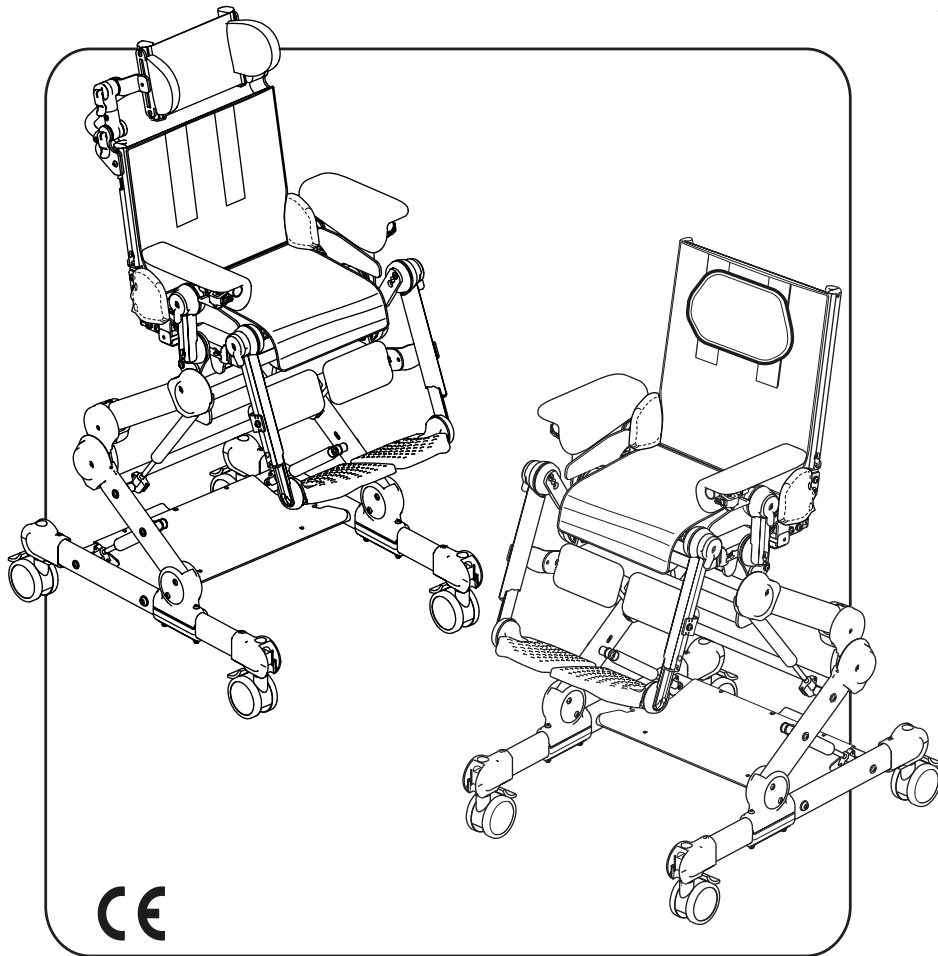


GRILLO

adaptive seating

Seating system with adjustable configuration



USA Cod. 220680 15-02-23

USE AND MAINTENANCE HANDBOOK

ORMESA®

• MADE IN ITALY SINCE 1980 •



1. GENERAL INFORMATIONS	3
1.1 THANKS FOR CHOOSING THE MEDICAL DEVICE.....	3
1.2 CONTACT DETAILS FOR ASSISTANCE.....	3
1.3 PACKAGING INFORMATION. UNPACKING INSTRUCTIONS AND SUPPLY COMPOSITION	4
1.4 MECHANICAL AND DIMENSIONAL CHARACTERISTICS	6
1.5 PRODUCT PARTS LEGEND.....	7
1.6 SYMBOLOGY USED IN THE MANUAL.....	8
1.7 IDENTIFICATION PLATE	8
2. LEGAL AND REGULATORY REFERENCES	9
2.1 LEGAL REFERENCES	9
2.2 REGULATORY REFERENCES	9
2.3 WARRANTY CONDITIONS	10
3. SAFETY WARNINGS.....	10
3.1 MEDICAL DEVICE RISK CLASS ACCORDING TO ANNEX VIII OF REGULATION (EU) 745/2017	10
3.2 GENERAL WARNINGS	10
3.3 SPECIFIC WARNINGS	11
3.4 REASONABLY FORESEEABLE MISUSE	11
3.5 CONTRAINDICATIONS AND SIDE EFFECTS.....	12
3.6 OPERATING ENVIRONMENTAL CONDITIONS	12
3.7 CONDITIONS OF TRANSPORT AND PACKAGING.....	12
3.8 PRE-INSTALLATION/INSTALLATION AND COMMISSIONING	13
4. DEVICE DESCRIPTION	13
4.1 INTENDED USE OF THE MEDICAL DEVICE.....	13
4.2 MAINS COMPONENTS/AVAILABLE VERSIONS.....	13
4.3 DESCRIPTION OF THE MEDICAL DEVICE	13
5. OPERATING INSTRUCTIONS	14
5.1 FIRST USE.....	14
5.2 ASSEMBLY	14
5.3 ADJUSTMENT AND CONFIGURATION OF THE MEDICAL DEVICE by the health professional.....	16
BRAKING.....	16
BACKREST HEIGHT ADJUSTMENT.....	17
BACKREST INCLINATION ADJUSTMENT.....	18
863 HEADREST ADJUSTMENT.....	19
SEAT TILT ADJUSTMENT (TILT IN SPACE).....	21
SEAT DEPTH ADJUSTMENT	23
PELVIC SIDE SUPPORTS ADJUSTMENT	24
ARMREST ADJUSTMENT.....	26
CALF RESTS ADJUSTMENT	28
LEGREST ADJUSTMENT	30
FOOTRESTS ADJUSTMENT.....	32
5.4 ADJUSTMENT AND CONFIGURATION OF THE ADDITIONAL COMPONENTS BY THE HEALTH PROFESSIONAL	33



POSTURAL HEADREST 863	33
HOW TO REMOVE THE HEADREST 863	35
HEADREST 835 AND 865	36
PELVIC BELT WITH VARIABLE ANGLE 947	37
FOUR POINT PELVIC BELT 920	38
TRUNK SIDE SUPPORTS 838.....	39
WRAPPABLE AND FLEXIBLE TRUNK SUPPORTS 868	41
ELBOW SIDE SUPPORTS 961	43
VEST HARNESS 853	44
SLIM FOUR POINT SHAPED HARNESS 853	45
ADJUSTABLE ABDUCTION BLOCK 834R	46
NARROW ABDUCTION BLOCK 834N	48
TRAY WITH WRAP-AROUND RECESS 824	49
HEEL RESTS 960	54
FRONT FOOT STRAPS AND HEEL REST 962	55
5.5 INSTRUCTIONS FOR DAILY USE by the family, or care giver.....	56
HEIGHT ADJUSTMENT	56
TILT ADJUSTMENT OF THE SEAT, BACKREST, LEG REST AND ARMRESTS and SEAT HEIGHT ADJUSTMENT	57
6. CLEANING AND DISINFECTION	58
6.1 INFORMATION.....	58
6.2 WARNINGS	58
6.3 PROCEDURE.....	59
7. ORDINARY AND EXTRAORDINARY MAINTENANCE.....	60
7.1 ORDINARY MAINTENANCE OPERATIONS (monthly).....	60
REGISTRATION OF ADJUSTMENT LOCKING LEVER.....	62
7.2 PREVENTIVE MAINTENANCE OPERATIONS (biennial)	64
7.3 PEZZI DI RICAMBIO E PRODOTTI DI CONSUMO	64
7.4 EXTRAORDINARY OR CORRECTIVE MAINTENANCE OPERATIONS	64
8. LIFE SPAN AND CONDITIONS FOR REUSE.....	65
9. END-OF-LIFE MANAGEMENT OF THE MEDICAL DEVICE.....	66
9.1 USER OBLIGATIONS	66
9.2 END-OF-LIFE DISPOSAL	66
10. MANUFACTURER'S DECLARATION	67
10.1 FACSIMILE EU DECLARATION.....	67



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 Adaptive Seating is a compact high chair for children and young people designed to be used in the performance of school, daily and play 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 Adaptive Seating**, 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..

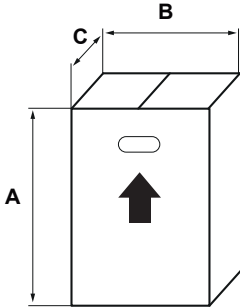
1.2 CONTACT DETAILS FOR ASSISTANCE

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

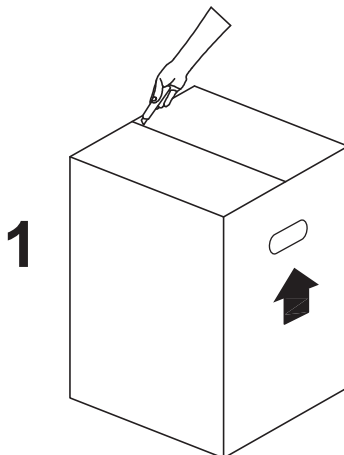


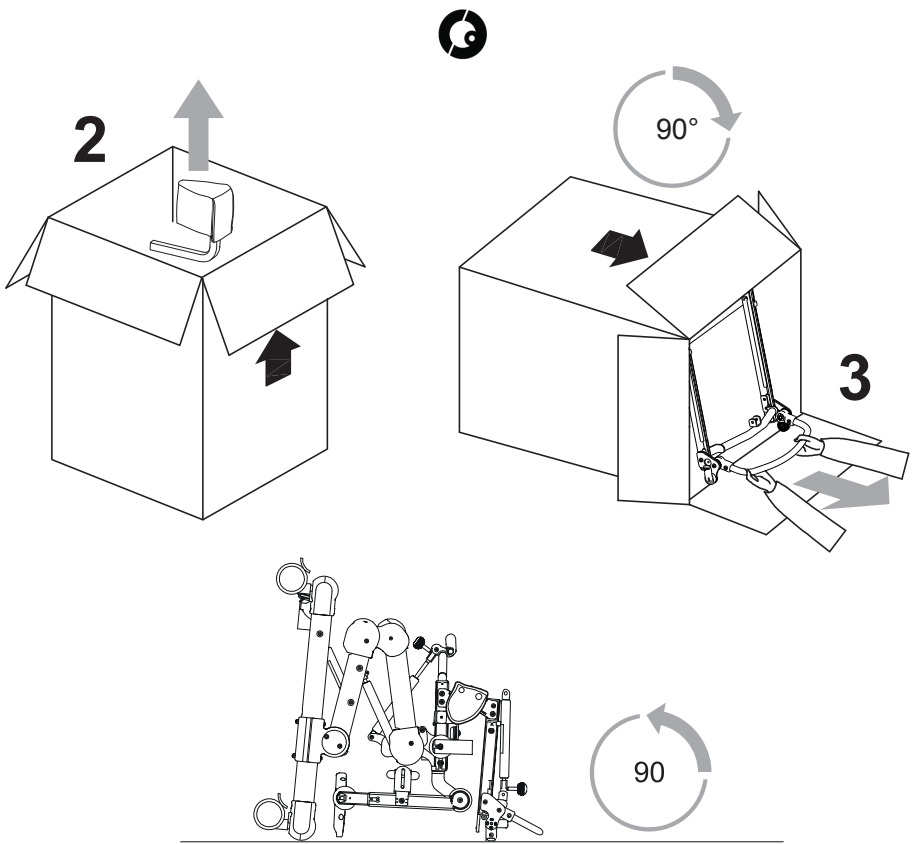
SIZE	A cm	B cm	C cm	VOLUME m ³	WEIGHT Kg
mini	74	76	68	0,38	31,5
Small	80	76	68	0,41	34
Medium	80	76	68	0,41	36,5

SIZE	A in	B in	C in	VOLUME in ³	WEIGHT Lb
mini	29,1	29,9	26,7	23.231	69,4
Small	31,4	29,9	26,7	25.067	74,9
Medium	31,4	29,9	26,7	25.067	80

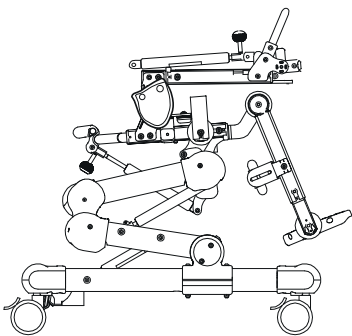
HOW TO TAKE GRILLO ADAPTIVE SEATING OUT OF THE BOX

- 1) CAUTION! CUT WITHOUT PRESSING TOO HARD WITH THE BLADE SO AS NOT TO DAMAGE THE CONTENTS OF THE BOX
- 2) TAKE THE ACCESSORIES OUT OF THE BOX
- 3) TILT THE BOX TAKING CARE NOT TO SMEAR THE CONTENTS

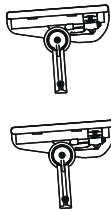




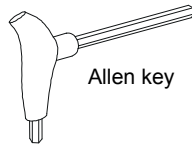
SUPPLY COMPOSITION



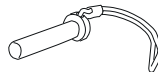
Grillo adaptive seating



2 armrest



Allen key



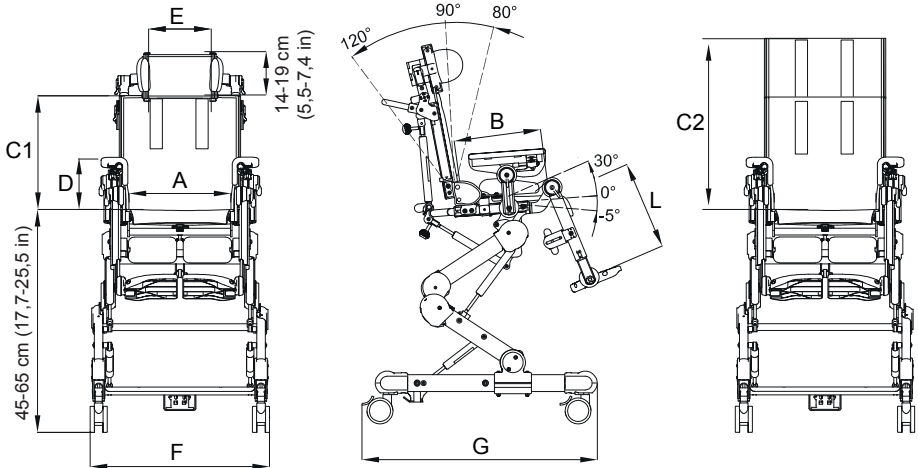
Pin



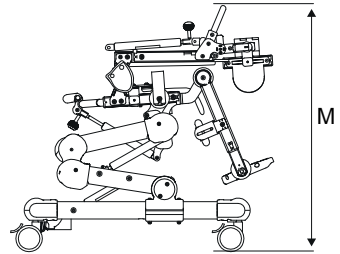
Use and maintenance handbook



1.4 MECHANICAL AND DIMENSIONAL CHARACTERISTICS



User height size mini: 75-105 cm (29,5-41,3 in)
 User height size S: 90-120 cm (35,4-47,2 in)
 User height size M: 110-145 cm (43,3-57 in)



SIZE	A (cm)	B (cm)	C1 (cm)	C2 (cm)	D (cm)	E (cm)	F (cm)	G (cm)	L (cm)	M (cm)	peso totale (kg)	portata max. (kg)
mini	16-26	16-26	30-41	30-50	12-15	15	49	59	15-25	68	20,4	25
Small	20-30	20-30	35-47	35-60	15-20	17	53	65	20-31	68	22,6	35
Medium	25-35	28-43	40-55	40-70	16-20	20	58	74	25-40	70	24,3	45

SIZE	A (in)	B (in)	C1 (in)	C2 (in)	D (in)	E (in)	F (in)	G (in)	L (in)	M (in)	WEIGHT (lb)	MAX LOAD (lb)
mini	6,2-10,2	6,2-10,2	11,8-16,1	11,8-19,6	4,7-5,9	5,9	19,2	23,2	5,9-9,8	26,7	44,9	55,1
Small	7,8-11,8	7,8-11,8	13,7-18,5	13,7-23,6	5,9-7,8	6,6	20,8	25,5	7,8-12,2	26,7	49,8	77,1
Medium	9,8-13,7	11-16,9	15,7-21,6	15,7-27,5	6,2-7,8	7,8	22,8	29,1	9,8-15,7	27,5	53,5	99,2

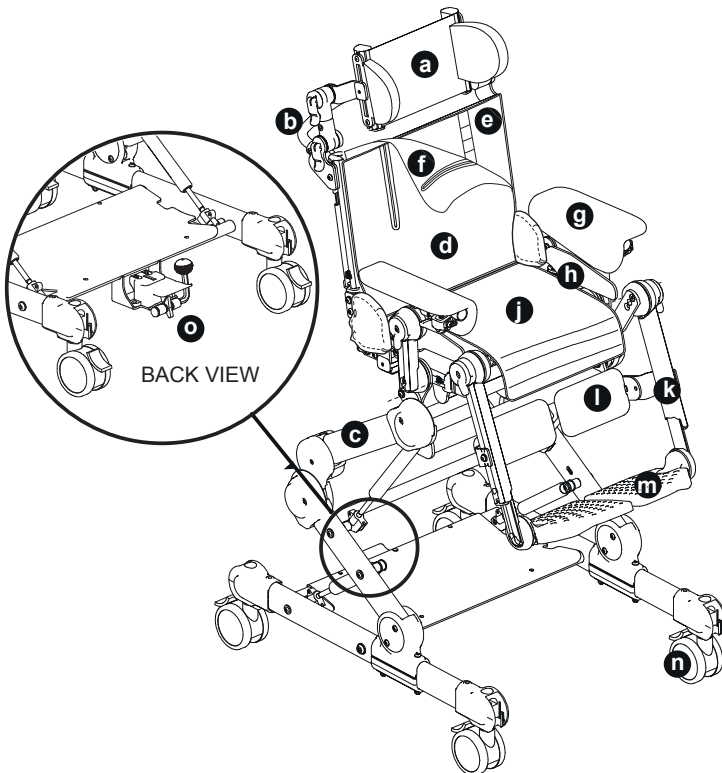
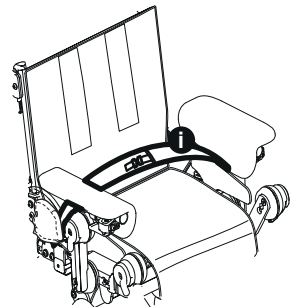
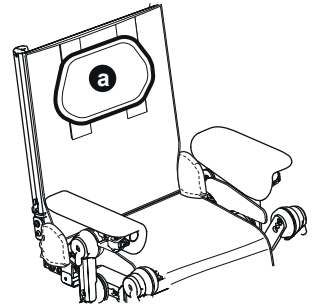
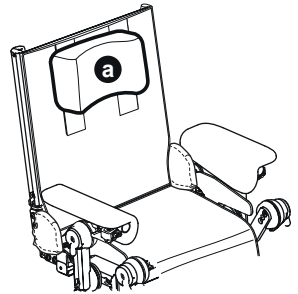
The weight was measured with the following components: armrests, legrests, headrests

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



1.5 PRODUCT PARTS LEGEND

- a) HEADREST (according to the chosen configuration)
- b) HANDLE
- c) FRAME
- d) BACKREST
- e) LOAD-BEARING UPHOLSTERY
- f) REMOVABLE COVER
- g) HARMRESTS
- h) PELVIC SIDE SUPPORTS
- i) PELVIC BELT WITH VARIABLE ANGLE (947)
provided as standard
- j) SEAT
- k) LEGRESTS
- l) CALF RESTS
- m) FOOTRESTS
- n) WHEELS
- o) RED SAFETY KNOB AND RED PEDAL FOR HEIGHT
ADJUSTMENT





1.6 SYMBOLOGY USED IN THE MANUAL



Consult the use and maintenance handbook



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



European conformity mark.



Do not bleach



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 iron



Do not tumble dry



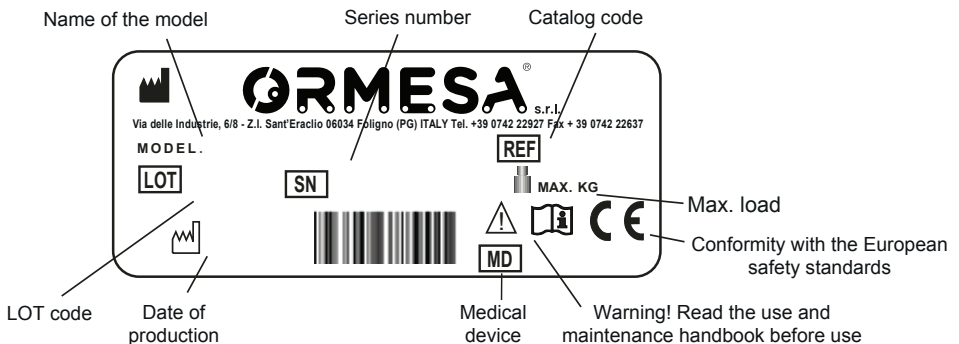
Do not disperse the product in the environment after use



Dry horizontally

1.7 IDENTIFICATION PLATE

THE CE MARKING CERTIFIES GRILLO ADAPTIVE SEATING 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	Dispositivi medici - Sistemi di gestione per la qualità - Requisiti per scopi regolamentari <i>Medical devices - Quality management systems - Requirements for regulatory purposes</i>
EN ISO 14971	Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici <i>Medical devices - Application of risk management to medical devices</i>
UNI CEI EN ISO 15223-1	Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite - Parte 1: Requisiti generali <i>Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements</i>
UNI EN ISO 10993-3	Valutazione biologica dei dispositivi medici. <i>Biological evaluation of medical devices</i>
UNI EN 12183	Prodotti destinati all'assistenza di persone con disabilità – Requisiti generali e metodi di prova <i>Manual Wheelchairs - Requirements And Test Methods EN 12182:2012 Technical aids for disabled persons – general requirements and test methods</i>

INTERNATIONAL STANDARDS

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

NATIONAL STANDARDS

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



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 Adaptive seating 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. 6.
- **GRILLO ADAPTIVE SEATING is a MECHANICAL MEDICAL DEVICE:**



THE USER has to perform REGULAR MAINTENANCE and CLEANING following the instructions shown in the "Maintenance" chapter on page 58-59-60-61-62-63 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 58-59-60-61-62-63 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 ADAPTIVE SEATING 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.
- GRILLO ADAPTIVE SEATING is a mechanical medical device. It must be delivered to the user by a health care professional who is responsible for explaining its functionality, the warnings and maintenance contained in this manual, performing the assembly/adjustment of components, and providing aftercare on the product.
- BEFORE USING IT, always check the brake efficiency and the wheel wear.
- BEFORE MAKING ANY ADJUSTMENT and IN THE EVENT OF A STOP, even on level ground, ALWAYS LOCK THE BRAKES.
- AFTER MAKING ANY ADJUSTMENT, make sure the adjustable elements are locked.
- With the external headrest 863 do not raise the backrest beyond the red line (see pages 31-32)

3.4 REASONABLY FORESEEABLE MISUSE

- DO NOT USE THE MEDICAL DEVICE WITH SUBJECTS WITH DIMENSIONS GREATER THAN those indicated on pag. 6.
- 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 USE THE MEDICAL DEVICE ON ACCIDENTED GROUND NEAR STRONG SLOPES OR STAIRS.
- DO NOT PLACE THE MEDICAL DEVICE IN PARK ON SLOPING GROUND.
- DO NOT USE THE STROLLER 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, LEGRESTS, FOOTRESTS.
- 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 ALLOW ANYONE TO STAND ON THE FOOTREST OR STANDING BEHIND the GRILLO Adaptive Seating
- DO NOT USE THE MEDICAL DEVICE IF THERE ARE DAMAGED OR MISSING PARTS.


3.5 CONTRAINDICATIONS AND SIDE EFFECTS

GRILLO Adaptive Seating generalmente non è indicato per soggetti con deformità muscolo scheletriche strutturate gravi, che necessitano di unità posturali.

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 58-59-60-61-62-63 AND THE WARNINGS  ON PAGE 60.



3.8 PRE-INSTALLATION/INSTALLATION AND COMMISSIONING

GRILLO ADAPTIVE SEATING 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 ADAPTIVE SEATING is an adjustable configuration high chair intended for children and young people with disabilities who require special supports, braces and adjustments in carrying out daily, educational and play activities, easily adaptable due to its modularity.

Enables the positioning of the person with disabilities of varying complexity in the most appropriate and functional posture for the different contexts of daily life.

Indicated for users who have little or no trunk and head control and who require adequate stabilization at the pelvic level in order to assume, in situations where residual function permits, the most appropriate posture in different contexts.

4.2 MAINS COMPONENTS/AVAILABLE VERSIONS

GRILLO ADAPTIVE SEATING 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 § 5.3 on page 16.

4.3 DESCRIPTION OF THE MEDICAL DEVICE

Grillo Adaptive Seating is a compact adjustable configuration seating system that is ideal for use in many contexts, such as performing daily activities at school, at home, and during leisure time.

The seat is made with fire retardant, comfortable and breathable load-bearing upholstery. Upholstered with removable padded upholstery, which allows optimal weight distribution. Sanitizing and drying is quick and easy.

Postural options (trunk side supports, vest, belts) allow for stability of the pelvis, lower limbs, trunk, and head, and for different positions through backrest recline, tilt in space, and footplate elevation.

GRILLO ADAPTIVE SEATING, thanks to its patented height adjustment system, can be operated with the child seated. Equipped with four swivel casters, it allows it to be pulled next to countertops and all surfaces with ease

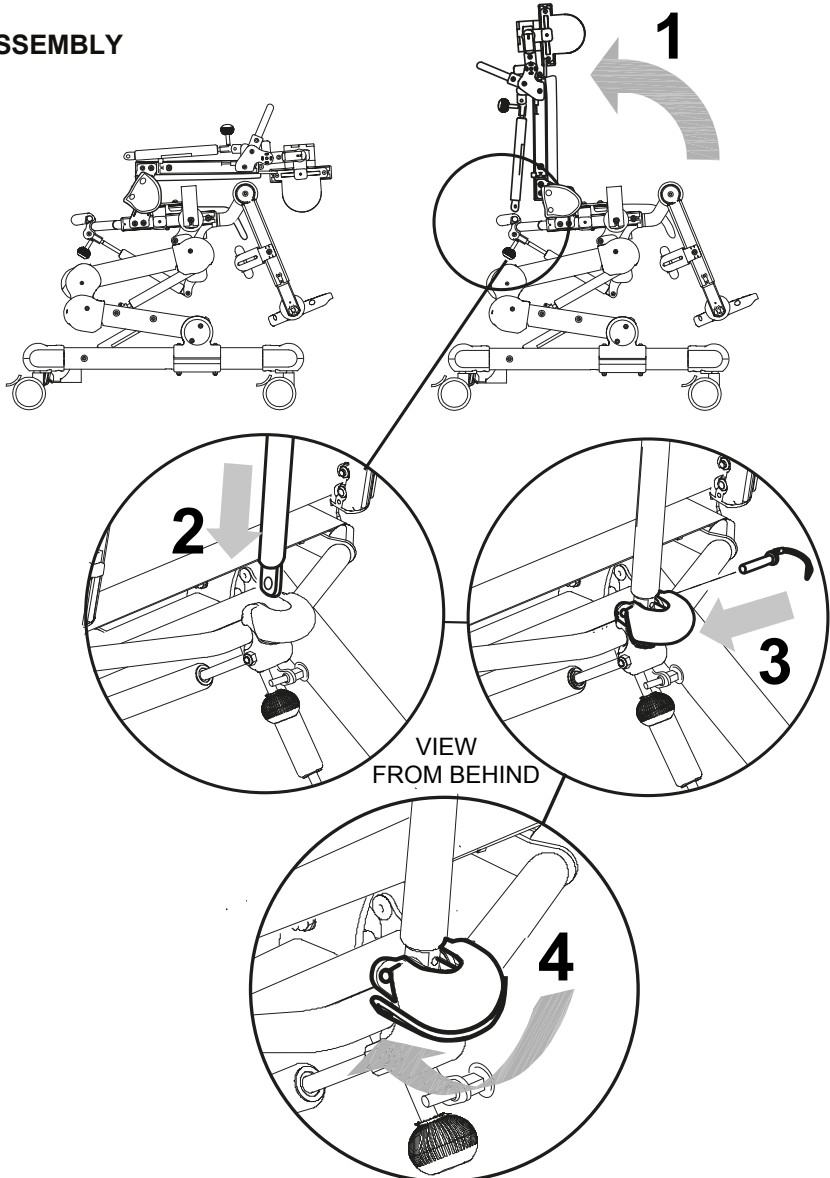


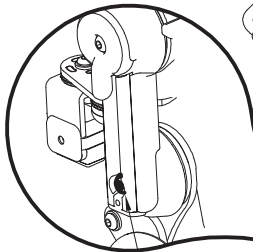
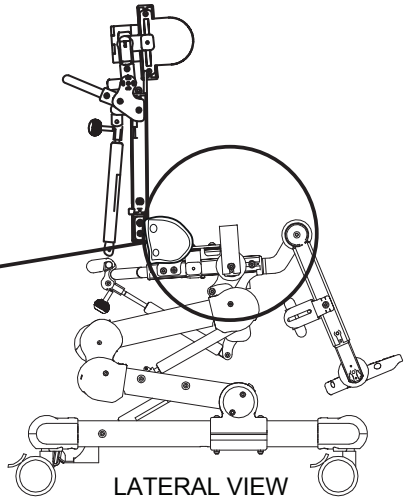
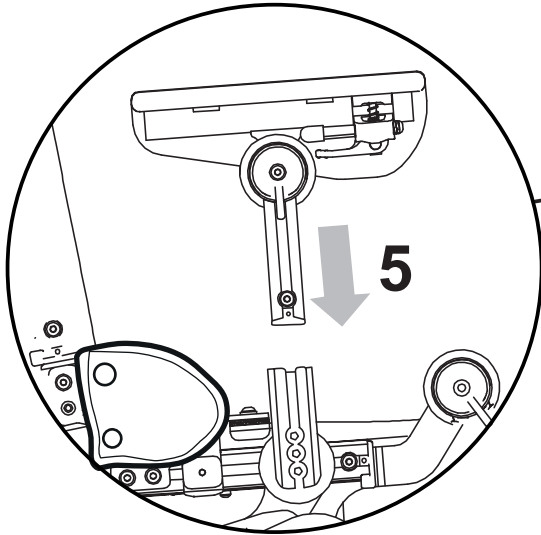
5. OPERATING INSTRUCTIONS

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 (§ 5.3 and 5.4)

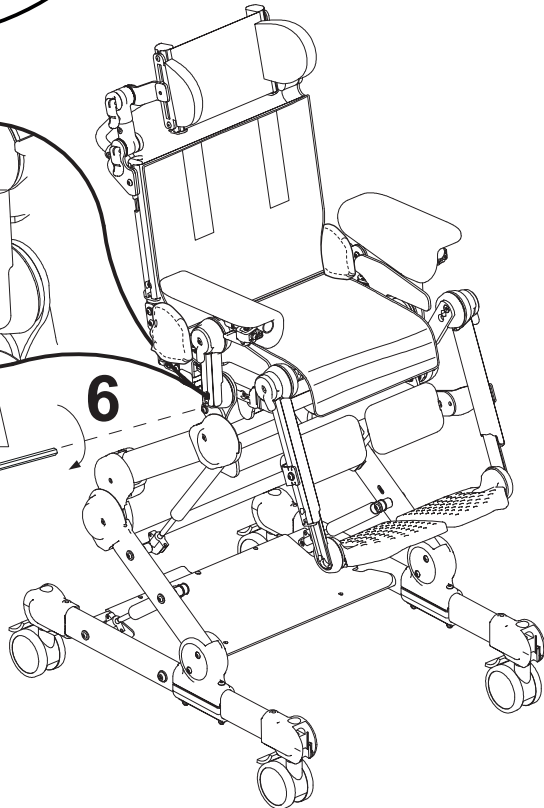
5.2 ASSEMBLY





ARMREST HEIGHT
ADJUSTMENT SCREW

WRENCH SUPPLIED





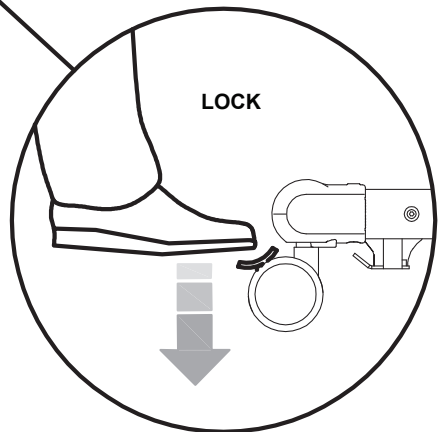
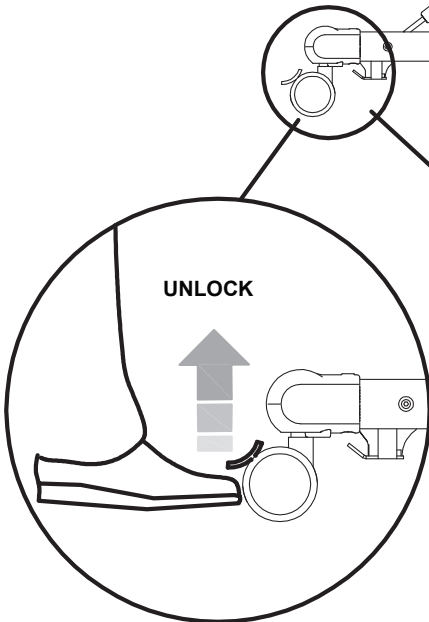
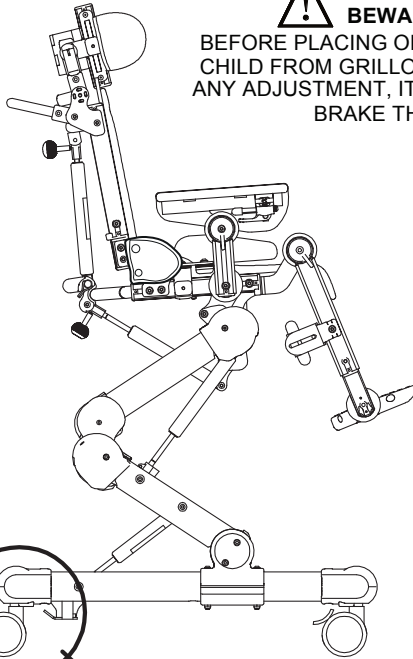
5.3 ADJUSTMENT AND CONFIGURATION OF THE MEDICAL DEVICE by the health professional

BRAKING



BEWARE!

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

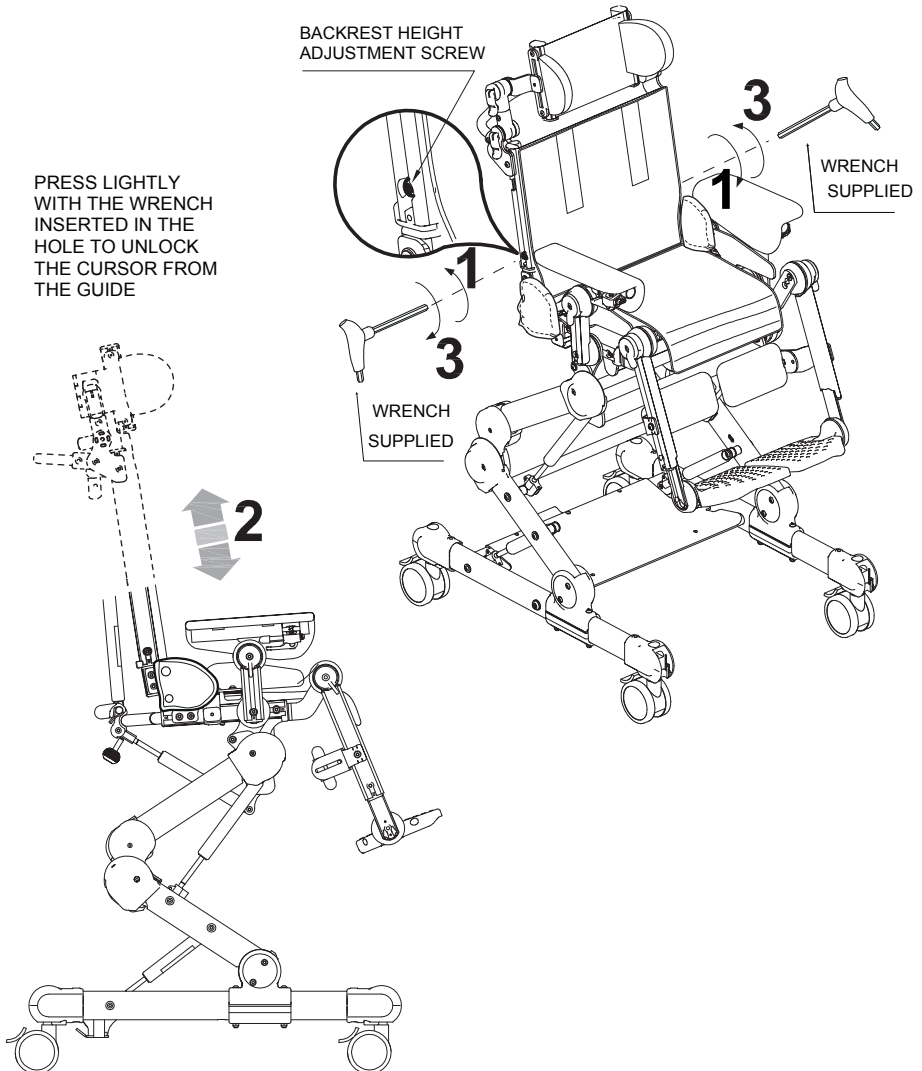




BACKREST HEIGHT ADJUSTMENT

(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

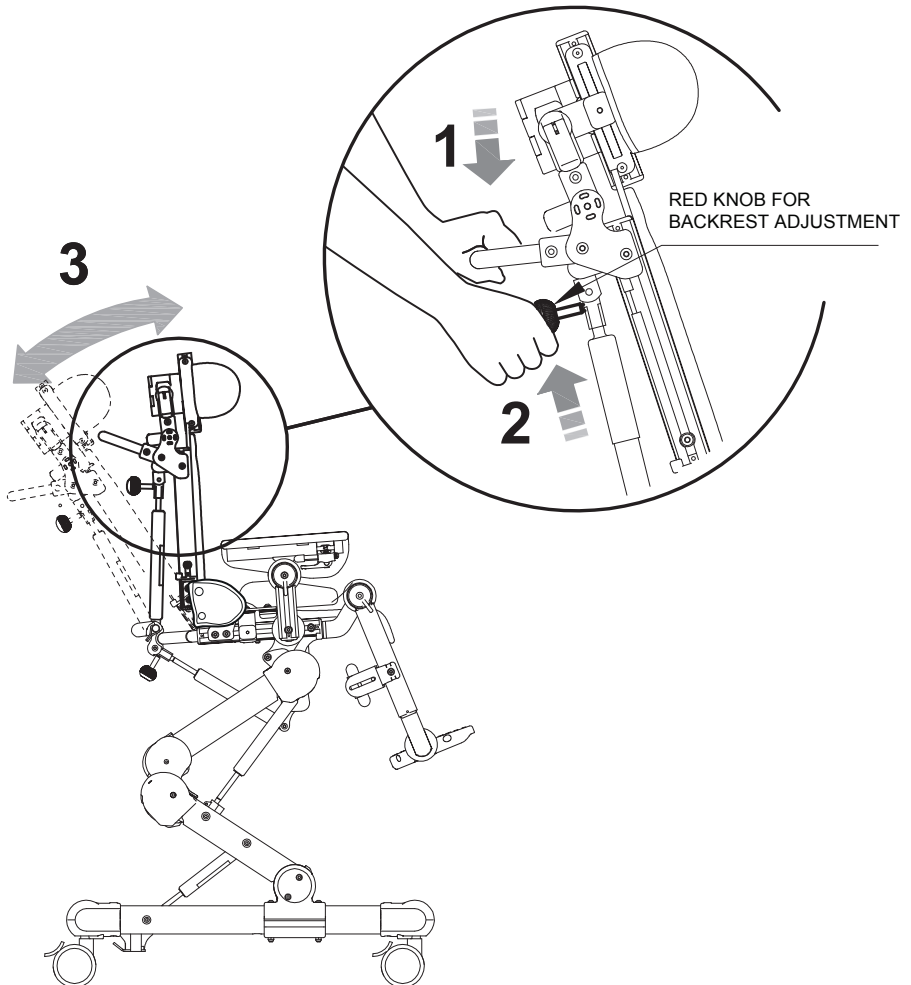




BACKREST INCLINATION ADJUSTMENT

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

- 1) PLACE YOUR HAND ON THE HANDLE
- 2) WITH THE OTHER HAND LOWER THE RED KNOB TO ADJUST THE INCLINATION OF THE BACKREST
- 3) TILT THE BACKREST HOLDING DOWN THE KNOB (2) AND LEAVE IT WHEN THE BACKREST HAS REACHED THE DESIRED POSITION. AVOID BROSCH MOVEMENTS TO THE USER

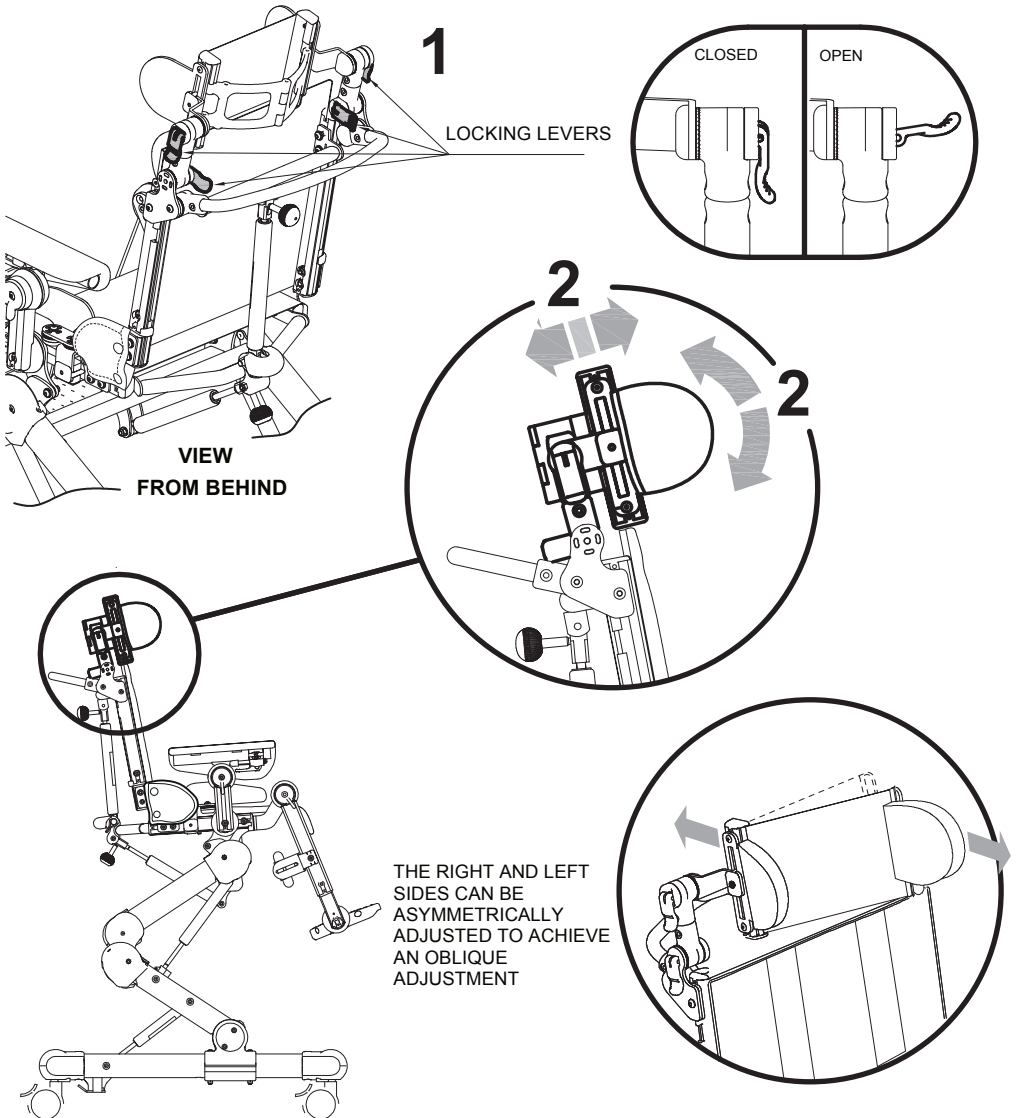




863 HEADREST ADJUSTMENT

A. INCLINATION AND DEPTH ADJUSTMENT

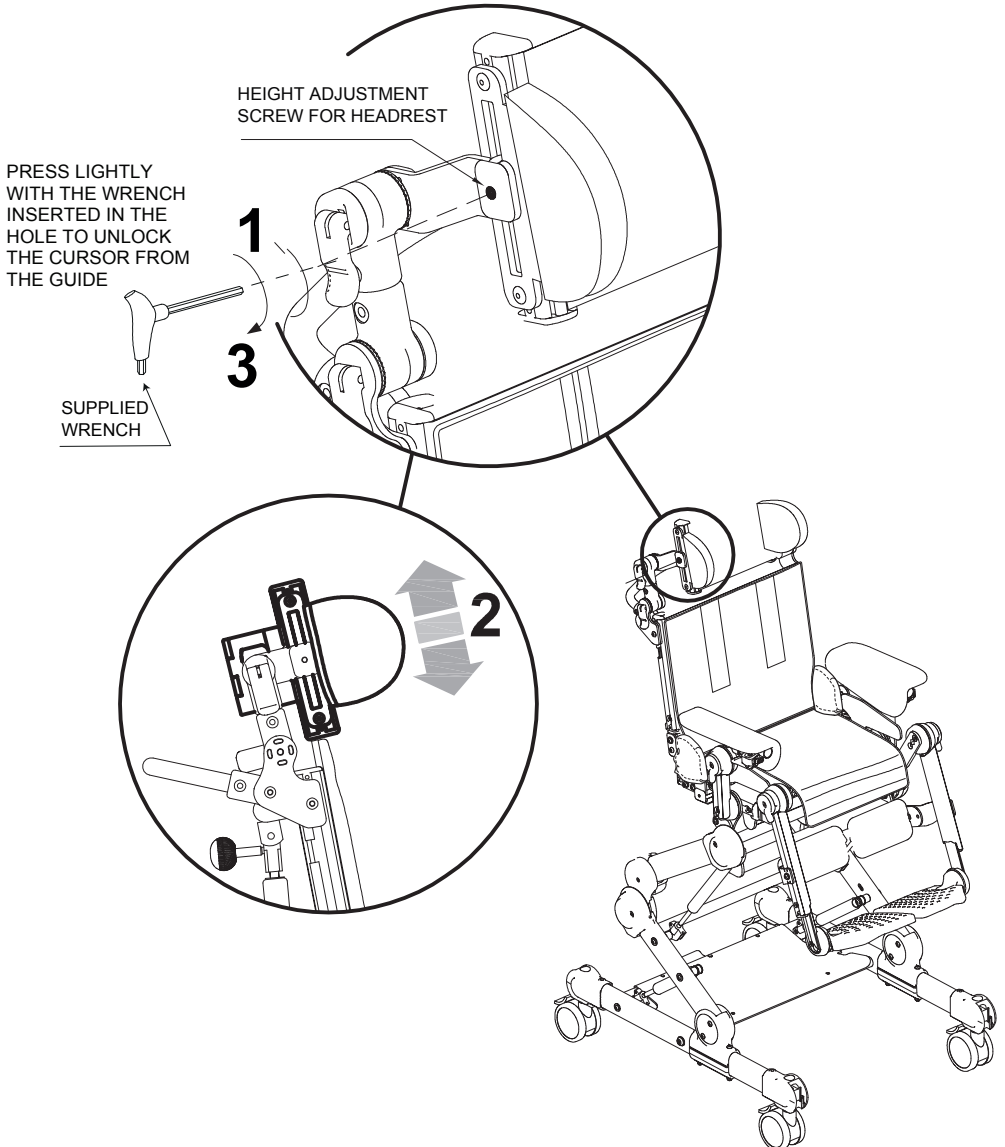
- 1) OPEN THE 4 LOCKING LEVERS
- 2) ADJUST THE INCLINATION AND DEPTH OF THE HEADREST
- 3) CLOSE THE LOCKING LEVERS





B. HEIGHT ADJUSTMENTS

- 1) LOOSEN THE SCREWS (BOTH SIDES)
- 2) ADJUST THE HEIGHT OF THE HEADREST
- 3) TIGHTEN THE SCREWS (BOTH SIDES)

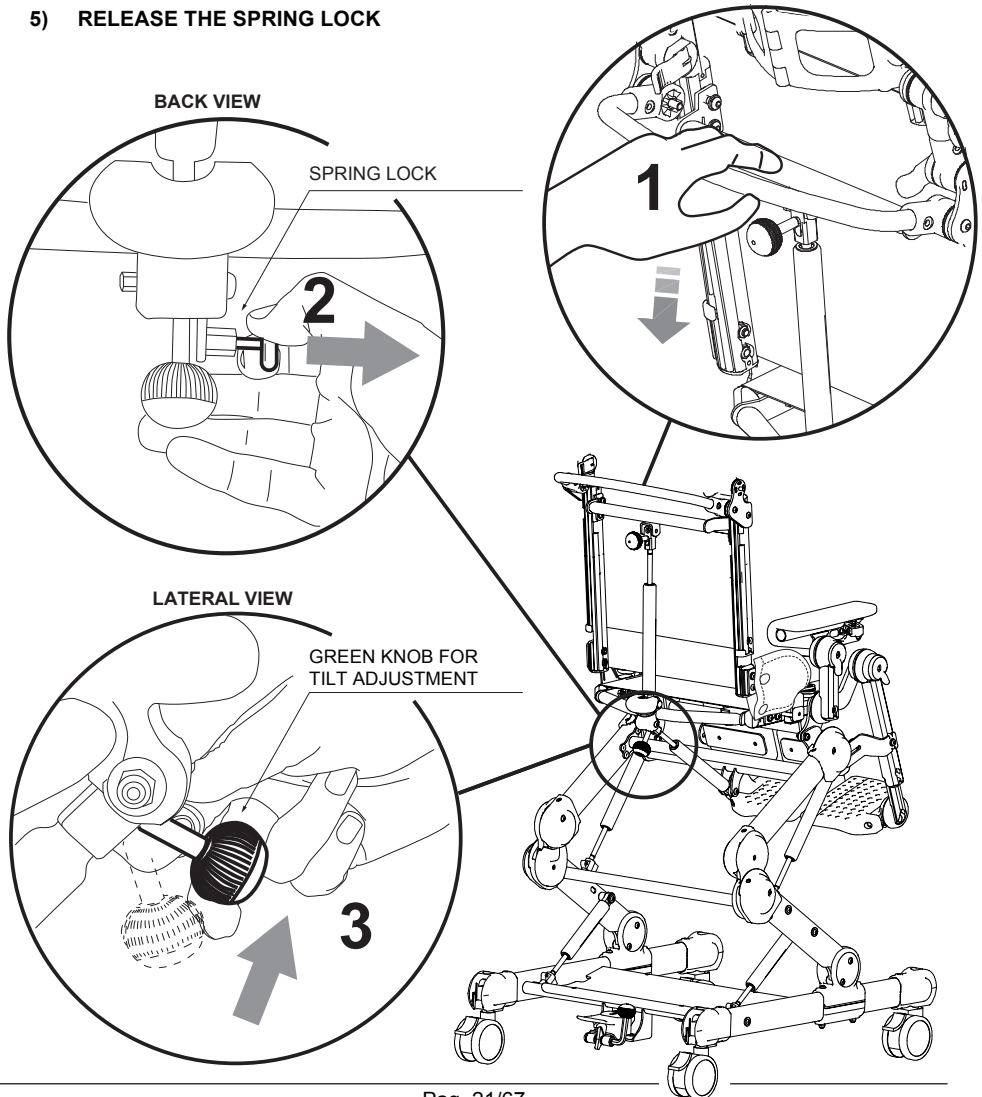




SEAT TILT ADJUSTMENT (TILT IN SPACE)

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

- 1) PLACE YOUR HAND ON THE HANDLE
- 2) WITH YOUR OTHER HAND OPEN THE SPRING LOCK AND HOLDING IT OPEN
- 3) MOVE THE GREEN TILT ADJUSTMENT KNOB UPWARDS
- 4) TILT THE SEAT BY HOLDING PULLED THE KNOB (3) AND LET GO WHEN THE BASCULATION HAS REACHED THE DESIRED POSITION.
- 5) RELEASE THE SPRING LOCK

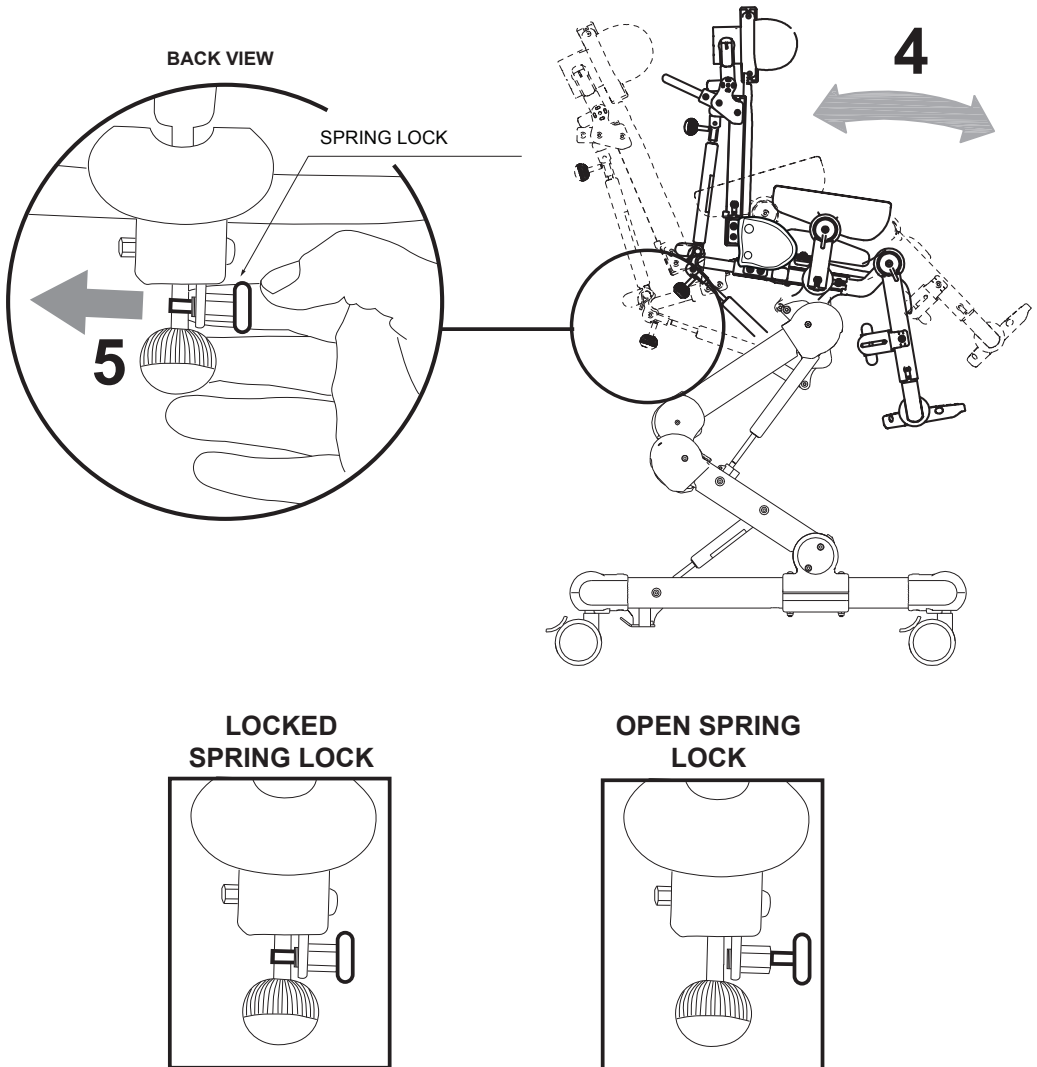




ATTENTION!

BEFORE ADJUSTING THE TILT OF THE SEAT WITH THE USER, MAKE SURE THAT THE BELT PROVIDED IS CORRECTLY ATTACHED, SO AS TO AVOID IT SLIDING FORWARD.

AVOID SUDDEN MOVEMENTS TO THE USER SEATED/POSITIONED





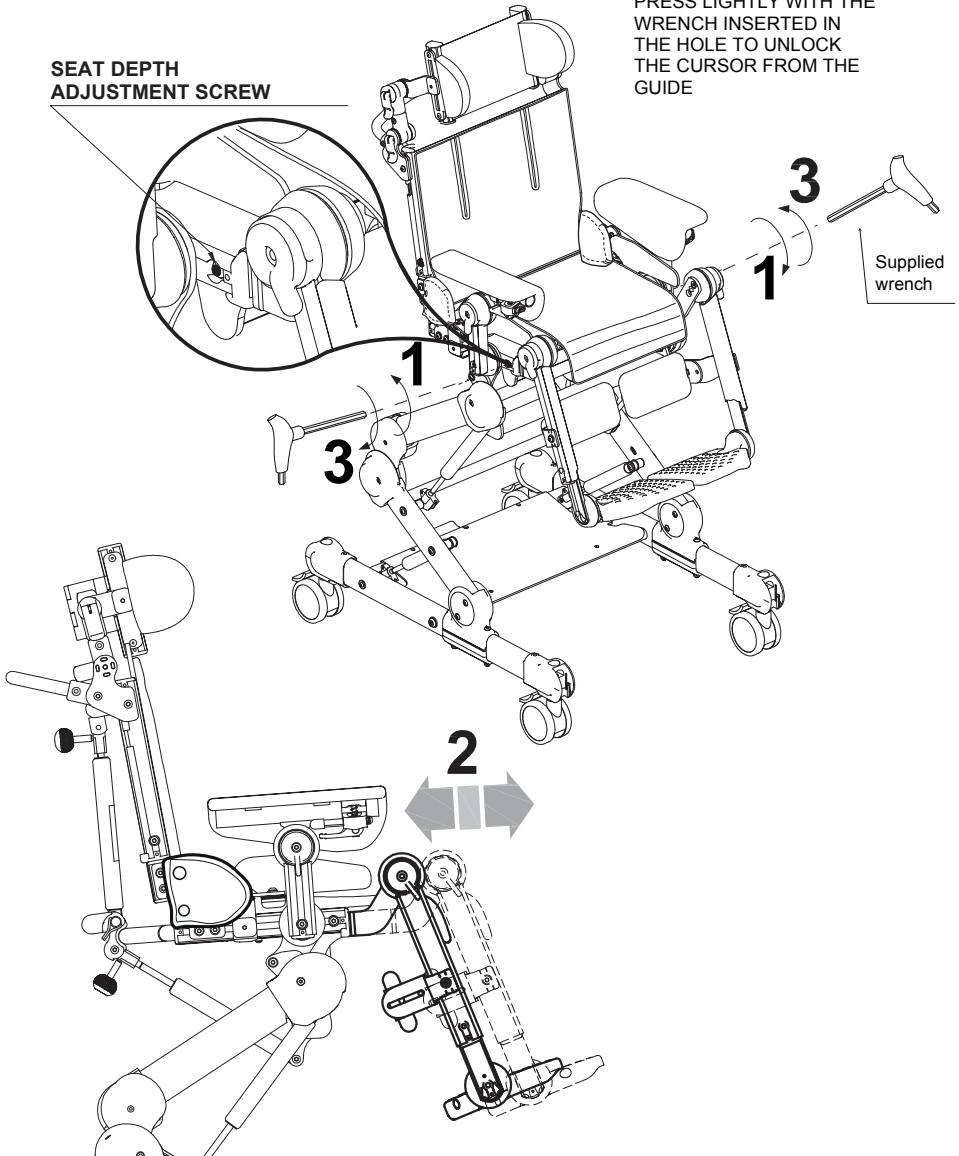
SEAT DEPTH ADJUSTMENT

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

- 1) LOOSEN THE SCREWS
- 2) ADJUST THE DEPTH OF THE SEAT
- 3) TIGHTEN THE SCREWS

SEAT DEPTH
ADJUSTMENT SCREW

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

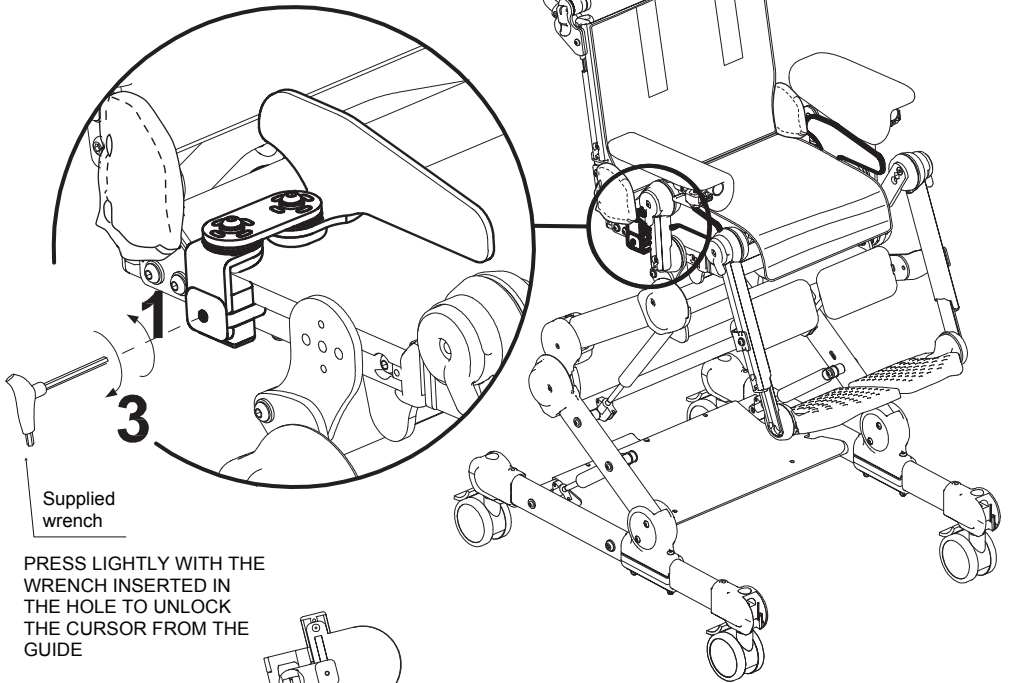




PELVIC SIDE SUPPORTS ADJUSTMENT

A. DEPTH ADJUSTMENT

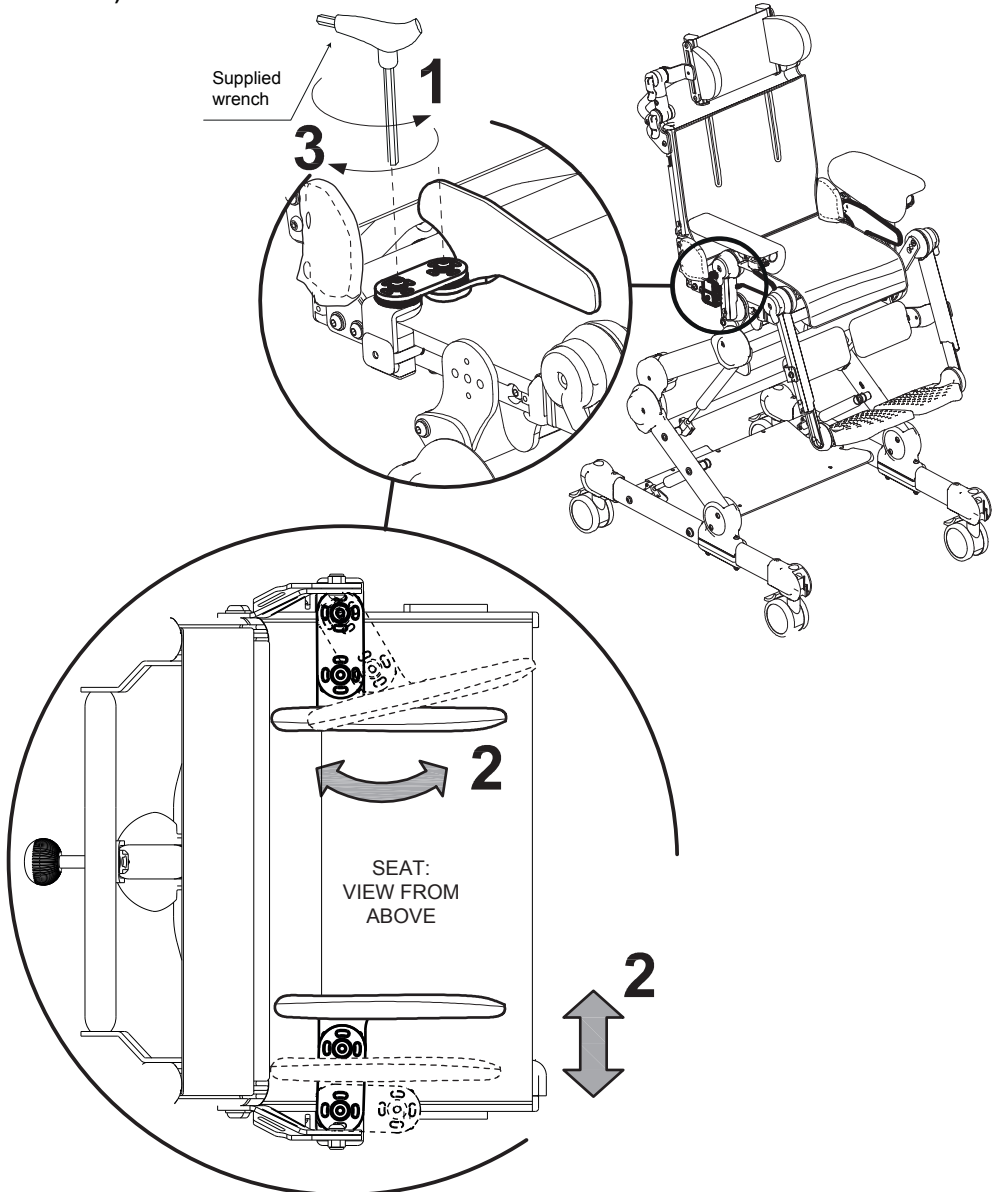
- 1) LOOSEN THE SCREWS
- 2) ADJUST THE DEPTH OF THE PELVIC SIDE SUPPORTS
- 3) TIGHTEN THE SCREWS





B. TILT AND WIDTH ADJUSTMENT

- 1) LOOSEN THE SCREWS
- 2) ADJUST THE SIDE SUPPORT IN TILT AND WIDTH
- 3) TIGHTEN THE SCREWS

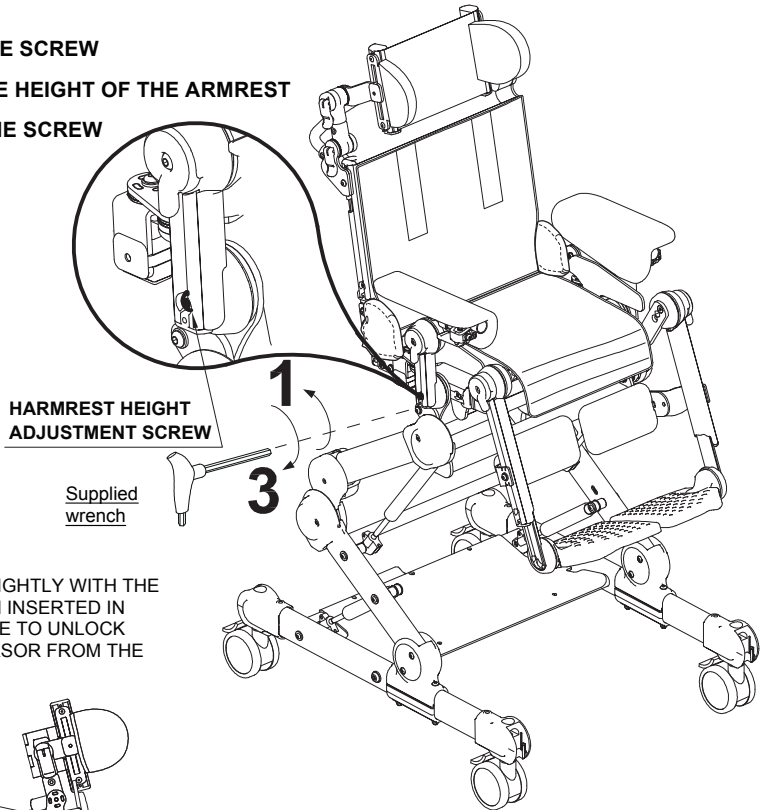




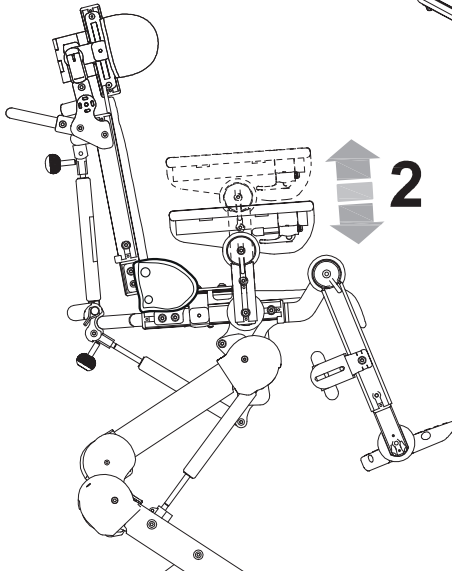
ARMREST ADJUSTMENT

A. HEIGHT ADJUSTMENT

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



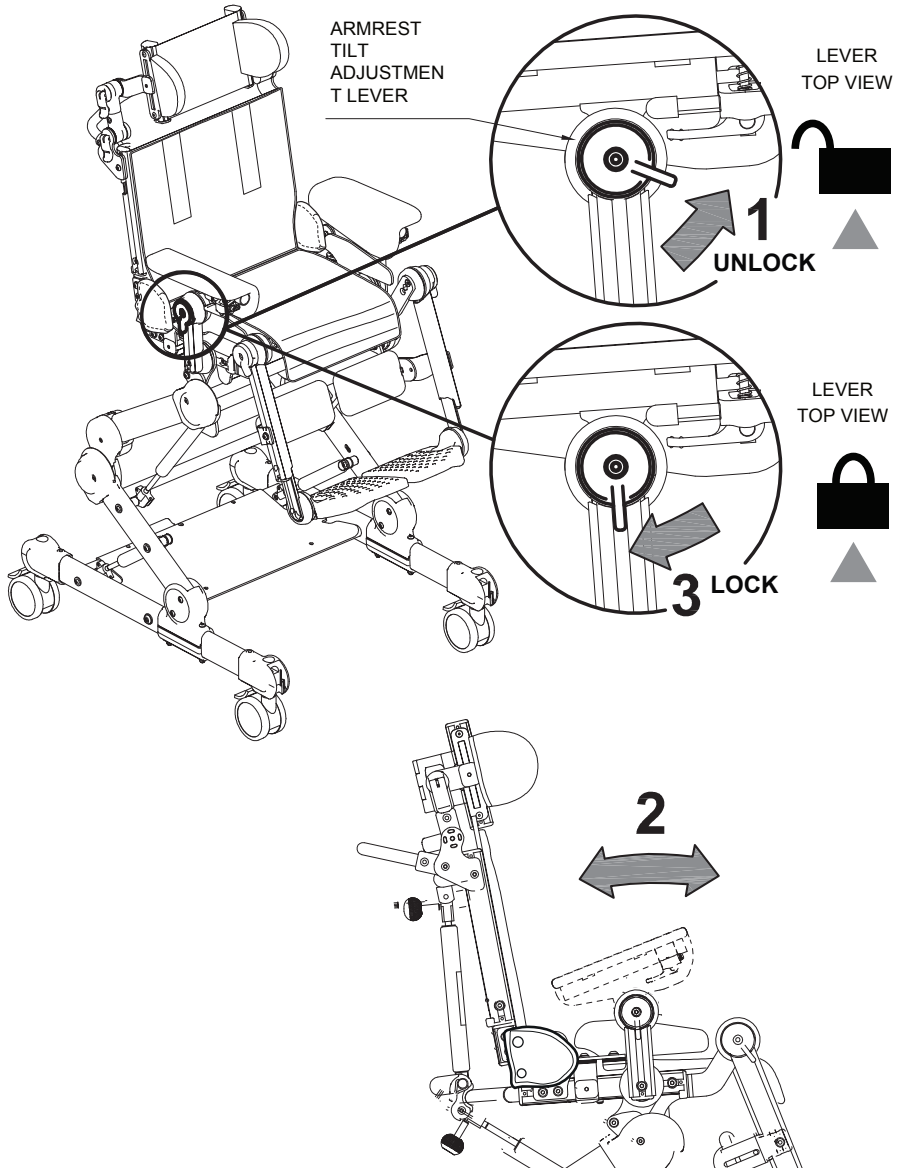
PRESS LIGHTLY WITH THE
WRENCH INSERTED IN
THE HOLE TO UNLOCK
THE CURSOR FROM THE
GUIDE





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





CALF RESTS ADJUSTMENT

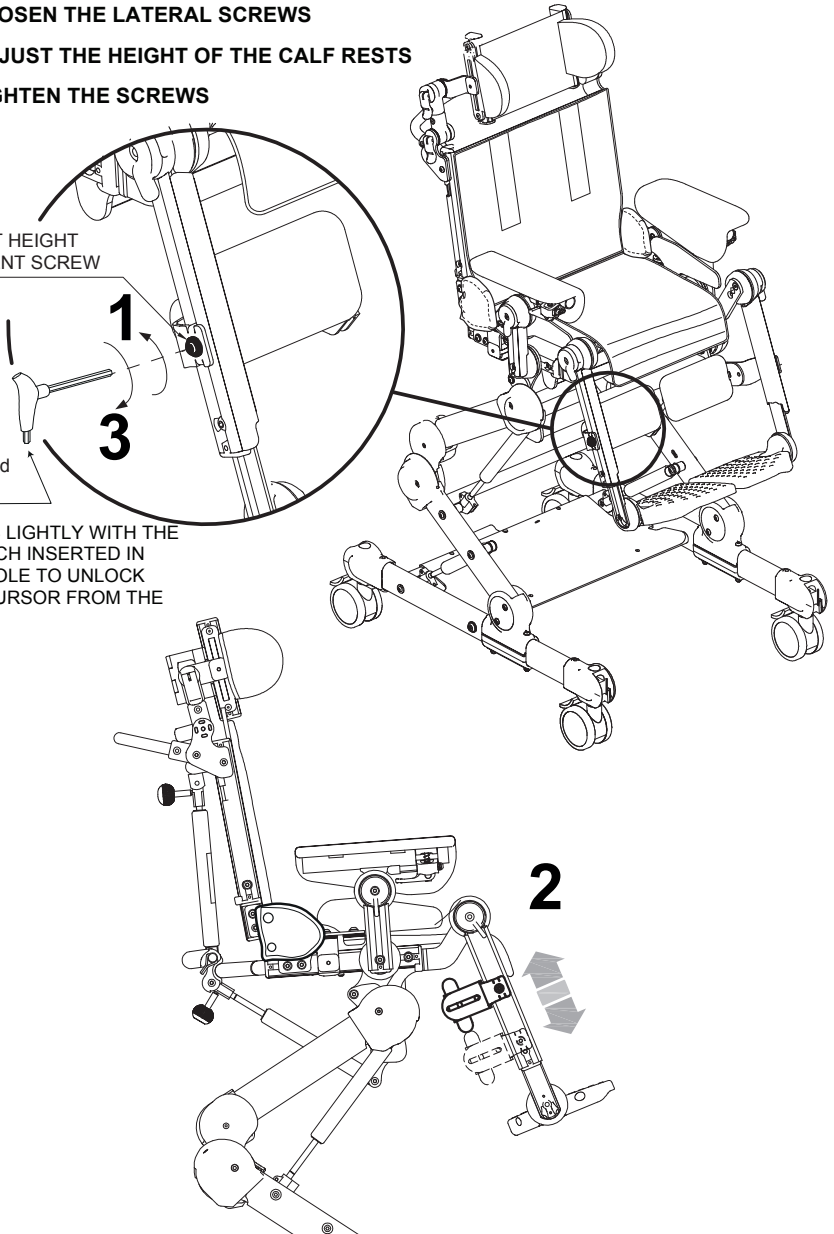
A. HEIGHT ADJUSTMENT

- 1) LOOSEN THE LATERAL SCREWS
- 2) ADJUST THE HEIGHT OF THE CALF RESTS
- 3) TIGHTEN THE SCREWS

CALF REST HEIGHT
ADJUSTMENT SCREW

Supplied
wrench

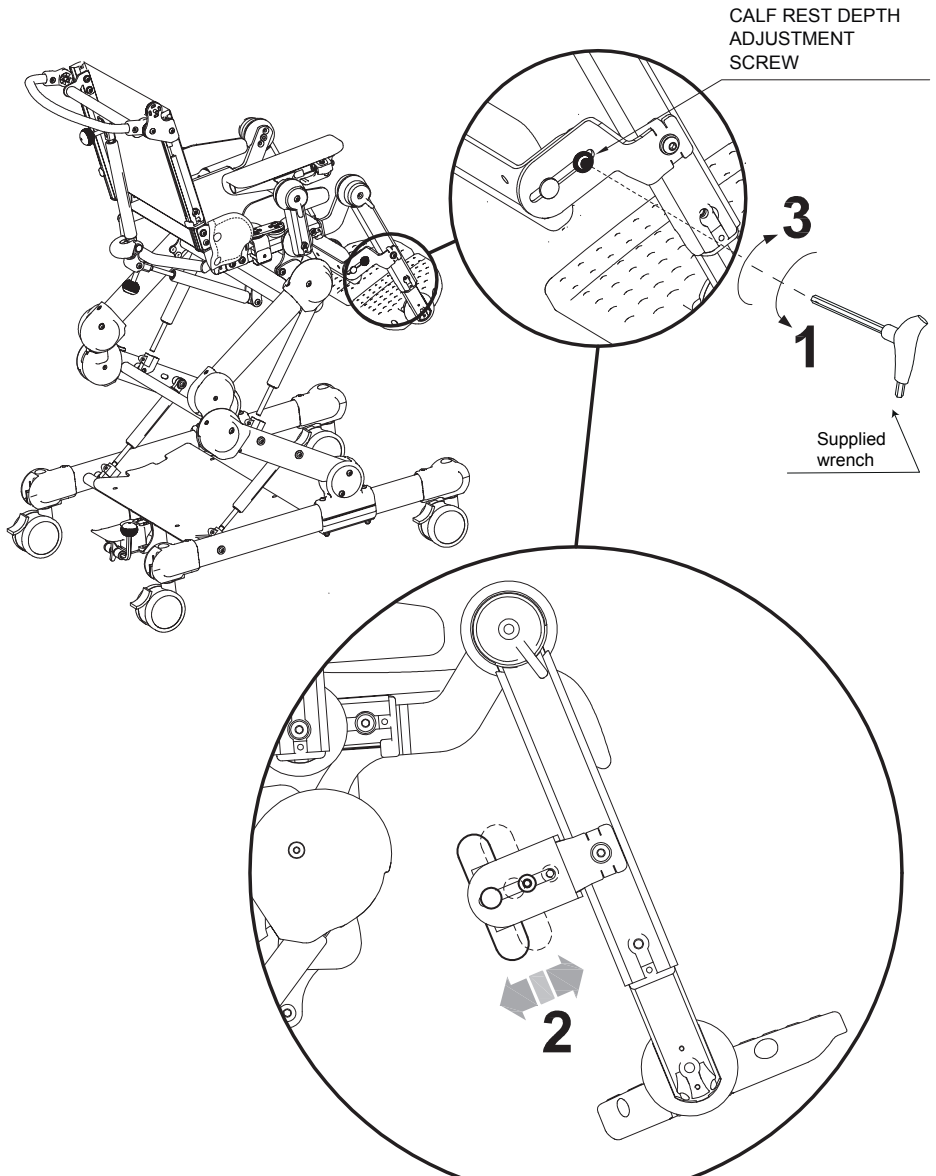
PRESS LIGHTLY WITH THE
WRENCH INSERTED IN
THE HOLE TO UNLOCK
THE CURSOR FROM THE
GUIDE





B. DEPTH ADJUSTMENT

- 1) LOOSEN THE LATERAL SCREWS
- 2) ADJUST THE DEPTH OF THE CALF RESTS
- 3) TIGHTEN THE SCREWS

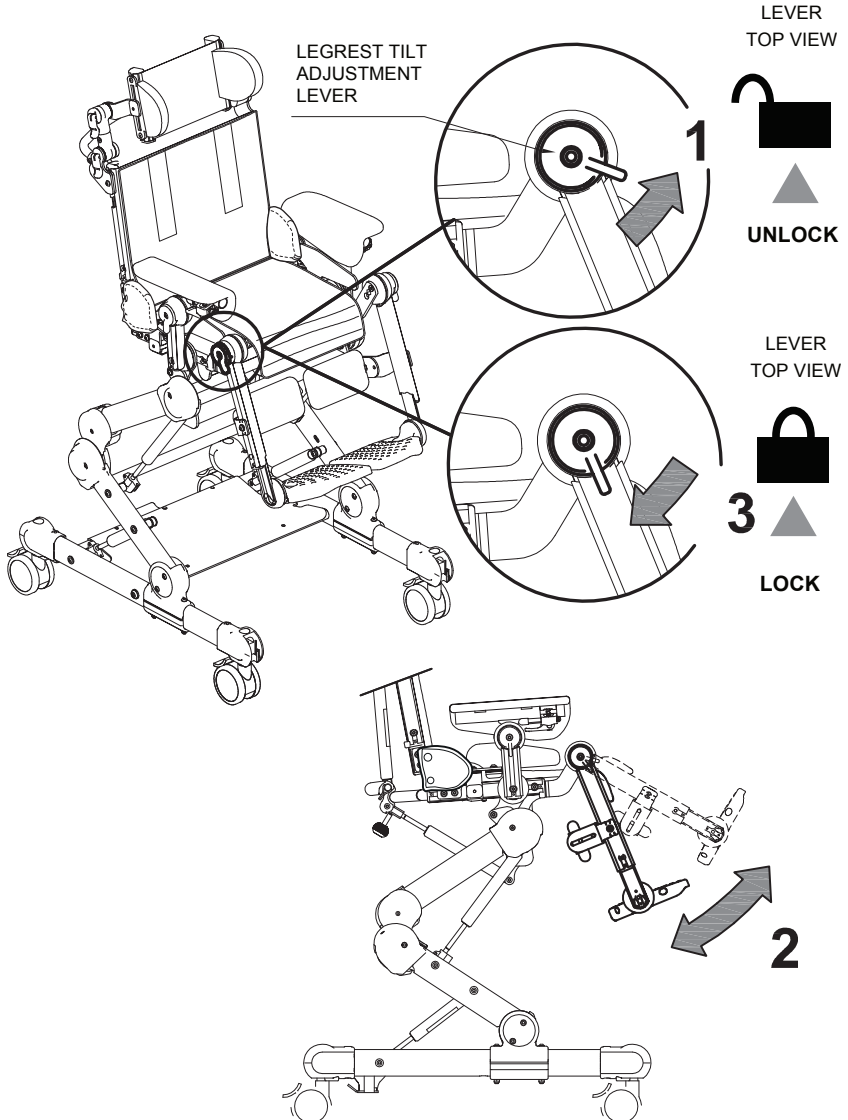




LEGREST ADJUSTMENT

A. TILT ADJUSTMENT

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



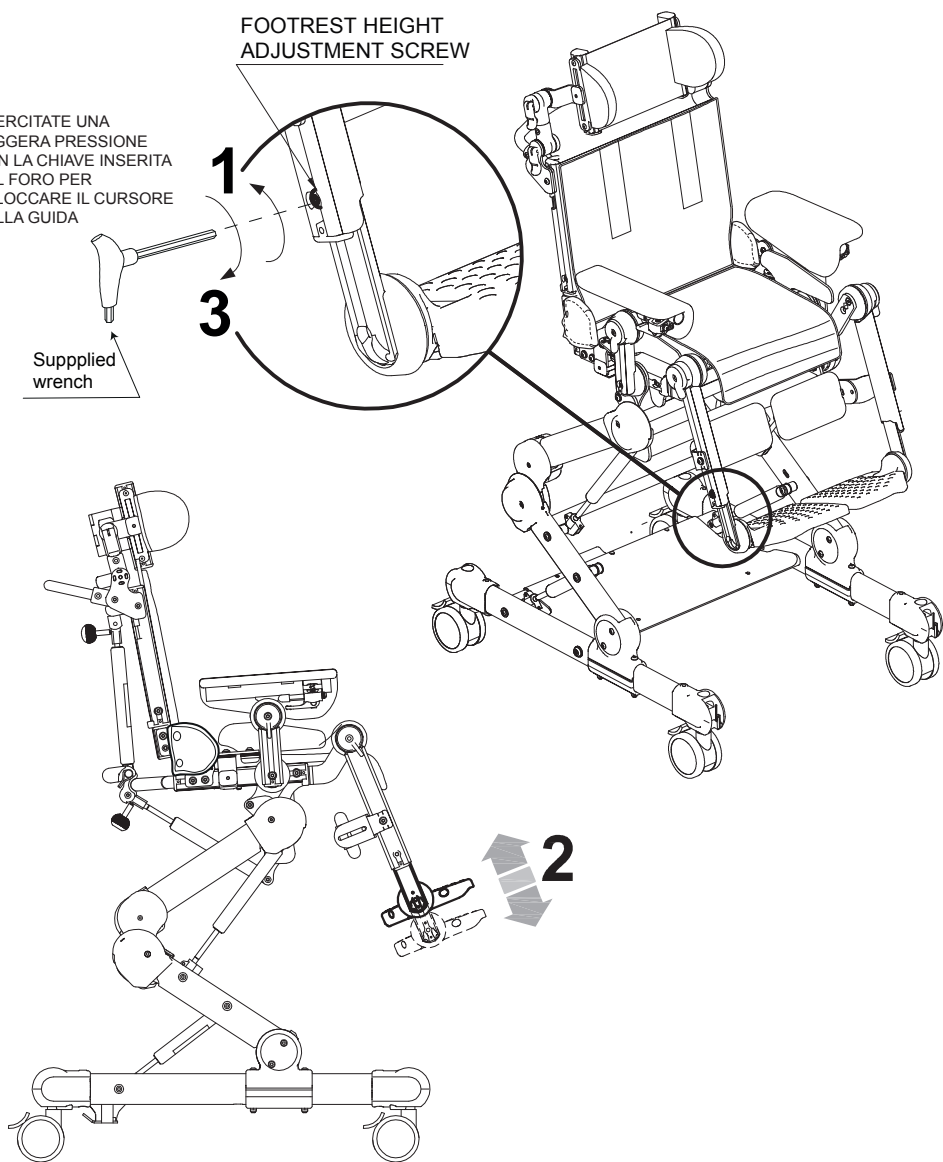


B. HEIGHT ADJUSTMENT

- 1) LOOSEN THE LATERAL SCREWS
- 2) ADJUST THE HEIGHT OF THE FOOTREST
- 3) TIGHTEN THE SCREWS

ESERCITATE UNA
LEGGERA PRESSIONE
CON LA CHIAVE INSERITA
NEL FORO PER
SBLOCCARE IL CURSORE
DALLA GUIDA

Supplied
wrench

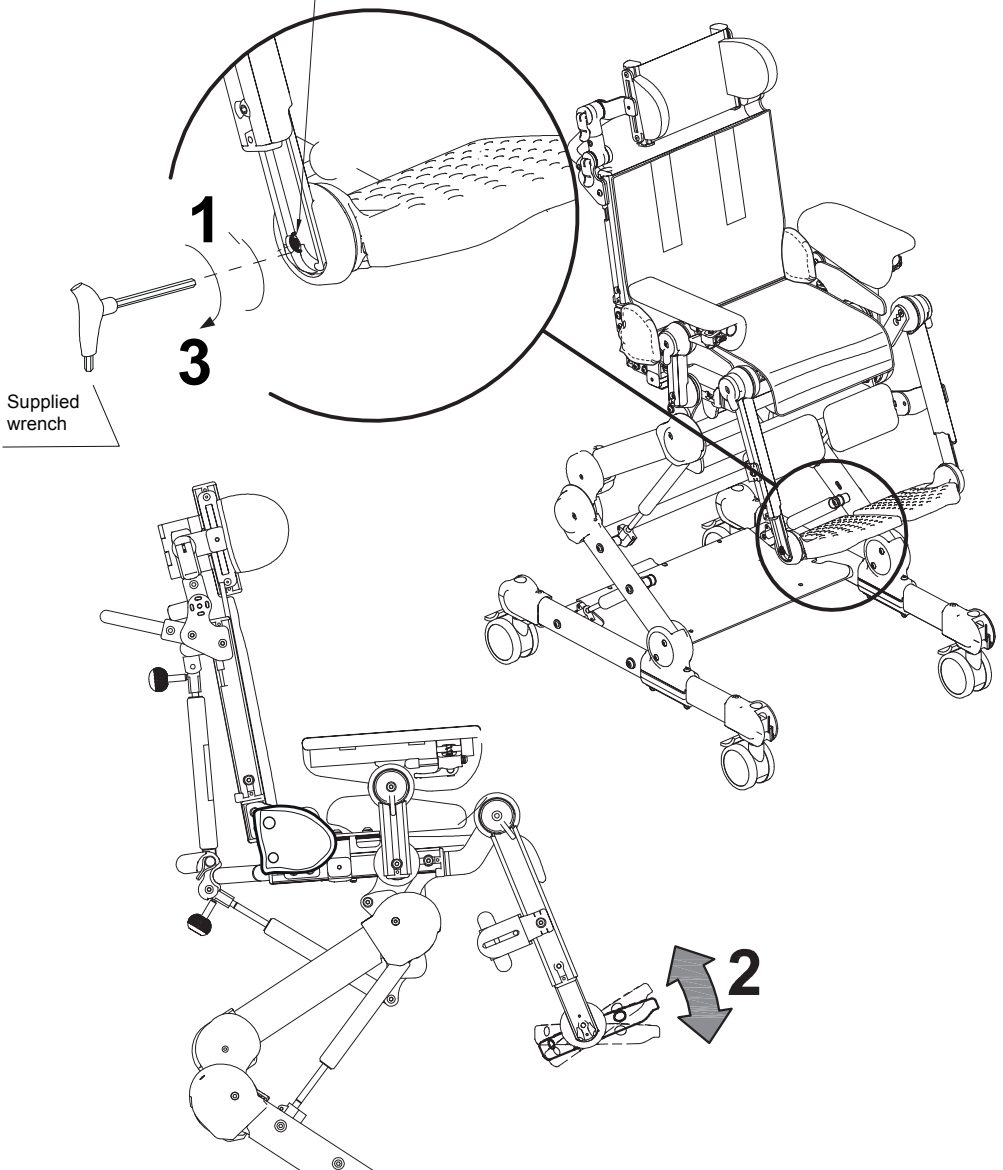




FOOTRESTS ADJUSTMENT

- 1) LOOSEN THE LATERAL SCREWS
- 2) ADJUST THE FOOTREST IN PLANTAR-DORSAL FLEXION.
- 3) TIGHTEN THE SCREWS

SCREW ADJUSTMENT FLEXION-EXTENSION



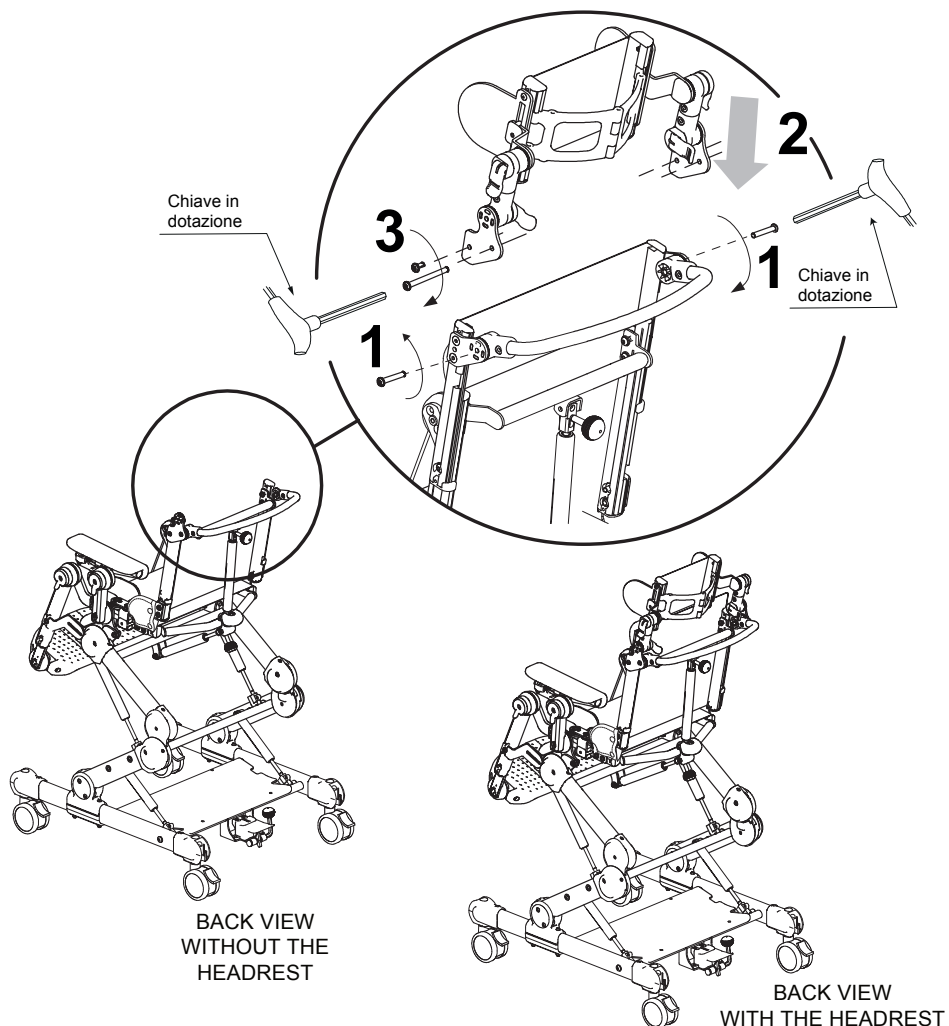


5.4 ADJUSTMENT AND CONFIGURATION OF THE MEDICAL DEVICE BY THE HEALTH PROFESSIONAL

POSTURAL HEADREST 863

Adjustable in height, tilt, depth and laterally

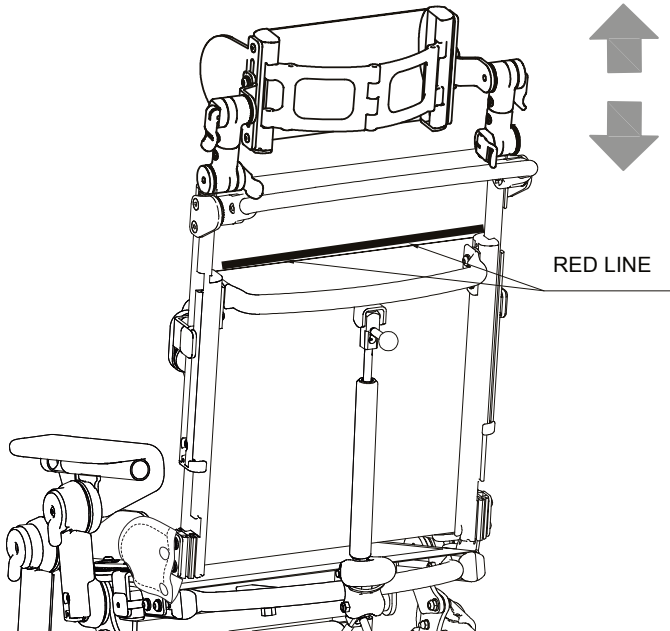
- 1) LOOSEN THE SCREWS
- 2) MOUNTING THE HEADREST
- 3) INSERT THE SCREWS PROVIDED WITH THE HEADREST AND SCREW THEM IN





ADJUST THE HEIGHT OF THE BACKREST

(the red line indicates the maximum height of the backrest with the headrest 863 inserted)



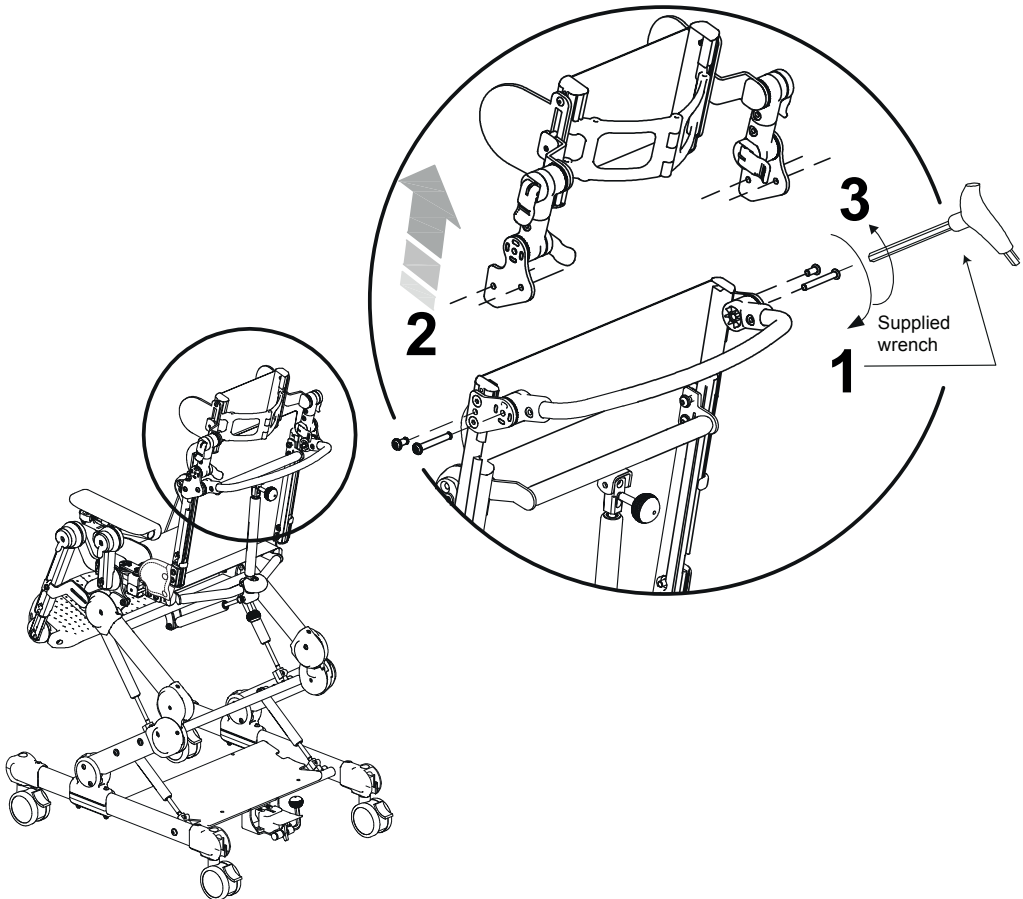
BACK VIEW



HOW TO REMOVE THE HEADREST 863

REMOVE THE EXTERNAL HEADREST 863 WHEN IT IS APPROPRIATE TO USE A HEADREST INSIDE THE BACKREST

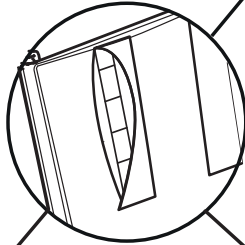
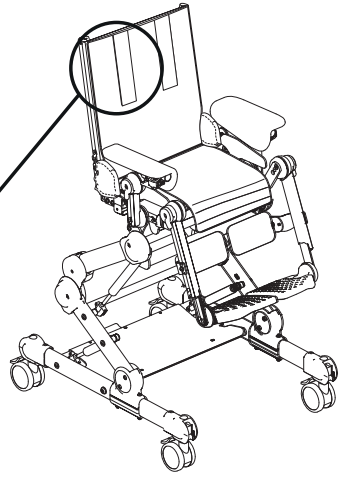
- 1) RAISE THE BACKREST
- 2) REMOVE THE SCREWS
- 3) REMOVE THE HEADREST
- 4) INSERT THE SCREWS IN THE SAME POSITIONS AND TIGHTEN THEM
- 5) FIT THE PADDED HEADREST 865 OR THE MOLDED HEADREST 835 SEE P. 31



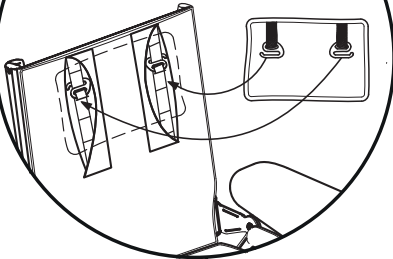


HEADREST 835 AND 865

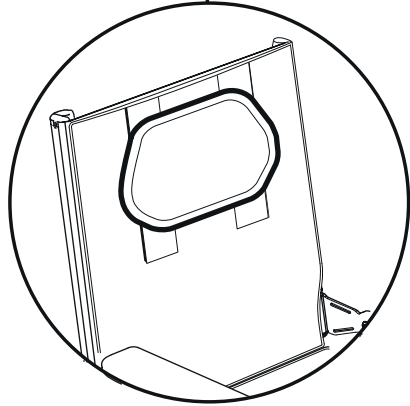
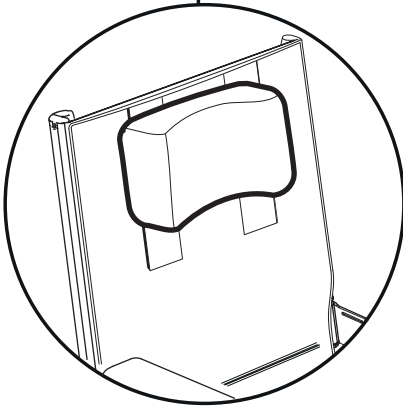
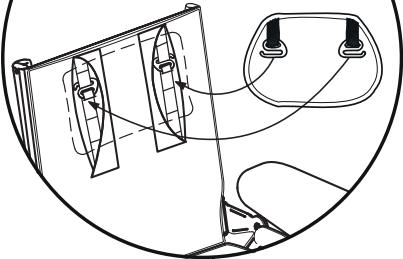
Adjustable in height



**BACK VIEW
OF THE 835 HEADREST**

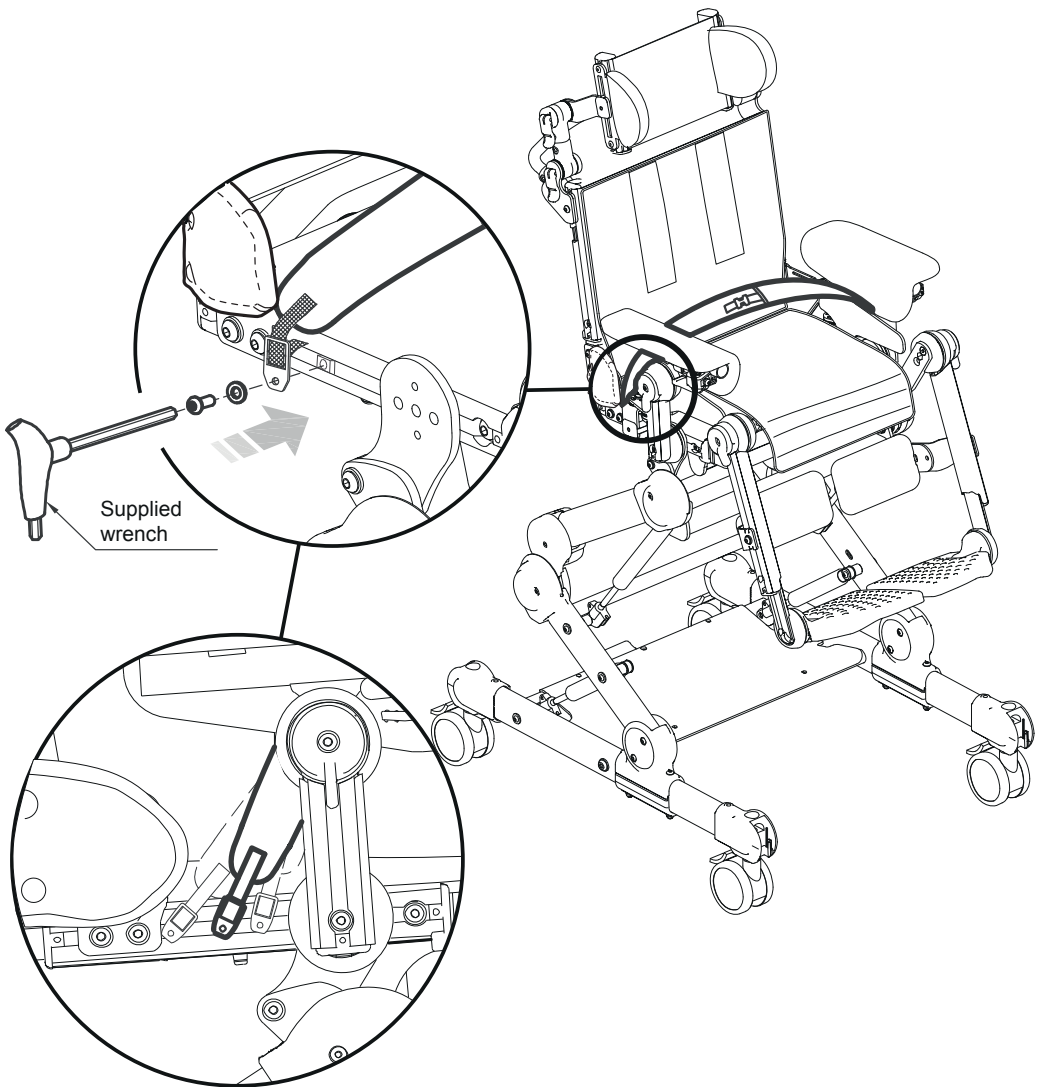


**BACK VIEW
OF THE 865 HEADREST**





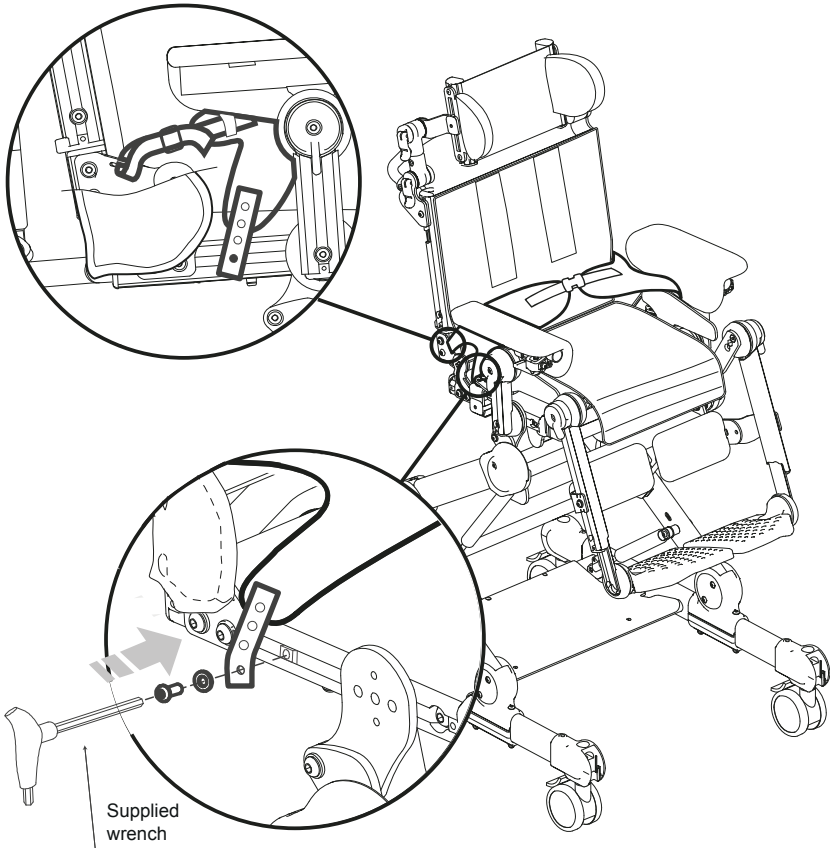
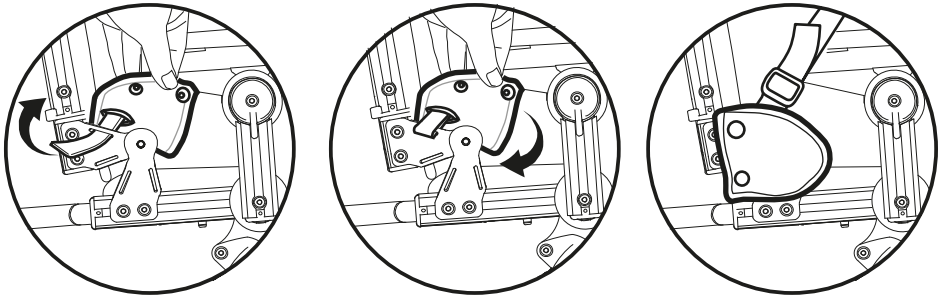
PELVIC BELT WITH VARIABLE ANGLE 947 (Provided as standard)





FOUR POINT PELVIC BELT 920

AVAILABLE ONLY FOR GRILLO AS SMALL AND MEDIUM



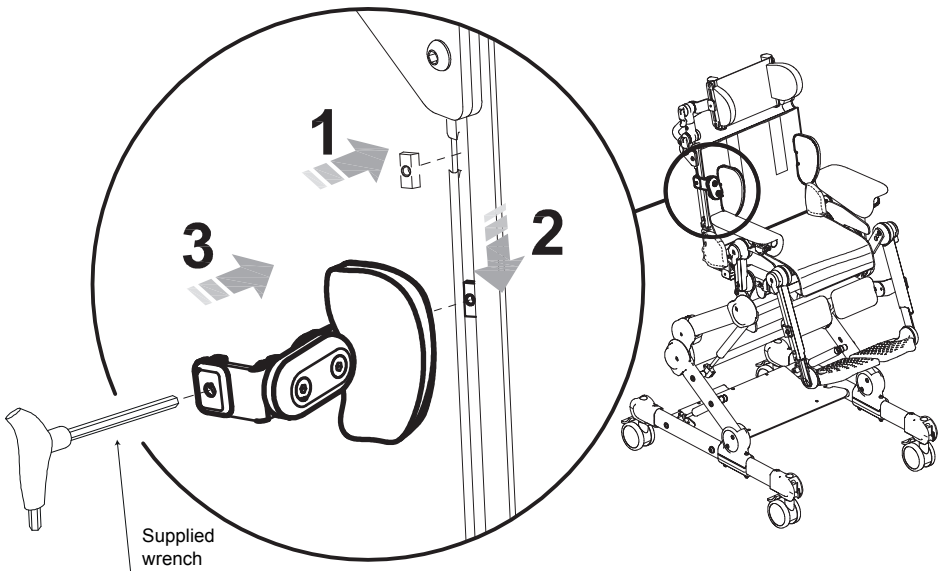


TRUNK SIDE SUPPORTS 838

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

A. MOUNTING

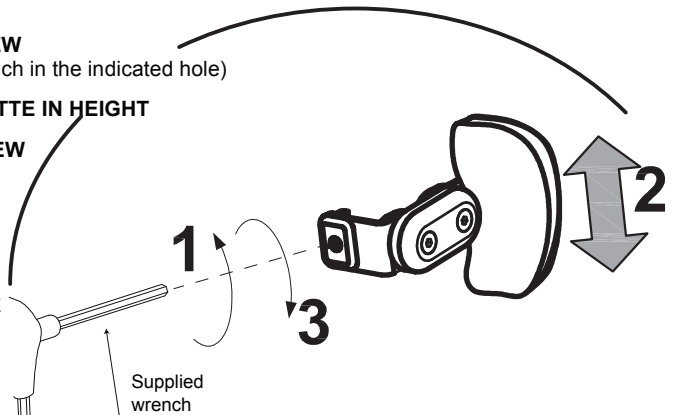
- 1) **2) INSERT THE CURSOR IN THE GUIDE**
- 3) **INSERT THE PELOTTE TO THE DESIRED HEIGHT AND TIGHTEN THE SCREW**
(by inserting the wrench in the indicated hole)



B. HEIGHT ADJUSTMENT

- 4) **LOOSEN THE SCREW**
(by inserting the wrench in the indicated hole)
- 5) **ADJUST THE PELOTTE IN HEIGHT**
- 6) **TIGHTEN THE SCREW**

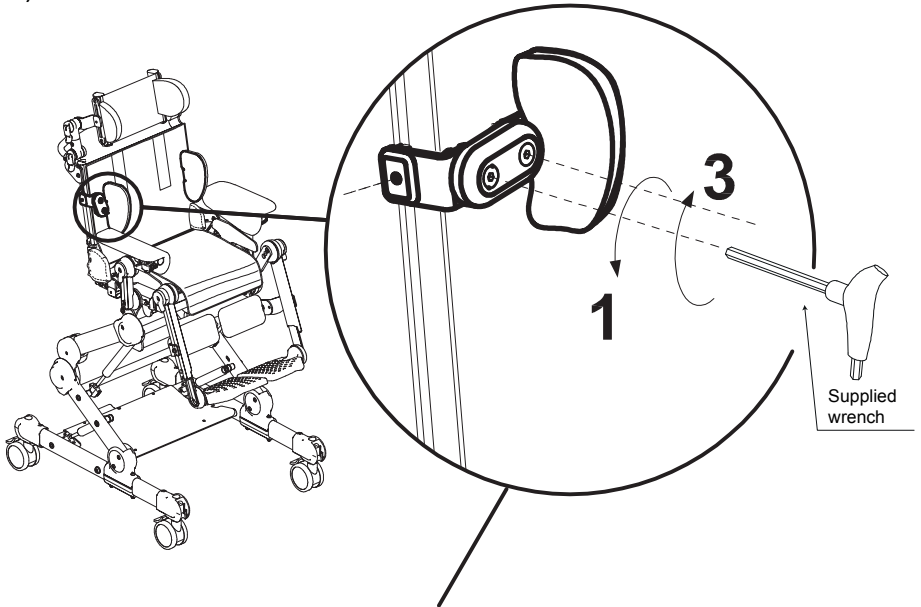
PRESS LIGHTLY WITH THE WRENCH INSERTED IN THE HOLE TO UNLOCK THE CURSOR FROM THE GUIDE



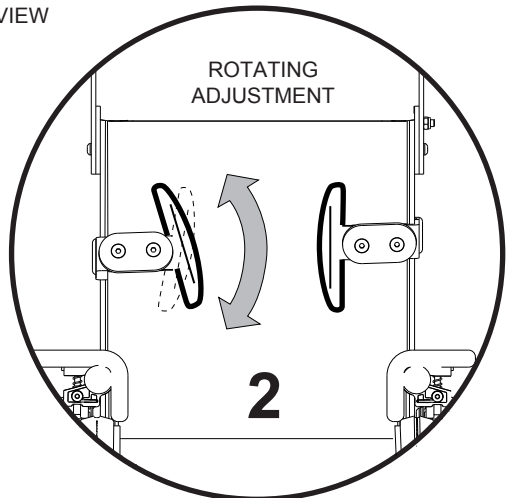
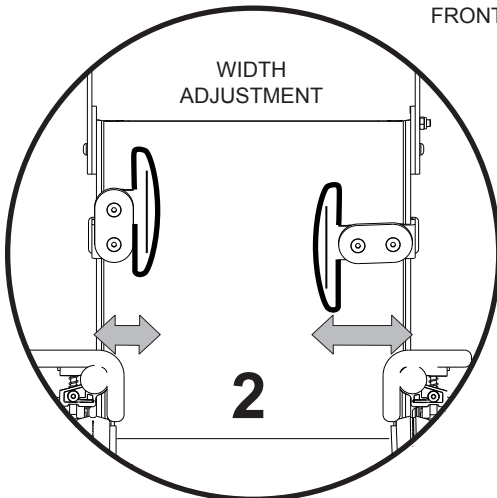


C. WIDTH AND ROTATION ADJUSTMENT

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



BACKREST
FRONT VIEW





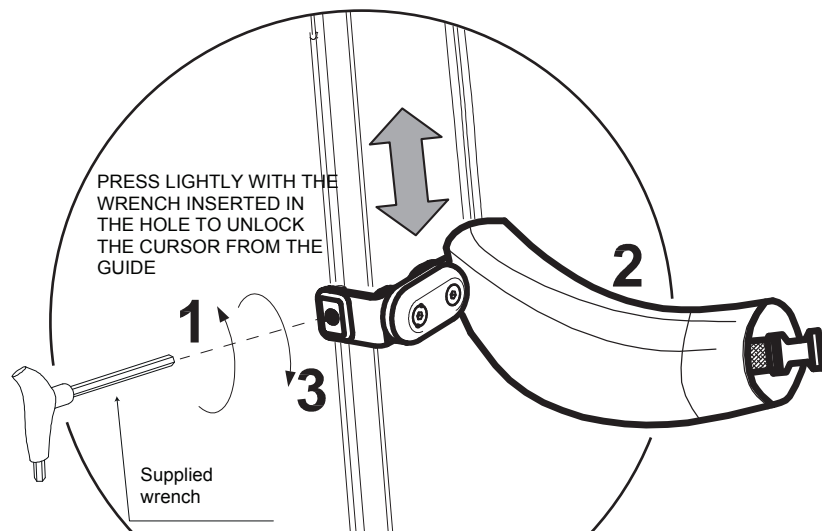
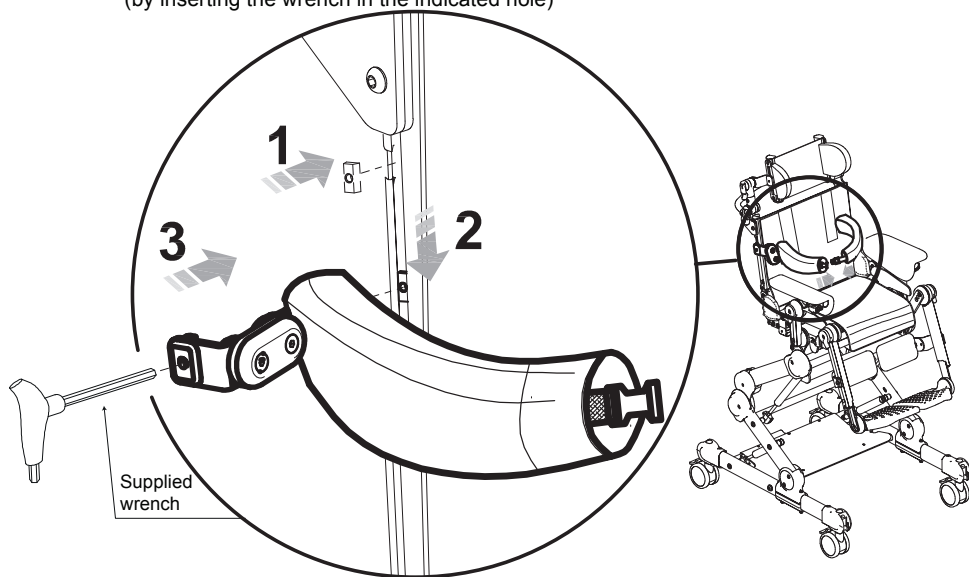
WRAPPABLE AND FLEXIBLE TRUNK SUPPORTS 868

multiadjustable in height, width and inclination

A. MOUNTING AND HEIGHT ADJUSTMENT

- 1) 2) INSERT THE CURSOR INTO THE GUIDE
- 3) INSERT THE PELOTTE TO THE DESIRED HEIGHT AND TIGHTEN THE SCREW

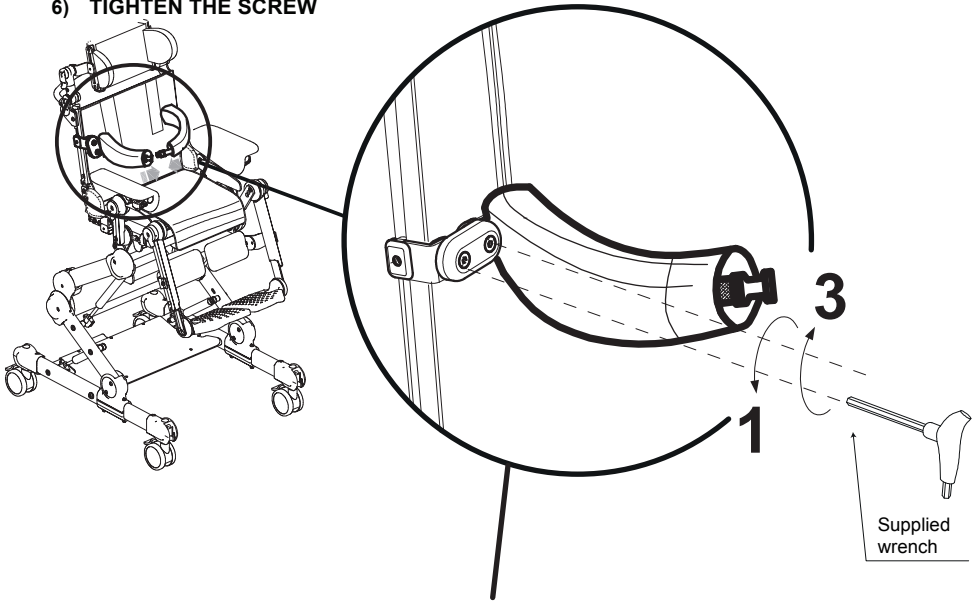
(by inserting the wrench in the indicated hole)



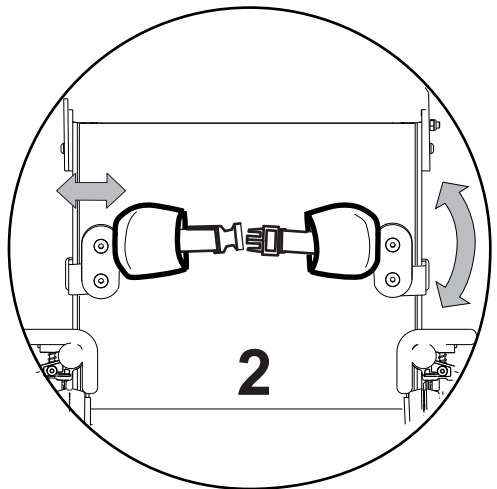
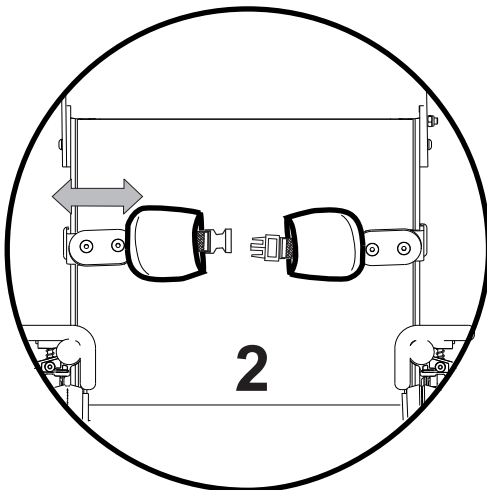


B. WITH AND ROTATION ADJUSTMENT

- 4) LOOSEN THE SCREW
- 5) ADJUST THE PELOTTE IN WIDTH AND ROTATION
- 6) TIGHTEN THE SCREW



BACKREST
FRONT VIEW

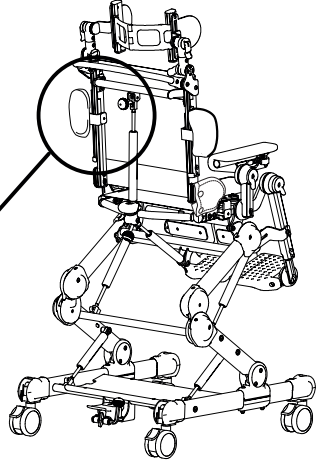
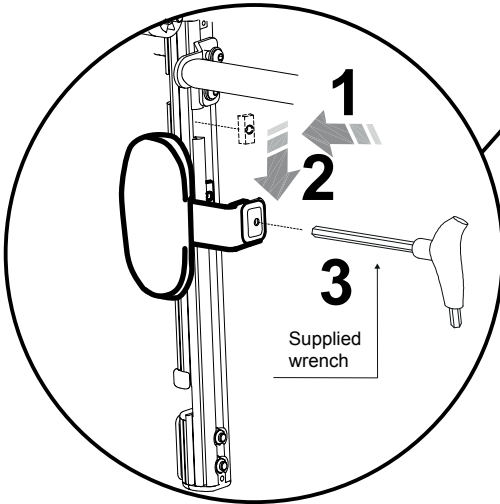




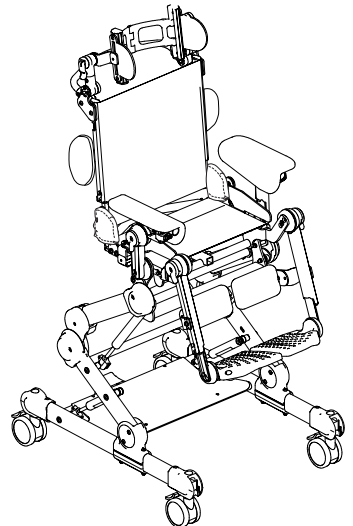
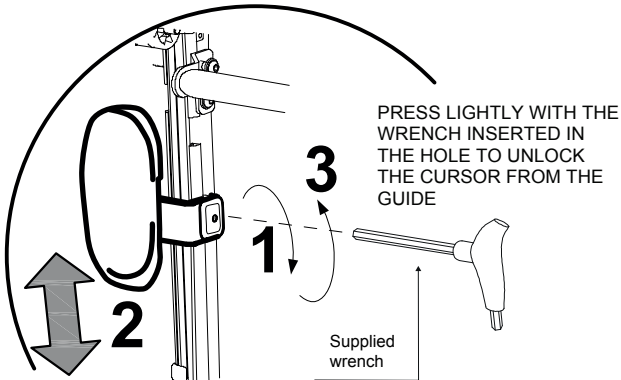
ELBOW SIDE SUPPORTS 961

A. MOUNTING AND HEIGHT ADJUSTMENT

- 1) 2) INSERT THE CURSOR INTO THE GUIDE
- 3) INSERT THE PAD TO THE DESIRED HEIGHT AND TIGHTEN THE SCREW
(by inserting the wrench in the indicated hole)



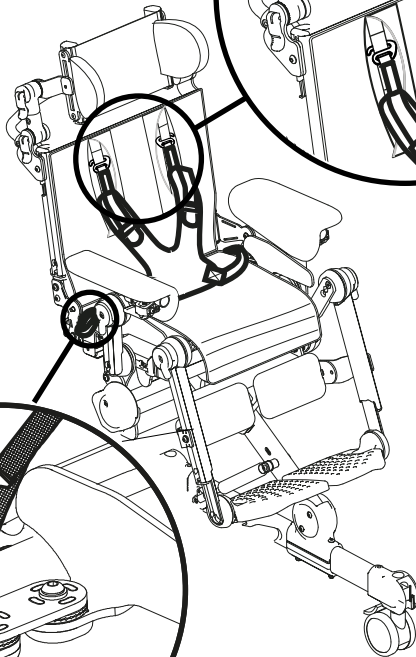
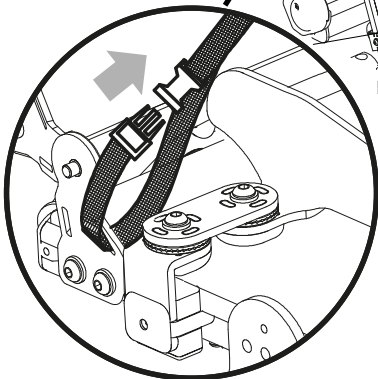
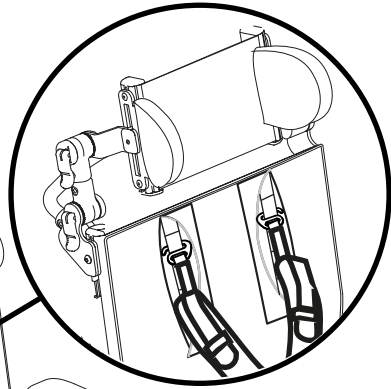
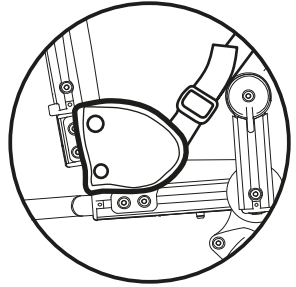
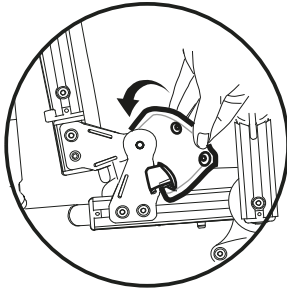
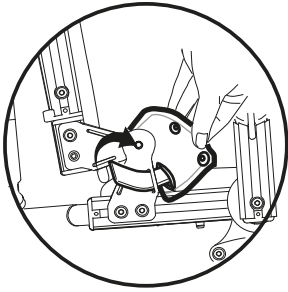
BACK VIEW



FRONT VIEW

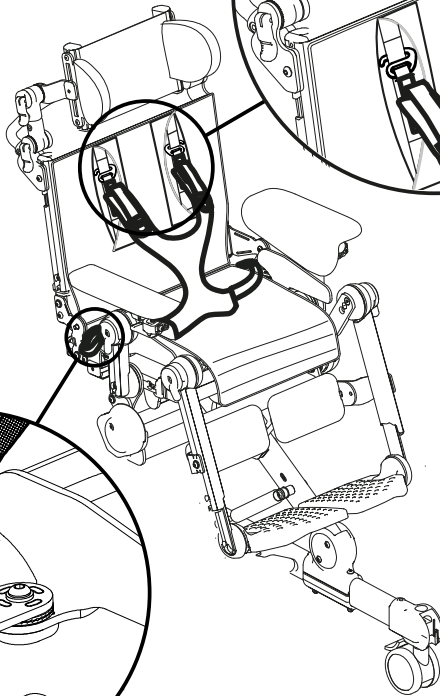
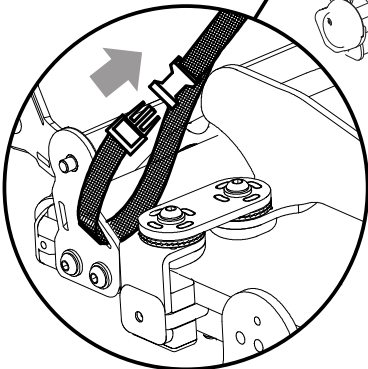
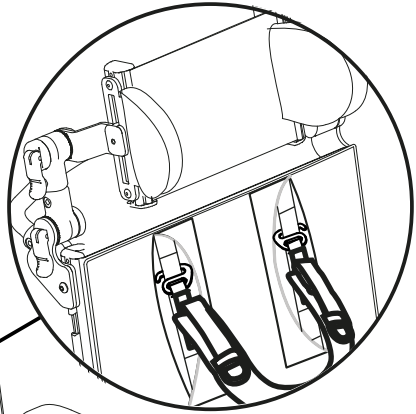
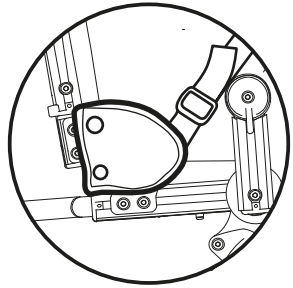
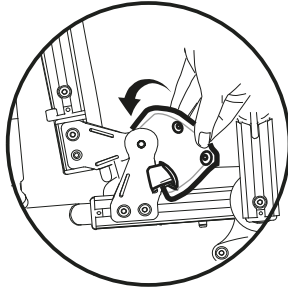
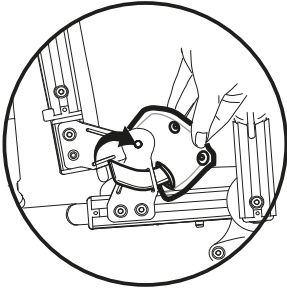


VEST HARNESS 853





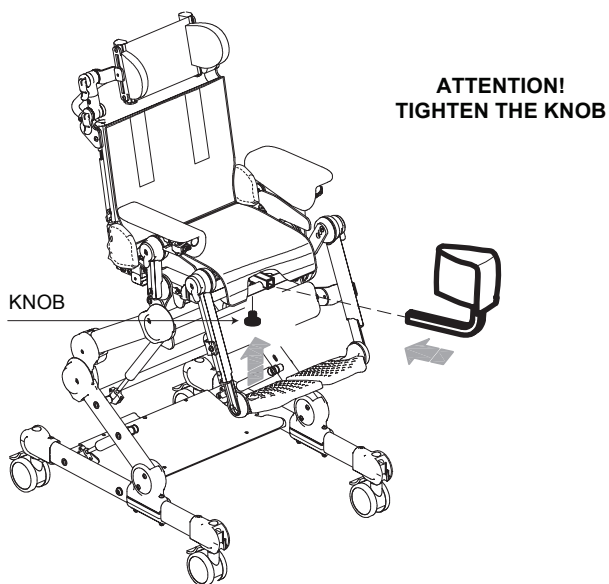
SLIM FOUR POINT SHAPED HARNESS 853



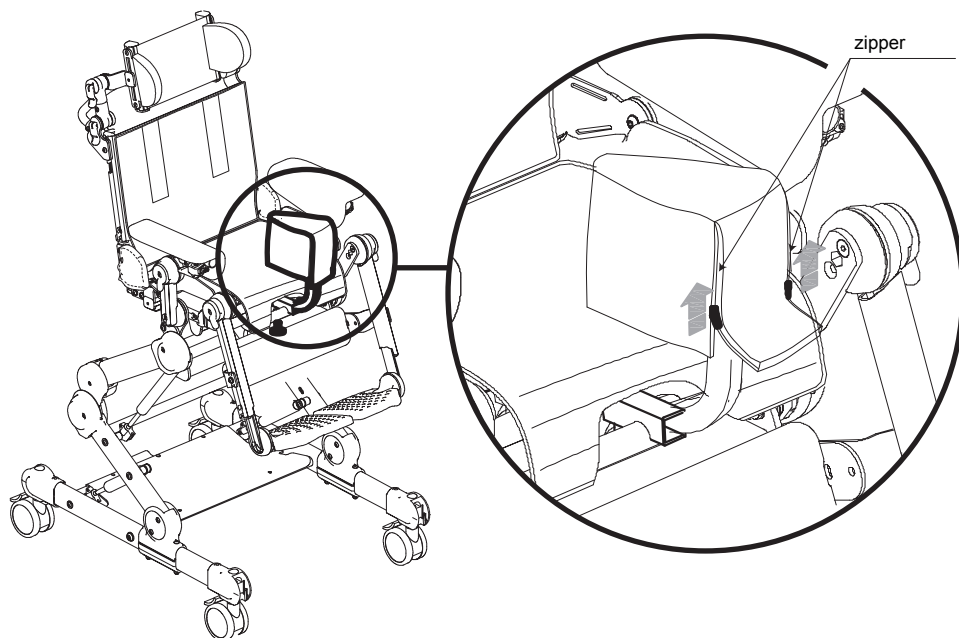


ADJUSTABLE ABDUCTION BLOCK 834R

MOUNTING THE ABDUCTION BLOCK AND TIGHTEN THE KNOB

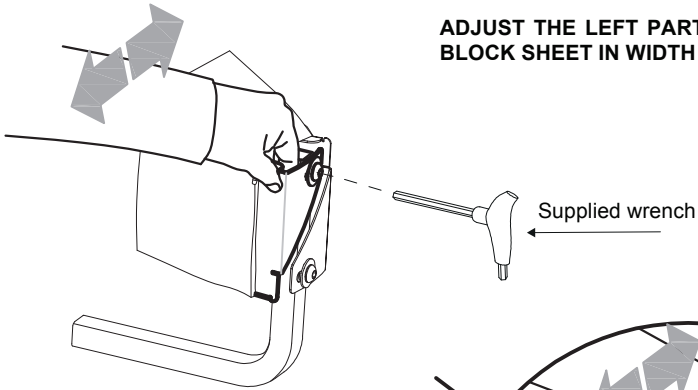


OPEN THE FLAPS VIA THE TWO ZIPPERS

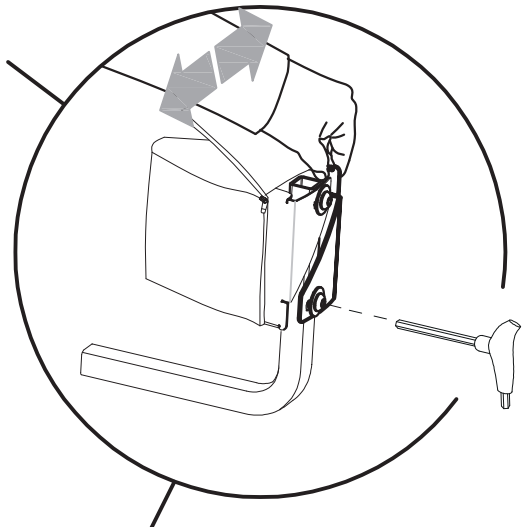




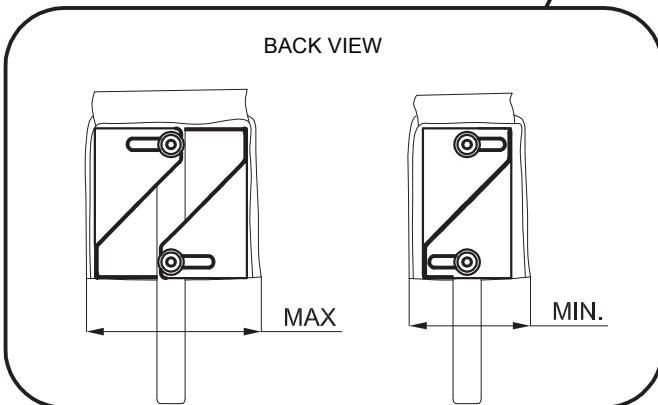
ADJUST THE LEFT PART OF THE ABDUCTION BLOCK SHEET IN WIDTH



ADJUST THE RIGHT PART OF THE ABDUCTION BLOCK SHEET IN WIDTH



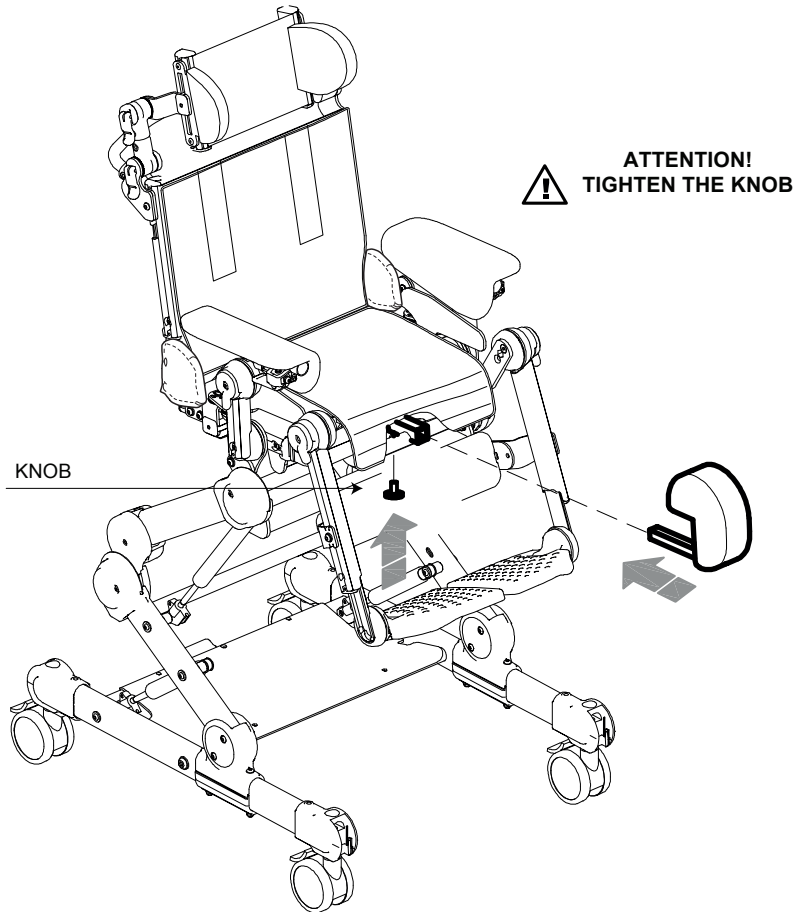
BACK VIEW





NARROW ABDUCTION BLOCK 834N

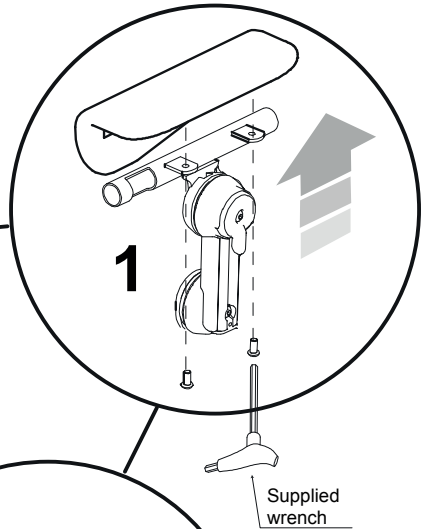
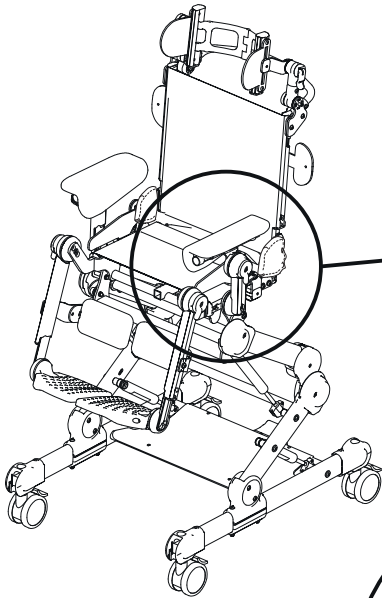
MOUNTING THE ABDUCTION BLOCK AND TIGHTEN THE KNOB



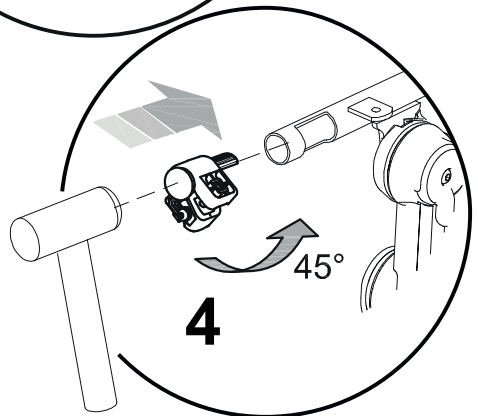
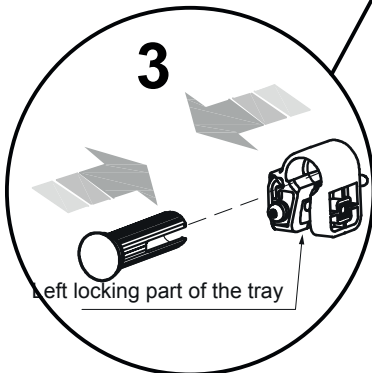
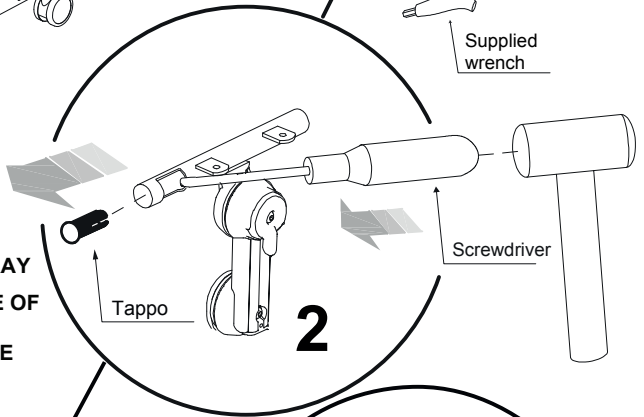


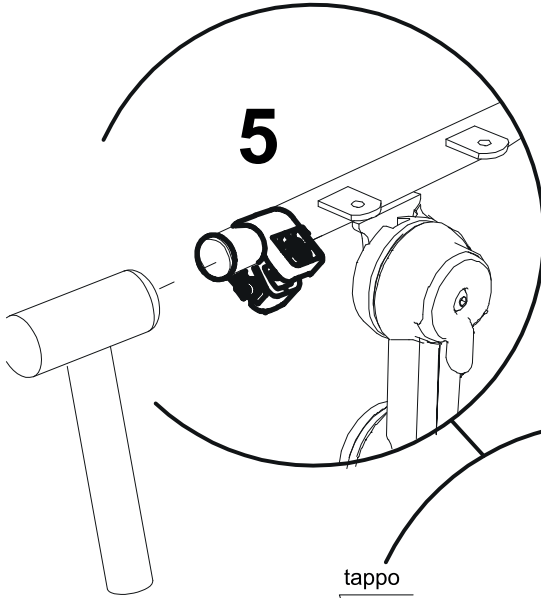
TRAY WITH WRAP-AROUND RECESS 824

A. RIGHT AND LEFT MECHANISM



- 1) REMOVE THE ARMREST
- 2) PULL THE STOPPER OUT
- 3) PUT THE STOPPER IN THE LOCKING PART OF THE TRAY
- 4) INSERT THEM IN THE TUBE OF THE ARMREST USING A RUBBER HAMMER (ROTATE 45° OUTSIDE)

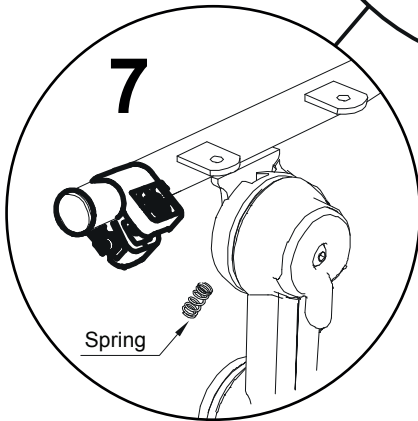
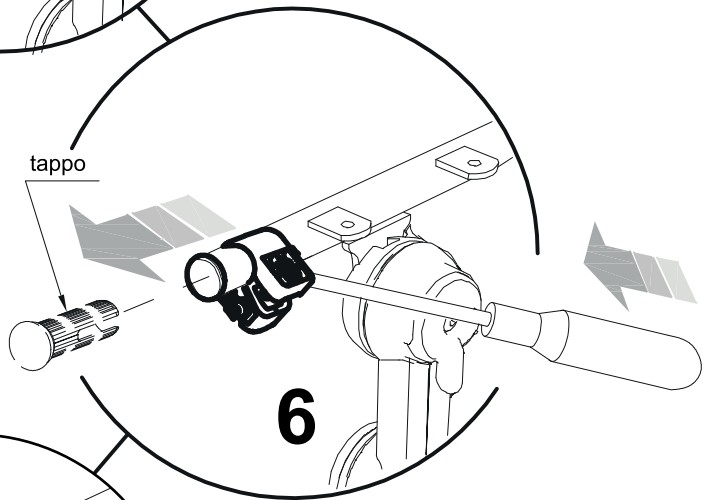


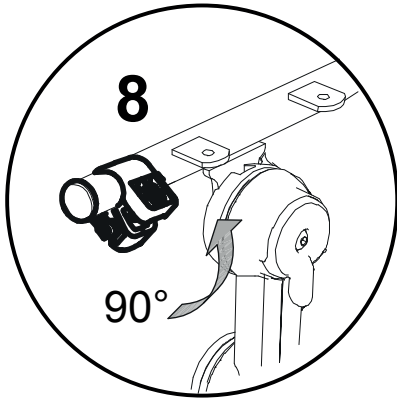


5) HIT THE TRAY LOCK WITH THE RUBBER HAMMER SLIGHTLY SO THAT IS INSERTS INTO THE TUBE SLOT

6) PULL THE STOPPER OUT USING A SCREWDRIVER

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

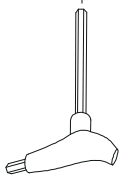
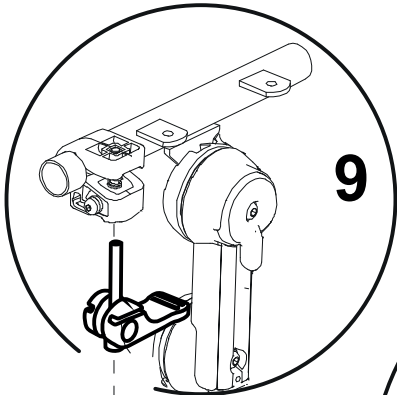




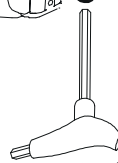
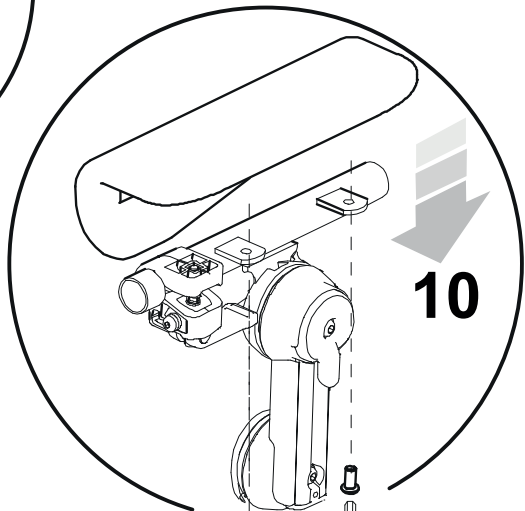
8) TURN THE LOCKING PART OF THE TRY OUTWARDS

9) INSERT THE GREEN LEVER AND TIGHTEN THE SCREW

10) REASSEMBLE THE ARMREST



Supplied
wrench

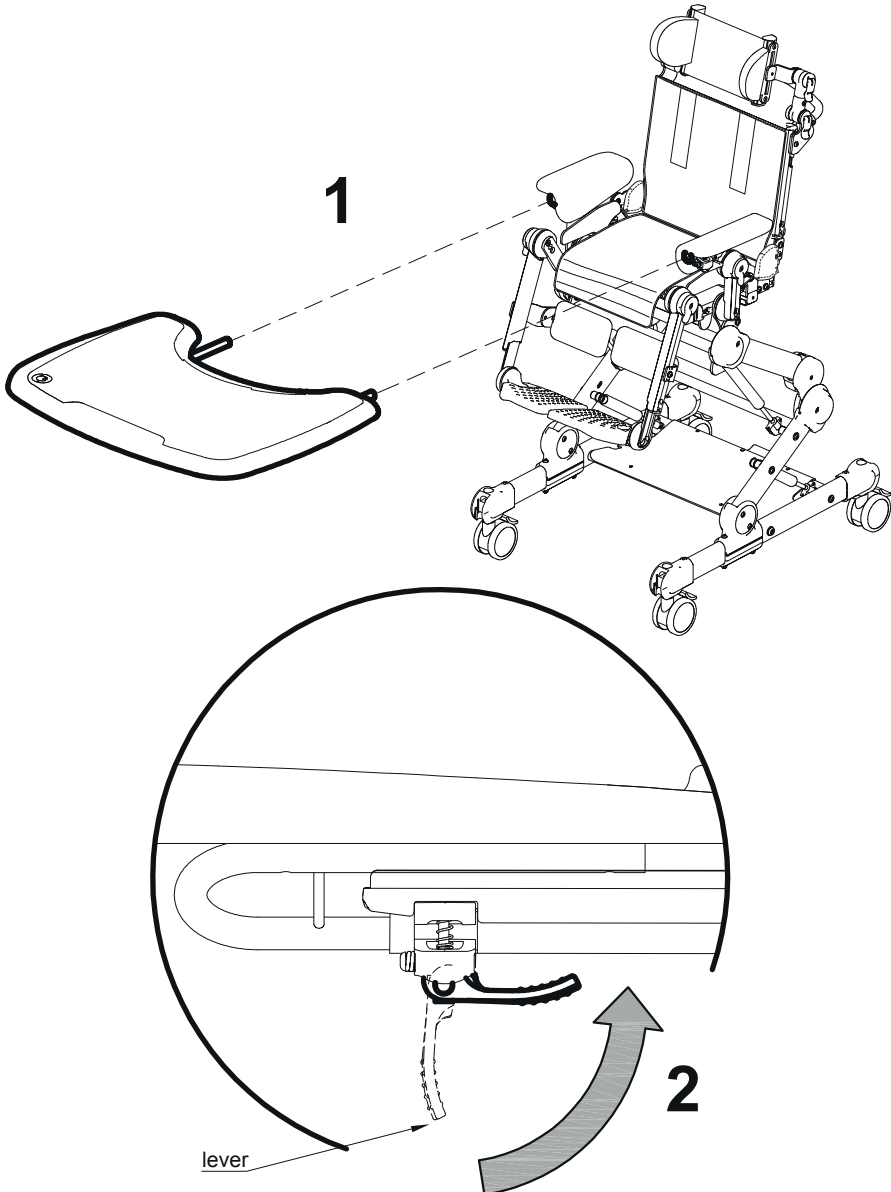


Supplied
wrench



B. INSERTION AND FIXING

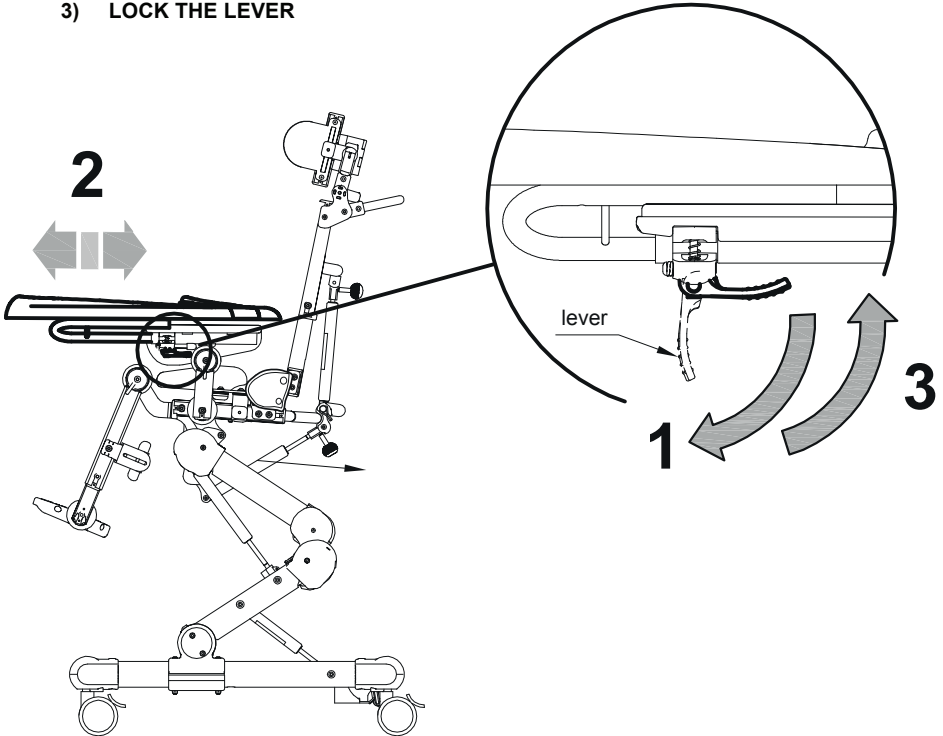
- 1) INSERT THE TRY SO THAT THE TOP IS HORIZONTAL
- 2) LOCK THE INDICATED LEVER





C. DEPTH ADJUSTMENT

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

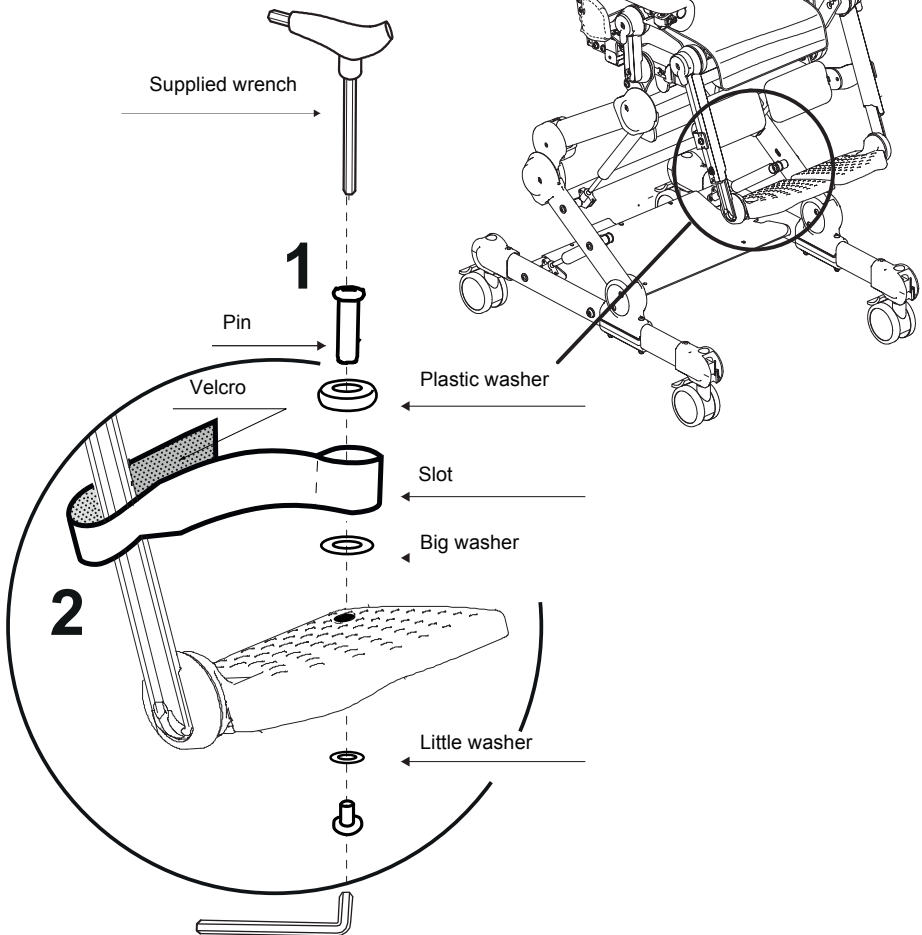


WARNING!
BEFORE CHANGING THE INCLINATION OF THE SEAT (TILT-IN-SPACE) MAKE SURE THERE ARE NO HOT OBJECTS OR LIQUID CONTAINERS ON THE TRAY WICH, BY SPILLING, COULD CAUSE DAMAGE OR BURN TO THE USER.



HEEL RESTS 960

- 1) TIGHTEN THE PIN ON THE FOOTREST BY INSERTING THE SLOT BETWEEN THE TWO WASHERS
- 2) PLACE THE VELCRO STRAP ON THE FOOTREST



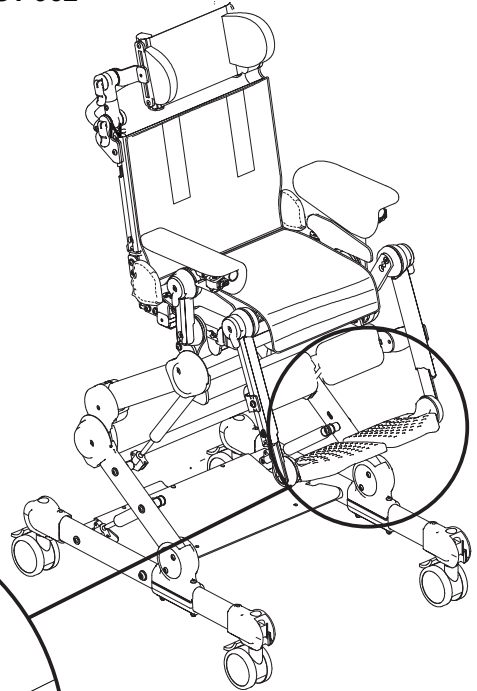


FRONT FOOT STRAPS AND HEEL REST 962

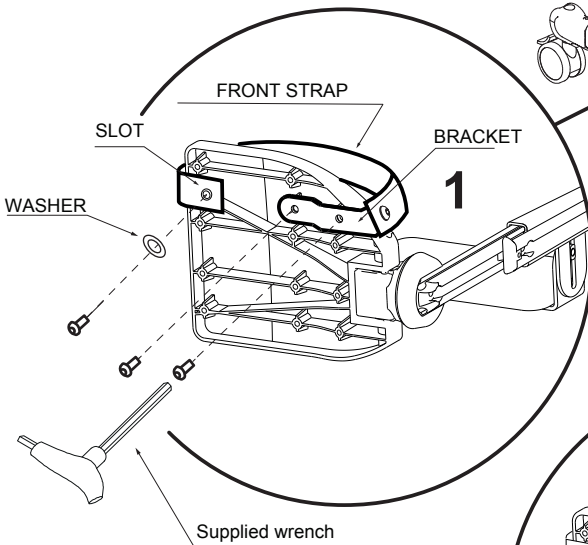
Adjustable by velcro

ASSEMBLE THE HEEL RESTS AS ON THE PREVIOUS PAGE

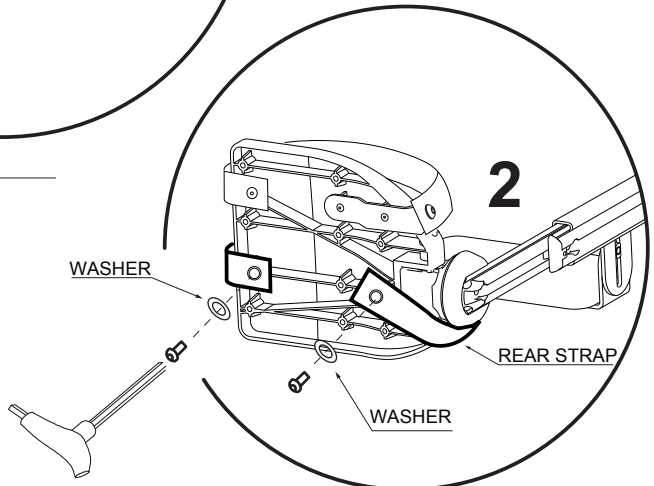
- 1) **ASSEMBLE THE FRONT STRAP WITH THE BRACKET ON THE OUTSIDE OF THE FOOTREST AND THE SLOT ON THE INSIDE**
- 2) **FIX THE REAR STRAP**



BELOW VIEW



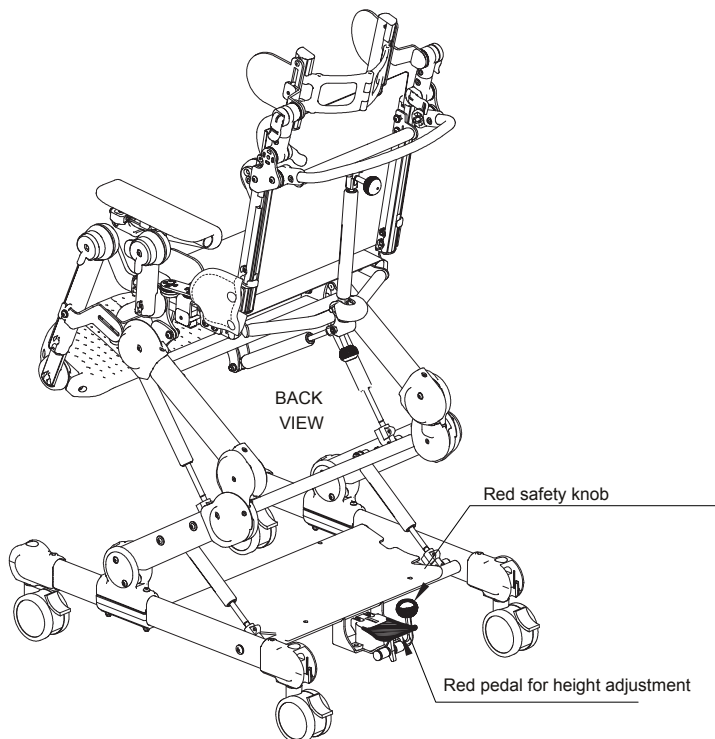
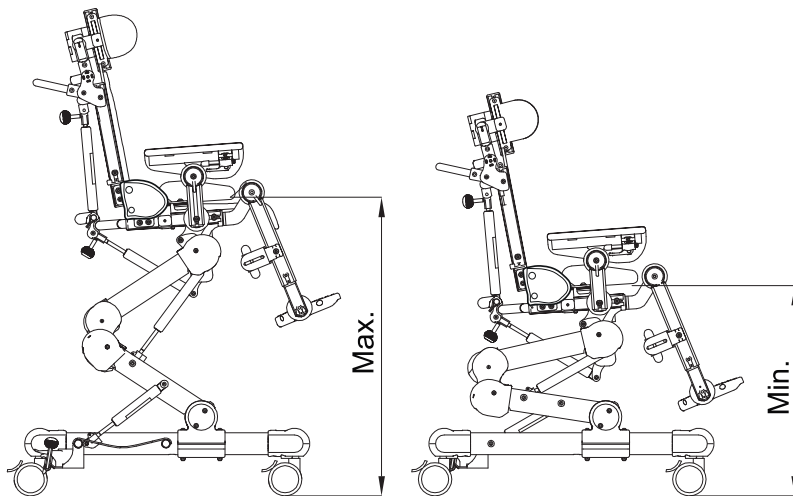
BELOW VIEW





5.5 INSTRUCTIONS FOR DAILY USE by the family, or care giver

HEIGHT ADJUSTMENT

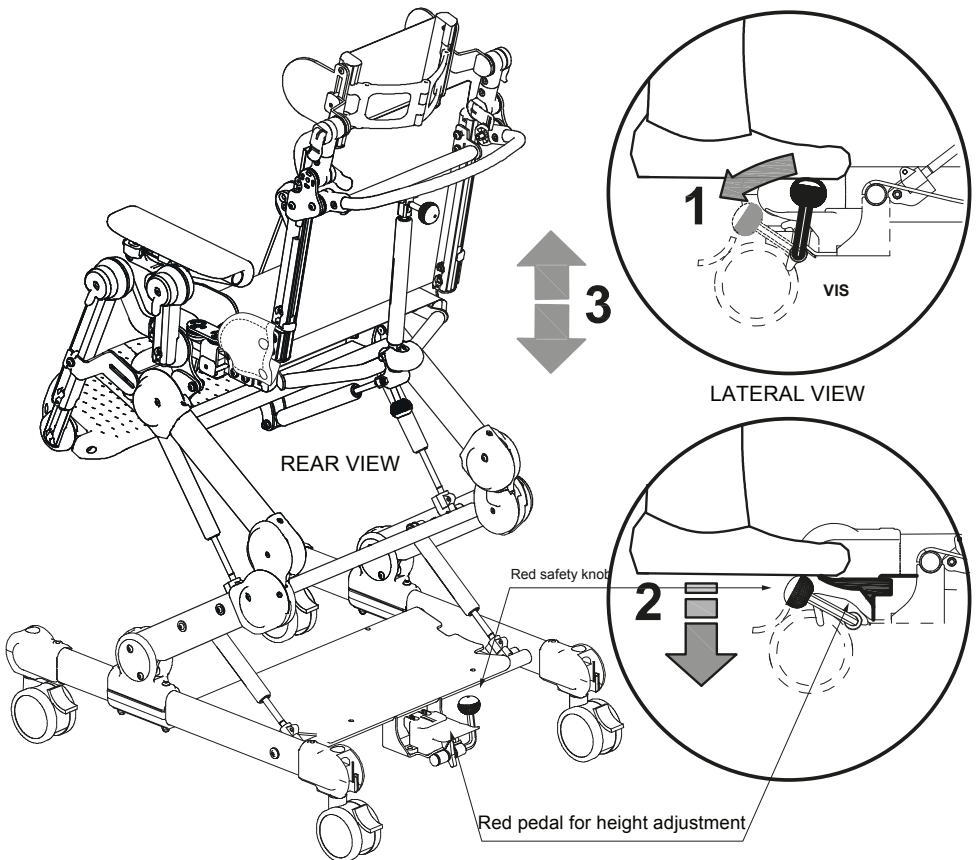




WE RECOMMEND ADJUSTING THE HEIGHT WITH THE USER SITTING ON THE MEDICAL DEVICE
BECAUSE THE ADJUSTMENT IS MANAGED BY A GAS SPRING THAT SUPPORTS THE WEIGHT

(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**



SEAT, BACKREST, LEG REST AND ARMRESTS TILT ADJUSTMENT

CAN BE CARRIED OUT BY THE FAMILY OR THE CARE GIVER AT THE DIRECTION OF THE HEALTH PROFESSIONAL.

see § 5.3



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	<ul style="list-style-type: none">Remove any dust and dirt from the wheels to maintain smoothness and braking efficiency.Check that the wheels turn freely. <p>If unsuccessful, contact the health professional who provided it or distributor for replacement with an original component.</p>	functional/visual test
BRAKES	<ul style="list-style-type: none">Check the efficiency of the braking system and the operation of the relative mechanisms as reported in the user manual. <p>If unsuccessful, contact the health professional who provided it, for replacement with an original component.</p>	functional test
BOLTS / SCREWS	<ul style="list-style-type: none">Check the tightness of all bolts and screws; especially those on the hinges of the backrest recline and seat basculation <p>Tighten them if loose.</p>	Visual/ tools
BACKREST / SEAT	<ul style="list-style-type: none">Check for any visible damage or deterioration of the SUPPORTING UPHOLSTERY. <p>If unsuccessful, discontinue use and contact the health professional who provided it, for replacement with an original component.</p>	visual
ADJUSTING MECHANISMS	<ul style="list-style-type: none">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



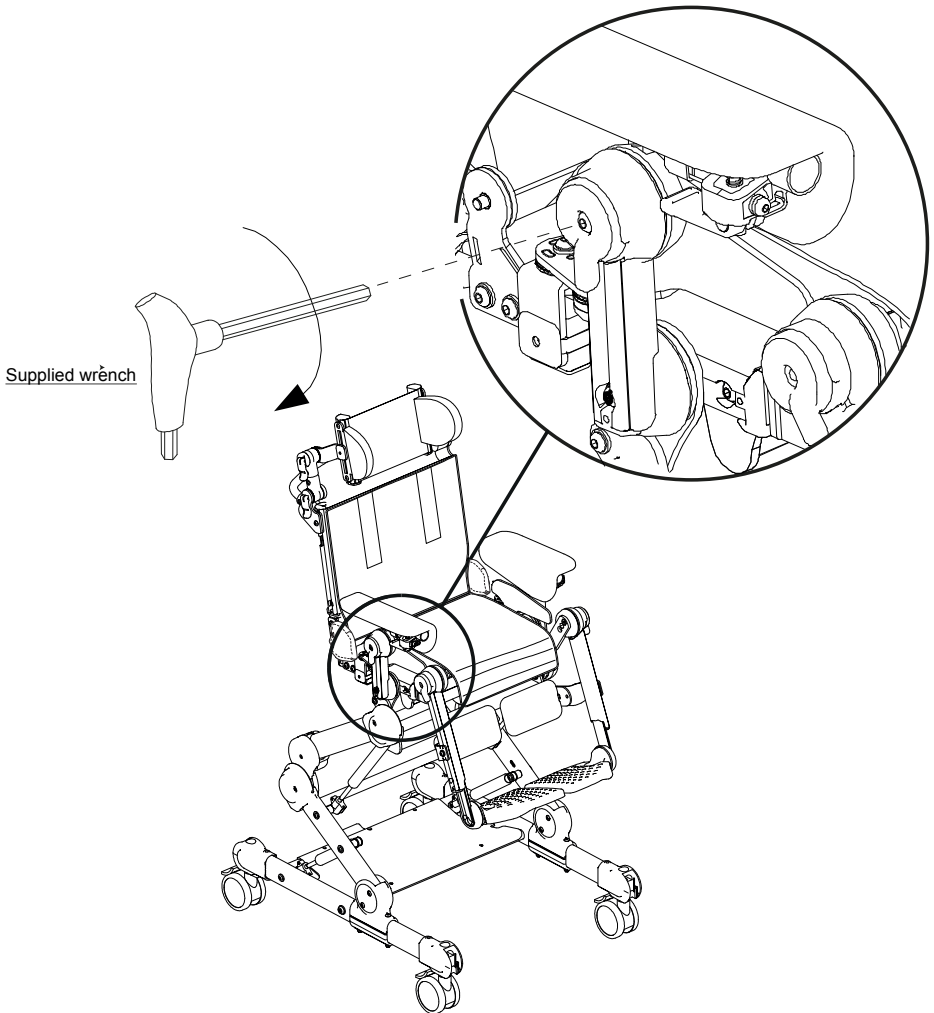
	<ul style="list-style-type: none">▪ Check the tightness of the adjustment mechanisms. <p>If unsuccessful, contact the health professional who provided it, or distributor for replacement with an original component.</p> <p>In case you have encountered an inefficiency in TIGHTENING of the ADJUSTMENT LOCKING LEVERS of the ARMREST, LEGREST, HEADREST, TABLE, discontinue use and contact the health professional who provided it, to register the levers as described in the following § "ADJUSTMENT LOCKING LEVERS".</p>	
PRODUCT INTEGRITY	<ul style="list-style-type: none">▪ 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. <p>If unsuccessful, contact your health professional who provided it, for replacement with an original component.</p>	Visual/ tools



REGISTRATION OF ADJUSTMENT LOCKING LEVER

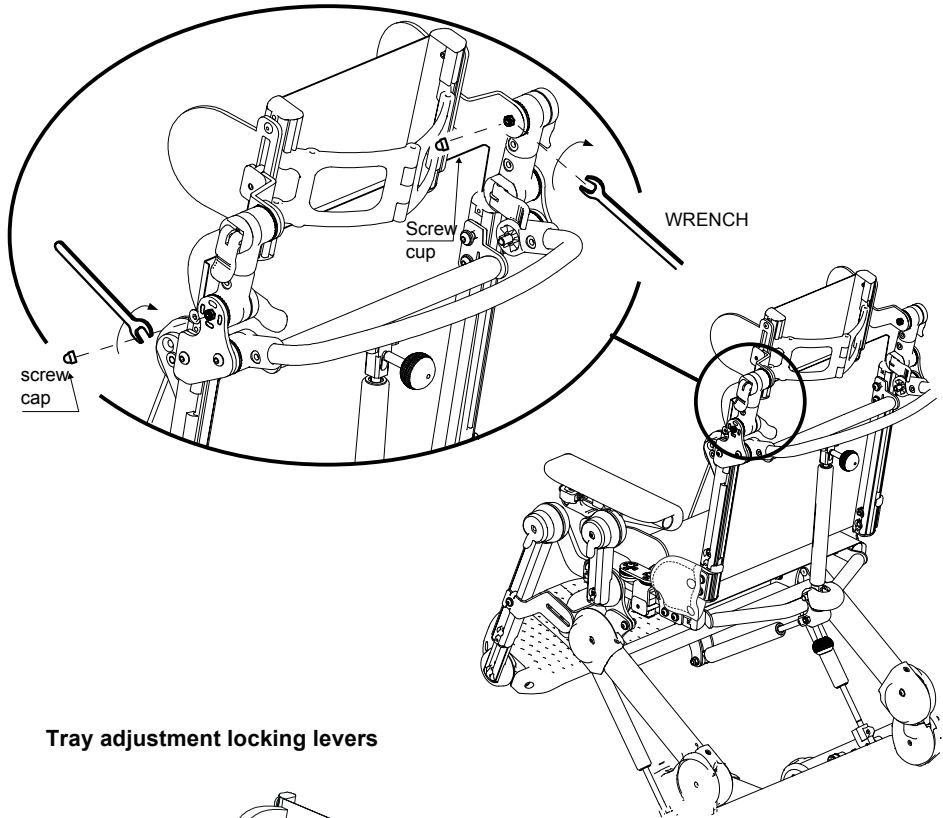
Adjust nuts and screws in small increments until proper tightness is restored

Armrest and leg rest adjustment locking levers

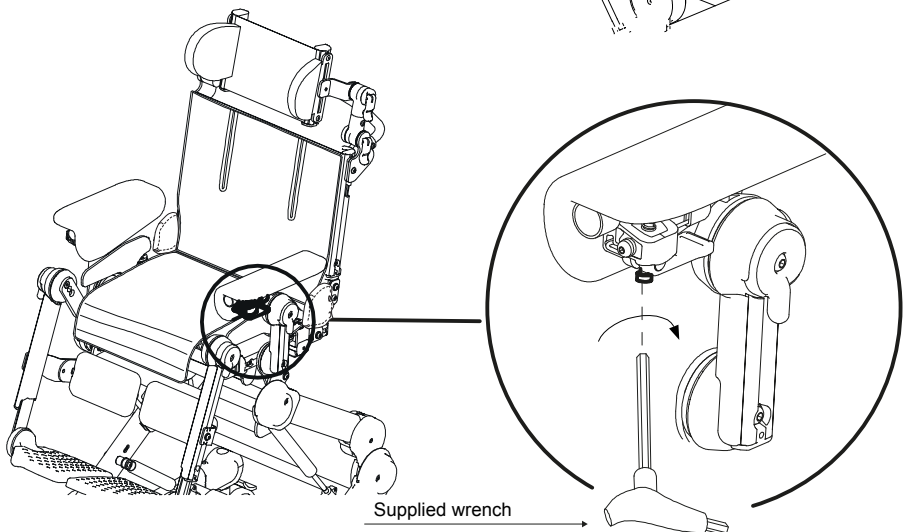




Headrest adjustment locking lever



Tray adjustment locking levers





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

 • MADE IN ITALY SINCE 1980 •	DICHIARAZIONE DI CONFORMITÀ "UE" PER DISPOSITIVI MEDICI EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES	Rev. 0 Date 13/10/2022
---	---	---

Nome Fabbricante:

Manufacturer's Name:

ORMESA s.r.l

Indirizzo Fabbricante:

Manufacturer's Address:

Via A. Da Sangallo, 1 | 06034 Foligno (PG) – ITALY

Certificazioni Fabbricante

(Manufacturer 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 ADAPTIVE SEATING

Codice DEL Dispositivo:

Product code:

Allegato 1 alla dich UE

Attachment 1 to the UE declaration

Destinazione d'uso:

Intended purpose:

Classificazione di Rischio:

Risk Classification:

Classe: / Class: I

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:

Nessuna

None

Norme Armonizzate e norme tecniche utilizzate

Harmonized and Technical Standards applied

Allegato 2 alla dich UE

Attachment 1 to the UE declaration

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, 08/06/2022

Firma / Signature: Chiara Menichini (Legale Rappresentante)



Ormesa srl Via delle Industrie, 6/8 - Z.I. Sant'Eraclio - 06034 FOLIGNO (PG) ITALY
P.I. IT 00574020541 CCIAA Perugia 119215 Iscr. Trib. Perugia 11907
Tel. + 39 0742 22927 Fax +39 0742 22637 info@ormesa.com

www.ormesa.com

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



DISTRIBUTOR FOR USA: INNOVATION IN MOTION
201 Growth Parkway ANGOLA, IN 46703
P 1.260.665.2769
F 1.260.665.3047
Toll free number 800-327-0681
E-mail: iim@mobility-usa.com

Health Professional

***As Manufacturer, ORMESA srl reserves the right to make any modifications it
deems appropriate to the data in this user and maintenance manual***
