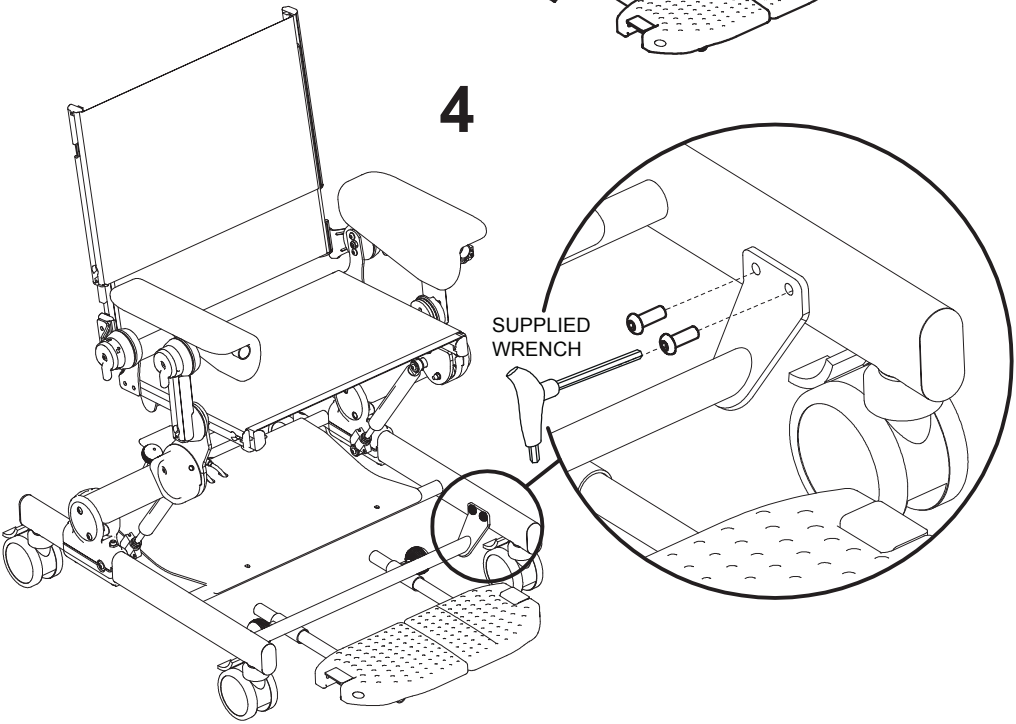
1



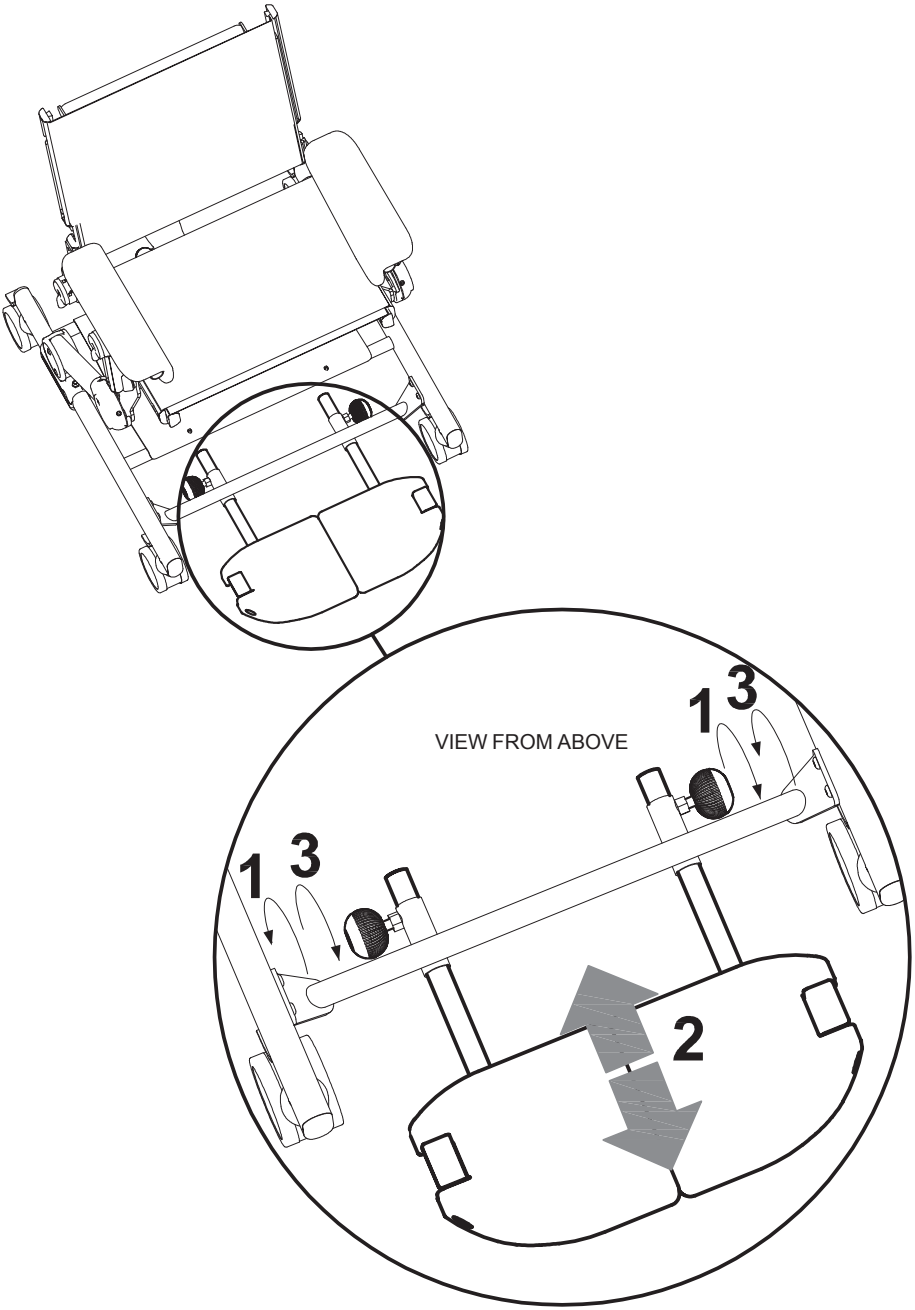
2




3

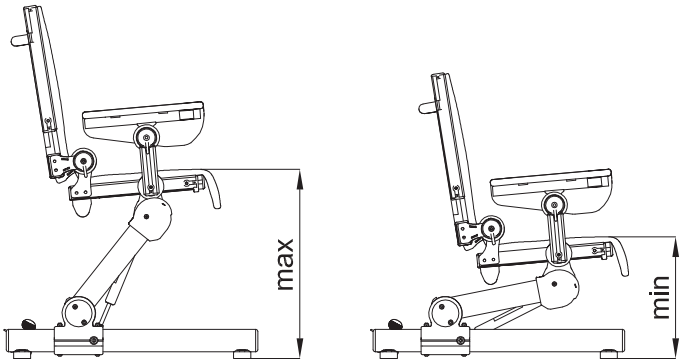

4
SUPPLIED
WRENCH

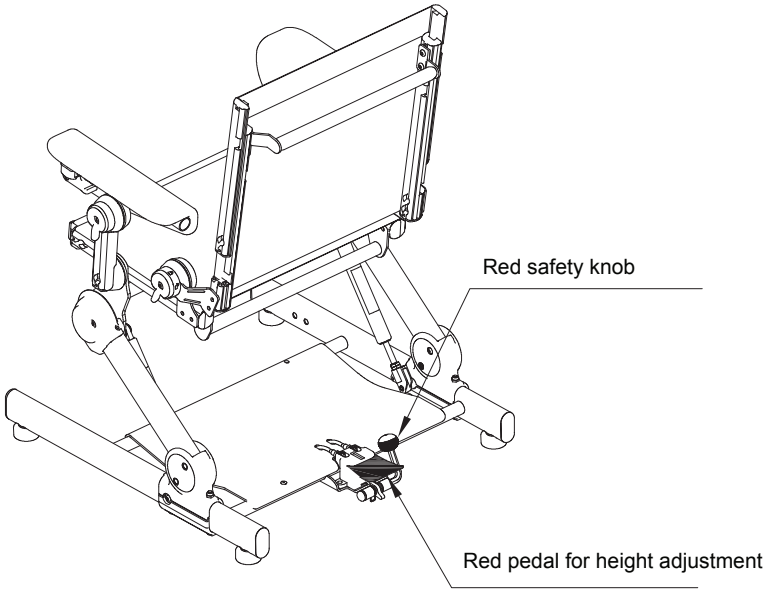
B. DEPTH ADJUSTMENT



5.4 ISTRUCTIONS FOR DAILY USE by the family, or care giver

HEIGHT ADJUSTMENT



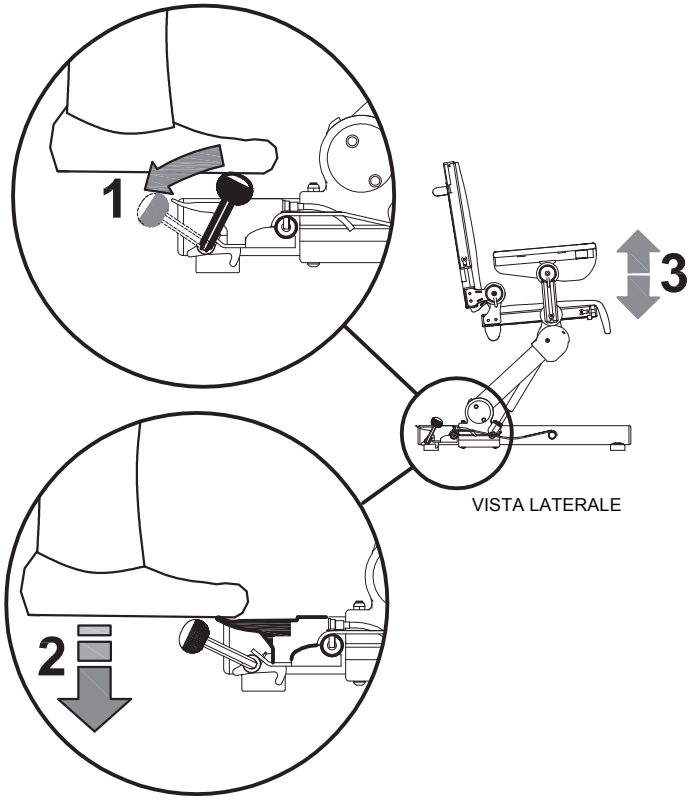


REAR VIEW

WE RECOMMEND ADJUSTING THE HEIGHT WITH THE USER SITTING ON THE MEDICAL DEVICE
BECAUSE THE ADJUSTMENT IS MANAGED BY A GAS SPRING THAT SUPPORTS THE WEIGHT

(video on the product page of the website www.ormesa.com)

1) **PUSH THE SAFETY KNOB WITH YOUR FOOT**
2) **SIMULTANEOUSLY PRESS THE HEIGHT ADJUSTMENT PEDAL**
3) **ADJUST THE HEIGHT OF THE GRILLO ADAPTIVE SEATING TO THE DESIRED POSITION AND REMOVE THE FOOT FROM THE PEDAL**



TILT ADJUSTMENT OF THE BACKREST, ARMRESTS and SEAT HEIGHT ADJUSTMENT

The adjustments of these postural components, referred to in the following pages, can be carried out by the family or by the care giver on the advice of the healthcare professional.

BACKREST TILT ADJUSTMENT : see § 5.2 pag 16
ARMREST TILT ADJUSTMENT: see § 5.2 pag. 18
SEAT HEIGHT ADJUSTMENT: see § 5.4 pag. 35

6. CLEANING AND DISINFECTION

Cleaning operations (and those of disinfection before reuse of the device with a new user) should be carried out regularly with the procedures and timelines outlined in § 6.3 by the family or care giver.

6.1 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 product.

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, and they are able to perform the cleaning (elimination of dirt) and disinfection (elimination of pathogenic microorganisms, i.e. bacteria due to disease and viruses) in a single operation**.**

Removable **UPHOLSTERIES** of additional components are washable respecting the symbols on the label. Washing is an extraordinary sanitation measure Replace the **REMOVABLE UPHOLSTERY** and the **PADDING** when worn / difficult to sanitize.

LOAD-BEARING UPHOLSTERY not removable, is washable according to the instructions in paragraphs 6.3.1 and 6.3.2

6.2 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 medical device.

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

On **COVERS** avoid prolonged contact with acidic or basic solvents and cleaners; Do not use abrasive processes or products that may damage the product

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

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

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

6.3 PROCEDURE

Activities	Cadence	Description
6.3.1 FRAME and UPHOLSTERY 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 (colorless and non-abrasive) with neutral detergent previously diluted in warm water (max. 40°). It is advisable to let the detergent act for a few minutes. Rub upholstery, frame, additional components and finally wheels. If necessary rub the surface with brushes having only soft bristles. Remove any traces of product by wiping with a clean damp sponge or cloth. Dry with a clean soft cloth. Proceed with any disinfection
6.3.2 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 finally the wheels, until complete evaporation.
6.3.3 REMOVABLE UPHOLSTERY WASHING	**Based on use**	The REMOVABLE UPHOLSTERY of the seat and the additional components are washable respecting the indications given in the washing labels (see page 8 for the description of the symbols). 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.
6.3.4 SANIFICATION WITH PERCARBONATE	**Based on use**	The percarbonate is a natural product of mineral origin that is commercially available; when dissolved in water, it releases active oxygen already at 30 ° with disinfectant, antibiotic and antibacterial action. **For a sanitizing action during the cleaning of the frame and the washing of the harness and removable upholsteries, you can add 1 teaspoon of percarbonate > 30% to the detergent:** - In the washing machine: add 1 teaspoon of percarbonate in the drum together with the detergent. - By hand/ for the frame cleaning: dissolve 1 teaspoon of percarbonate in the bowl together with the detergent, proceed with the washing, and cleansing. **WARNING!** **When washing / cleaning the fabric it is recommended not to mix sodium percarbonate with acids (for example: Vinegar, Lemon), as it could create chemical reactions that could damage it.**

7. ORDINARY AND EXTRAORDINARY MAINTENANCE

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

If in doubt about the safety or damage of the product, cease use and contact the orthopedic workshop that supplied the product, or ORMESA.

7.1 ORDINARY MAINTENANCE OPERATIONS (monthly)

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 stroller**

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

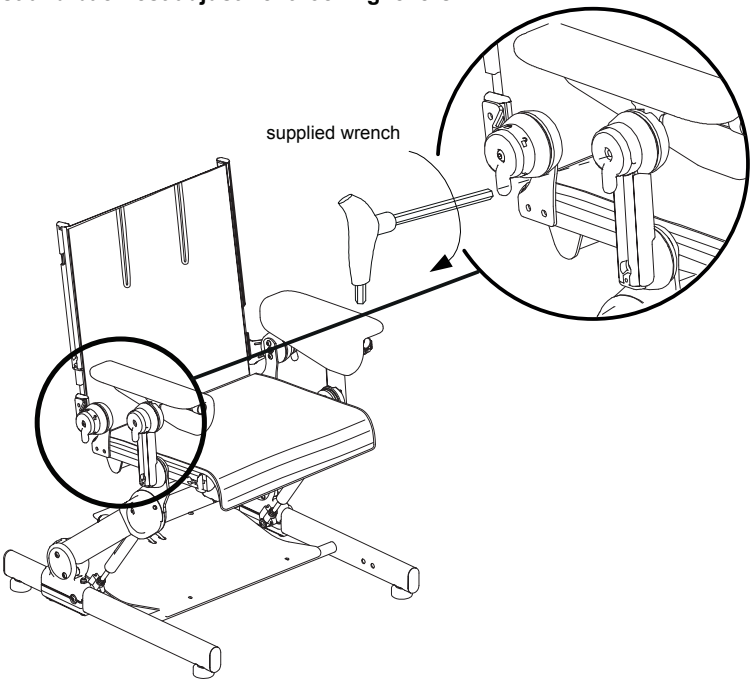
PART	DESCRIPTION / INTERVENTION	MODE
WHEELS (only with 959)	▪ **Remove any dust and dirt from the wheels to maintain smoothness and braking efficiency.** ▪ **Check that the wheels turn freely.** **If unsuccessful, contact the health professional who provided it or distributor for replacement with an original component.**	**functional/visual test**
BRAKES (only with 959)	▪ **Check the efficiency of the braking system and the operation of the relative mechanisms as reported in the user manual.** **If unsuccessful, contact the health professional who provided it, for replacement with an original component.**	**functional test**
BOLTS / SCREWS	▪ **Check the tightness of all bolts and screws; Tighten them if loose.**	**Visual/ tools**
BACKREST / SEAT	▪ **Check for any visible damage or deterioration of the SUPPORTING UPHOLSTERY.** **If unsuccessful, discontinue use and contact the health professional who provided it, for replacement with an original component.**	**visual**
ADJUSTING MECHANISMS	▪ **check the smooth operation of the MOVING PARTS and keep them clean from dust and dirt in order to avoid friction that could compromise correct functioning.** ▪ **If unsuccessful, lubricate them with commercial silicone dry oil following the instructions on the container label. After lubrication, fully dry the treated parts using a soft cloth to remove any residual grease** ▪	**functional/visual test**

	▪ **Check the tightness of the adjustment mechanisms.** **If unsuccessful, contact the health professional who provided it, or distributor for replacement with an original component.** **In case you have encountered an inefficiency in TIGHTENING of the ADJUSTMENT LOCKING LEVERS of the ARMREST,BACKREST, TABLE, discontinue use and contact the health professional who provided it, to register the levers as described in the following § "ADJUSTMENT LOCKING LEVERS".**	
PRODUCT INTEGRITY	▪ **Check the presence of all parts and components described in the manual.** ▪ **Check the frame and ensure the absence of oxidised parts as well as the uniformity of the paint work on the support or tightening elements.** **If unsuccessful, contact your health professional who provided it, for replacement with an original component.**	**Visual/ tools**

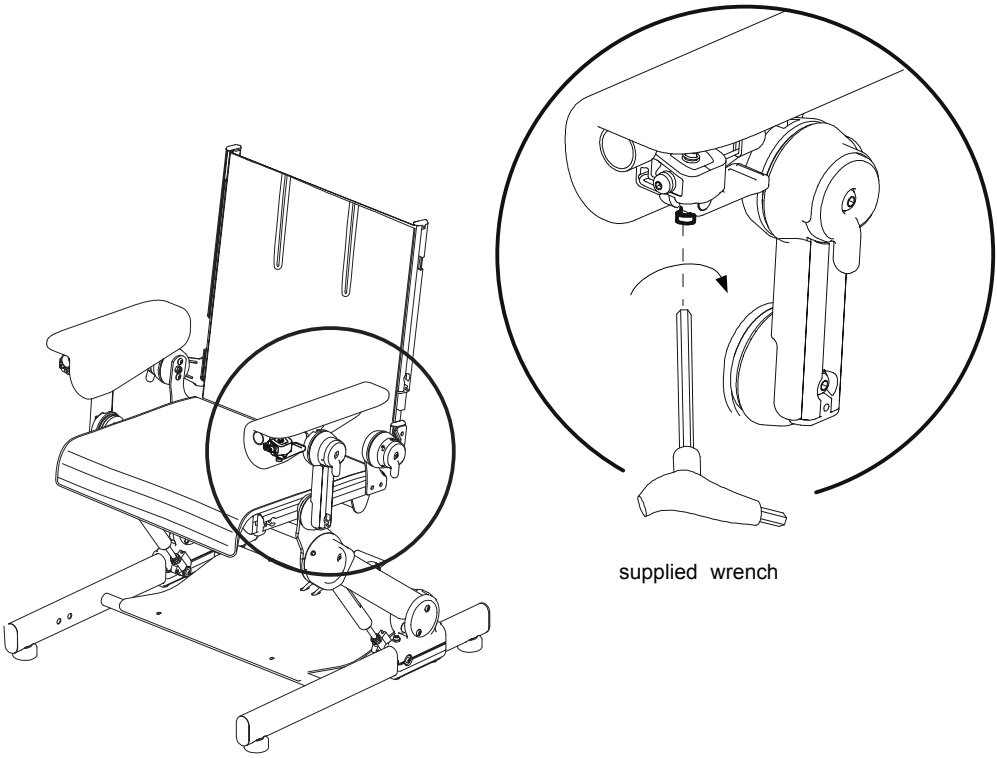
REGISTRATION OF ADJUSTMENT LOCKING LEVER

Adjust nuts and screws in small increments until proper tightness is restored

Armrest and backrest adjustment locking levers



Tray adjustment locking levers



supplied wrench

7.2 PREVENTIVE MAINTENANCE OPERATIONS (biennial)

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

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

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

The person who performed the maintenance is required to issue A REPORT WITH THE EVIDENCE OF THE INTERVENTIONS (VERIFICATIONS, REPAIRS, CONTROLS, SANITIZATIONS)

7.3 PEZZI DI RICAMBIO E PRODOTTI DI CONSUMO

If you require service or spare parts, contact only the health professional who supplied the product.

7.4 EXTRAORDINARY OR CORRECTIVE MAINTENANCE OPERATIONS

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

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

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

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

For each maintenance work, the following must be performed:

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

THE MANUFACTURER or the AUTHORIZED PARTY must issue A REPORT WITH EVIDENCE OF THE INTERVENTIONS (CHECKS, REPAIRS, TESTS, SANITATION) CARRIED OUT

8. LIFE SPAN AND CONDITIONS FOR REUSE

Granted that Ormesa products should be selected, evaluated and ordered for the needs of an individual user, reuse is however possible with the respect of 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 ADAPTIVE SEATING 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 health professional, 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 medical device 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 to keep written records on all inspections performed on the product before any assignment to the new user.

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

9. END-OF-LIFE MANAGEMENT OF THE MEDICAL DEVICE

9.1 USER OBLIGATIONS

Comply with applicable local regulations and do not dispose of old products in normal household waste but separately in appropriate collection places.

Proper disposal of the product helps to avoid possible negative environmental and human health consequences. A benefit to the environment for the benefit of all.

9.2 END-OF-LIFE DISPOSAL

The aluminum frame can be delivered to licensed recyclers.

Wheels and upholstery are composite components, therefore non-hazardous special waste to be sent to the 'ecological island in your city.

10. MANUFACTURER'S DECLARATION

10.1 FACSIMILE EU DECLARATION

ORMESA® • MADE IN ITALY SINCE 1980 •	**DICHIARAZIONE DI CONFORMITÀ "UE" PER DISPOSITIVI MEDICI** *EU Declaration of Conformity FOR MEDICAL DEVICES*	Rev. **1** Date **2/11/22**

Nome Fabbricante:
Manufacturer's Name:
ORMESA s.r.l

Indirizzo Fabbricante:
Manufacturer's Address:
Via delle Industrie n. 6 | 06034 Foligno (PG) – ITALY

Certificazioni Fabbricante
(Manfacturer Certifications)
UNI EN ISO 13485:2016
Dispositivi medici - Sistemi di gestione per la qualità. Requisiti per scopi regolamentari
Medical devices - Quality management systems. Requirements for regulatory purposes

SRN
(Numero di Registrazione Unico):
(Single Registration Number):
Non ancora disponibile
Not yet available

ORMESA srl dichiara sulla sua responsabilità che il Dispositivo Medico
Ormesa srl declares on its own responsibility that the Medical Device

UDI-DI di base:
Basic UDI-DI:
805571570GRILLOSEATINGNL

Nome del Dispositivo:
Name of the Device:
GRILLO CHAIR

Codice del Dispositivo:
Product code:
Vedi Allegato 1 da pagina 2 a pagina 3
See Attachment from page 2 to page 3

Destinazione d'uso:
Intended purpose:

Classificazione di Rischio:
Risk Classification:
Classe: */ Class:1*

soddisfa le prescrizioni del Regolamento (UE) MDR 2017/745 relativo ai i dispositivi medici
Is compliant with the requirements of the Regulation (EU) 2017/745 on medical devices.

Specifiche comuni utilizzate:
Common Specification applied:
Non disponibili
Not available

Norme utilizzate
Standards applied
Vedi Allegato 2 a pagina 2
See Attachment on page 2

Valutazione della Conformità:
Conformity Assessment Route:
Dichiarazione di Conformità "UE" in accordo con Allegato II & III del Regolamento (UE) 2017/745
EU conformity declaration according to Annex II & III of the Regulation (EU) 2017/745

Foligno, 2/11/22

Firma / *Signature:* Chiara Menichini (Legale Rappresentante)

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Health Professional