ermes
sistema di postura pediatrico

INSTRUCTION MANUAL

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Risposte reali a bisogni speciali

Pro Medicare®

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NOTE The illustrations in the following Instruction Manual may differ from reality; however, the methods of use and operation remain valid at all times. All technical data in this manual are approximate and do not constitute specifications.

INTRODUCTION

Dear User, thank you for choosing highly performing Pro Medicare medical device.
ERMES is the Positioning System for children and teenagers, it is the combination of technology and experience in the development of Positioning Systems for users with limited mobility. Thanks to its modularity and different possibilities of adjustment, *ERMES* allows effective adaptation to changes of the user's needs, providing the best comfort with maximum functionality.
As manufacturer, Pro Medicare declares that the medical device complies with Regulation (EU) 2017/745.
Pro Medicare's Quality Management System is certified according to UNI EN ISO 9001 and UNI EN ISO 13485 standards. This manual, drawn up on the basis of the requirements of Regulation (EU) 2017/745 on medical devices, is an indispensable tool for learning how to use the Device safely.
This manual contains all instructions for a correct and safe use of the positioning system combined with the Pro Medicare frame for positioning system. To this end, it is important to read the information about how to use it carefully, with the express invitation to follow the prescribed indications.
As a manufacturer, Pro Medicare refers to the *Professional User* as the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), and to the *End User* (or *lay person*) as the person who is intended to use the Device (caregivers, family members, etc.).

⚠ *The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User.*

The Technical features of the device are reported in the Annex A "*Technical Features".*
After consulting this manual, for further information, please contact the Technical Sales Department at the number **+39 0831 777840**, Monday to Friday from 9 a.m. to 1 p.m. and from 2.30 p.m. to 6.30 p.m.
In case of emergencies outside the working hours, please send an email to **sales@promedicare.it**
We will call you back as soon as possible.
In order to ensure appropriate After-Sale Monitoring of Devices placed on the market and put into service, or in the event of an incident during the use, please refer to the instructions stated in the relevant chapter.

USE

ERMES positioning systems has been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745. Its modularity, allows a wide variety of configurations which make the device able to follow of the pathology, somatic growth and the consequent postural adaptations.
The positioning system in combination with the frame for positioning system is intended to be used both indoors and outdoors, for personal use only and with the assistance of caregivers.
In accordance with the applicable standards the professional user has the responsibility to ensure the safe combination designed for the specific user of the *ERMES* positioning system and the relevant frame for positioning system.
The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User. If a custom-made Positioning solution is fitted and adjusted as prescribed, it may not be used for other users.
The CE Declaration of Conformity refers exclusively to the Medical Device prepared and provided by the manufacturer, "as-is", when the Device is unchanged with respect to the standard configuration. Pro Medicare is constantly dedicated to innovate its own Devices; This can entail changes in form or technique on the devices and/or related accessories. Therefore, hypothetical complaints on values, images and schemes defined in the this manual, will not be accepted. Furthermore, for the complete list of the optional parts and/or accessories, plase refer to the latest order form in force.

1. INSTRUCTION OF USE

1.1 Packaging and Transport

The original packaging contains the following components:

- *ERMES* positioning system
- any accessories as per the order form
- labeling and Instruction Manual.

Upon delivery, please check for the integrity of the package and immediately note any damages or anomalies on the shipping document. Then open up the packaging and check that the various parts do not show dents, drippings, deformations or tears. Otherwise note the anomalies found on the shipping document.
After performing these checks and if the product has not to be put into immediate use, we recommend to repack and store it in a dry place.
The above operation will be carried out by the Professional User who has to perform the assembling procedures of the *ERMES* positioning system with the relevant frame for positioning system.

1.2 Preliminary Operations for correct Commissioning

If the positioning system is used in combination with frames for positioning system manufactured by other companies, it must have a suitable interface system for safe connection.
The professional user and the end-user must check, by inspection, that the positioning system/frame for positioning system connection system is made safely.
The positioning system comes in compact version with the removable components disconnected; it must be put into operation.

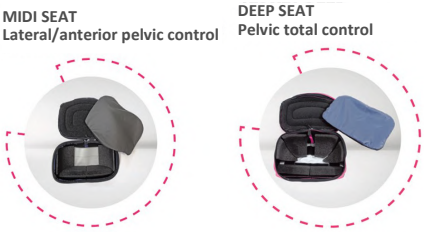
These operations must exclusively be performed by the Professional User, who is responsible for the safety perfor-mance of the combination and/or configuration.

1.2.1 Operations for the "Commissioning of the Positioning System"

The *ERMES* positioning system, in its standard configuration consists of a seat with multi-adjustable hip guides and a backrest.
The seat and backrest padding provides maximum softness and comfort. It is self-modeling and distributes the body weight uniformly over the entire surface by reducing contact pressure significantly. The cover is available in different colors, it is fire retardant, breathable, latex-free and with a low risk of skin irritation, it is commonly used in medical devices. Furthermore, depending on the particular needs and clinical conditions of the user, the positioning system can be supplied with thoracic supports, harnesses and pelvic belts, head positioning system, lower limb support elements and trays.
The components are reported below:

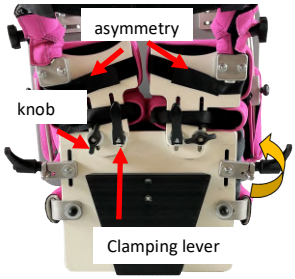
1) Seat

The seat is based upon the "INSERTO SEAT (PTS)" technology. It consists of a set of wedges which are placed inside the cover in order to provide greater modularity and adjustments possibility. Everything is positioned on the metal structure with velcro. It is a pelvis positioning system which provides containment, support and the compensation of the deformities by preventing the pressure sores. The seating system, in its completeness, comes highly comfortable and offers a highly postural solution.
The following pictures show the two types of seat (pic.1)



pic. 1: *Types of seat*

♦ Asymmetry and adduction/abduction adjustment (pic. 2.1 e pic. 2.2)



pic. 2.1: *Asymmetry adjustment - bottom view*

fig. 2.2: *Asymmetry adjustment - top view*

To perform asymmetry/adduction/abduction adjustment, please, perform as follows:
- loosen the clamping levers and the knobs
- move the asymmetries inward or outward with adduction/abduction to the desired position
- tighten the clamping levers and the knobs
- put the wedges above asymmetries.

2) Backrest

The backrest is based on the "INSERTO BACK (TTS)" technology, it is similar to the Inserto Seat but consists of a set of lumbar contours and a lumbar support, which are placed inside the cover/covers in order to provide greater modularity and adjustments possibility. Everything is positioned on the metal structure with velcro. The backrest is the positioning system designed to provide the trunk support. It is modular and multi-adjustable whose aims is to support the user's trunk through its positioning. The pic. 3 shows the backrest)

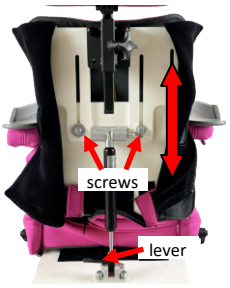
pic. 3: *backrest type*

♦ Height adjustment

To perform the backrest height adjustment, please, perform as follows (pic. 4):
- loosen the screws
- move the shell up and down
- tighten the screws
- place the wedges and padding on the whole backrest.

♦ Backrest reclining

The reclining is performed by the gas spring activating the control lever located on the lower end of the spring (pic. 4).
Reclining is continuously adjustable by activating the lever.
Once released the lever, the spring will block the backrest to the position reached.
If the adjustment is done with the user seated in the system, it is necessary to hold the backrest until the gas spring lever is released.
Proceed slowly, gradually and pay careful attention.



pic. 4: *Backrest adjustment*

Once the posture has been adjusted, it is advisable to sit the user for at least an hour and examine any possible areas of pressure overload; if so, it will be necessary to reposition the wedges, while if not, the product will be ready to be used.

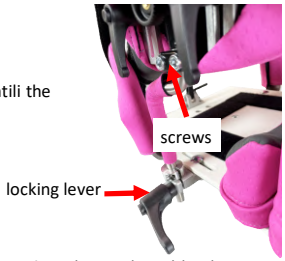
3) Multiadjustable Kit

This Kit allows to perform adjustments for the hip guides and arm support, in particular,

A) *Pelvis*

Possible adjustments are: in width, depth, height e adduction/abduction:

- Width and/or adduction/abduction adjustment (pic. 5):
  1. loosen the locking lever to ensure the movement of the steel rod
  2. loosen the two cap screws to provide the movement of the hip guides
  3. move the hip guide to the outside and to the inside with adduction/abduction untili the desired position
  4. tighten the two cap screws to block the hip guide.



pic. 5: *hip guide width adjustment*

- Depth adjustment (pic. 6):
  1. loosen the Knob to unlock the Hip Guide to the Clamp
  2. move Hip Guides horizontally and along the slots until the desired position
  3. tighten the knob to block the Hip Guide.
- Height adjustment (pic. 6):
  1. loosen the locking lever to ensure the movement of the steel rod
  2. move Hip Guides vertically until the desired position
  3. tighten the locking lever
  4. put the collar on the clamp by screwing the two screws; To get the right position is important that the two screws are oriented in the same direction of the locking lever.

pic. 6: *hip guide depth/height adjustment*

B) *Arm Support*

The arm support is fixed to the hip guide through two slotted L-shaped brackets. The arm support present two rows of holes to allow multiple adjustments.

- Height and/or tilt adjustment (pic. 7):
  1. loosen the two locking levers to ensure the sliding of the brackets which are fixed to the arm support
  2. move the arm support vertically or tilt it until the desired position
  3. tighten the locking lever to block the arm support.

pic. 7: *arm support height and/or tilt adjustment*

- Width and internal/external rotation adjustment (pic.8)
  1. unscrew and loosen the round head screws of the L-shaped Brackets which are fixed under the arm support
  2. slide Arm support inward or outward (internal/external rotation) until the desired position
  3. tighten and fix the Round head screws.
- Depth adjustment (pic. 8):
  1. unscrew and loosen the round head screws of the L-shaped Brackets which are fixed under the arm support
  2. slide Arm support forward or backward until the desired position and in relation to the rows of holes located under the arm support
  3. punch the cover, insert and fix the round head screws
  4. tighten and fix the round head screws.

pic. 8: *arm support width/ depth adjustment*

Ensure the multi adjustable kit works properly and safely by checking:
1) tightening of levers and screws
2) the impossibility of the hip guide and arm support to be detached.

4) Thoracic support (if required)

The modular and multi-adjustable thoracic support consists of fixed/flip metal bracket and of a flat or contoure shaped padded part.

It is used to facilitate the search for symmetry, giving lateral and/or anterior support and a gentle push of the trunk.

It can be adjusted in height and/or width by using the locking nuts on the rear part (pic. 9).

Check that the screws are properly tightened.

pic. 9: *Thoracic support adjustment*

5) Headrest (if required)

The headrest is the positioning system for the head support and it is designed to provide support and a horizontal view wherever possible. It is multiadjustable (pic. 10) and different types are available. It can be fixed, which is firmly anchored to the structure, or removable by removing it from its housing byusing the tightening knob.

- Height and depth adjustment

  Adjustments are performed as follows:
  - loosen the fixing screws of the headrest arms
  - move the headrest arms until the desired position
  - tighten the screws of the headrest arms.
- Angle adjustment

  Adjustment is performed as follows:
  - loosen the two screws of the headrest spherical part
  - adjust the angle until the desired position
  - tighten the two screws.

pic. 10: *headrest adjustment*

6) Harnesses (if required)

There are two types of harnesses (if required): a dynamic butterfly harness and a jacket harness (example. pic. 11).

The Dynamic butterfly herness provides stability of the trunk and shoulders allowing to keep the position, accompanying small movements. The jacket harness provides total stability of the thorax. Any type of harness chosen must be anchored to the back of the backrest, using the screws for adjusting the height of the backrest for the upper part of the harness and the screws for anchoring the backrest reclining plate for the lower part. To complete the trunk stabilization accessories, there is a front pad (pic. 12) which impede theanterior lean of the trunk and it is anchored to the thoracic supports. Both the harnesses and the front pad are equipped with easy-to-operate release buttons.

pic. 11: *harness adjustment*

pic. 12: *harness adjustment*

7) Pelvic belt (if required)

The pelvic belt (pic. 13) provides the pelvis stabilization by preventing it from moving forward on the seat and by adjusting its position on the sagittal plane.

The two fixing point pelvic belt is fixed to the lower part of the seat shell by engaging the ancho-ring screws of the reclining plate; if it is a 4 fixing point pelvic belt, it will be fixed both to those screws and to the screws of the Lateral kit armrest kit. Any pelvic belt chosen is equipped with easy-to-operate release buttons.

pic. 13: *pelvic belt adjustment*

8) Lower limb positioning system (if required)
Lower limb positioning system provides lower limb support and containment. Adjustments are as follows:

pic. 14: *Footrest tube angle adjustment and knee angle adjustment*

- Angle adjustment of the Footrest tube (pic.14):
  - loosen the two tightening nuts of the knee angle clamp
  - adjust the angle of the tube to the desired position
  - tighten the two nuts.
- Knee angle adjustment (pic.14):
  - unscrew and loosen the fixing knob
  - rotate the legrest tube to the desired position
  - tighten the fixing knob gradually in order to allow the engagement of the toothing that blocks the position of the leg rest tube.

pic. 15: *footplate height adjustment and other adjustments*

- Footplate height adjustment (pic. 15):
  - loosen the clamping screw of the footplate clamp.
  - move the clamp of the footplate along the tube to the desired position
  - tighten the clamping screw.
- Footplate adjustment (pic. 15):
  The possible adjustments are:
  A) *tilt adjustment*:
    - unscrew and loosen the 2 countersunk head fixing screws
    - rotate the footrest clockwise or counter-clockwise to the desired position
    - reinsert and tighten the fixing screws

  B) *depth adjustment*:
    - unscrew and loosen the 2 countersunk head fixing screws
    - rotate the footrest clockwise or counter-clockwise to the desired position
    - reinsert and tighten the fixing screws

  C) *internal/external rotation adjustment (only for slotted footplates):*
    - unscrew and loosen the 2 countersunk fixing screws without removing them
    - rotate the footrest inward or outward to the desired position
    - screw and tighten the two screws

9) Tray (if required)
The Tray provides proper forearms support, it allows the discharge of the trunk and arms weight from ischial tuberosities and promotes residual activities/abilities.
The locking of the Tray is performed by inserting the Steel Rod into its housing which is located under the tray and tighten the Knob (pic. 16).

Verify the tray is assembled properly by checking the impossibility of movements.
Check the stability of the tray. Be careful not to hit the user when moving the tray.
Do not adjust the depth of the tray too forward, as this may cause the tray to tip over when a weight is placed on it.

pic. 16: *Tray adjustment*

10) Calf Strap (where provided)
It provides support at the posterior part of the leg, preventing it from sliding backwards, and guarantees a good positioning of the foot on the footplate; this fitting is performed by the fastening system.
To assemble it, please proceed as follows:
1) determine the position along the tube where the strap needs to be mounted
2) adhere the adhesive tape to the tube which is at the end of the strap
3) insert the ring-shaped ends of the strap into the two legrest tubes and fix them onto the adhesive tape placed in step 2)
4) adjust the padding of the Calf Strap by using the fastening system to give a correct support to the leg.

Check regularly the skin to ensure that no sores have developed due to excessive pressure. Do not place the calf strap on any sensitive part.

11) Calf support (if required)
The Calf Support (single or separate) provides the posterior and lateral containment of the leg. It can be adjustable in height, by engaging the holes holes on the back, or in depth by engaging the holes on the side of the hardware.

12) Shoes Holder (if required) (pic.17)
It provides the foot support by preventing it from sliding backwards and ensures a discreet positioning of the foot on the footplate. It is possible to adjust the depth and tilt by using a knob located under the footplate.

pic. 17: *shoes holder*

1.3 Combination with the frame for positioning system

Ermes Positioning System is designed to be used in combination with Frame for Positioning System. The professional user, the end user must check, by inspection, that the combination is performed safely.

⚠ *The first combination of the ERMES positioning system and the relevant frame for positioning system must exclusively be performed by the Professional User.*

Combination with Adacta Giò frame for positioning system
Adacta Giò Frame comes with the seat base; the seat base presents female interface plate which is useful to be combined with Ermes Positioning System. The combination is performed as follows:

1) Mounting Ermes Positioning System (pic. 18)
To combine the Ermes positioning system with the base, pleas, perform as follows:
- apply the Base Frame Parking Brake
- unlock the interface plate safety pin located under the seat base (pull the safety pin outward and rotate it 90 degrees)
- place Ermes Positioning System on the Base to combine the Trapezoidal Male Interface Plate with the Female Interface Plate.
- push Ermes Positioning System towards the backrest tubes
- lock the safety pin (rotate 90° and let the spring return the pin to its natural position).

Check the block of the positioning system trying to pull it outward and towards the castors. Performing the above operations, the Ermes positioning system will not have possibility of movement.

⚠ *After having performed these operations make sure that the frame combined with the positioning system is stable, easy to move and that all components work in harmony. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.*

pic. 18: *Ermes positioning system mounting*

2) *Disengaging the Ermes positioning system*
To disengage the Ermes positioning system from the base, proceed as follows:
- apply the parking brakes
- unlock the safety pin of the interface plate (pull outwards and turn 90°)
- push the Ermes positioning system towards the castors.
- lift the Ermes positioning system.

Combination with the TIPCO Indoor frame for positioning system
Tipco Frame comes with female interface plate which is useful to be combined with Ermes Positioning System. The combination is performed as follows:

1) *Mounting Ermes Positioning System* (pic. 19)
To perform the combination of Ermes positioning system with the base, please, perform as follows:
- apply the posterior wheels Parking Brake
- unlock the female interface plate safety pin (pull the safety pin outward and rotate it 90°)
- place Ermes Positioning System on the Base to combine the Trapezoidal Male Interface Plate with the Female Interface Plate.
- push Ermes Positioning System towards the backrest tubes.

pic. 19: *Tipco Base*

Check the block of the positioning system trying to pull it outward and towards the castors. Performing the above operations, the Ermes positioning system will not have possibility of movement.

After having performed these operations make sure that the frame combined with the positioning system is stable, easy to move and that all components work in harmony. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

2) *Disengaging the Ermes positioning system* (pic. 20)
To disengage the Ermes positioning system from the base, proceed as follows:
- apply the parking brakes
- unlock the safety pin of the interface plate (pull outwards and turn 90°)
- push the Ermes positioning system towards the castors.
- lift the Ermes positioning system.

pic. 20 *Ermes positioning system*

Combination of the seat base with other frame for positioning system

The seat base presents female interface plate which is useful to be combined with Ermes Positioning System. The combination is performed as follows:

1) *Mounting the Seat Base* (pic. 21)
It is really important to fix the seat base on the frame for positioning system with the fixing kit.
Follow the instructions provided with the fixing kit. Verify that the safety pin is easy to handle. Verify the correct mounting of the seat base and the impossibility of movements by:
- moving it back and forth along the seat tubes of the frame
- moving it upward.

Performing the above operations, the seat base will not have possibility of movement.

pic. 21 *Seat base/ interface*

After having performed these operations make sure that the base, easy to move and that all components work in harmony. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

2) *Mounting Ermes Positioning System*
To combine the Ermes positioning system with the base, pleas, perform as follows:
- apply the Base Frame Parking Brake
- unlock the interface plate safety pin located under the seat base (pull the safety pin outward and rotate it 90°)
- place Ermes Positioning System on the Base to combine the Trapezoidal Male Interface Plate with the Female Interface Plate.
- push Ermes Positioning System towards the backrest tubes
- lock the safety pin (rotate 90° and let the spring return the pin to its natural position).

Check the block of the positioning system trying to pull it outward and towards the castors. Performing the above operations, the Ermes positioning system will not have possibility of movement.

After having performed these operations make sure that the frame combined with the positioning system is stable, easy to move and that all components work in harmony. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

3) *Disengaging the Ermes positioning system*
To disengage the Ermes positioning system from the base, proceed as follows:
- apply the parking brakes
- unlock the safety pin of the interface plate (pull outwards and turn 90°)
- push the Ermes positioning system towards the castors.
- lift the Ermes positioning system.

1.4 How to use it

The *ERMES* positioning system combined with the relevant frame for positioning system, after the Professional User has performed the commissioning, is ready to be used. Daily operations such as the transfer from and to the system, must normally be performed by parents or caregiver.
Following there are all modes of use. Before to start any operation the professional user needs to educate the parent or caregiver about use. It will require to practise all daily operations and manoeuvre the system in areas where it should be used. It is good to develop one's own methods for safe use, adapted to the needs.

During daily use, components and/or accessories may become loose and affect adjustments. Check periodically that they have not changed. Never make any adjustments or changes without the intervention of the professional user.

A) Use of the frame for positioning system components

Please, follow the instructions reported in the frame for positioning system instruction manual

B) Use of Ermes and Ermes accessories

- Mountig/disengaging of the ERMES positioning system from the relevant frame for positioning system

Depending on the type of frame, please, follow the relevant instructions. In particular:
- with ADACTA GIO' FRAME follow the instructions reported on page 10
- with TIPCO FRAME follow the instructions reported on page 10
- with SEAT BASE MOUNTED ON OTHER FRAMES FOR POSITIONING SYSTEM follow the instructions reported on page 11.

- Multiadjustable Kit

Engagement

1. insert the rod into the hole of the clamp
2. slide the rod until the collar reaches the clamp
3. pay attention to the two screws on the collar; to define the correct position, the two screws must be oriented in the same direction as the locking lever
4. tighten the locking lever.

Disengagement

1. loosen the locking lever to release the rod
2. detach the kit.

Ensure the multi adjustable kit works properly and safely by checking:
1) tightening of the locking lever
2) the screws of the collar and of the locking lever must have the same direction
3) the impossibility of the kit to be detached.

- Tray (where provided)
Please, follow the instructions reported on page 9 point 9

- Thoracic support (where provided)
Please, follow the instructions reported on page 8

- Pelvic belts and harnesses(where provided)
Please, follow the instructions reported on page 8

Be careful during the removal of pelvic straps, chest supports or trays to avoid hitting the end user.

C) End-user transfer from/to the System

Before performing these operations, it is important to discuss with the end user and about the most natural and regular operations that needs to be done. This will help to make it easier for the user and it will reduce possible dangers.

Transfer from the System

√ Ensure the brakes are on, and the system is locked from movements
√ Ensure the anti-tip device is correctly positioned
√ Put the seat into a horizontal position as reported in the frame for positioning system instruction manual
√ Loosen any fixing harness
√ Disengage any thoracic supports and the multiadjustable kit.

Now the user is ready to be transferred. Please pay particolar attention to this operation.

Transfer to the System

√ Engage the brakes and make sure the system is locked
√ Ensure the anti-tip device is correctly positioned
√ Put the seat into a horizontal position as reported in the frame for positioning system instruction manual
√ Lift and transfer the user to the system by paying particular attention to this operation
√ Engage any thoracic supports and the multiadjustable kit
√ Fasten any fixing components
√ Make sure that the user is in his normal seating position.

While the positioning operation is ongoing, ensure that no part of the body is trapped.

D) Trasporting the System

Disassemble the ERMES Positioning System from the Frame and make it compact for transportation in a vehicle
To transport the system it is necessary to disassemble the ERMES positioning system from the frame as shown on pages 10 and 11 and to make compact the frame structure by proceeding with the operations described in the instruction manual of the relevant frame for positioning system.

Pay particular attention to these operations; do not lift the backrest by the thoracic supports and the seat by the armrests: they can become loose and change the configuration of the System. Lift only the components that cannot be detached. Be careful when folding the System as to not trap any moving part. Finally, upon reassembly, check that all configuration and settings have not been altered. If changes are noted, please contact the Professional User.

Subsequent start-up of the Frame and recombination of the Positioning System with the Frame
At the end of the trip, bring out the ERMES positioning system and the frame and proceed with commissioning of this one by proceeding with the operations described in the instruction manual of the relevant frame for positioning system.
Finally, it is necessary to combine the ERMES positioning system on the frame as described pages 10 and 11.
Please, follow the instructions of the relevant instruction manual.

After having performed these operations make sure that the Frame combined with the Positioning System is stable, easy to move and that all components work in harmony. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

1.5 Recommendations for Use

In order to guarantee safe use and a long lasting performance of the Positioning System, please find below advices for the user and/or caregiver:

√ Carefully follow the instructions reported in this manual
√ Follow the recommendations provided by the Professional User
√ Keep the Device away from heat sources
√ Carry out thorough cleaning and pay close attention to the standard maintenance.

2. GENERAL WARNINGS

All announcements reported in this section describe the conditions and situations that may cause danger to the user or to third parties. Please read carefully before using and putting in service the System. To ensure the correct use of the Device, some operations, such as the first commissioning and adjustments, must only be performed by authorized people - *the Professional User* - Some daily operations can obviously be performed by the *End User* (or *lay person*). Therefore, there will be specific warnings for those concerned. In particular, the term *Professional User* describes the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), while, the term *End User* describes the person who is intended to use the Device (caregivers, family members, etc.).

2.1 Warnings for the Professional User

For further information, please contact the Technical Sales Department at the following number:

+39 0831 777840

- Max. Load: See Annex A *"Technical Features"*

- Preliminary Operations for correct Commissioning : (to be performed in accordance with the instructions provided in *sect.* 1.2)
  - After having performed these operations make sure that the Frame combined with the Positioning System is stable, easy to move and that all components work in harmony

* Check for noise, vibration, or changes to the normal conditions of use to ensure safety conditions and the suitability for use.

- Adjustments: (to be performed in accordance with the instructions provided in *sect. 1.3*)
  - These operations must be performed by authorized people
  - During adjustments, the anti-tip system must be correctly positioned
  - After having performed these adjustments, be aware of any noise, vibrations or any changes to the normal conditions of use to ensure the safety conditions and suitability for use
  - Unauthorized modifications or the use of parts not supplied or approved by the manufacturer may affect the safe and operational integrity of the system and be cause of danger.

- Combination with the positioning system: (please, perform this operation as by following the instructions described on *sect. 1.3).*
For the combination with the frame, please also refer to the warnings reported on the relevant instruction manual.

2.2 Warnings for the End User

Before using the Device ensure the Professional User explains the procedures for correct commissioning and standard maintenance For further information, please contact the Professional User.

- Maximum Load: See Annex A *"Technical Features"*

- Environmental Conditions

a. For the frame for positioning system, please, refer to the relevant instruction manual
b. Contact with water and excessive moisture can cause components of the structure to oxidise and start to show signs of decay, so:
- Do not use the system in the shower, pool or environment in contact with water. Some components may be damaged and cause malfunctions
- Avoid extreme humid places (for example: do not bring the system into a steamy bathroom after a shower)
- Avoid contact with seawater
- If the device comes in contact with water or dirt, please carry out an immediate and thorough clearing.

c. Severe environmental conditions may affect the features of the materials used, the functionality and performance of the structure, so:
- Avoid the exposure to extreme temperatures
- Avoid prolonged exposure to sunlight. Some parts may overheat.

- Components and options

***Footrests*:** The footrests are the lower part of the frame and closer to the floor, so avoid to pass over obstacles that may collide with them causing damages. Also:
- Make sure user's feet do not "hang" over or become trapped between the footplates
- Do not place any weight on the footrest to prevent the system tipping forwards
- Do not stand or lean the system on the footrest; they may detach from the footrest tubes or break.
- Make sure, after each adjustment, that the footrest does't touch the front wheels.

***Armrest*:** The armrests cannot support the weight of the system. if used for lifting the system, they may become damaged and can break.

- Use

- **Maximum Load:** See "Technical Features" reported on the Annex A
- If you hear noise, vibrations or any abnormality after a few days of use, please contact the professional user
- Be careful when moving the system over uneven ground or obstacles, which if in contact with wheels, they can cause the system to tilt.
- To reduce the risk of a tipping, do not hang bags, backpacks or any other weight on the system
- Max accepted gradient: as reported on the frame for positioning system instruction manual
- In the event that an accident causes a loss of performance, do not use the system and consult the professional user
- In the case of a sudden deterioration in performance, do not use the system and consult the professional user
- In case of malfunctions resulting from other causes, including poor maintenance of the system, the professional user should be consulted.
- Frequently check all the connections between the Ermes positioning system and the frame and verify for a safe and fully functional operations.
- Pay attention to the hands when opening the footrest platforms

For the combination with the frame, please also refer to the warnings reported on the relevant instruction manual.

3. NEGATIVE ADVERSE EFFECTS

Generally the use of the *ERMES* positioning system combined with the Tipco or Adacta Giò frame for positioning system should not cause any adver effects such as allergies, skin irritations or redness when in contact (the cover is latex-free, is at low risk of irritation to the skin and it is commonly used in medical devices). Otherwise, please contact both the Doctor and the Professional User immediately. Daily monitor the skin area which is in contact with the Device for evidence of pressure sores caused by incorrect or outdated adjustments; in this case it is suggested to suspend the use and contact the Professional User. For the combination with the frame, please also refer to the negative adverse effect repored on the relevant instruction manual.

4. RESTRICTIONS OF USE

The *ERMES* for Positioning System has been designed and manufactured to provide the end user the correct positioning support within the normal activities of social relations, school or leisure time. Any other use may compromise the safety of the Device.

Mandatory Requirements

- Do not drill or crush the gas spring
- Do not drive the ERMES positioning system combined with the frame for positioning system fully tilted on steep slopes
- When the system is not tilted, make sure the user is not too forward to kepp the system stable
- When the user in on board, avoid lifting the system by the legrests or any posture accessories. If it is necessary, lift the system by the sides of the structure, making sure the seat doesn't move during this operation
- Get help from additional people when you have to lift the system over obstacles or down stairs
- All replacement parts or adjustments not authorized by the manufacturer are strictly forbidden
- For safety, never leave the user alone on the system, especially in the case of children
- Apply the brakes whenever the system with the user positioned is stationary
- Please, pay particular attention when moving on rough or uneven terrain which can damage the system
- It is not recommended to use any kind of belt/ harness as a safety belt
- It is not recommend the use of the System for users who need shock absorbing/dynamic systems.
- Smoking and/or open flames are prohibited
- The system is not intended to be used on users who have injured skin or body surfaces (sores, etc.); therefore, use in such circumstances is prohibited.

For the combination with the frame, please also refer to the restrictions of use reported on the relevant instruction manual.

5. STANDARD MAINTENANCE

In order to guarantee a good functioning and long lasting performances in safe conditions it is necessary to check regularly and make periodically maintenance. This operation must be performed by the end user. The regular maintenance consists of two parts: cleaning and mechanical parts checking.

- *Cleaning* -

The metal and plastic parts can be cleaned with a damp cloth with cold water without the addition of detergent, taking care to go over everything with a dry cloth. All mechanism, such as the the backrest inclination, the brackets of the multiadjustable kit, Thoracic support brackets and Headrest hardware should always be checked to remove any dust or dirty that may affect the performances. Werecommend to perform these operations at least once a month. Regarding the cleaning of the padding, even if it is not in prolunged direct contact with the skin, we recommend to clean it in order to avoid infections. The cleaning can be performed with a damp cloth or a brush with natural bristles and tepid water (max 30°). It can be used a light gentle detergent. Wipe out the excess of water from the padding with a dry cloth. Then dry it away from heat sources. Do not dry with exposure to direct sunlight. It is advisable to perform the cleaning procedure at least once a week or when it is necessary. For a more accurate cleaning it is suggested to remove the cover. The cover can be hand-washed with tepid water (max. 30°) and the addition of a light gentle detergent without bleach, then it can be air dry. The cover is removable and easy to put back in place because of the elastic springs in the covers and the velcro for perfect fit. The transparent tray cannot be washed with alcohol or ammonia based products.

- *Mechanical Parts Checking* -

The following operations have to be performed:

- Daily general check to ensure that screws, nuts and knobs are not loosen, that there are no signs of wear and tear on covers, on parts with velcro and on metal parts, that the seat is firmly attached to the frame and that any accessories are firmly mounted to the structure

- Monthly check for wheels wear
- Monthly check the screws and their tightening mechanism
- Check the adjustments: it is strictly recommended to respect the program of the checks and monitoring scheduled with the professional user.

For the combination with the frame, please also refer to the standard maintenance reported on the relevant instruction manual.

6. ADAPTATIONS WITH STRUCTURAL CHANGES AND/OR SPECIAL MAINTENANCE

Special maintenance should be performed when one or more structural components deteriorate in such way to compromise the performance and safety of users. In this case do not use the Device and immediately contact the Professional User who shall promptly inform the manufacturer about the nature of the malfunction and/or the failures found in order to proceed with the necessary interventions.

The instructions below must be followed at all times:

- Check for the integrity of any knob, screw, nut and lever
- Structure mechanism failure, such as brackets, thoracic supports and screws in general: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions
- Breakages or tears of plates, tubes and linkage components of the base and linkage brackets use to connect hip guides to the seat and backerest: they must be replaced with original parts provided by the manufacturer
- For all structural components it is strictly forbidden to perform any repair and repair by welding, bolted or riveted joints
- We recommend a gradual adaptation of the system to any user's needs.

The non observance of the above clauses will automatically void the CE mark. For special maintenance, the End User must refer to the Professional User who has to send the appropriate form *"Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request for intervention. For the combination with the frame, please also refer to the special maintenance reported on the relevant instruction manual.

7. PERFORMANCE AND DURABILITY

Pro Medicare S.r.l. ensures that its own production of the ERMES positioning system combined with ADACTA GIO' frame for positioning system and the TIPCO indoor frame for positioning system has been designed and produced in compliance with the safety regulations as required by the relevant Regulation (EU) 2017/745. The benefits provided by the above mentioned medical device, are therefore suitable and respond to the project's purpose, which is the mobility of users with severe disabilities, considering a more effective rehabilitation plan based on correct posture and stability. La The realistic life span of the ADACTA GIO' frame for positioning system and the TIPCO indoor frame for positioning system is 5 years, the realistic life span of the ERMES positioning system (padding) is 3 years. These value is purely indicative because, even if the duration expected in the design phase is much greater, it is significantly determined by the way the device is used, by the correct use and careful maintenance.

It is also reasonable to consider a slight reduction in performance over time due exclusively to:

- shocks and accidental events
- natural wear of the components.

Both performance and relative life span expectancy are however dependent by the periodic verification of the suitability, safety and the integrity of the system and have to be exclusively performed by the Professional User. If the Professional User deems it necessary, he can make adjustments to provide the morphological, dimensional readjustment, the right support and maintenance. For the combination with the frame, please also refer to the performance and durability reported on the relevant instruction manual.

8. WARRANTY

Pro Medicare S.r.l. warrants the devices functionality for a maximum period of 24 months, covering all manufacturing defects from the first commissioning and 12 months on components and covers replaced under special maintenance starting from the date of commissioning after refurbishment and 12 mounths for wear parts. The warranty is valid if the device is used as indicated within this instruction manual.

The warranty is voided in the following cases:

- improper use and/or in case of force majeure
- improper and/or inappropriate use for users affected by high tone and/or movement disorders
- a failure arising from an unauthorized tampering or faulty maintenance by third party that compromises the correct functionality and safety of the products
- any modification made without the manufacturer's authorization
- accidental damages and wear of the essential components

- structural changes of the end user
- failure or damages during the transportation: the Professional User is pleased to refer to the general sales conditions
- stolen or loss.

For warranty replacement of components, the End User must refer to the Professional User who has to send the appropriate form "*Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request of intervention. It is also essential for the manufacturer to receive a completed *Warranty Registration Form.* For the combination with the frame, please also refer to the warranty conditions reported on the relevant instruction manual.

9. POST-MARKET SURVEILLANCE AND POSSIBLE INCIDENTS

Pro Medicare S.r.l. ensures that their medical devices have been manufactured within the strict compliance, criteria and requirements established by the relevant applicable standards, guarantee functioning under the safety conditions prescribed by Regulation (EU) 2017/745.

The post-market surveillance system is set up and implemented in accordance with the quality management system adopted by Pro Medicare S.r.l. and is aimed to actively and systematically collect, record and analyse relevant data on the quality, performance and safety of its devices during their whole life, to establish the necessary conclusions and to determine, implement and monitor any preventive and corrective actions (art. 83 MDR).

These activities are also ensured through accurate market surveillance of the medical devices already present on the market, as also included in Art. 84 of the same Regulation (EU)2017/745.

To ensure Post-Market Surveillance, Pro Medicare S.r.l. shall implement all activities together with Professionals and Stakeholders to establish and keep updated a systematic procedure which is useful to collect and promptly analyze the experience gained on devices that have been placed on market, in order to identify any need for improvement or modification.

This surveillance activity also includes any incidents or serious incidents defined by the MDR as:

- "incident": means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (art. 2(64) MDR)
- "*serious incident*": means any incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person; b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; c) a serious public health threat (art. 2(65) MDR).

Serious incidents must be reported to the manufacturer and, through EUDAMED, to the competent authority.

Non-serious incidents, on the other hand, do not have to be reported to the competent authority; they must, however, be documented and taken into account in the manufacturer's quality management system and reported in accordance with the requirements of Art. 88 MDR.

It follows, therefore, that upon the occurrence of both serious incidents and possible non-serious incidents to end users and their companions or to professional users in connection with the use of the device **it is mandatory to send** to **Pro Medicare** a copy of a fully completed "*Annex 2 - Reporting of after-sale incidents*".

Pro Medicare S.r.l., as soon as it receives the aforementioned form, will provide the appropriate communications to the professional/end user, including the possible authorization to repair the damaged device or its replacement, also providing for the adoption of measures within its competence, appropriate to the nature and gravity of the incident detected.

In cases of particular urgency **it is mandatory to** contact the manufacturer at the following number **+39 0831 777840** sending to ***sales@promedicare.it*** the fully completed *Annex 2* as soon as possible.

10. DISPOSAL/RECYCLING

Please, follow the local disposal and recycling regulations.

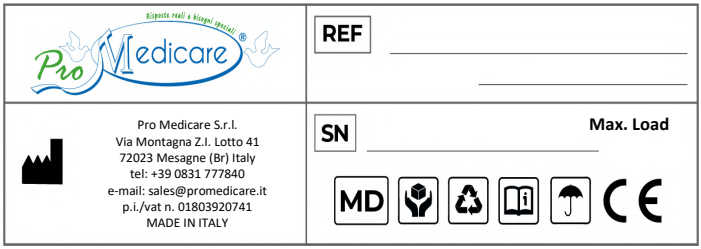
Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of Positioning System accessories):

- Aluminium: seat and backrest shells, legrest tubes connecting brackets
- Steel: fixing point; screws, multiadjustable kit rod, headrest shell and hardware
- Plastic: handgrips; footplates; harness fixing elements; containing pads; covers, plastic bags
- Synthetic fabric covers (polyester, elastane, etc.) and padding belonging to the polyethylene or polyurethane foam family
- Paper: cartoon or wrapping paper.

For the combination with the frame, please also refer to the information reported on the relevant instruction manual.

11. LABELING

The label is placed on the lower part of the positioning system and it is also sticked on the second page of this manual. Product data are indicated on the label. In case of replacing parts orders and/or reports, the serial number of the product is duly requested. A facsimile of the label is shown below:



Manufacturer

MD Medical Device

Handle with care

Recovery/Recyclable

Consult Instruction for Use

Keep dry

CE Mark

SN Serial Number

REF Catalog Number

Annex - A "Technical Features"

The following Annex shows the description of Ermes Positioning System, The Ermes Positioning System and Adacta Giò Frame configuration, the Ermes Positioning System and Tipco Indoor Frame Configuration and all their technical and functional features. It is an integral part of the Instruction Manual. For further information, please contact the Technical Sales Department at the number +39 **0831 777840.**

It is the modular Positioning System for the trunk and pelvis with its containment accessories, the product has been designed exclusively for children and it allows to achieve the proper posture, adapting to the needs of the End User.

TECHNICAL FEATURES

		Size 2	Size 3	Size 4
ERMES	Seat Width (cm)	≤25	18-28	22-35
	Seat Depth (cm)	19-26	22-34	31-43
	Trunk Height (cm)	26-38	33-45	41-53
	Chest Width (cm)	bracket A 19-25	bracket A 22-28	bracket A 27-33
		bracket B 14-20	bracket B 17-23	bracket B 22-28
	Leg Maximum Abduction (°)	16	16	16
	Leg Maximum Adduction (°)	16	16	16
	Height of Popliteal space to footrest (cm)* **if fitted with knee angle and footrest*	8-19	8-29	8-39
	Armrest Height (cm)	14-19	20-26	20-26
	Backrest Reclining (°)	-3+20	-3+20	-3+20
	Ermes Load (kg)	25	35	50
	Ermes Weight (kg)	5.2	8.1	12.1

		Size 2	Size 3	Size 6
ADACTA GIÒ	Seat to floor height (cm)	43	43	43
	Width overall dimension (*with 400/500 wheels*) (cm)	48	53	58
	Min/max depth overall dimensions (cm)	73-100	75-102	81-109
	Tilt in space (°)	2-35 *(da 6-39)**		
	**Tilt in space can be up-graded of 4° with an increment of the starting inclination of the frame by operating on the positioning holes of the castors forks*			
	Predetermined backposts reclining (°)	3 – 10 – 18		
	Adacta Giò load *(standard configuration)* (kg)	30	50	50
	Adacta Giò Weight (kg)	12.8	13.4	14.5
	Total Weight *(Adacta Giò+Ermes)* (kg)	18	21.5	26.6

		Size 2	Size 2	Size 3
TIPCO	Seat to floor height (cm)	63	63	63
	Width overall dimension (cm)	67	67	67
	Depth overall dimension (cm)	80	80	88
	Tilt in space (°)	-5+30	-5+30	-5+30
	Tipco Load (kg)	50	50	50
	Tipco Weight (kg)	13.6	13.6	14
	Total Weight *(Tipco+Ermes)* (kg)	18.8	21.7	26.1