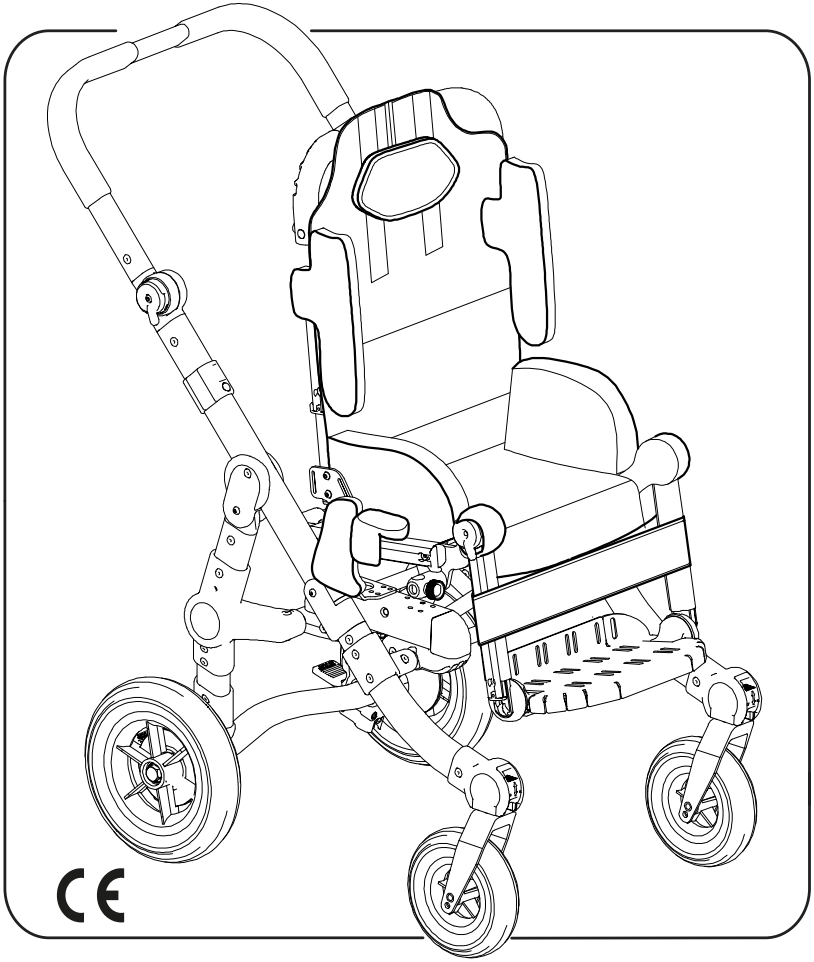
GRILLO

POSTURAL SYSTEM

Cod. 220733 - 26.01.24



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 Postural System**, a medical device designed and manufactured by ORMESA Srl, an **ISO 13485** certified company.

GRILLO Postural System 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 Postural System,** 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

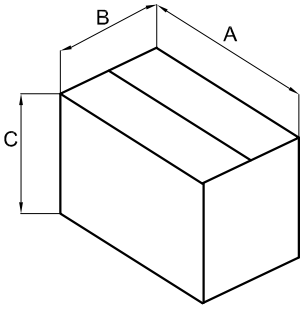
For service on this device contact only the Health Professional who supplied it to you or contact **ORMESA** directly at 0742 22927; by fax at 0742 22637; or by e-mail at info@ormesa.com.

1.3 CONTACT DETAILS FOR INCIDENT OR NEAR INCIDENT

Contact info@ormesa.com or the orthopaedic workshop that supplied the aid, to take the necessary actions in accordance with Regulation (EU) 745/2017, annex I, GSPR 23.4.z)

1.4 PACKAGING INFORMATION. UNPACKING INSTRUCTIONS AND SUPPLY COMPOSITION

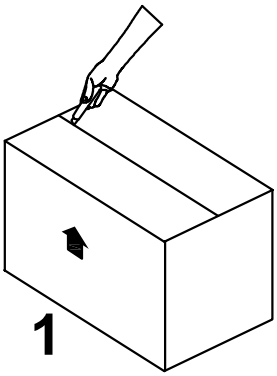
PACKAGING INFORMATION

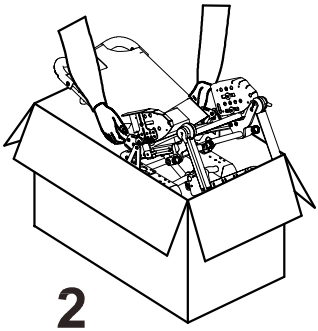


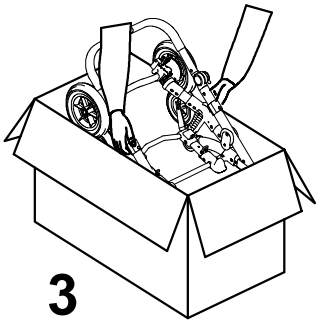
GRILLO PS	A cm	B cm	C cm	VOLUME m³	WEIGHT kg
SIZE MINI	95	65	48	0.296	24
SIZE SMALL	95	65	48	0.296	25
SIZE MEDIUM	75	65	103	0.502	28

HOW TO TAKE GRILLO POSTURAL SYSTEM OUT OF THE BOX

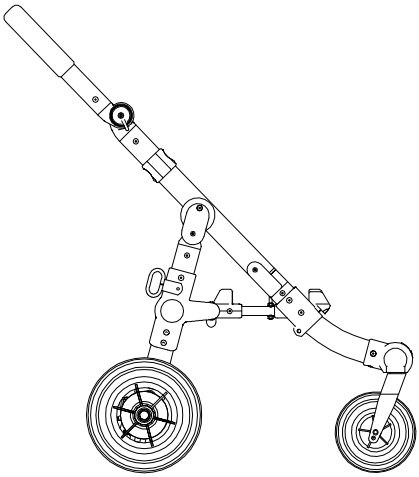
1) **CAUTION! CUT WITHOUT PRESSING TOOT HARD WITH THE BLADE SO AS NOT TO DAMAGE THE CONTENTS OF THE BOX. TAKE THE ACCESSORIES OUT OF THE BOX**
2) **REMOVE FIRST THE SEAT FROM THE BOX**
3) **REMOVE THEN THE FRAME**



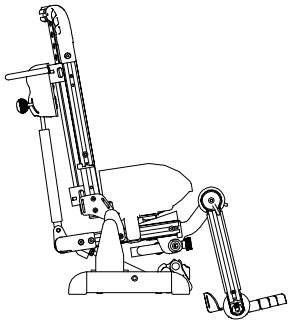




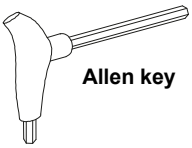
SUPPLY COMPOSITION



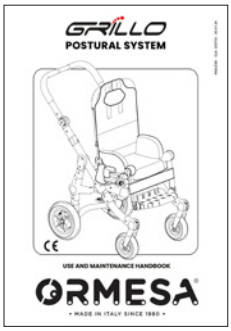
Grillo Postural System - External Base



Grillo Postural System - Seat Unit



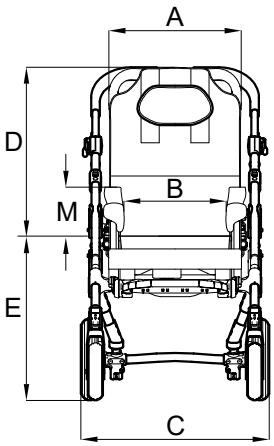
Allen key

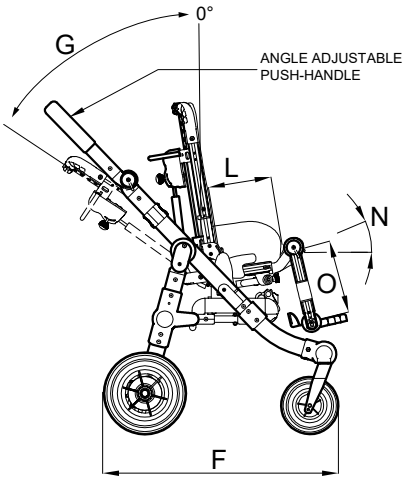


Use and maintenance handbook

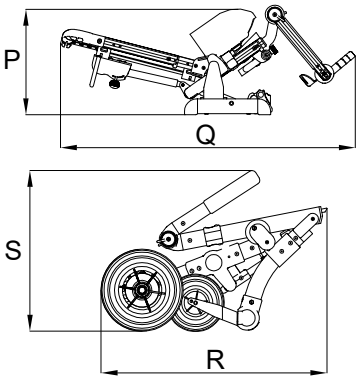
1.5 MECHANICAL AND DIMENSIONAL CHARACTERISTICS

Measures in cm, weight in kg

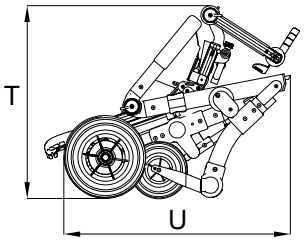




STROLLER CLOSED WITH SEAT REMOVED



STROLLER CLOSED WITH SEAT ATTACHED



User height size mini cm 75 - 100
User height size S cm 90 -120
User height size M cm 115 - 140

SIZE	A	B	C	D	E	F	G	L	M	N	O	P	Q	R
MINI	31	16-26	57	42-52	51	72	45°	16-26	11,5-14	30°	15-25	31	65	69
SMALL	37	20-30	57	48-62	52	72	45°	20-30	13-16,5	30°	21-31	33	74	69
MEDIUM	43	25-35	63	60-75	55	81	45°	28-40	16-20	25°	26-38*	34	88	70

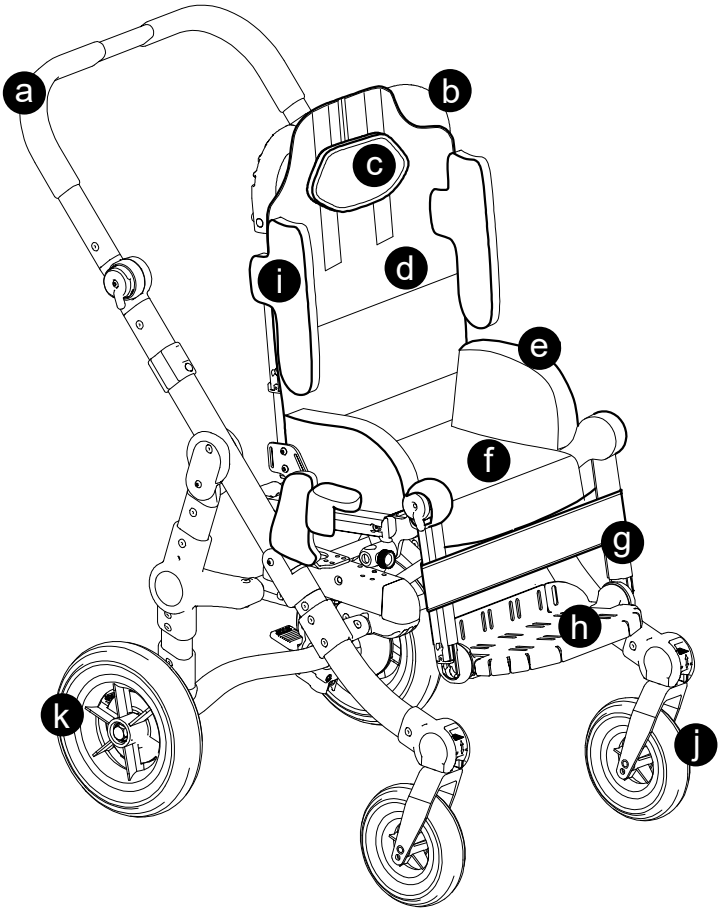
*26-35 mother facing stroller

SIZE	S	T	U	FRAME WEIGHT	SEAT WEIGHT	TOTAL WEIGHT
MINI	49	57	80	kg 9,8	kg 9,2	kg 19
SMALL	49	57	80	kg 9,8	kg 10,3	kg 20,1
MEDIUM	58	66	88	kg 10,8	kg 12,4	kg 23,2

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

1.6 PRODUCT PARTS LEGEND

a) **HANDLEBAR**
b) **BACKREST**
c) **HEADREST**
d) **UPHOLSTERY**
e) **ARMRESTS**
f) **SEAT**
g) **LEGREST**
h) **FOOTREST**
i) **FRAME**
j) **FRONT WHEEL WITH DIRECTION LOCKS**
k) **REAR WHEELS WITH PEDAL BRAKE**
l) **SHOULDERS LATERAL SUPPORT**



1.7 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

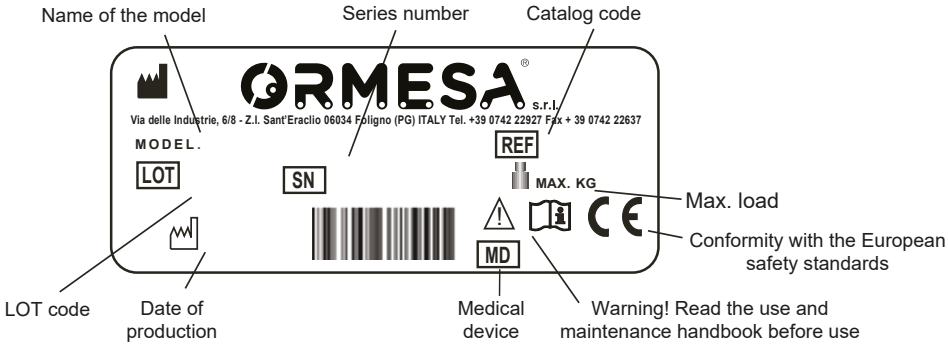
Do not tumble dry

Do not disperse the product in the environment after use

Dry horizontally

1.8 IDENTIFICATION PLATE

THE CE MARKING CERTIFIES GRILLO POSTURAL SYSTEM 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 13485:2021	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 14971:2022	Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici *Medical devices - Application of risk management to medical devices*
UNI CEI EN ISO 15223-1:2021	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 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*
UNI EN 12183:2022	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*

INTERNATIONAL STANDARDS

UNI CEI EN ISO 20417:2021	Informazioni fornite dal fabbricante di dispositivi medici *Information provided by the medical device manufacturer*
UNI EN ISO 9999:2022	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*
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 7176-3:2012	Sedie a rotelle – parte 3. determinazione della efficacia dei freni *Wheelchairs - Part 3: Determination of effectiveness of brakes*
ISO 7176-5:2008	Sedie a rotelle – parte 5. determinazione delle dimensioni complessive, massa e ingombro di sterzata *Wheelchairs - part 5: determination of overall dimensions, mass and turning space*
ISO 7176-7:1998	Sedie a rotelle – parte 7. determinazione delle misurazioni di seduta e delle dimensioni delle ruote *Wheelchairs- part 7: measurement of seating and wheel dimensions*

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 ofr information disclosure, documentation and labelling*
ISO 7176-22:2014	Sedie a rotelle – parte 22. Procedure *Wheelchairs - part 22: set-up procedures*

2.3 WARRANTY CONDITIONS

ORMESA warrants 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 Postural System 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 POSTURAL SYSTEM is a MECHANICAL MEDICAL DEVICE:**

⚠ **THE USER has to perform REGULAR MAINTENANCE and CLEANING following the instructions shown in the "Maintenance" chapter on page 64-65-66-67-68-69 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 shownon page 64-65-66-67-68-69 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 POSTURAL SYSTEM 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 POSTURAL SYSTEM 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.**

- **Base 869 was designed for outdoor use. Base 856 is only intended for indoor use.**

- **The direction locks on the front wheels of outdoor bases were exclusively designed to use the aid on rough terrain: in all other cases, they must be disengaged to avoid difficulty in maneuvering the device**

- **The upholstery is flame retardant (FR) according to EN 1021-1: 1: 2014 - and EN 1021-2: 2014.**

- **Oeko-Tex Certificate: for all fabrics that are in direct contact with the skin, to guarantee quality and safety for health.**

3.4 REASONABLY FORESEEABLE MISUSE

- **DO NOT USE THE MEDICAL DEVICE WITH SUBJECTS WITH DIMENSIONS GREATER THAN** those indicated on pag. 6.
- **DO NOT USE THE MEDICAL DEVICE ON ACCIDENTED GROUND NEAR STRONG SLOPES OR STAIRS.**
- **NEVER LEAVE THE USER ALONE** in the medical device.
- **DO NOT ALLOW CHILDREN TO USE THE PRODUCT, NOT EVEN FOR PLAYING**
- **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 ATTACH WEIGHTS TO THE PUSH HANDLE Of THE PUSHCHAIR SO AS NOT TO PUT AT RISK ITS STABILITY DURING USE**
- **NEVER LEAVE THE PRODUCT PARKED ON A SLOPING SURFACE**
- **DO NOT LET ANYONE CLIMB ONTO THE FOOTREST OR RIDE ON THE BACK OF THE OUTDOOR BASE**
- **DO NOT LIFT THE PRODUCT BY THE LEG SUPPORT FRAME OR FOOTREST (i.e. TO CLIMB OVER OBSTACLE)**
- **DO NOT USE THE PRODUCT TO CLIMB OR DESCEND STAIRS: ITS STRUCTURE WAS NOT DESIGNED FOR THIS PURPOSE**
- **NEVER LEAVE THE STROLLER PARKED FOR A LONG TIME IN DIRECT SUNLIGHT OR NEAR SOURCES OF HEAT: THIS WILL AVOID OVERHEATING THE DEVICE AND DISCOLOURING THE UPHOLSTERY**
- **DO NOT CLIMB PAVEMENTS OR STEPS WITH JUST THE STROLLER'S SIDE WHEELS (FRONT AND BACK) OF THE 869 BASE, BECAUSE THEY COULD TIP OVER**
- **When the SEAT is COMPLETELY TILTED BACKWARDS and the BACK is COMPLETELY RECLINED, DO NOT CLIMB OVER OBSTACLES OR STEEP SLOPES that, SINCE THEY COULD EXCEED 12°, COULD CAUSE THE STROLLER TO TIP OVER**
- **DO NOT USE THE PRODUCT IF PARTS ARE MISSING OR DAMAGED.**

3.5 CONTRAINDICATIONS AND SIDE EFFECTS

CONTRAINDICATIONS: There are no contraindications for using the device.
SIDE EFFECTS: As a consequence of a sitting posture maintained for TOO LONG without variations during the day, redness, muscle contractures and joint and spinal deformities may rarely occur. For these reasons GRILLO POSTURAL SYSTEM is equipped with two different gas springs to allow the seat inclination and backrest recline to be changed easily and safely

3.6 OPERATING ENVIRONMENTAL CONDITIONS

- **THE OPERATING ENVIRONMENT (temperature from -20° to + 40°, humidity of 5% to 100%) 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 64-65-66-67-68-69 AND THE WARNINGS ON PAGE 64.**

- **NEVER LEAVE THE STROLLER PARKED FOR A LONG TIME UNDER DIRECT SUNLIGHT OR NEAR SOURCES OF HEAT: this will avoid overheating the device and discoloring 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.**
- **TRANSPORT FACTORS such as temperature and humidity can damage the product the rehab pushchair. The manufacturer recommends the following condition:**
    - **temperatures between -20 ° C and + 75 ° C**
    - **humidity of 5 to 100%**

3.8 PRE-INSTALLATION/INSTALLATION AND PUTTING INTO SERVICE

GRILLO POSTURAL SYSTEM does not require installation.
For putting into service (including the possible insertion of postural components) **it requires configuration and adjustment exclusively by a health professional**.

4. DEVICE DESCRIPTION

4.1 INTENDED USE OF THE MEDICAL DEVICE

GRILLO POSTURAL SYSTEM is a postural sitting unit intended for children with disabilities (Infantile Cerebral Palsy, degenerative pathologies with functional impairments, syndromic pathologies with impairments functional) **easily adaptable thanks to its modularity.**

Suitable for users who have little or no control of the trunk and head and needing appropriate stabilization a pelvic level to be able to assume, in situations where residual functionality allows it, the more appropriate posture in different everyday contexts, both internally and externally.

The device must be prescribed by a specialistic doctor and must be configured and adjusted by a rehabilitation professional according to the laws in the user's place of residence.

4.2 MAINS COMPONENTS/AVAILABLE VERSIONS

GRILLO POSTURAL SYSTEM 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 18.

4.3 DESCRIPTION OF THE MEDICAL DEVICE

SEAT UNIT with SERVO-ASSISTED TILTING AND RECLINING SYSTEM

Tilting seat unit thanks to a gas spring. It is removable with practical, safe and error-proof lock/ unlock system, it is quickly reversible, facing-parents (outdoor base) and it is precisely and continuously adjustable in depth and also in width thanks to multi-adjustable padded supports

- The seat unit has an **extremely breathable upholstery**, comfortable, durable, **easy to wash and quick-drying,** consisting of:

  - Non-removable load-bearing upholstery: the essential design texture allows excellent breathability **that reduces sweating and bacteria formation.** The composition of the fabric allows **easy sanitation**. It maintains its performance even at high loads, it is fireproof according to fire reaction Class 1 (non-flammable combustible materials) according to M. dated 26th. June 1984 and subsequent amendments.

  - Removable cover composed of breathable material and **highly innovative** both internally and externally. The inner fabric is three-dimensional, lightweight and ensures high air circulation. It allows an **optimal weight distribution and excellent comfort.** The external fabric is also extremely abrasion resistant. Fire retardant according to EN 1021-1:2014 and EN 1021-2:2014. Washable at 40° C.

  - **Oeko-Tex Certificate**: for all fabrics that are in direct contact with the skin, to guarantee quality and safety for health.

- **Reclining backrest** by gas spring with comfortable, precise and continuous adjustment, also adjustable in height. The backrest is shaped with a restrained shape and thanks to the durable upholstery and to the aluminum bars, it ensures a greater seating comfort even when the seat unit is tilted and/or the backrest reclined .

- **Headrest** included into the backrest so that the child always has support when the seat unit is tilted and/or the backrest is reclined.

- **Multiadjustable armrests**

- **Multiadjustable pelvic supports**, adjustable in width, rotation and depth, to follow the growth and conformation of the child.

- **Leg rest** adjustable in height and tilt with physiological fulcrum that makes the adjustment comfortable. Adjustable in depth with the seat.

- **Heel rests and footplate**

OUTDOOR BASE, reversible facing-parents

- **Compact and lightweight frame** with the new innovative Ormesa Design, easily maneuverable and foldable, with tilting front handle. It adapts to the height of the mother and reduces the encumbrance in depth.

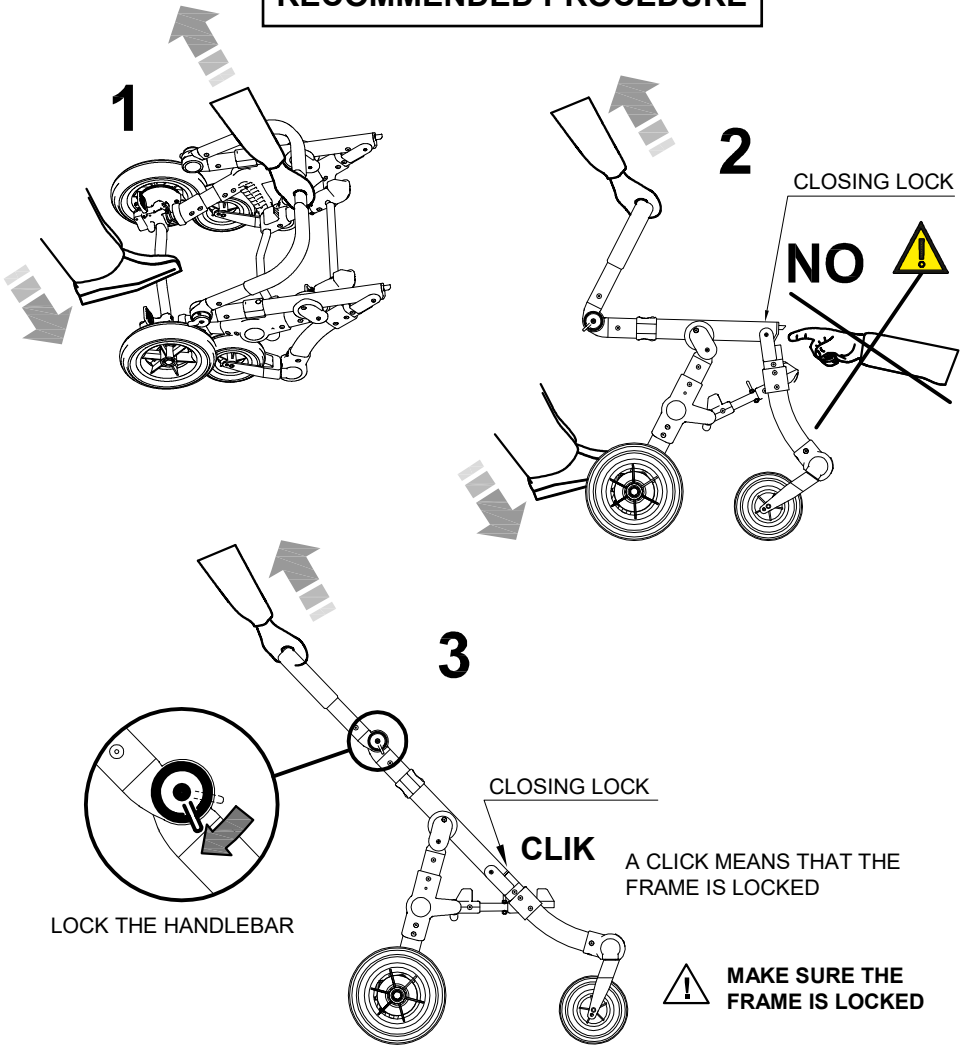
- Solid, light and sliding **wheels** on all surfaces: 17 cm. front wheels with directional locks, 30 cm. rear wheels with shock absorbers and independent drum parking brakes.

5. OPERATING INSTRUCTIONS

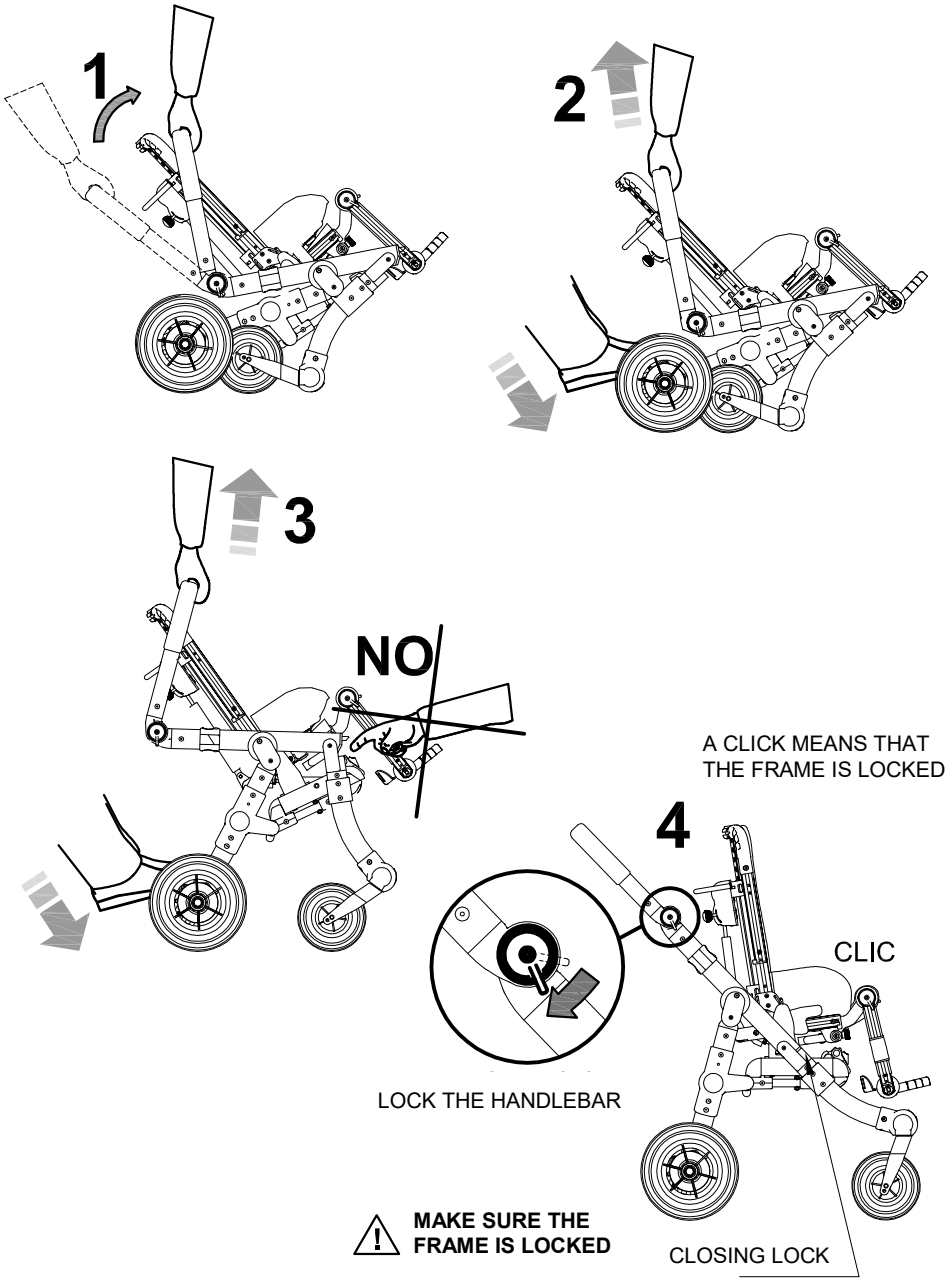
5.1 OPENING THE STROLLER

a) WITHOUT THE SEAT

RECOMMENDED PROCEDURE

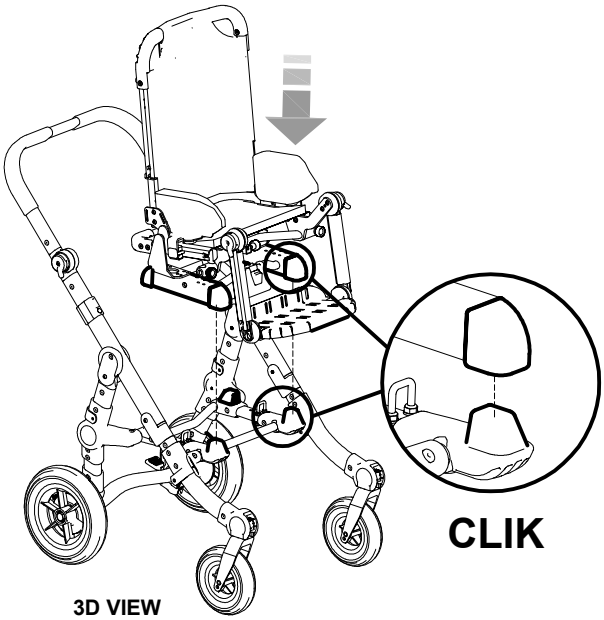


b) WITH THE SEAT ATTACHED

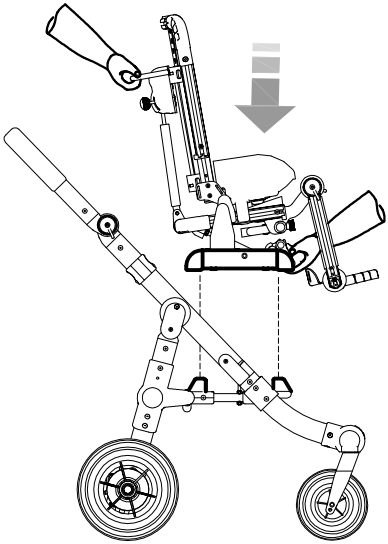


5.2 ADJUSTMENT AND CONFIGURATION OF THE MEDICAL DEVICE by the health professional

HOW TO ATTACH THE SEAT TO THE FRAME



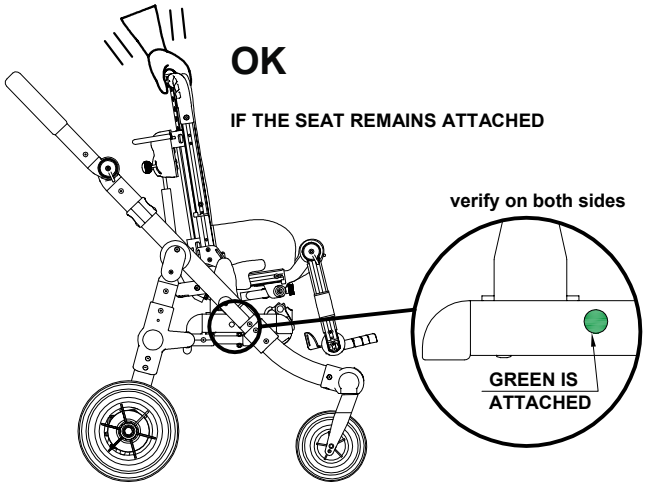
3D VIEW

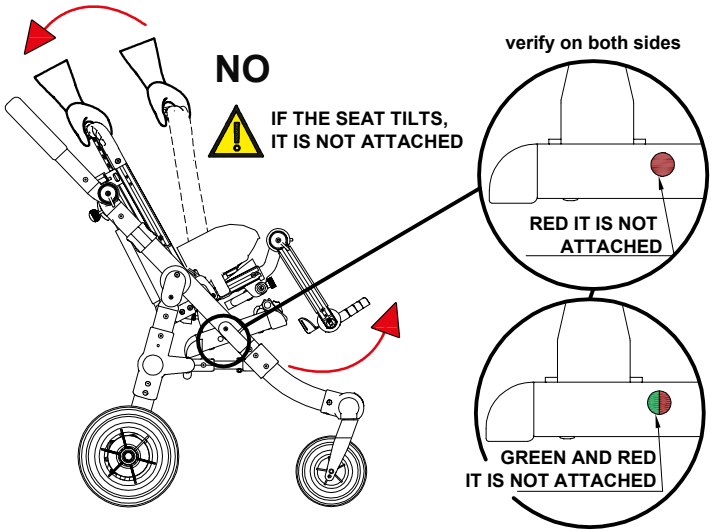


⚠ MAKE SURE THE FRAME IS LOCKED

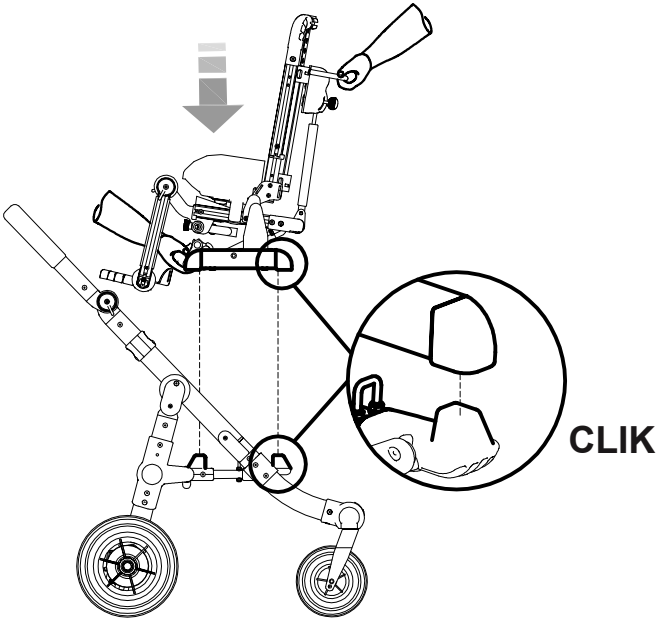
LATERAL VIEW

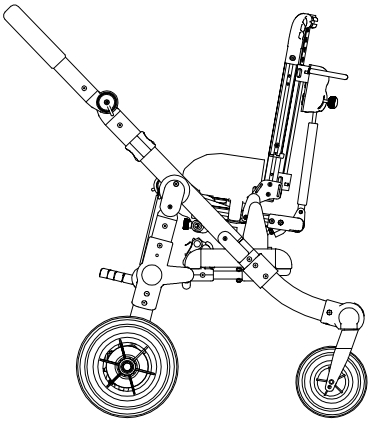
ATTENTION! BEFORE POSITIONING THE CHILD, MAKE SURE THAT THE SEAT UNIT IS ATTACHED TO THE FRAME





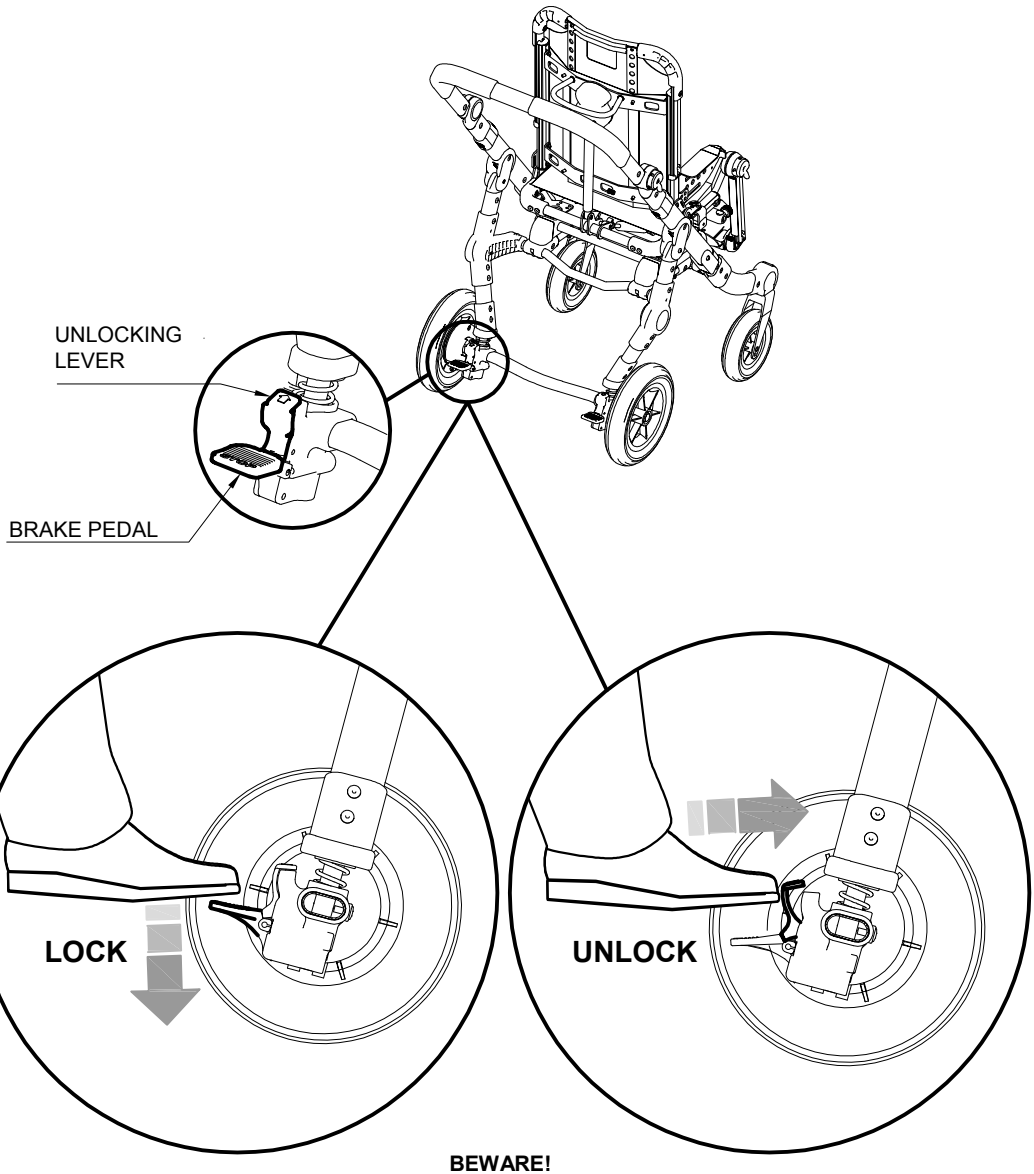
HOW TO ATTACH THE SEAT SO THAT THE CHILD FACES HIS MOTHER





MAKE SURE THE FRAME IS LOCKED

BRAKING



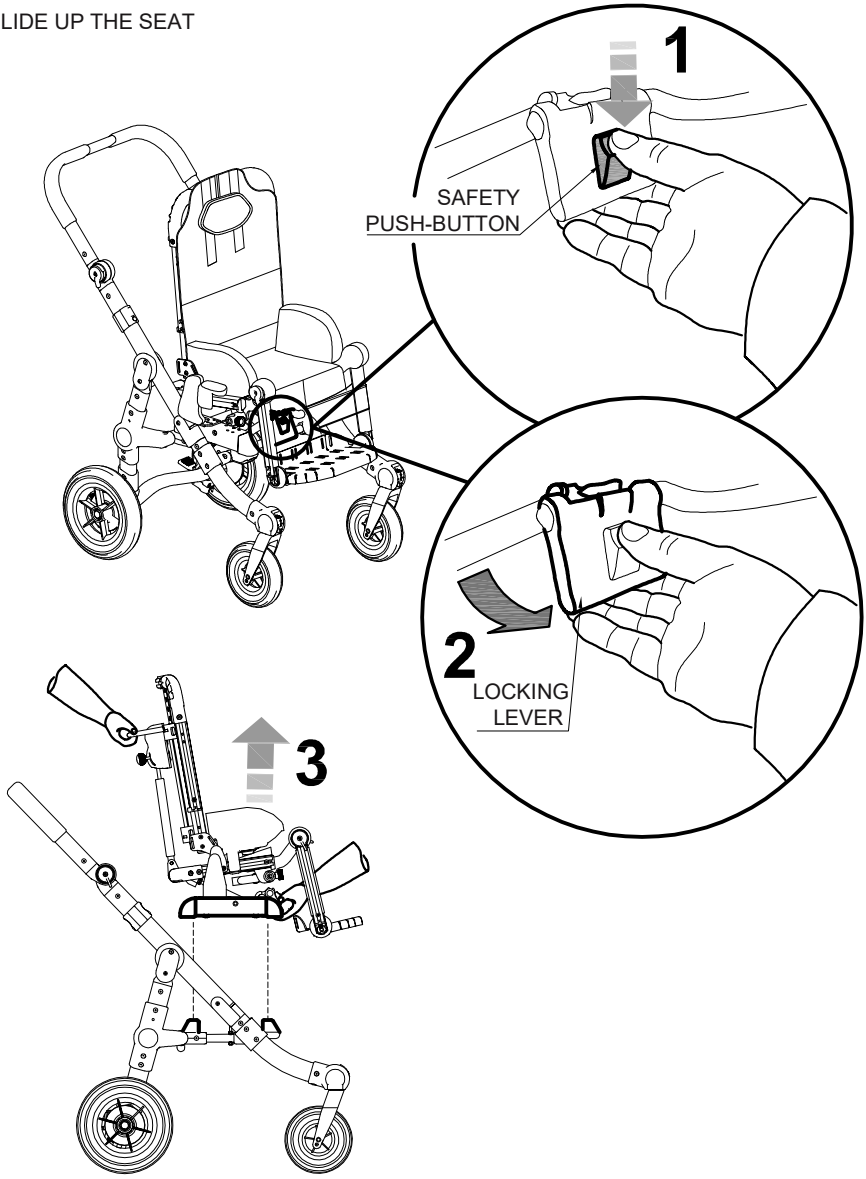
BEWARE!
BEFORE PLACING OR REMOVING THE CHILD FROM GRILLO POSTURAL SYSTEM AS AND BEFORE ANY ADJUSTMENT, **IT IS NECESSARY TO BRAKE THE AID.**

HOW TO DETACH THE SEAT FROM THE FRAME

1- PUSH THE SAFETY BUTTON DOWN WITH YOUR THUMB

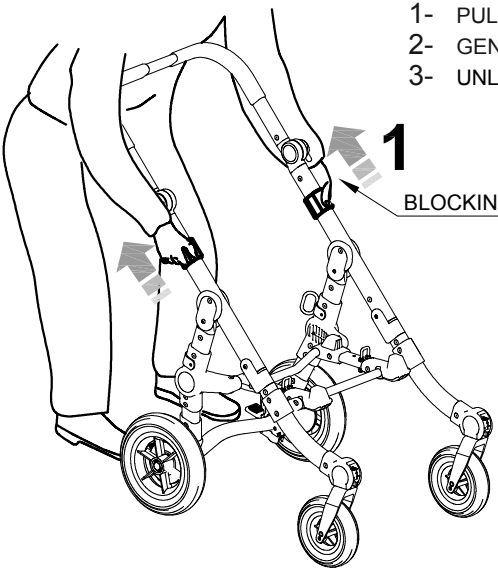
2- PULL THE LOCKING LEVER

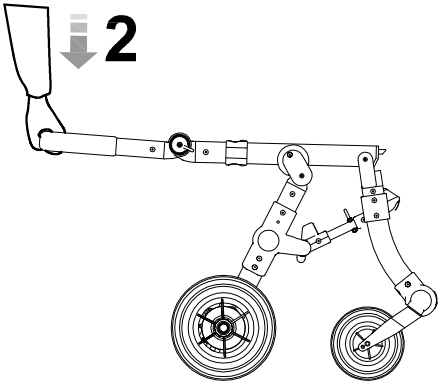
3- SLIDE UP THE SEAT

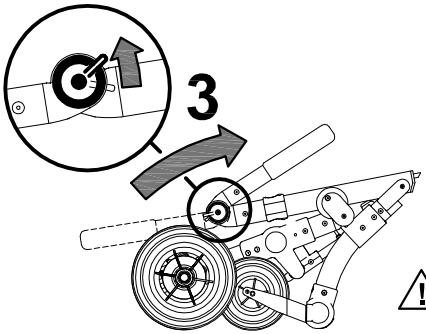


FOLDING THE BASE

1- PULL THE LOCKS WITH BOTH HANDS
2- GENTLY PULL THE HANDLE DOWNWARD
3- UNLOCK THE HANDLEBAR AND ROTATE IT



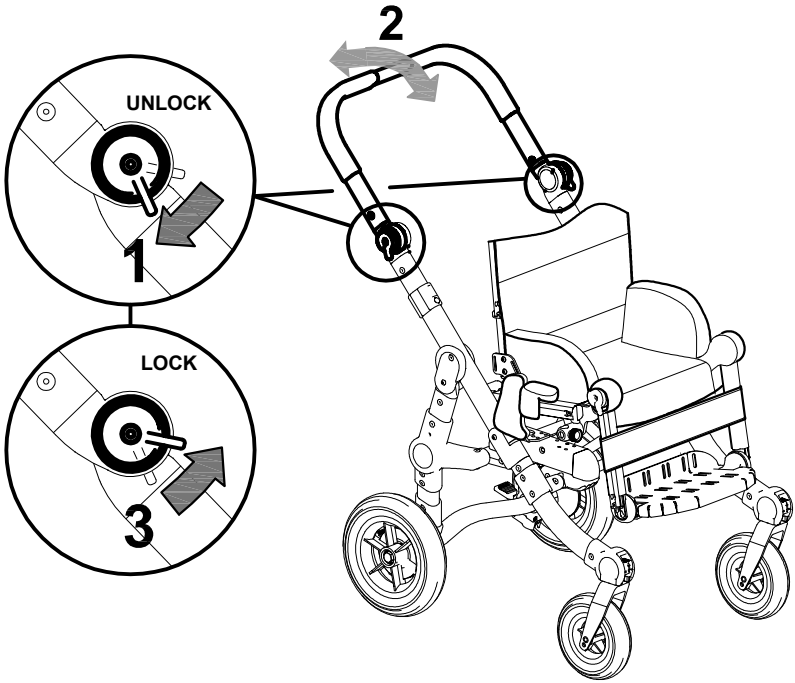




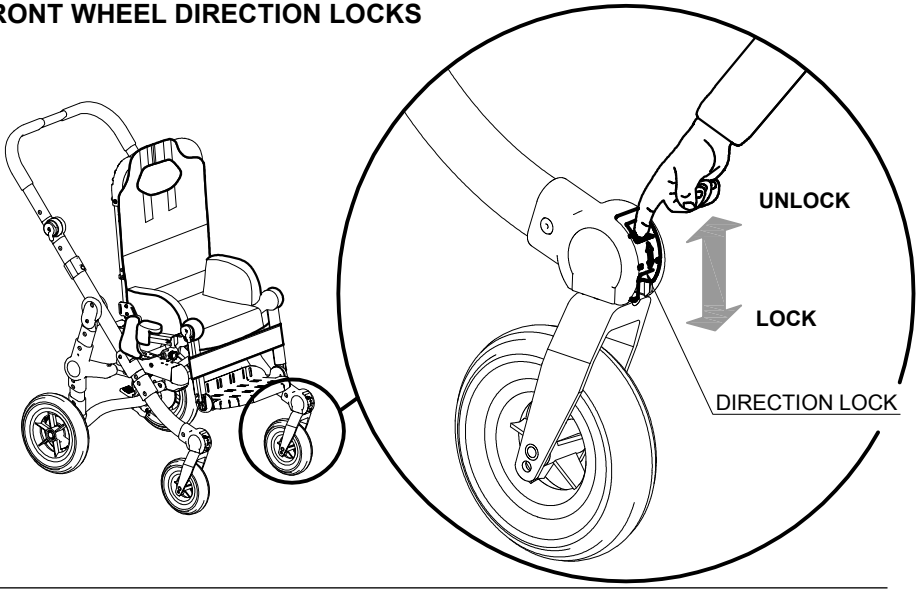
WE SUGGEST TO CLOSE THE BASE WITHOUT THE SEAT

ADJUSTING THE INCLINATION OF THE HANDLE

IT CAN BE ADAPTED TO DIFFERENT ASSISTANT'S HEIGHTS AND FACILITATES THE ENTRANCE INTO THE ELEVATOR AND ITS TRANSPORT INTO THE CAR



FRONT WHEEL DIRECTION LOCKS

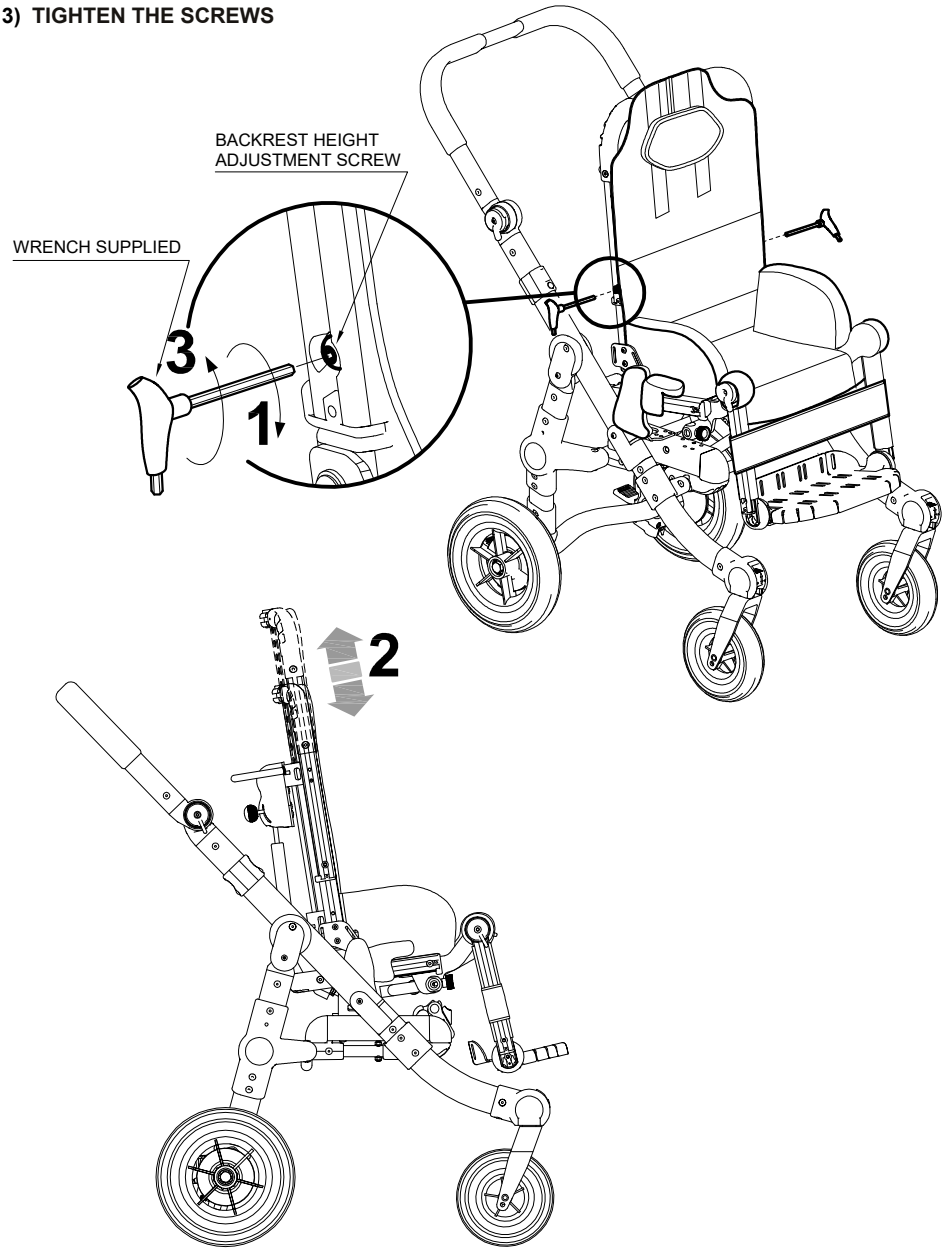


BACKREST HEIGHT ADJUSTMENT

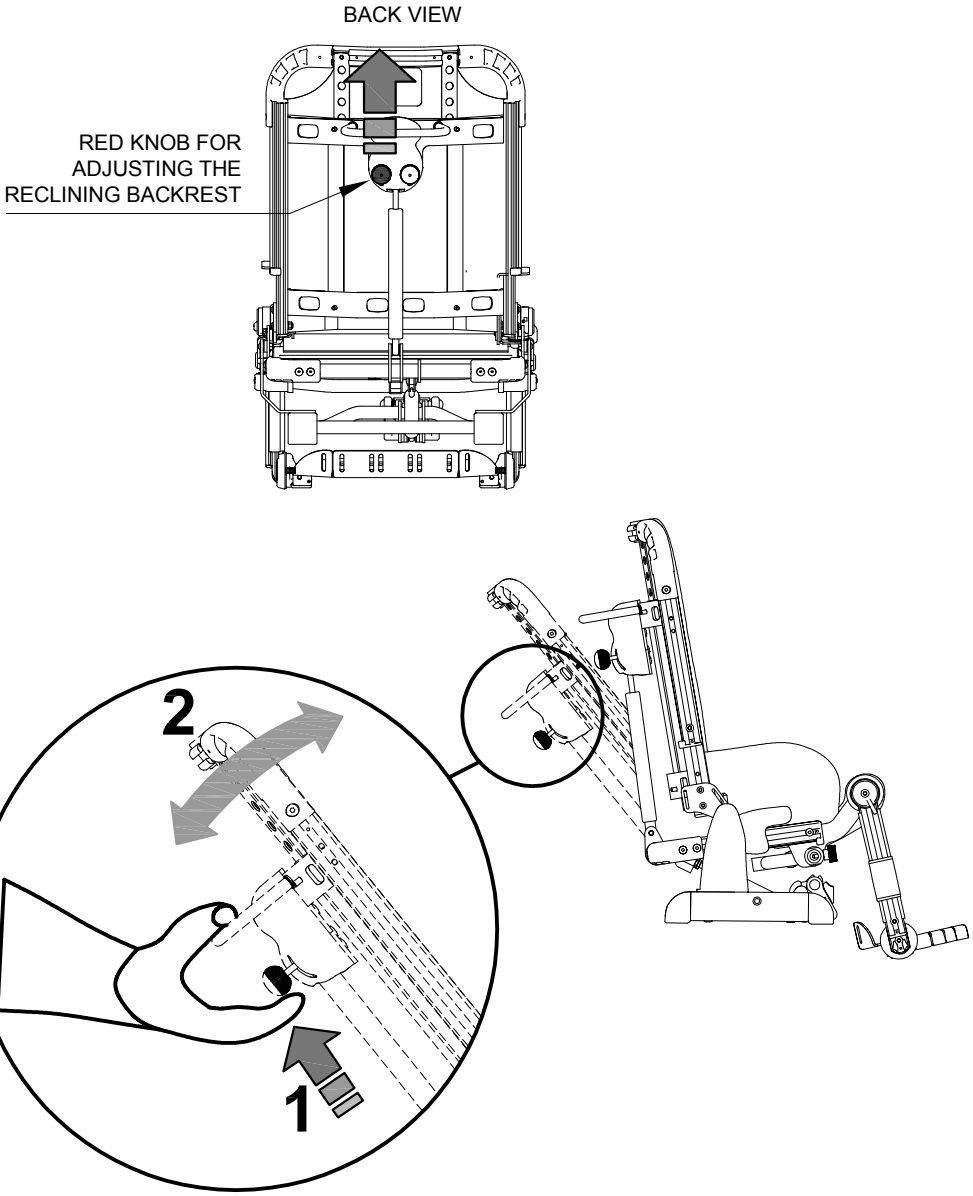
1) LOOSEN THE SIDE SCREWS INDICATED

2) ADJUST THE HEIGHT OF THE BACKREST TO THE DESIRED POSITION

3) TIGHTEN THE SCREWS

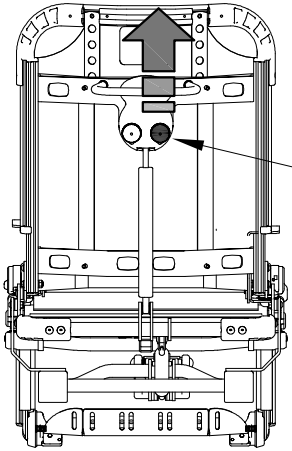


RECLINING THE BACKREST

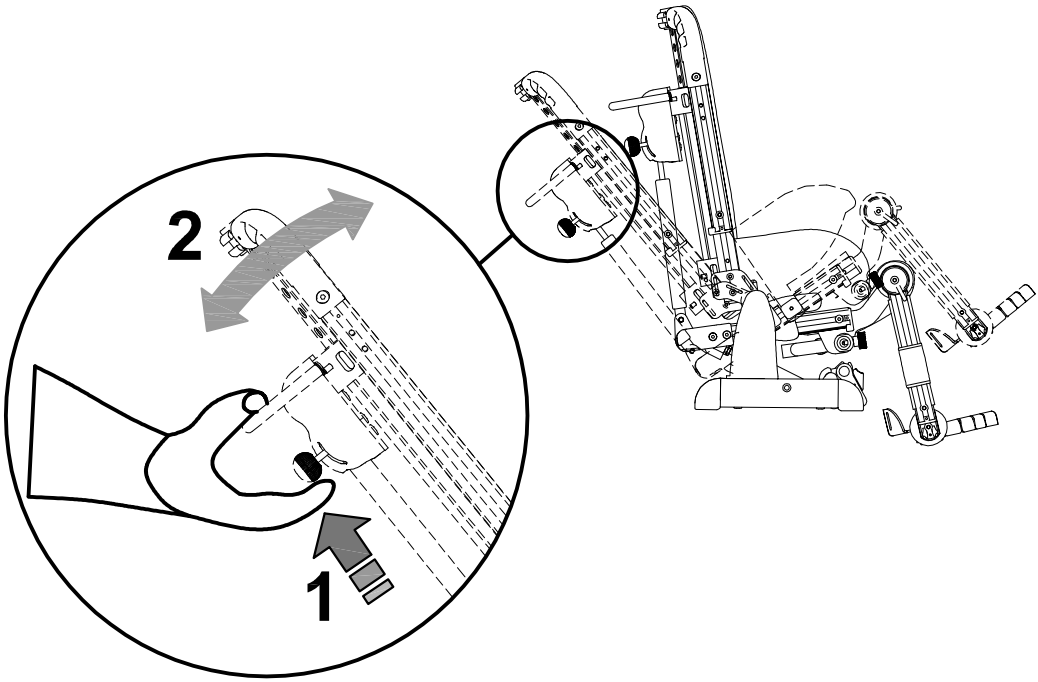


ADJUSTING THE INCLINATION OF THE SEAT (TILT-IN-SPACE SYSTEM)

BACK VIEW

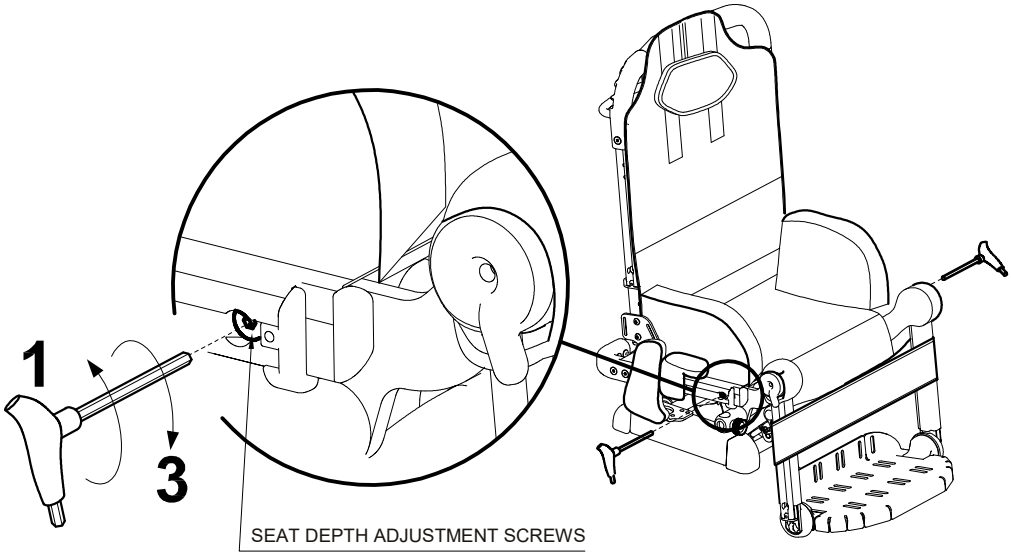


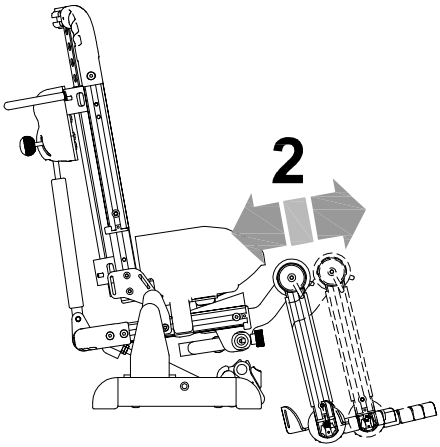
GREEN KNOB FOR ADJUSTING THE INCLINATION OF THE SEAT (TILT-IN-SPACE SYSTEM)



SEAT DEPTH ADJUSTMENT

1) **LOOSEN THE LATERAL SCREWS**
2) **ADJUST THE DEPTH OF THE SEAT TO THE DESIRED POSITION**
3) **TIGHTEN THE SCREWS**



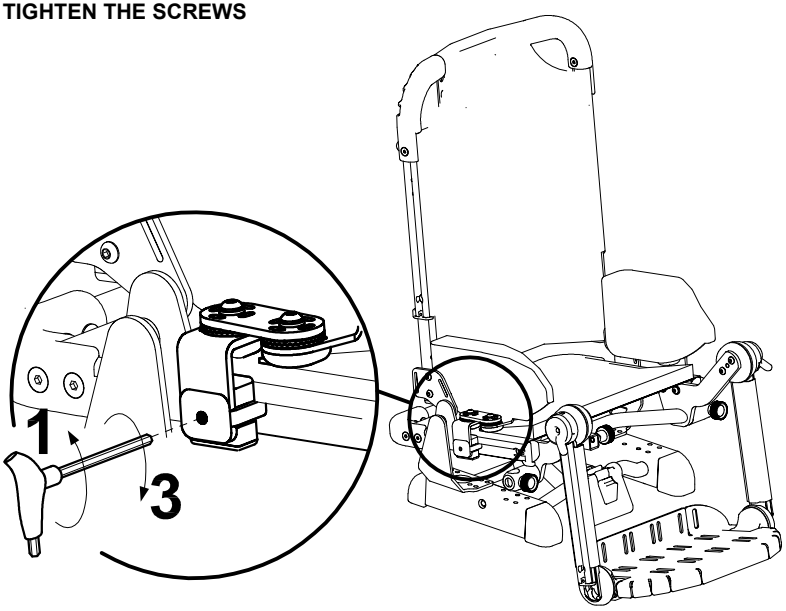


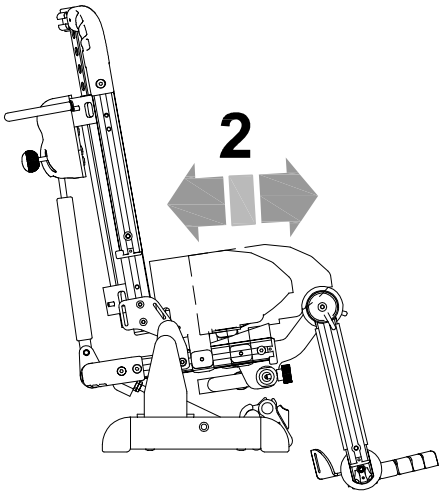
SEAT SIDE ADJUSTMENT

A DEPTH ADJUSTMENT

First remove the upholstery of the side joint

1. **LOOSEN THE LATERAL SCREWS**
2. **ADJUST THE SIDE IN DEPTH**
3. **TIGHTEN THE SCREWS**

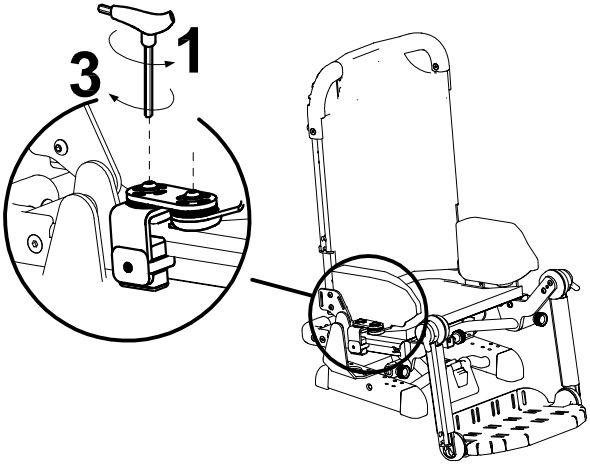




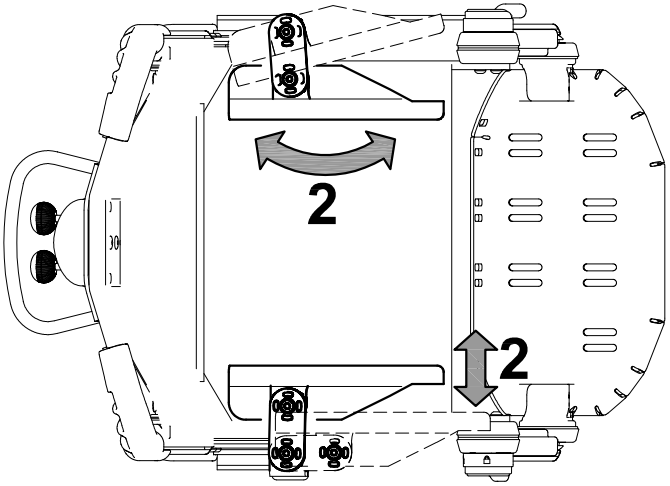
B WIDTH ADJUSTMENT AND HORIZONTAL TILT

First remove the upholstery of the side joint

1. **LOOSEN THE INDICATED SCREWS**
2. **ADJUST THE SIDE IN WIDTH AND HORIZONTAL TILT**
3. **TIGHTEN THE SCREWS**



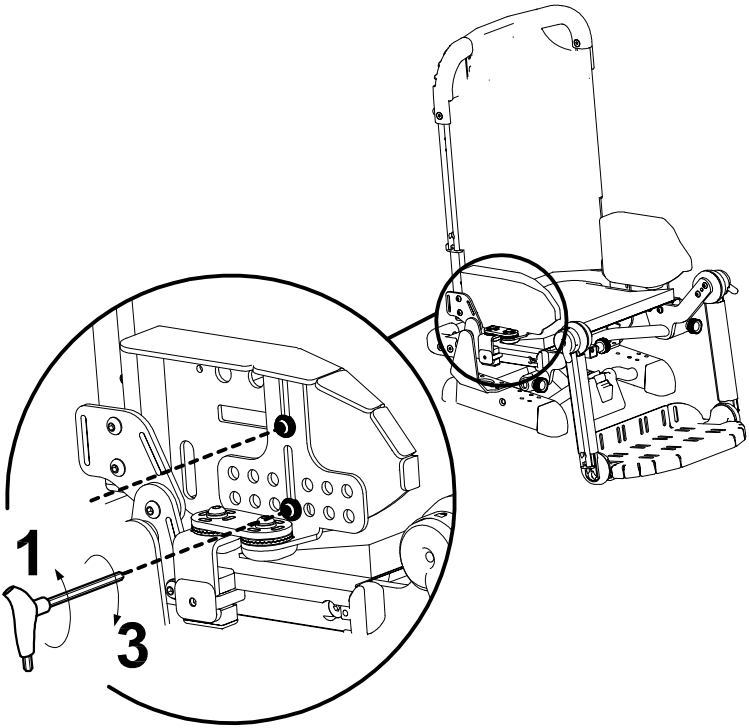
VIEW FROM ABOVE

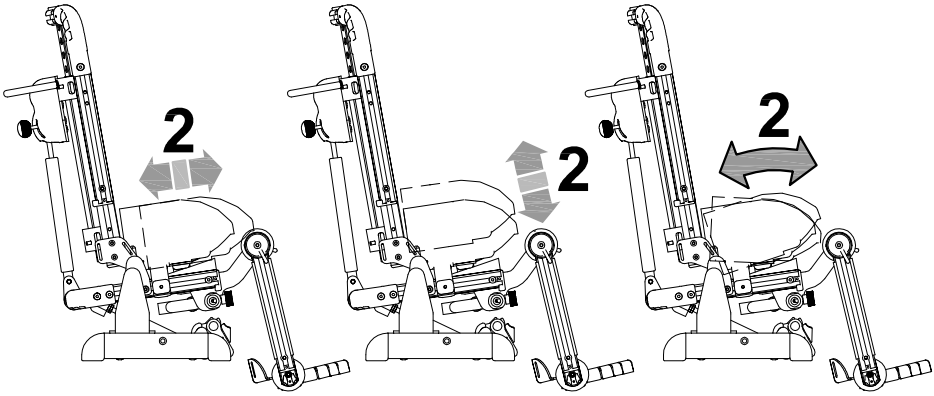


C HEIGHT ADJUSTMENT, ANTERO-POSTERIOR AND VERTICAL TILT ADJUSTMENTS

First remove the upholstery of the side joint

1. **LOOSEN THE INDICATED SCREWS**
2. **ADJUST THE SIDE TO THE DESIRED POSITION**
3. **TIGHTEN THE SCREWS**

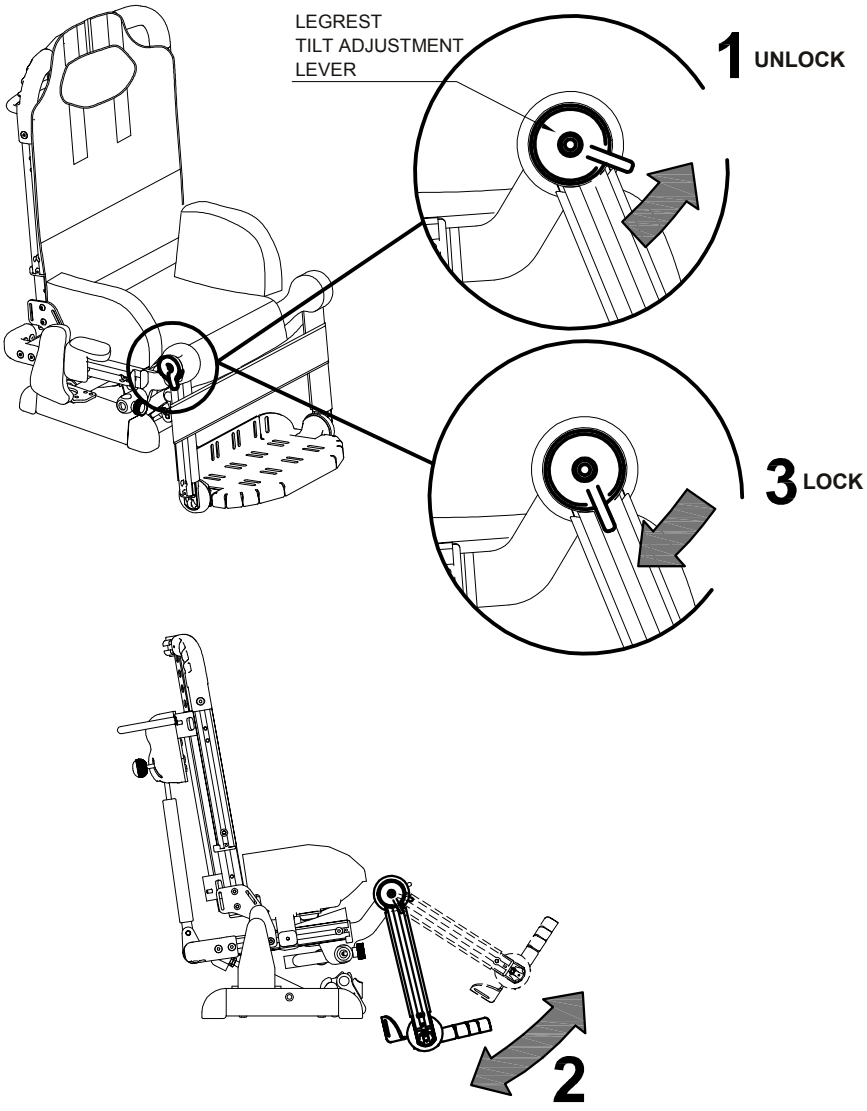




LEGREST ADJUSTMENT

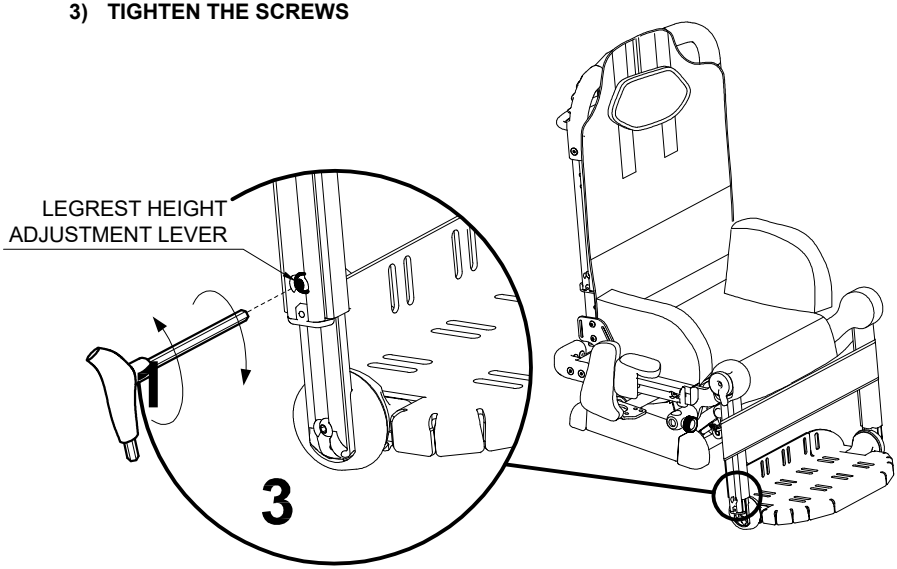
A TILT ADJUSTMENT

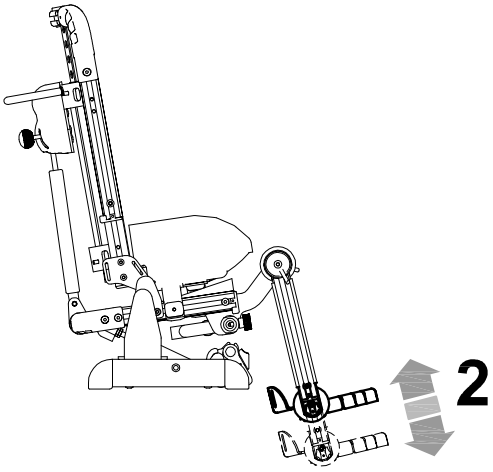
1) TURN THE LEVER COUNTERCLOCKWISE TO RELEASE THE LEGREST
2) ADJUST THE LEGREST IN TILT
3) TURN THE LEVER CLOCKWISE TO LOCK IT



B HEIGHT ADJUSTMENT

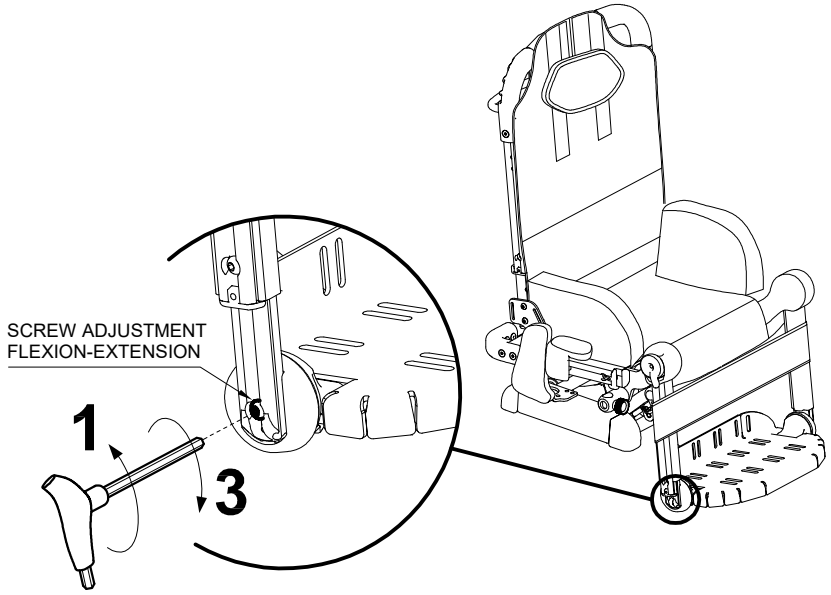
1) **LOOSEN THE LATERAL SCREWS**
2) **ADJUST THE HEIGHT OF THE FOOTREST**
3) **TIGHTEN THE SCREWS**

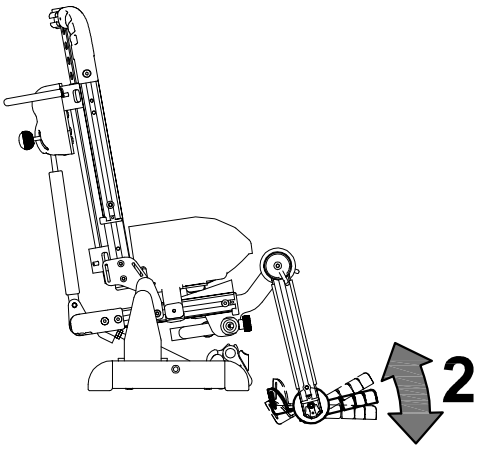




FOOTRESTS ADJUSTMENT

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



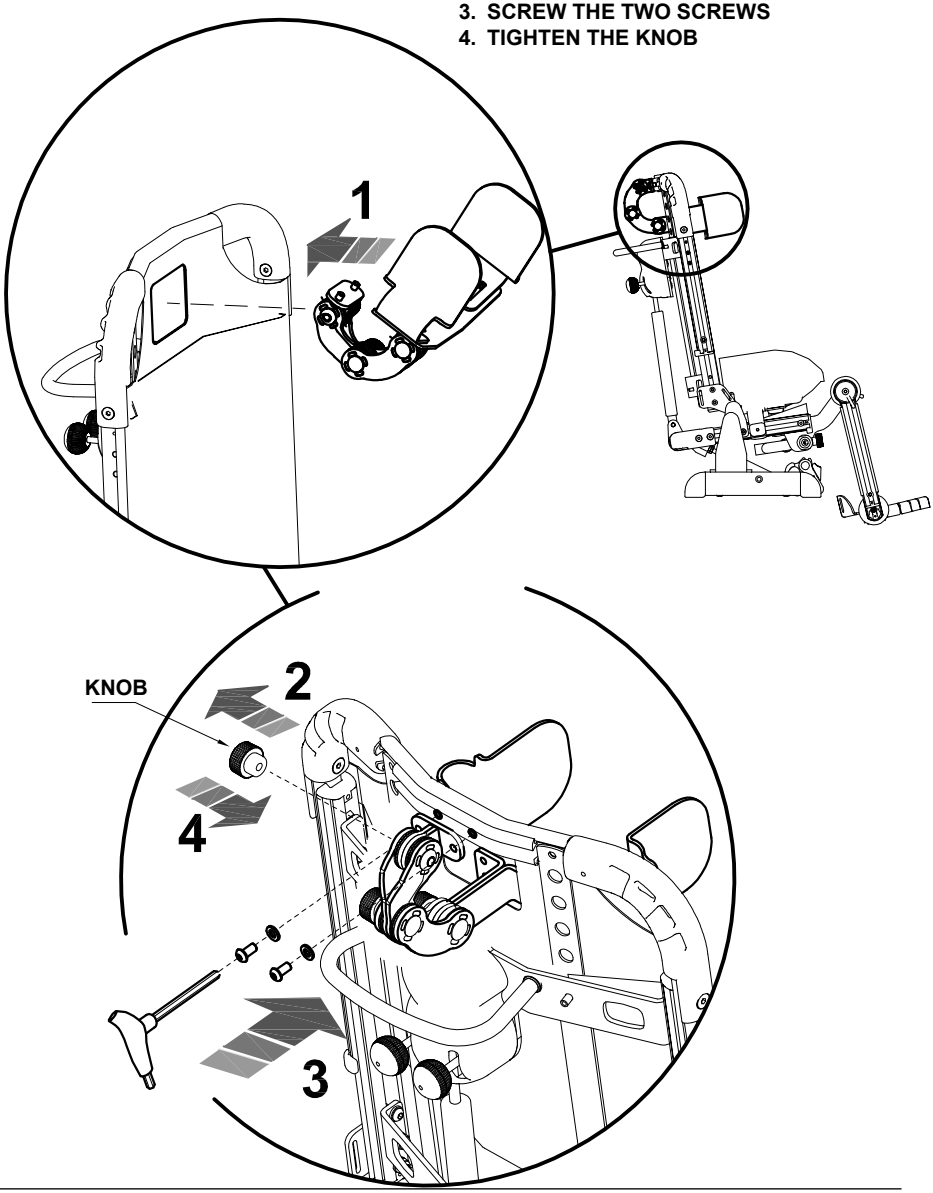


5.4 ADJUSTMENT AND CONFIGURATION OF THE ADDITIONAL COMPONENTS by the health professional

POSTURAL HEADREST 863

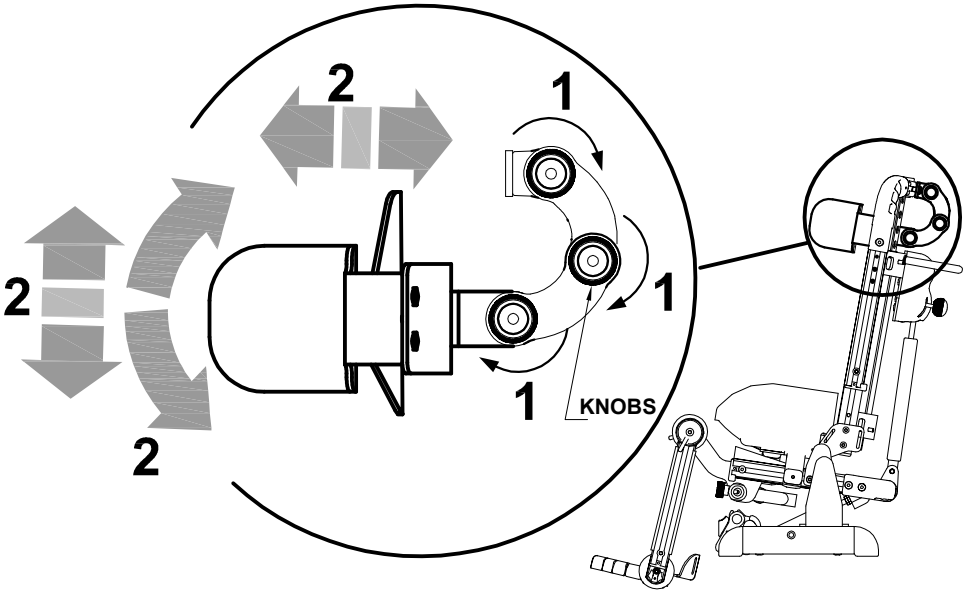
A MOUNTING

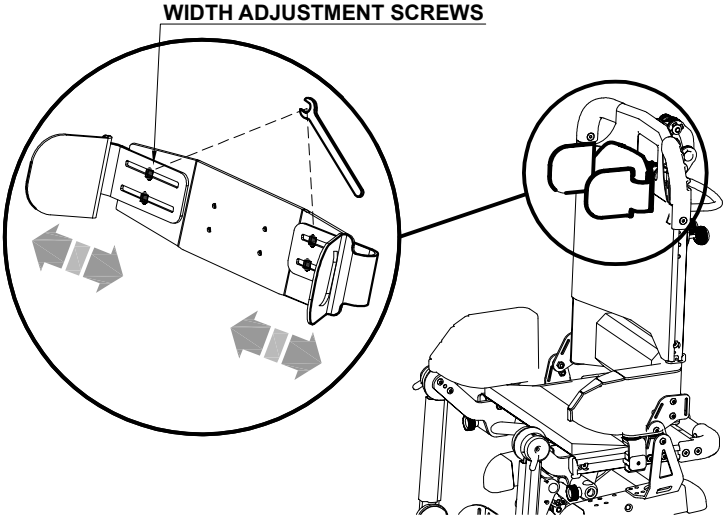
1. POSITION THE HEADREST ATTACHMENT ON THE BACK OF THE BACKREST
2. REMOVE THE UPPER KNOB
3. SCREW THE TWO SCREWS
4. TIGHTEN THE KNOB



B ADJUSTMENT

1. LOOSEN THE THREE KNOBS
2. ADJUST THE INCLINATION, THE HEIGHT AND DEPTH OF THE HEADREST
   TIGHTEN THE KNOBS

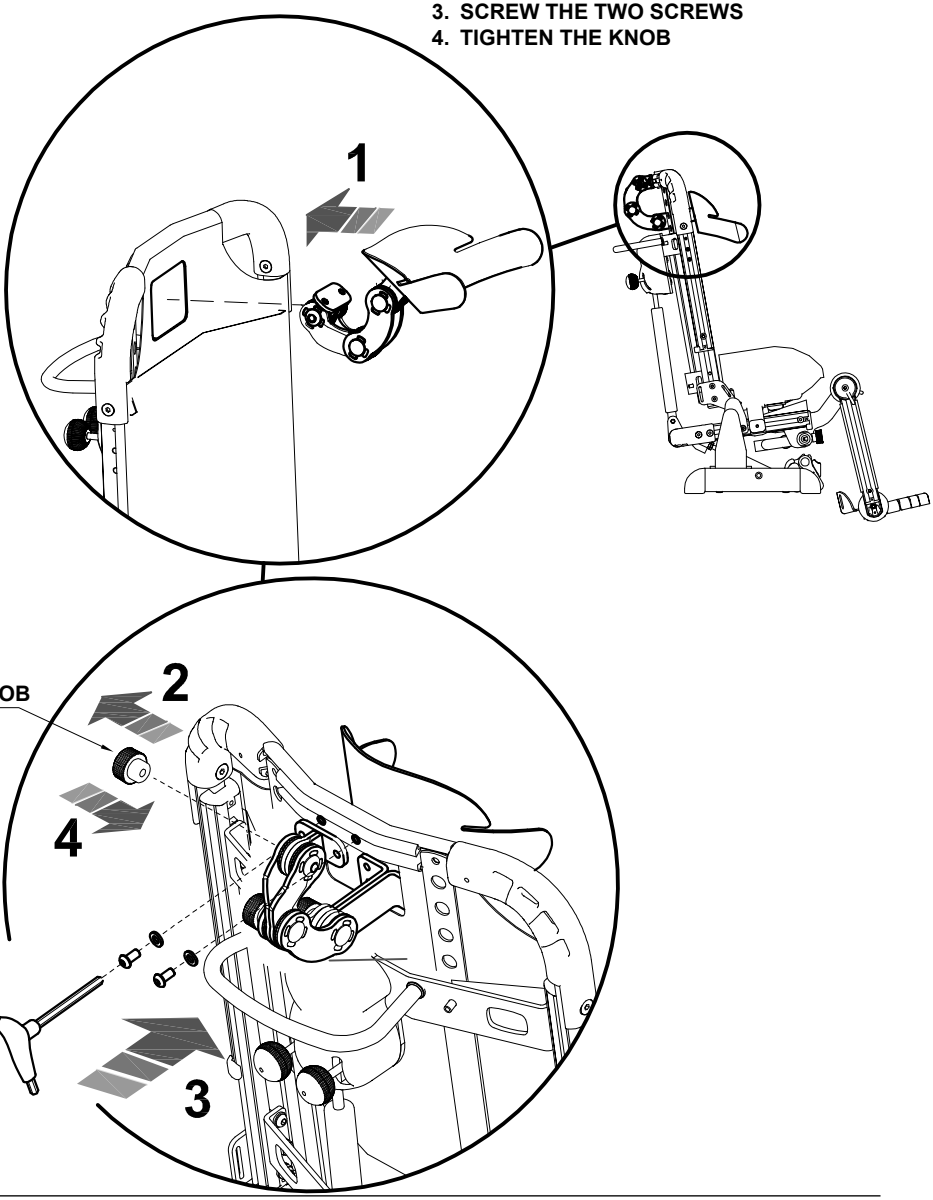




ERGONOMIC HEADREST 942

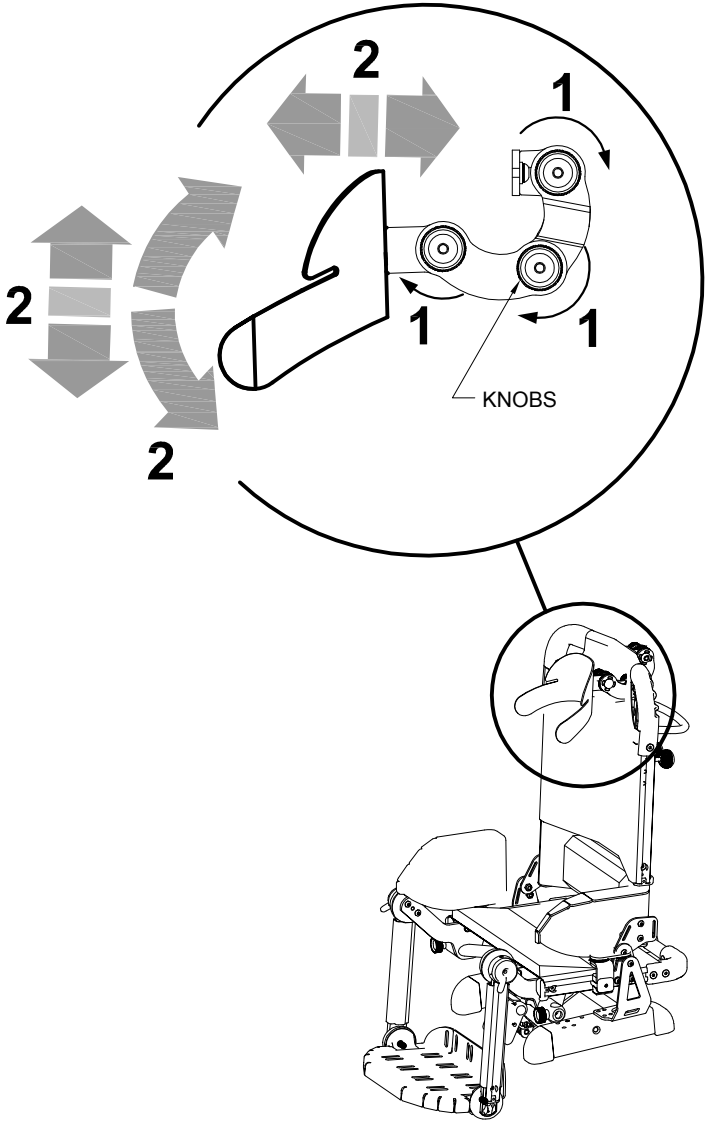
A MOUNTING

1. POSITION THE HEADREST ATTACHMENT ON THE BACK OF THE BACKREST
2. REMOVE THE UPPER KNOB
3. SCREW THE TWO SCREWS
4. TIGHTEN THE KNOB



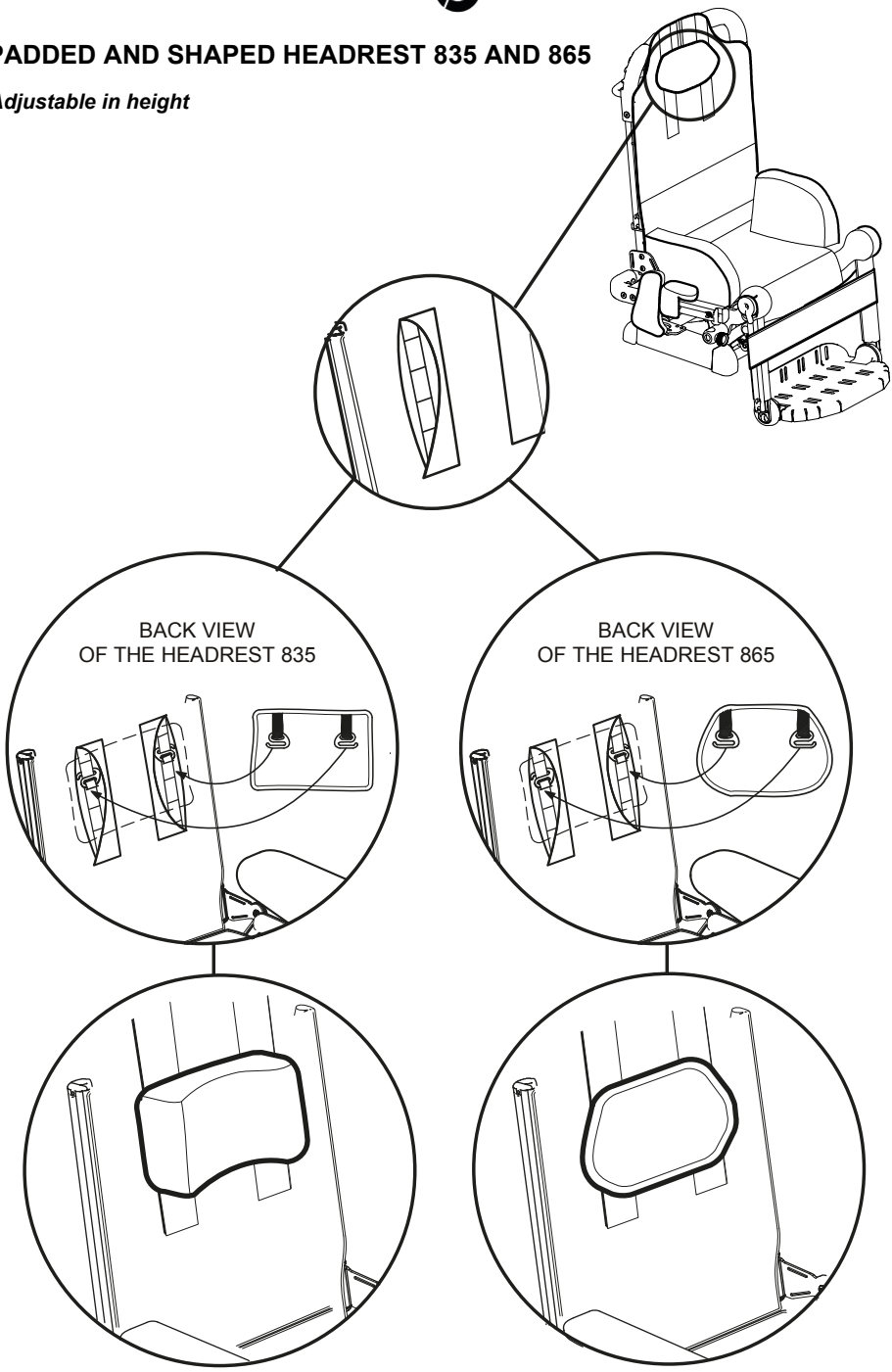
B ADJUSTMENT

1. LOOSEN THE THREE KNOBS
2. ADJUST THE INCLINATION, THE HEIGHT AND DEPTH OF THE HEADREST TIGHTEN THE KNOBS



PADDED AND SHAPED HEADREST 835 AND 865

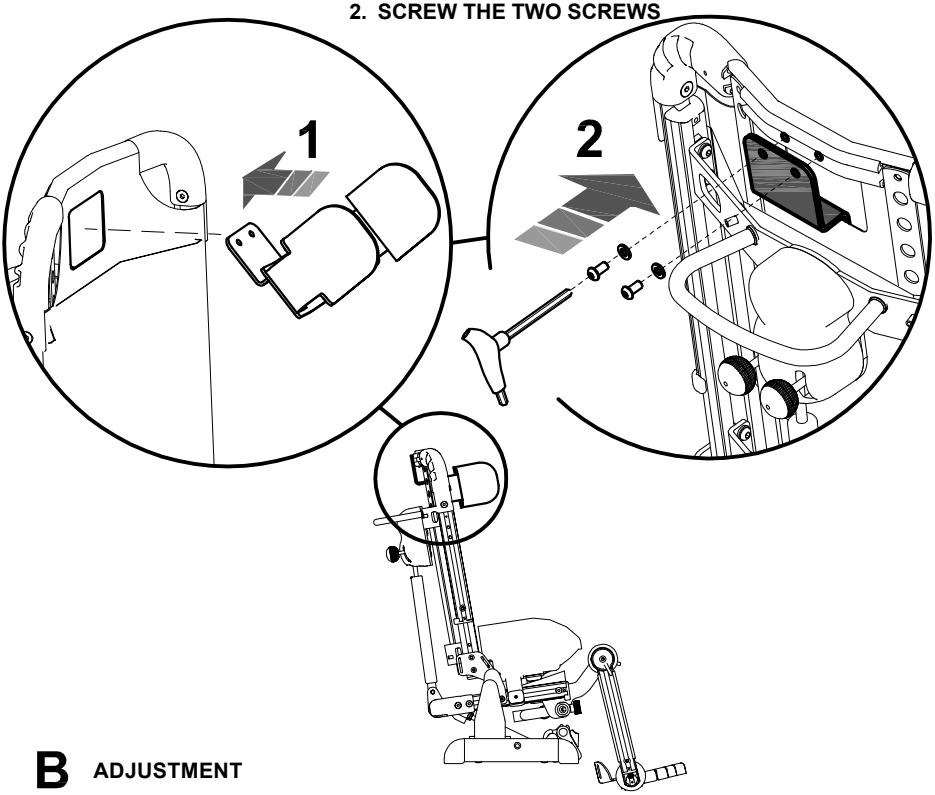
Adjustable in height



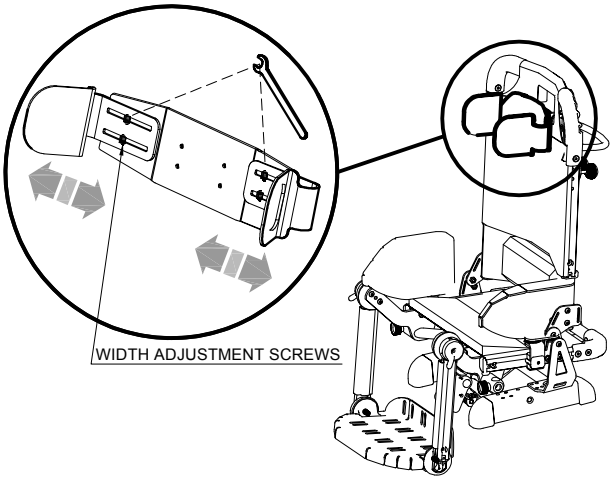
HEADREST with PARIETAL PROTECTIONS 852

A **MOUNTING**

1. **POSITION THE HEADREST ATTACHMENT ON THE BACK OF THE BACKREST**
2. **SCREW THE TWO SCREWS**



B **ADJUSTMENT**



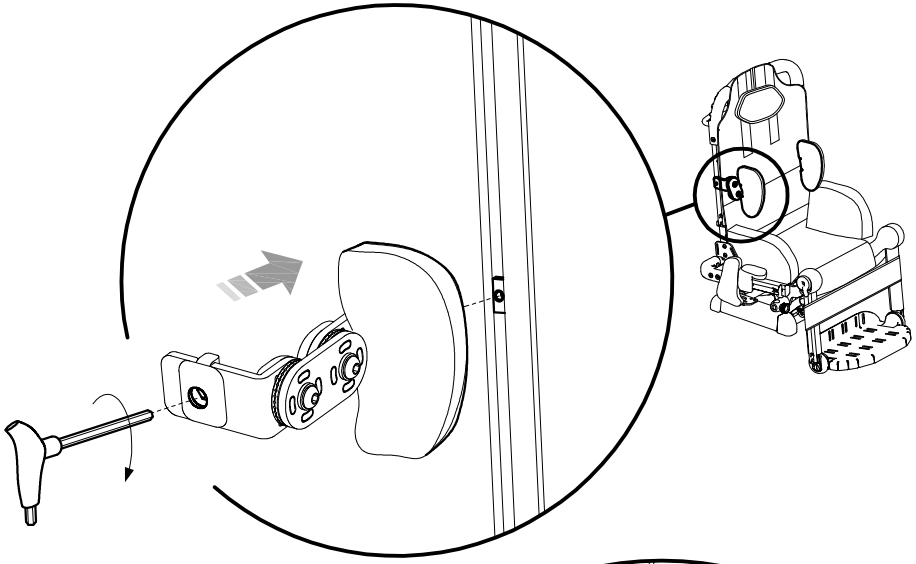
TRUNK SIDE SUPPORTS 838

First remove the upholstery of the side joint

A MOUNTING

INSERT THE SIDE SUPPORTS AND TIGHTEN THE SCREW

(by inserting the wrench in the indicated hole)



B HEIGHT ADJUSTMENT

First remove the upholstery of the side joint

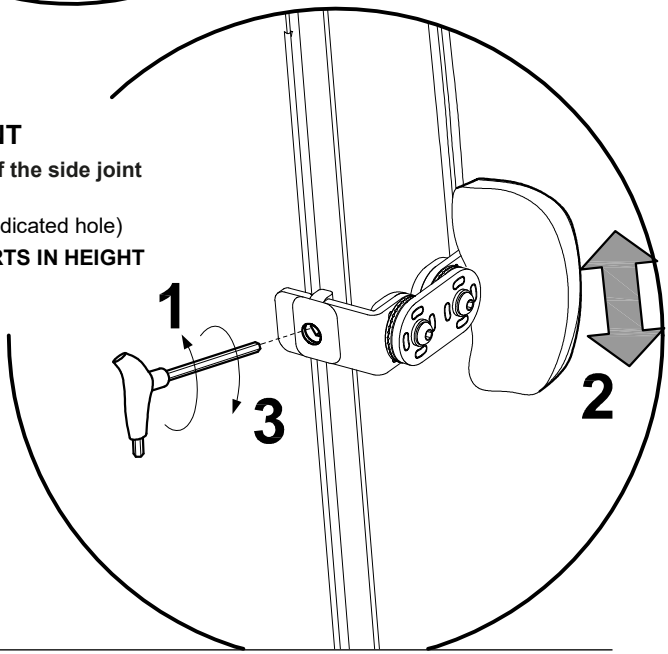
1) LOOSEN THE SCREW

(by inserting the wrench in the indicated hole)

2) ADJUST THE SIDE SUPPORTS IN HEIGHT

3) TIGHTEN THE SCREW

Supplied wrench



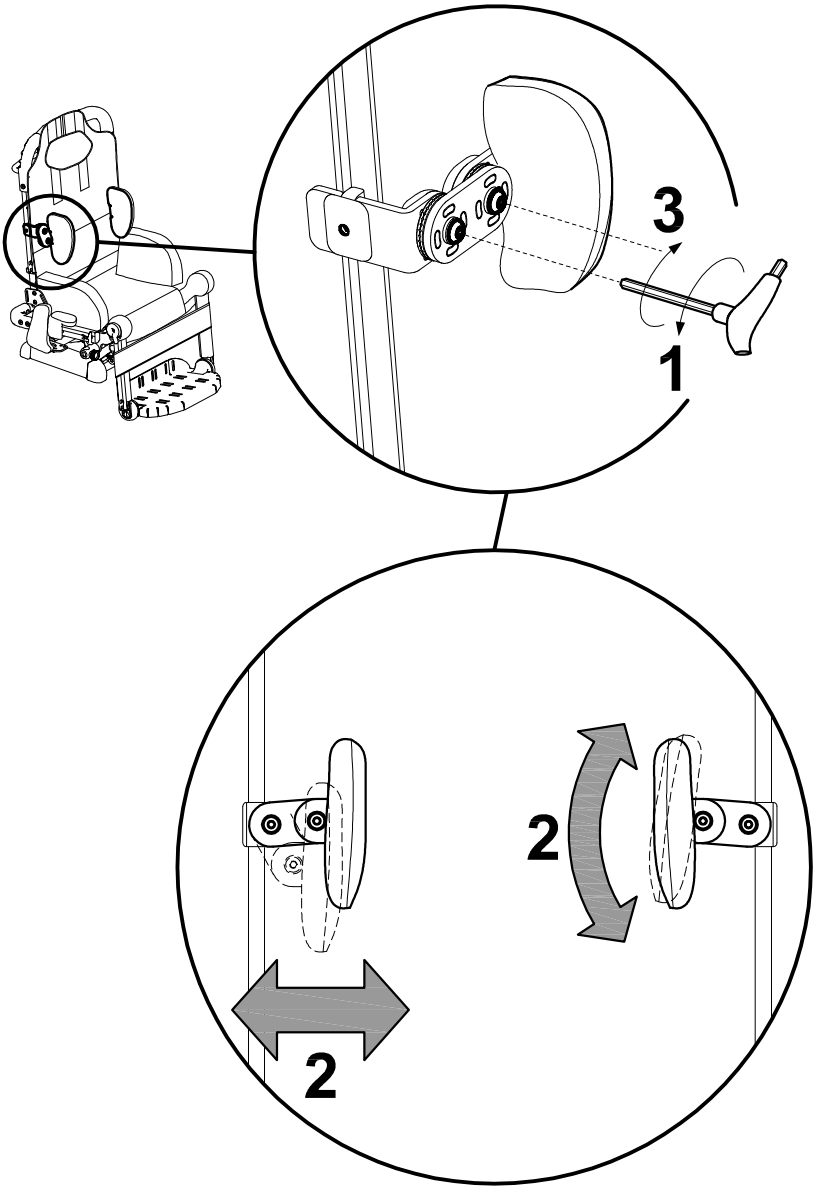
C WIDTH AND ROTATION ADJUSTMENT

First remove the upholstery of the side joint

1) LOOSEN THE INDICATED SCREWS

2) ADJUST THE SIDE SUPPORT IN WIDTH AND ROTATION

3) TIGHTEN THE SCREWS

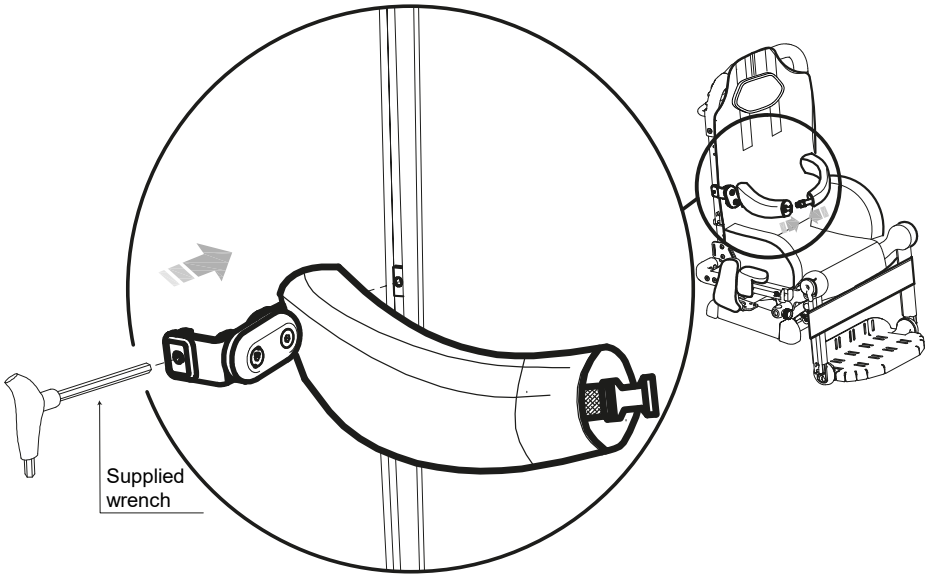


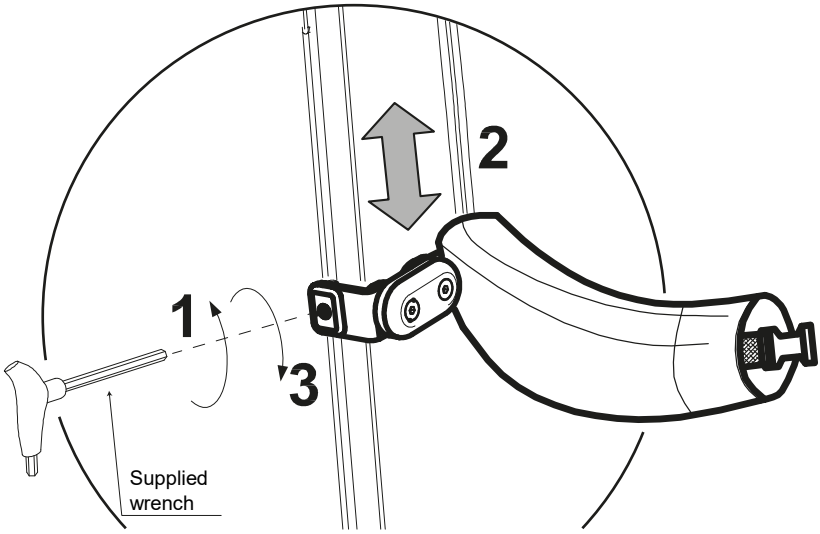
WRAPPABLE AND FLEXIBLE TRUNK SUPPORTS 868

multiadjustable in height, width and inclination

A MOUNTING AND HEIGHT ADJUSTMENT

INSERT THE SIDE SUPPORT TO THE DESIRED HEIGHT AND TIGHTEN THE SCREW
(by inserting the wrench in the indicated hole)





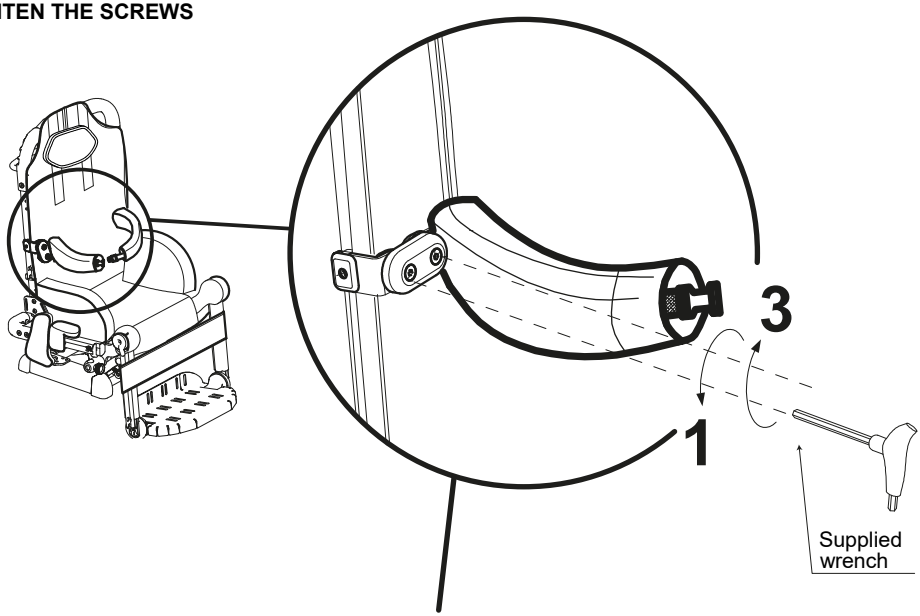
B WITH AND ROTATION ADJUSTMENT

First remove the upholstery of the side joint

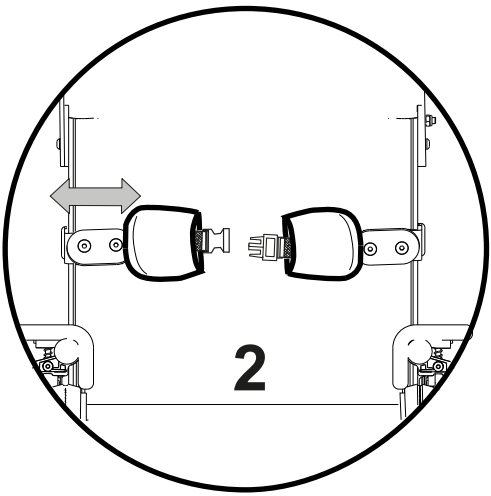
1) LOOSEN THE INDICATED SCREWS

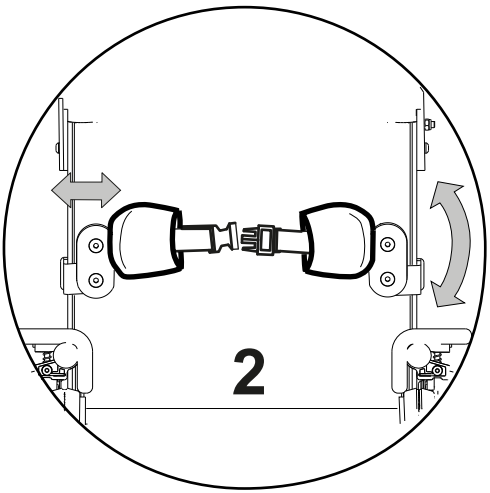
2) ADJUST THE SIDE SUPPORT IN WIDTH AND ROTATION

3) TIGHTEN THE SCREWS



BACKREST
FRONT VIEW

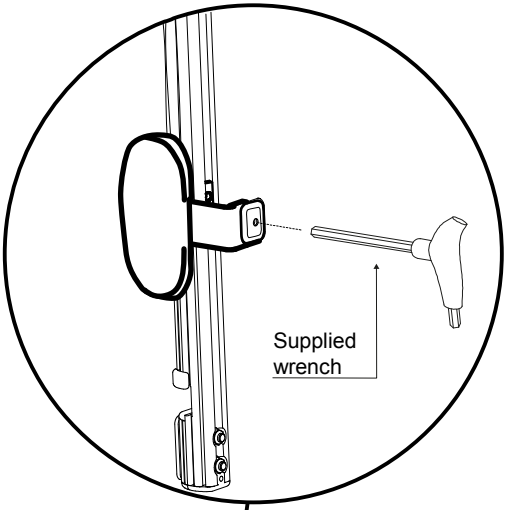


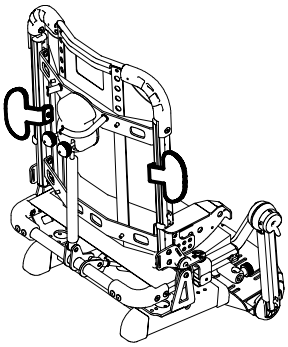


ELBOW SIDE SUPPORTS 961

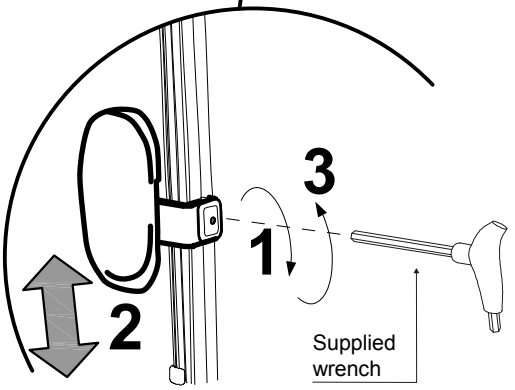
A MOUNTING AND HEIGHT ADJUSTMENT

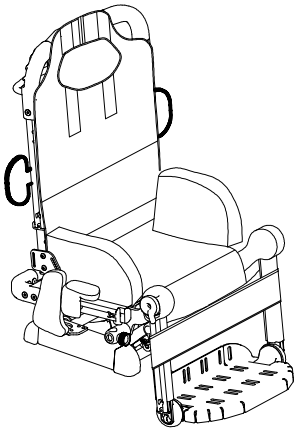
INSERT THE PAD TO THE DESIRED HEIGHT AND TIGHTEN THE SCREW
(by inserting the wrench in the indicated hole)





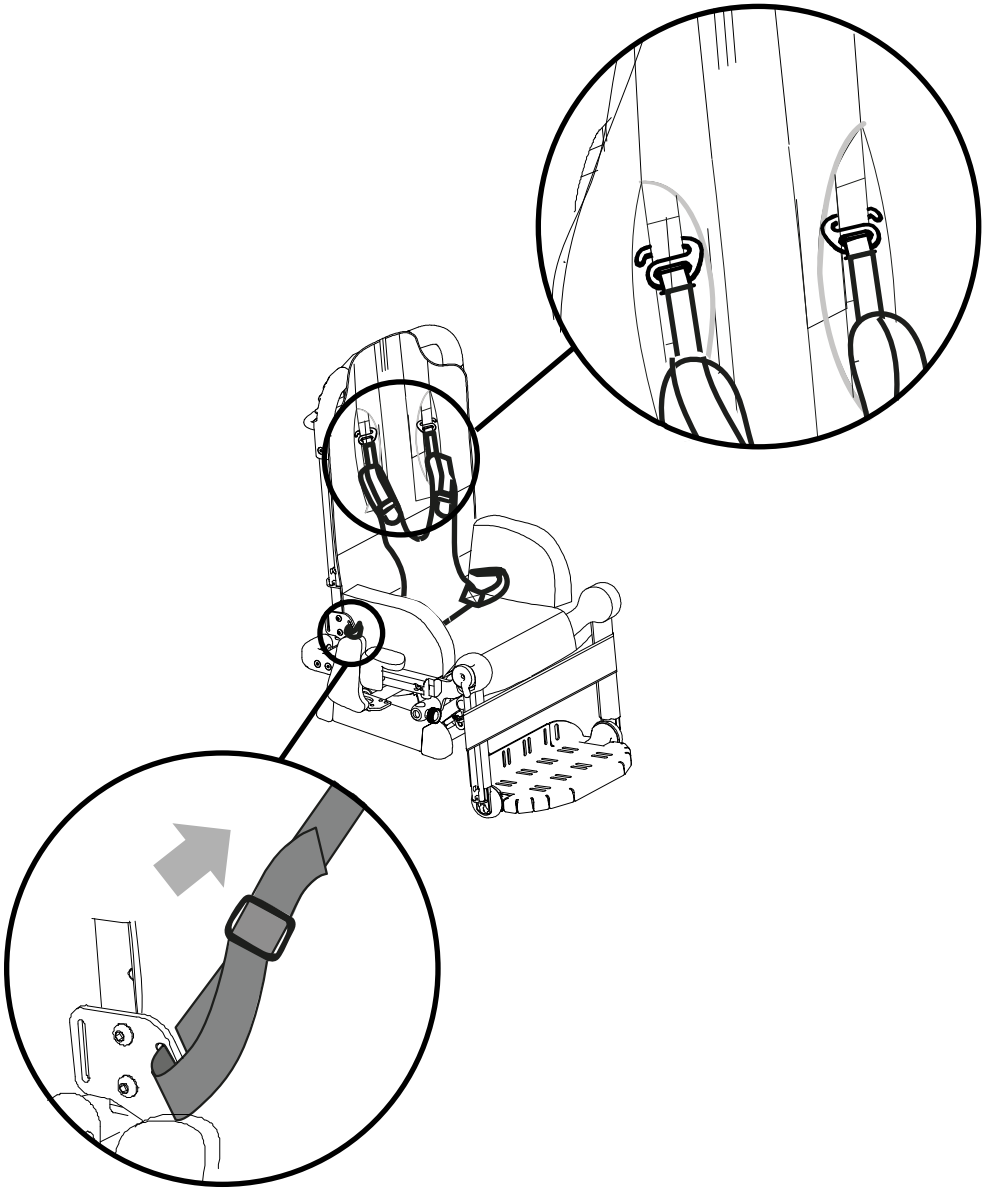
BACK VIEW



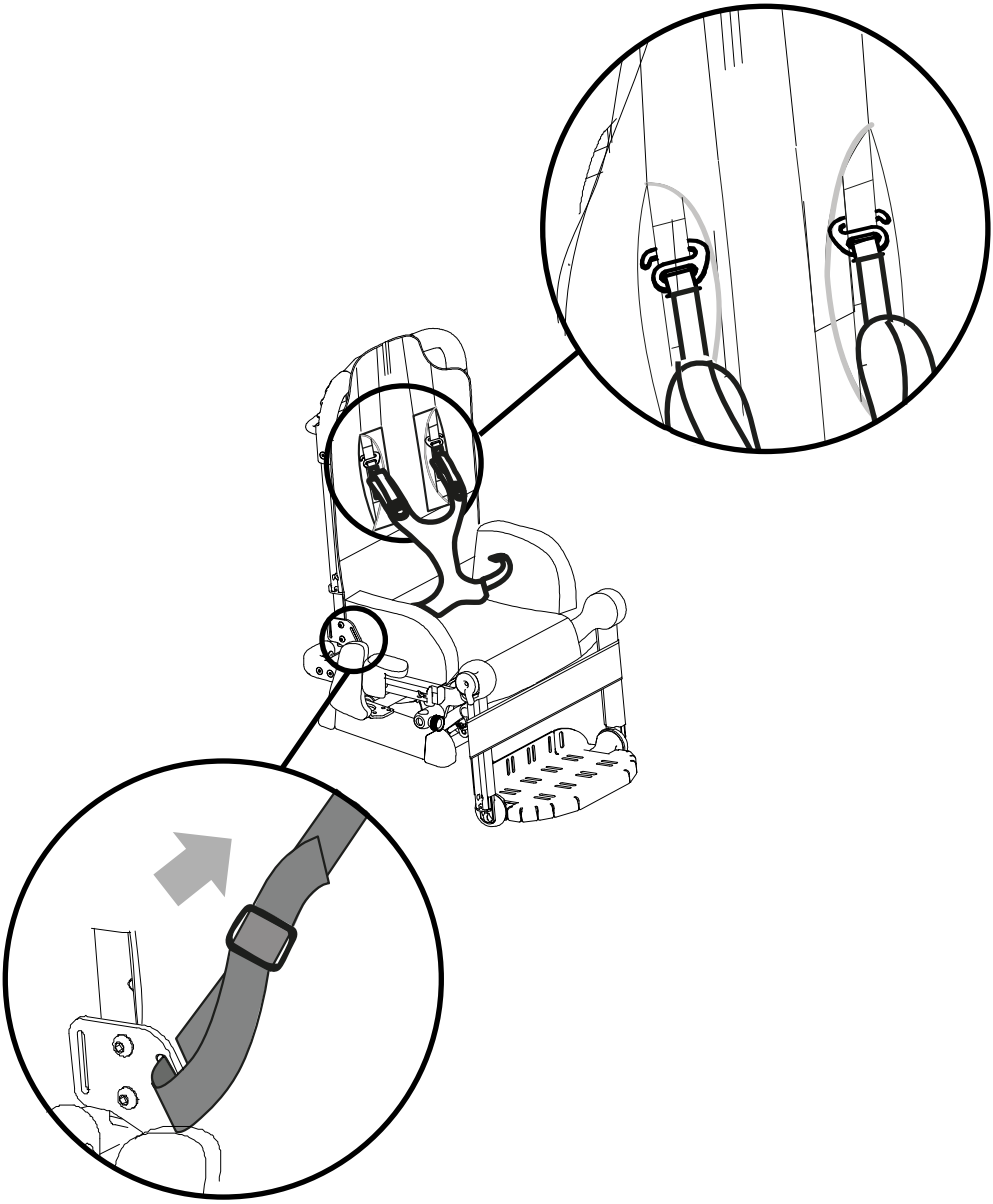


FRONT VIEW

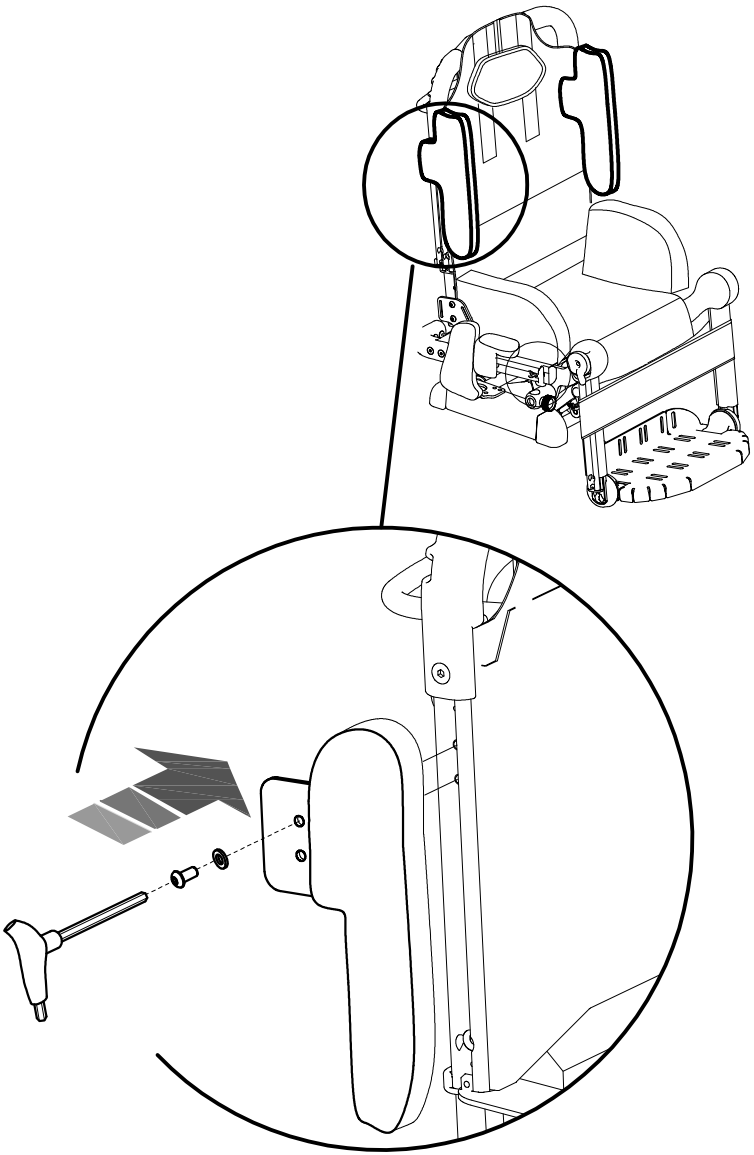
VEST HARNESS 853



SLIM FOUR POINT SHAPED HARNESS 853

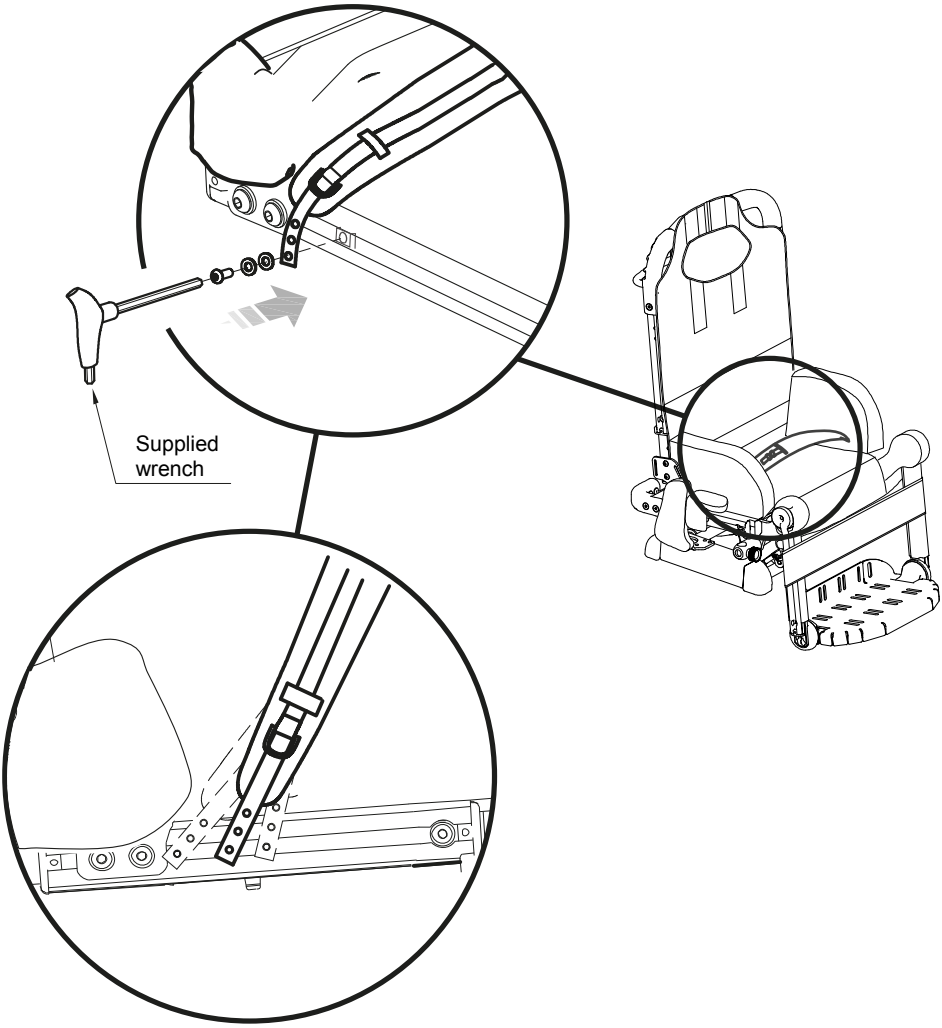


SHOULDERS LATERAL SUPPORT 967

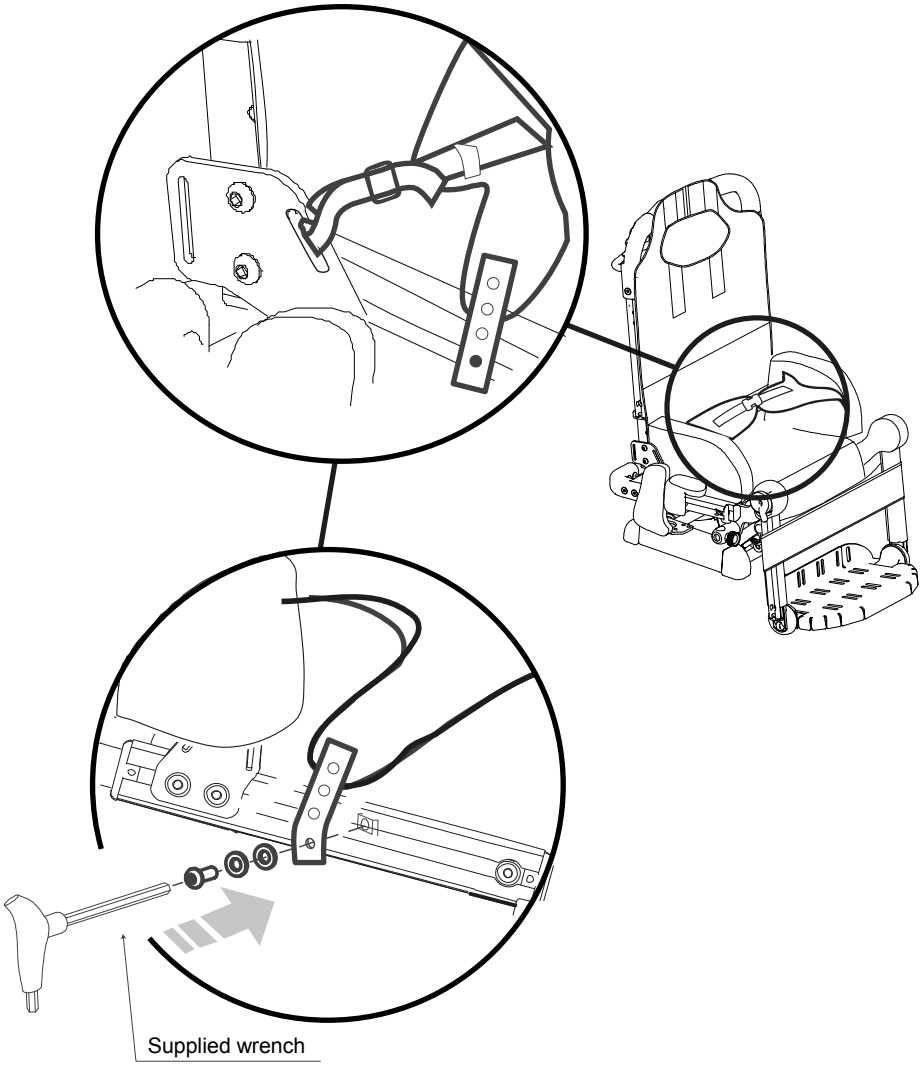


PELVIC BELT WITH VARIABLE ANGLE 947

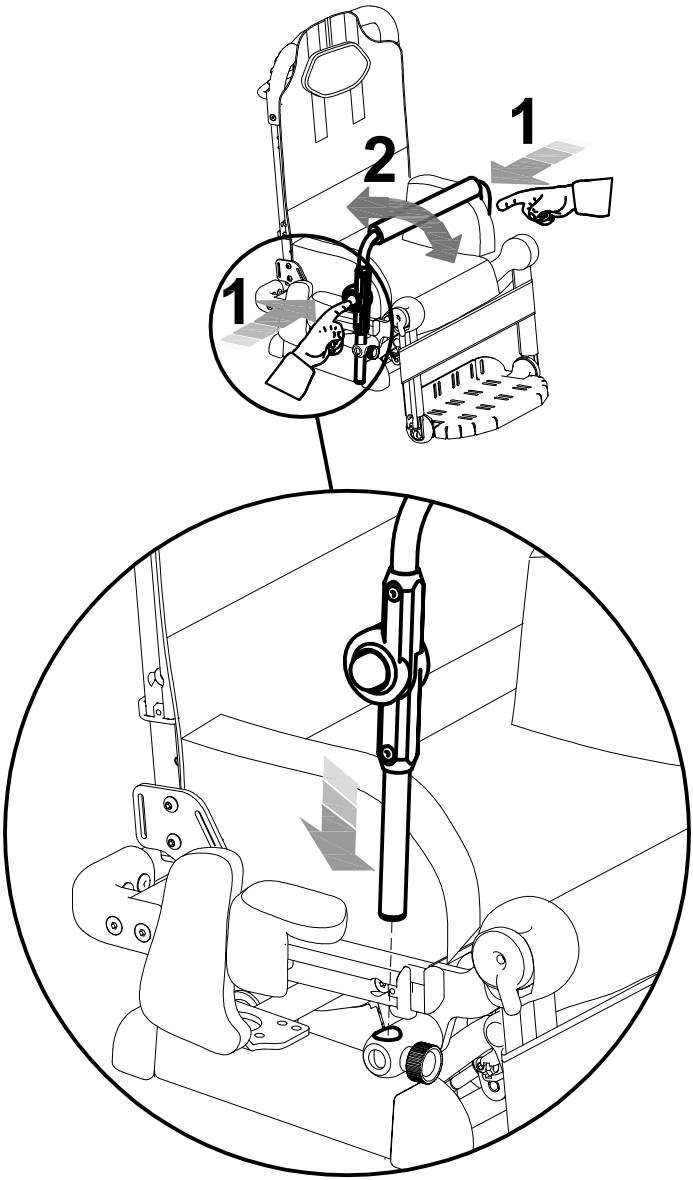
Fix to the desidered position



FOUR POINT PELVIC BELT 920

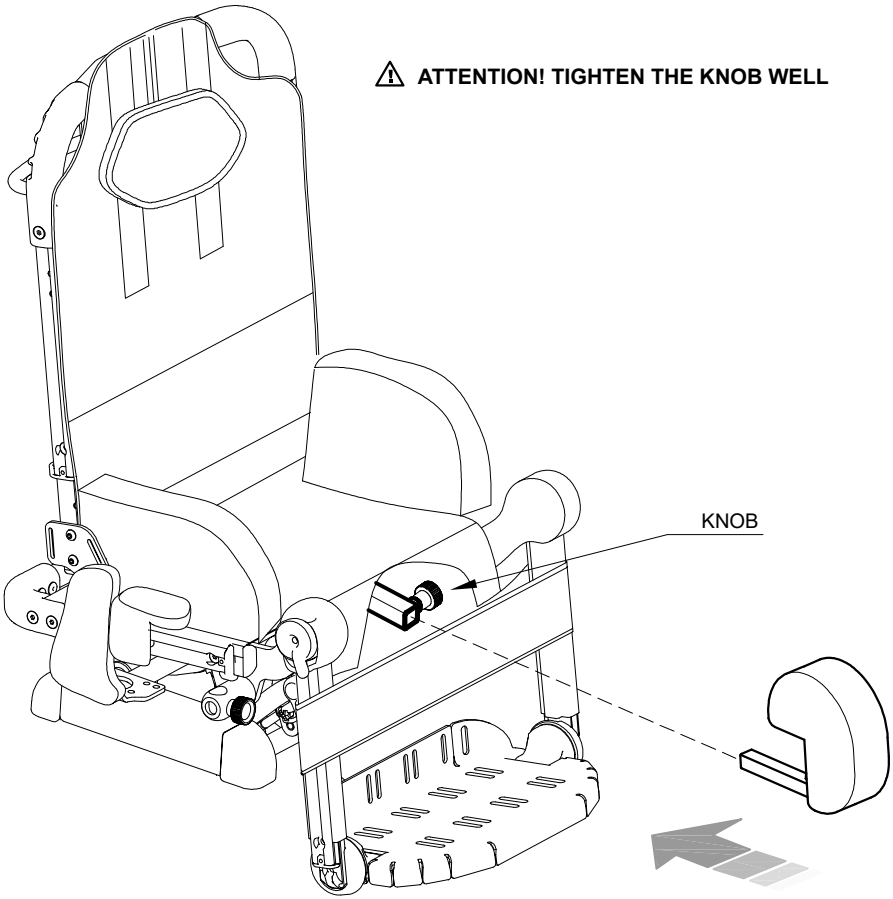


FRONT HANDLE 839



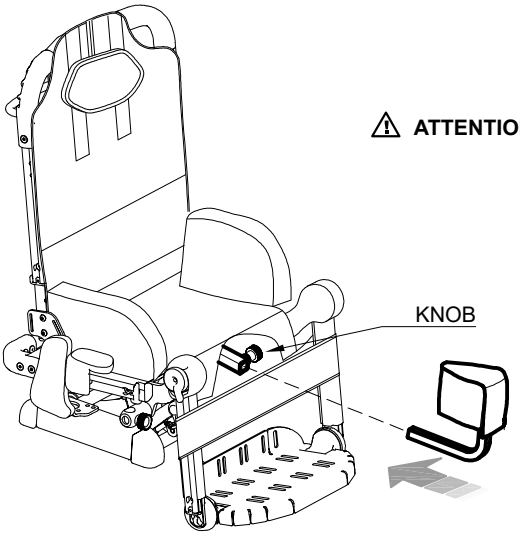
⚠ **ATTENTION! TIGHTEN THE KNOB WELL**

NARROW ABDUCTION BLOCK 834N



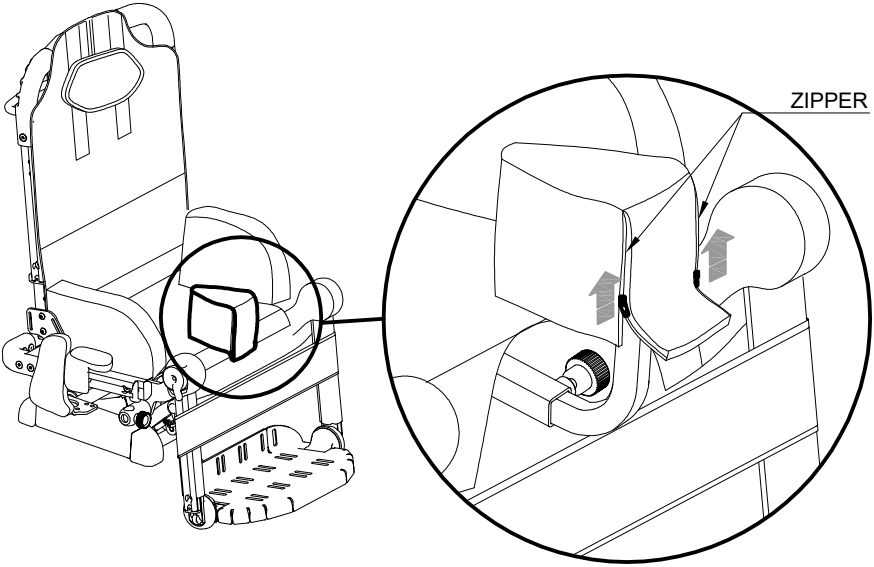
ADJUSTABLE ABDUCTION BLOCK 834R

INSERT THE ABDUCTION BLOCK AND TIGHTEN THE KNOB

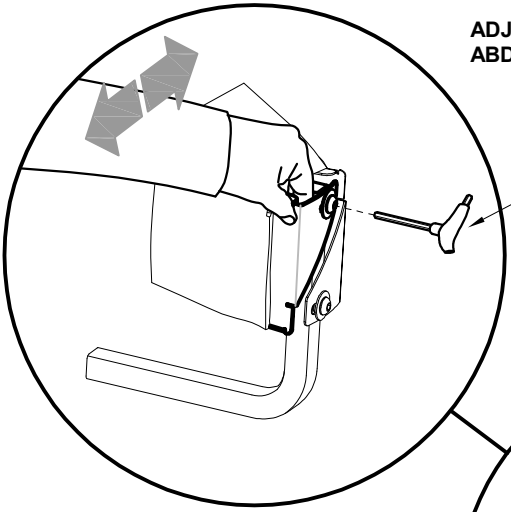


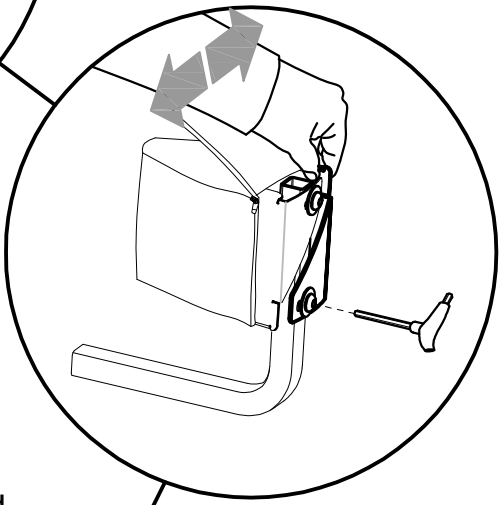
⚠ **ATTENTION! TIGHTEN THE KNOB WELL**

OPEN THE EDGE COVER USING THE TWO ZIPPERS

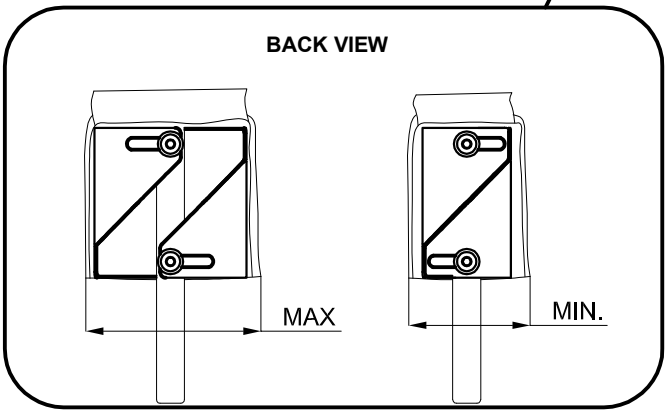


ADJUST THE LEFT PART OF THE ABDUCTION BLOCK SHEET IN WIDTH

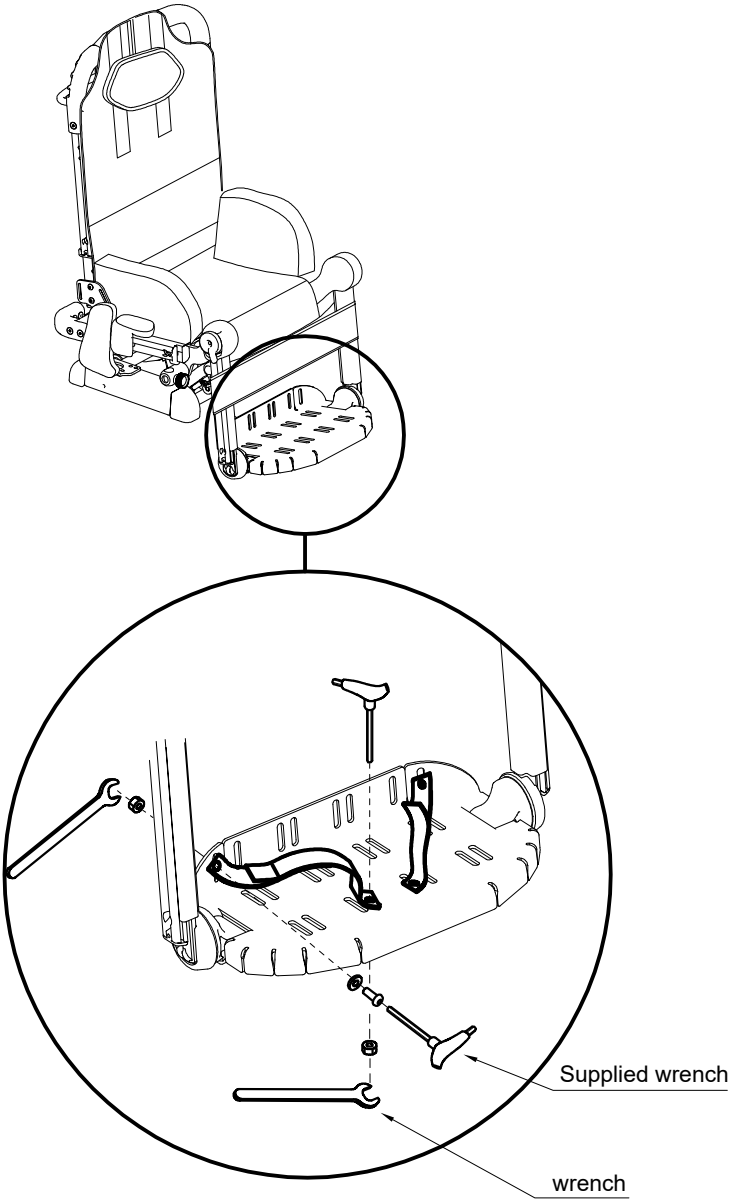




ADJUST THE RIGHT PART OF THE ABDUCTION BLOCK SHEET IN WIDTH

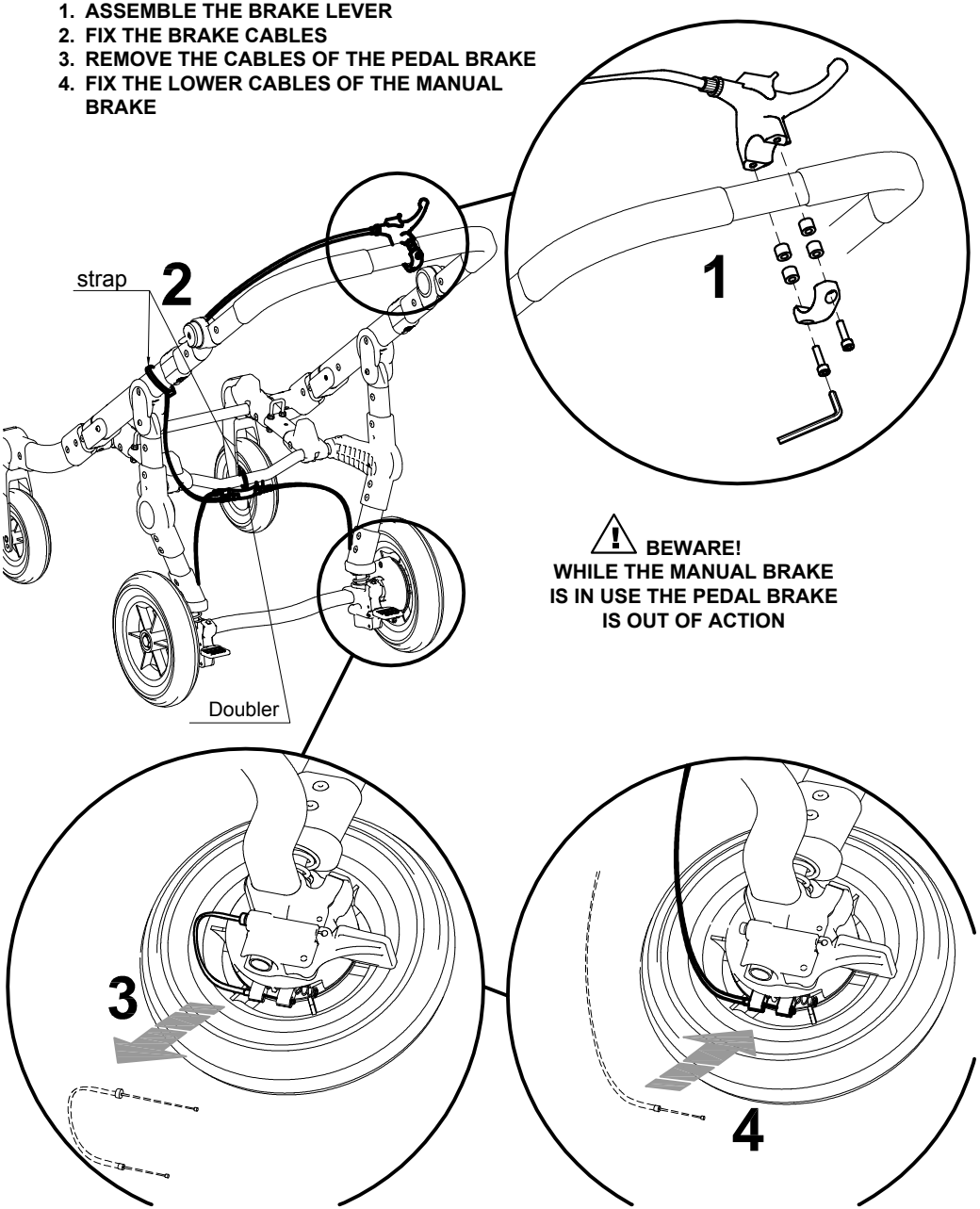


FOOT STRAPS 827



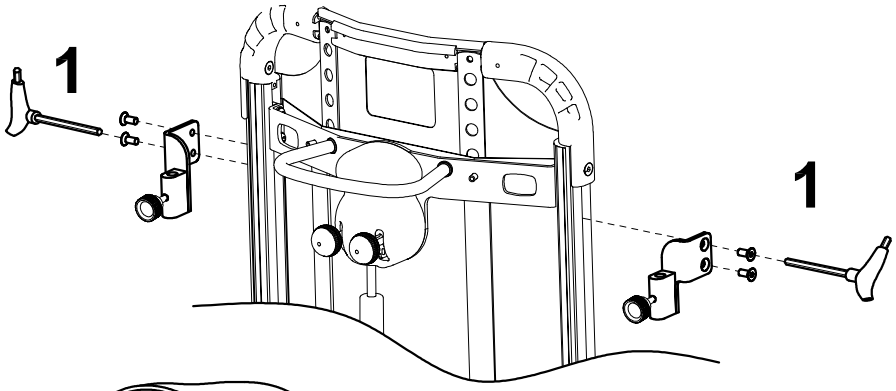
HAND BRAKE 905

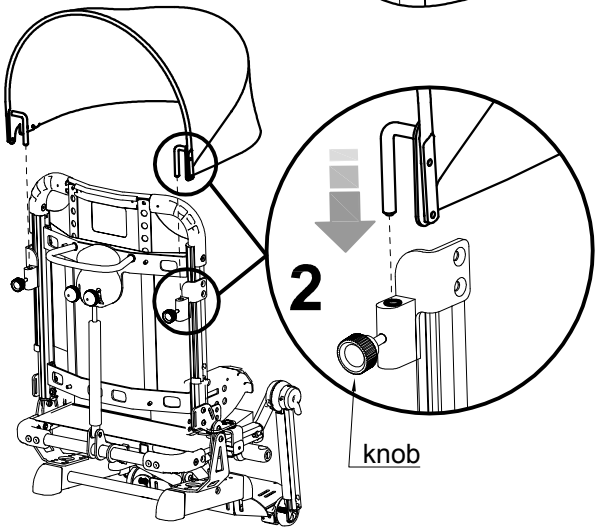
1. **ASSEMBLE THE BRAKE LEVER**
2. **FIX THE BRAKE CABLES**
3. **REMOVE THE CABLES OF THE PEDAL BRAKE**
4. **FIX THE LOWER CABLES OF THE MANUAL BRAKE**

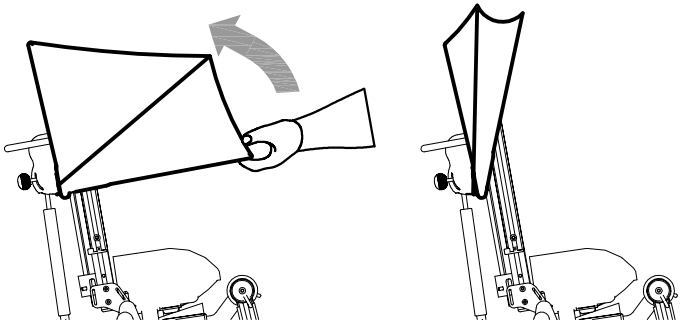


BEWARE!
WHILE THE MANUAL BRAKE IS IN USE THE PEDAL BRAKE IS OUT OF ACTION

CANOPY 819







RAIN COVER 825

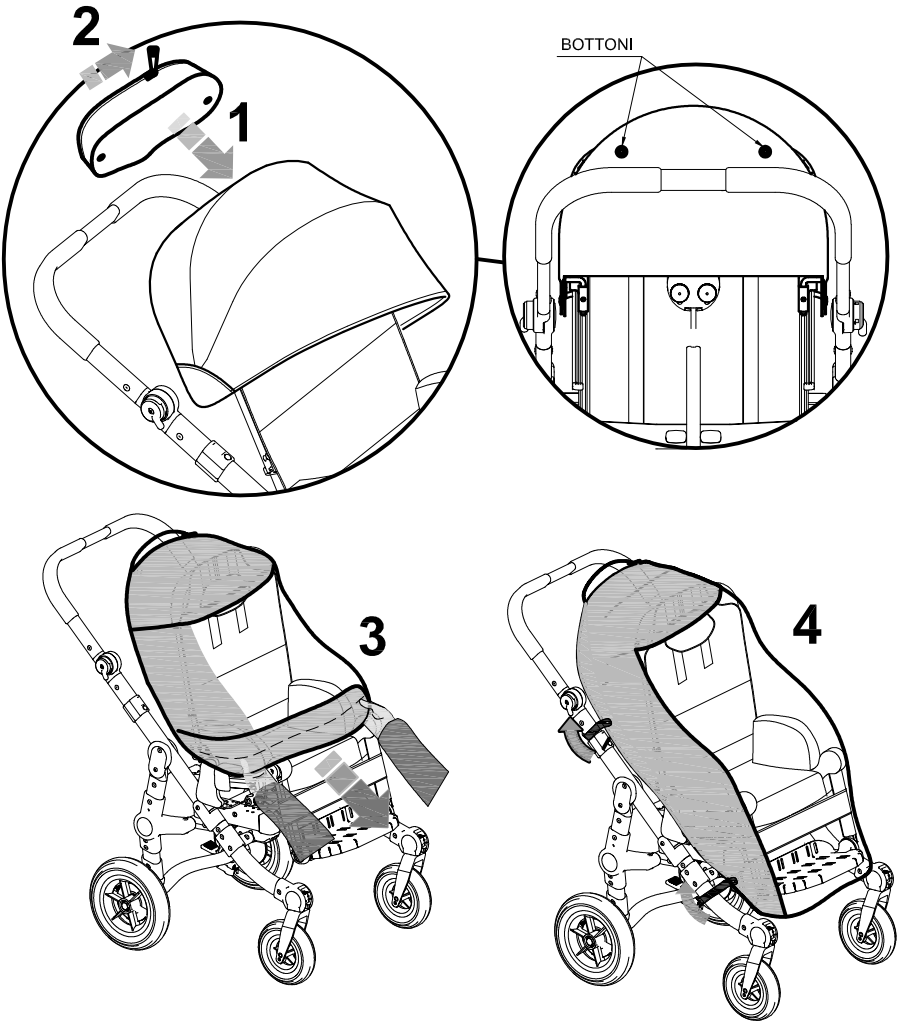
THE RAIN COVER CAN ONLY BE ATTACHED ON THE CANOPY (819)

1- ATTACH THE RAIN COVER POUCH WITH THE TWO BUTTONS LOCATED ON THE BACK OF THE CANOPY

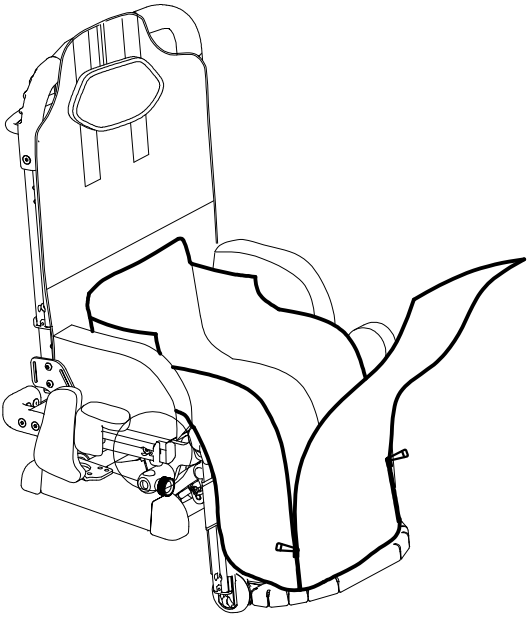
2- OPEN THE ZIPPER ON THE POUCH

3- REMOVE THE RAIN COVER FROM THE POUCH AND POSITION IT SO THAT IT COVERS THE STROLLER

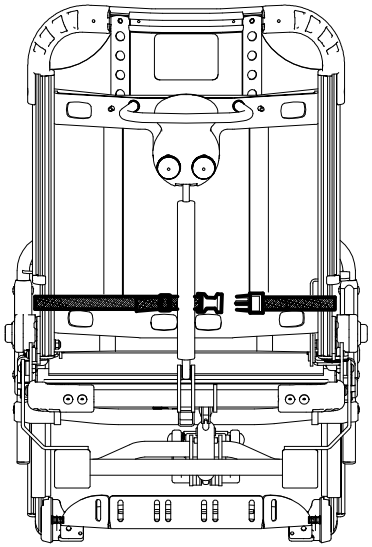
4- ATTACH THE RAIN COVER TO THE FRAME USING THE STRAPS WITH BUTTONS



THERMIC COVER 818

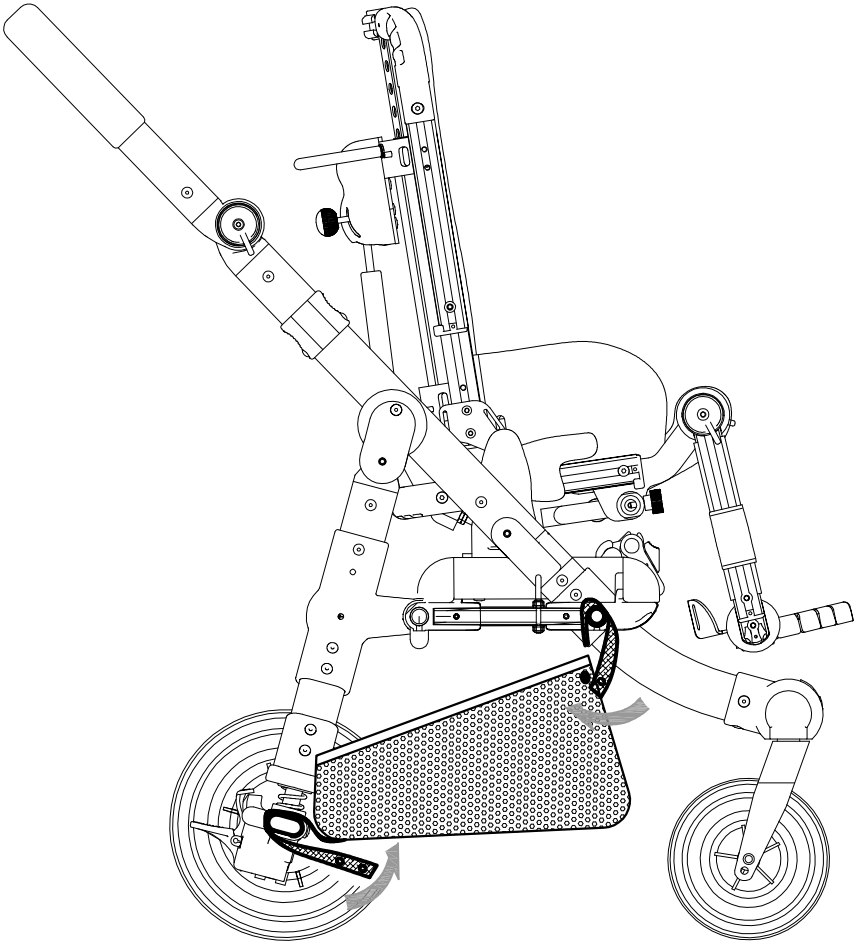


VIEW FROM BEHIND



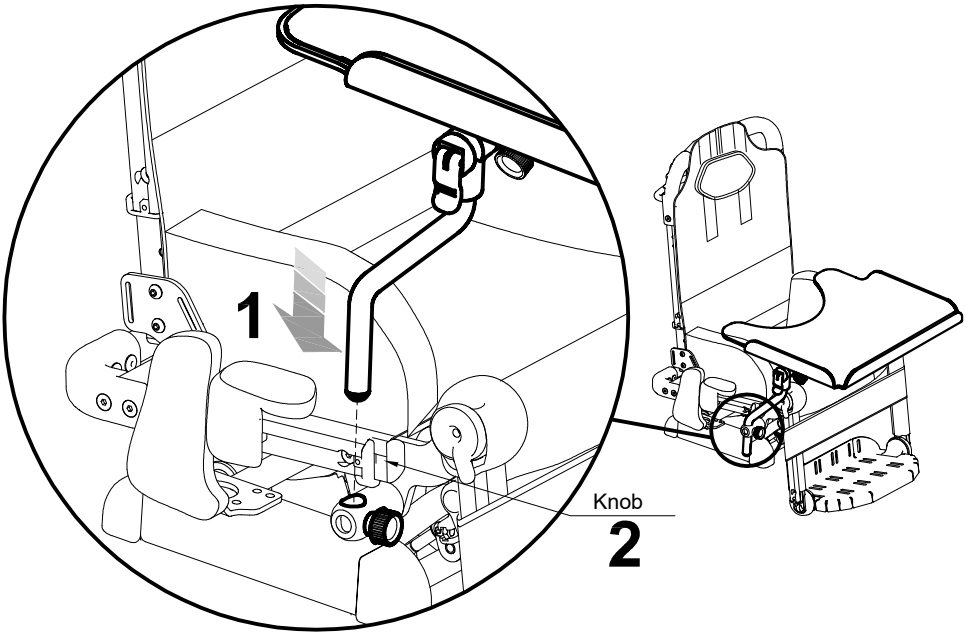
SHOPPING AND VENT TRAY BASKET 858

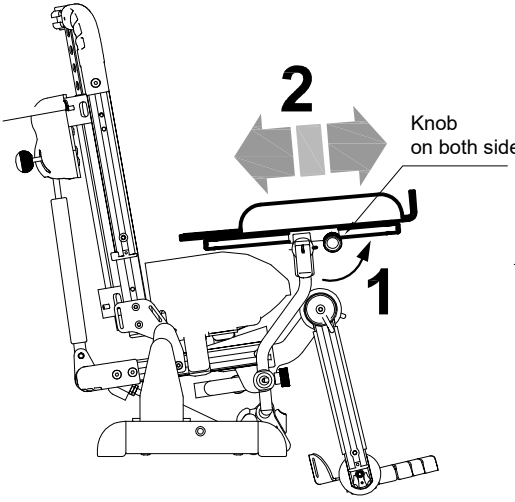
Available only for external base



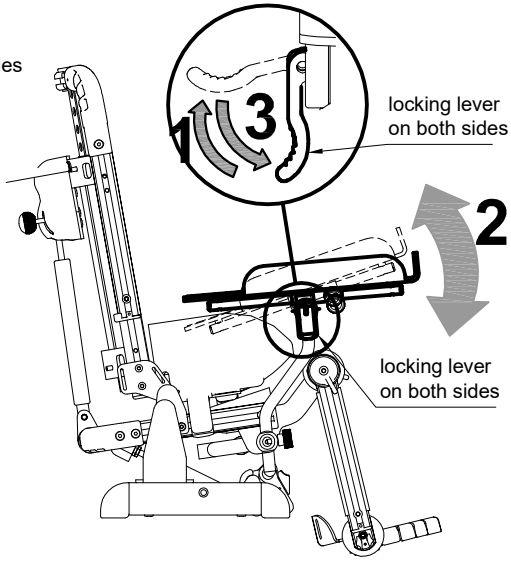
TRANSPARENT TRAY 824

Adjustable in height, depth and tilt





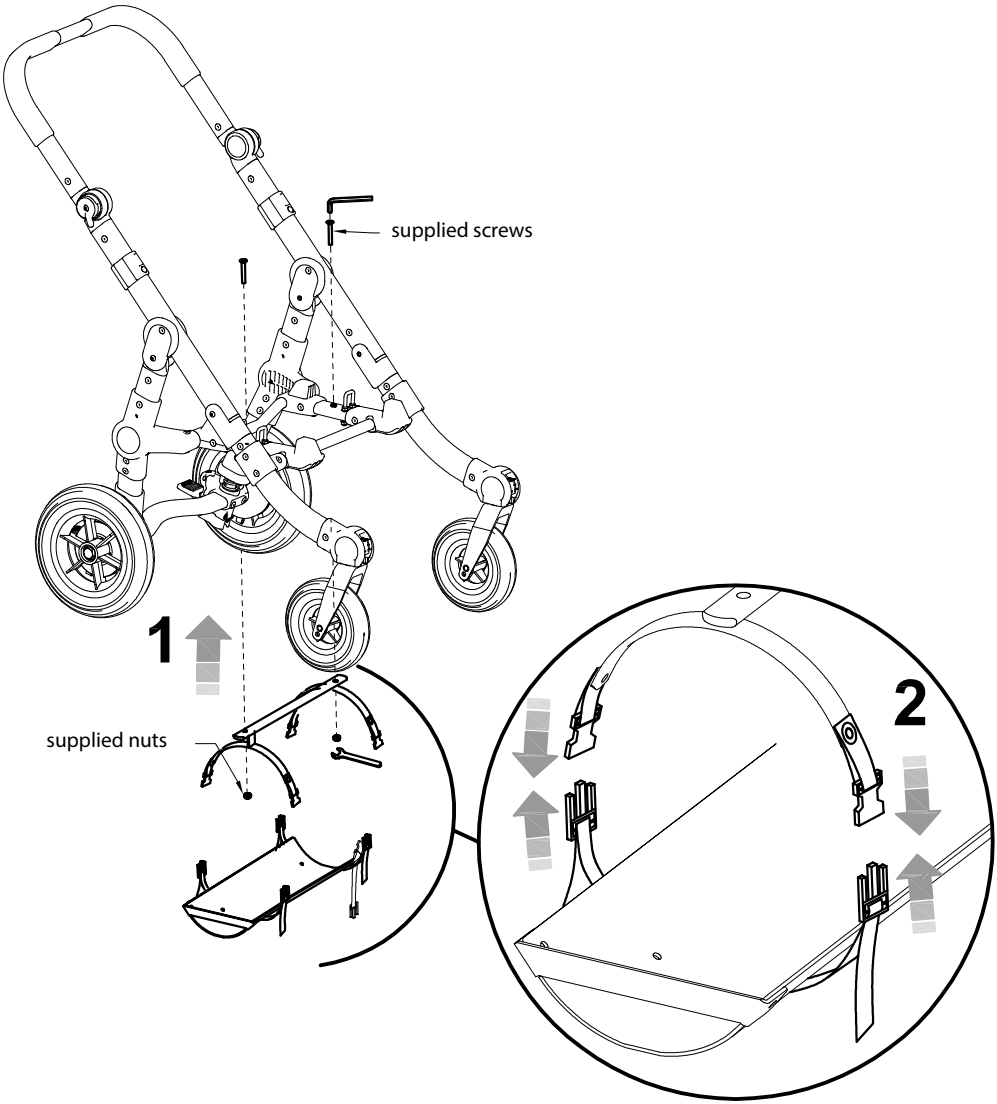
FRONTAL VIEW

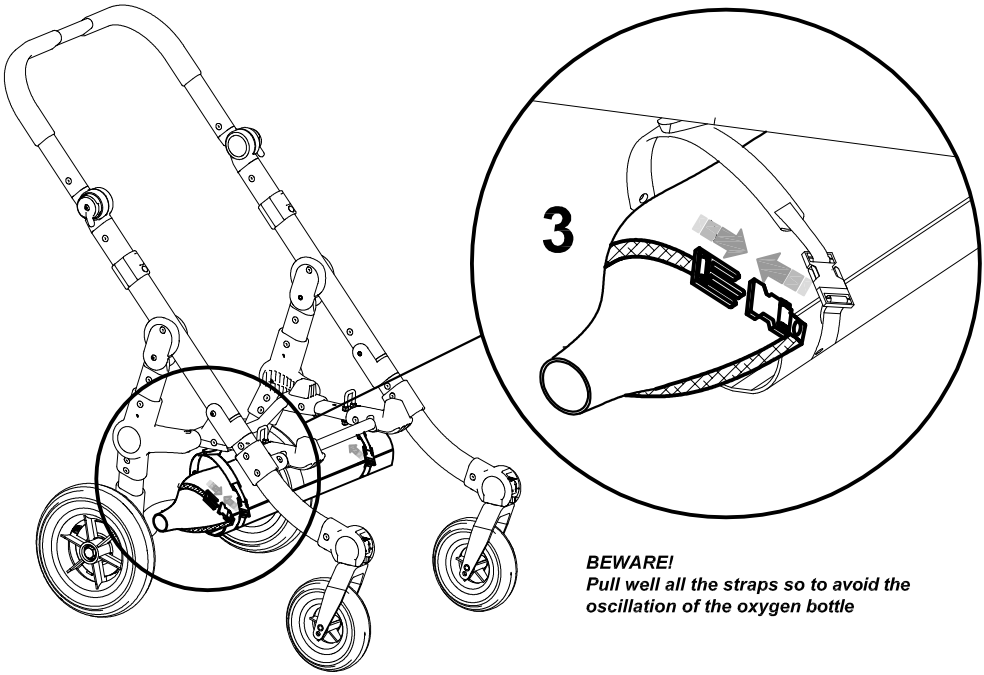


⚠ **TIGHTEN THE KNOB**

OXYGEN BOTTLE HOLDER 935

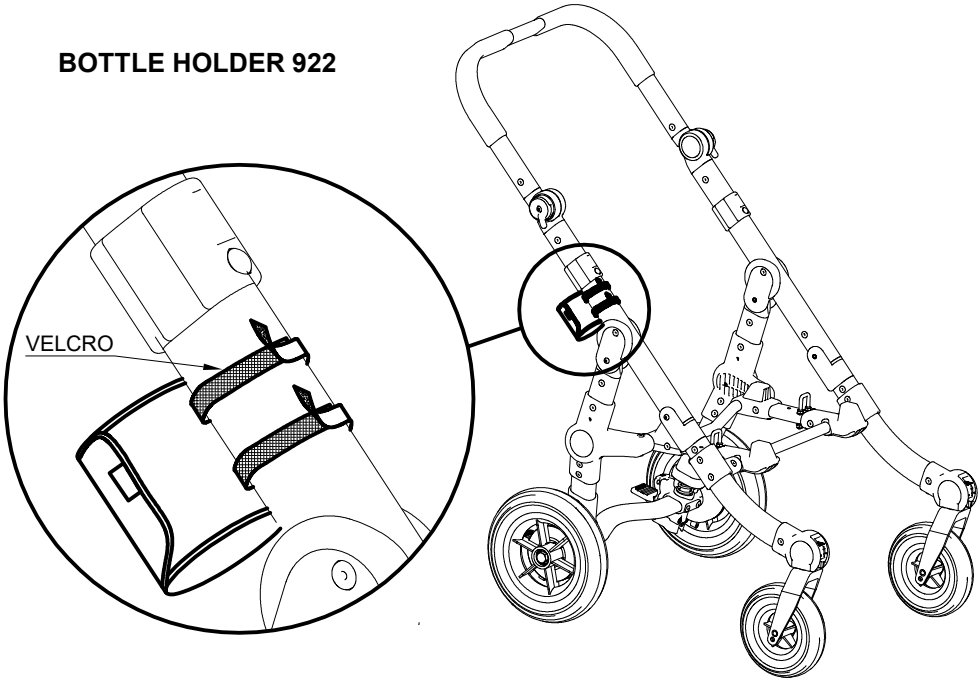
BEWARE!
during transport on a moving vehicle, **the oxygen bottle and the respirator have to be removed from the pushchair frame** to avoid damages in case of an accident, and **they have to be secured to the vehicle** to reduce the chances of injury to the other occupants





BEWARE!
Pull well all the straps so to avoid the oscillation of the oxygen bottle

BOTTLE HOLDER 922



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 **COVER and 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 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).**

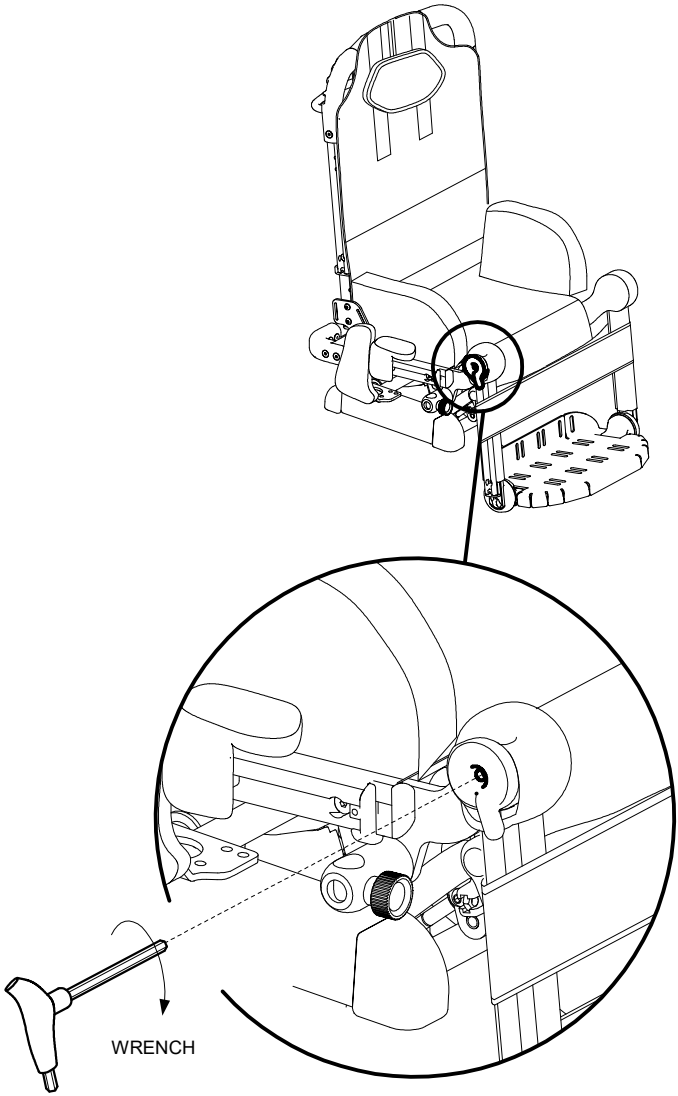
PART	DESCRIPTION / INTERVENTION	MODE
WHEELS	• **Remove any dust and dirt from the wheels to maintain smoothness and braking efficiency.** • **Check that the wheels turn freely.** **If unsuccessful, contact the health professional who provided it or distributor for replacement with an original component.**	**functional/visual test**
BRAKES	• **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; especially those on the hinges of the backrest recline and seat basculation** **Tighten them if loose.**	**Visual/ tools**
BACKREST / SEAT	• **Check for any visible damage or deterioration of the LOAD-BEARING UPHOLSTERY.** **If unsuccessful, discontinue use and contact the health professional who provided it, for replacement with an original component.**	**visual**
ADJUSTING AND OPENING/CLOSING MECHANISM	• **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, 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".**	
SEAT UNIT LOCKING MECHANISM	**Place the seating unit on the base (indoor or outdoor base) and push it down to attach. When both indicators are green check that the seat remains attached to the base.** **If unsuccessful, discontinue use and contact your dealer or distributor for replacement with an original component.**	**functional test**
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 leg rest 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 SPARE PARTS AND CONSUMER PRODUCTS

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 POSTURAL SYSTEM 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	DICHIARAZIONE DI CONFORMITÀ "UE" PER DISPOSITIVI MEDICI *EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES*	Rev. 0 Date 07/09/2023

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 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):*	IT-MF-000034824

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:*	805404040GRILLOPOSTSYSTRA
Nome del Dispositivo: *Name of the Device:*	GRILLO POSTURAL SYSTEM
Codice del Dispositivo: *Product code:*	Vedi Allegato I da pagina 2 a pagina 5 *See Attachment from page 2 to page 3*
Destinazione d'uso: *Intended purpose:*	Sistema di seduta posturale posizionabile sia su base da interno che da esterno indicata per bambini con disabilità (Paralisi Cerebrali Infantili, patologie degenerative con deficit funzionali, patologie sindromiche con deficit funzionali) facilmente adattabile grazie alla sua modularità. Indicato per utenti che abbiano scarso o nullo controllo del tronco e del capo e che necessitino di una adeguata stabilizzazione a livello pelvico per poter assumere, nelle situazioni in cui la funzionalità residua lo permetta, la postura più appropriata nei diversi contesti quotidiani, in ambito esterno ed interno. Il dispositivo deve essere prescritto da un medico specialista, configurato e regolato da un professionista sanitario abilitato dal SSN *Postural sitting unit intended for children with disabilities (Infantile Cerebral Palsy, degenerative pathologies with functional impairments, syndromic pathologies with impairments functional) easily adaptable thanks to its modularity. Suitable for users who have little or no control of the trunk and head and needing appropriate stabilization a pelvic level to be able to assume, in situations where residual functionality allows it, the more appropriate posture in different everyday contexts, both internally and externally.* *The device must be prescribed by a specialistic doctor and must be configured and adjusted by a rehabilitation professional according to the laws in the user's place of residence.*
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 applie*	Non disponibili *Not available*
Norme utilizzate *Standards applied*	Vedi Allegato 2 da pagina 5 a pagina 5 *See Attachment from page 4 to page 5*
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, 07/09/2023	Firma / *Signature:* Chiara Menichini (Legale Rappresentante)

Note:

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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