klim adacta®
base per sistemi di postura

INSTRUCTION MANUAL



Man.Ada.Kli. EN Rev.5 04/2026

Promedicare
Feel the ideal posture

Pro Medicare S.r.l.
Via Montagna, Z.I. Lotto 41 72023 Mesagne (Br) ITALY
TEL.: +39-0831-777840
E-mail: sales@promedicare.it
Website: www.promedicare.eu

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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.
ADACTA KLIM is the Frame for Positioning System for children, teenagers and adults, it is the combination of technology and experience in the development of Positioning Systems for users with limited ability. The high resistance aluminum structure combines an extraordinary precision mechanics with fluid and harmonic movements. If the *ADACTA KLIM* base is combined with the VERSA range Positioning Systems , it will provide the best comfort with the maximum functionality; its modularity and different possibilities of adjustment allow effective adaptation to changes of the user's needs and dynamic functions developed for patients with extensor movement disorders. 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 frame combined with the 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

The *ADACTA KLIM* Frame for Positioning System is made in aluminium alloy to ensure lightness and long-lasting durability during the use. It has been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745.
The *ADACTA KLIM* base, due to its modularity, is able to follow the evolutions of the pathological scheme of the users as well as the growth and the postural changes. The device, combined with the relevant positioning system, is intended for a personal use and has to be used with the assistence of a caregiver both indoor and outdoor.
The Professional User is the responsible for the safety performance of the *KLIM* base and the Positioning System combination specially manufactured for the specific user and in compliance with the Standards.
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. The Professional User has the responsibility to guarantee the effectiveness and efficiency of the Device specially manufactured for the specific user.
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, please refer to the latest order form in force.

1. INSTRUCTIONS OF USE

1.1 Packaging and Transport

The original packaging contains the following components:

- frame for Positioning System with backrest canes and push handles folded down, posterior wheels and footrest detached
- any Accessories as per 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 Frame for Positioning System with the Positioning System.

1.2 Preliminary Operations for correct Commissioning

A positioning system produced by different manufacturing company, when installed on a *KLIM* frame, should have the seat and backrest with a proper mounting system for a good fit on the tubes of the frame (25mm).
The professional user and the end user need to check that the frame/posture connection system is safely manufactured.
The frame is delivered with all movable components disassembled; it is necessary to put it in service.

⚠ *These operations must exclusively be performed by the Professional User, who is responsible for the safety performance of the combination and/or configuration. It is necessary to correctly position the user on the positioning system; an incorrect positioning would compromise its functioning (pay particular attention to the seat depth). The Adacta Klim frame for positioning system is equipped with elastic moving parts, so, during adjustments, pay particular attention to the safety of the user (limb entrapment, rubbing) and of the caregiver (backrest and headrest).*

1.2.1 Preliminary operations for correct commissioning

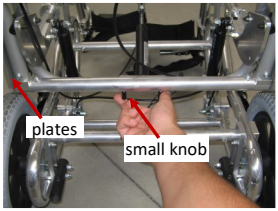
1) Assembling the posterior wheels

To assemble the posterior wheels, insert the quick-release axle in the special bush fixed in the mounting plate (pic. 1), by pressing and then releasing the button.
Verify the correct inserting of the wheels by checking:
- the release of the button of the quick-release axle
- the impossibility of movement of the wheel.

pic. 1: *Posterior wheels assembly*

2.a) Assembling the push handles

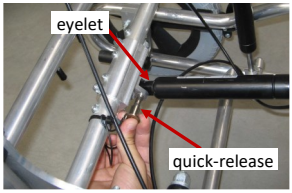
Pull the push handles, position them vertically and bring the small knobs located under the transversal tube closer together; push the trasversal tube to the front and insert it between the side plates to the desired position.
Release the two knobs and check for the full and correct engagement of the push handles (pic. 2).
Check for the correct pin insertion into both plates and that both backrest tubes are stable and do not move.



pic. 2: *Push handles assembly*

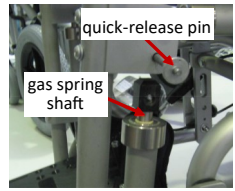
2.b) Assembling the backrest tubes

Pull the backrest tubes and bring them to a vertical position, insert the posterior eyelet of the gas spring into the appropriate seat, on the clamp attached to the backrest loop (pic. 3), and insert the quick release pin by pressing and releasing the button.
Check the backrest tubes are stable and do not move.



pic. 3: *Backrest tubes assembly*

3) Assembling the legrest tubes



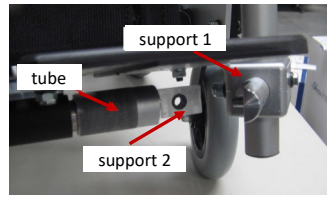
pic. 4.1: *Legrest tubes and footplates assembly*

A) footplates version

Rotate and lift each legrest until the gas spring shaft is aligned with the hole of the quick-release pin (pic. 4.1). Insert the quick-release pin and lock the position of the footrest, by checking:
- the quick-release pin
- the stability of the footrest.

B) footboard version

Align the two flat sides of supports 1 and 2 and insert the pin of the support 2 in the relative hole of the other, (pic. 4.2), slide the tube over the support assembly. Check the correct insertion by verifying the impossibility of detachment of the two supports.

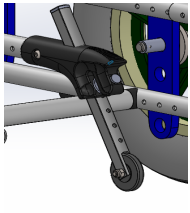


pic. 4.2: *Legrest tubes and footboard assembly*

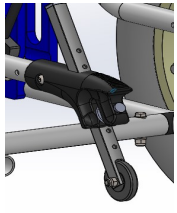
4) Checking anti-tip system

∗ Standard and fixed version:

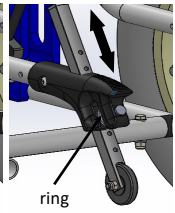
This component reduces the risk of the structure tipping over under normal conditions of use.
The anti-tip system works properly (pic. 5.1) if they are between 25 mm and 40 mm from the floor; if they are positioned too high they do not reduce the risk of tipping, if they are positioned too low they can hit obstacles.
To activate the anti-tip system (pic. 5.3) pull the ring outwards and slide the anti-tip system tube:
- pic. 5.2 shows the anti-tip system is positionated too high and it is not working properly
- pic. 5.1 shows the anti-tip system is positionated in a good distance from the floor and it is working properly.



pic. 5.1



pic. 5.2



pic. 5.3

∗ Detachable version (pic. 5.4) when provided:

This system can have the option to completely remove the anti-tip system from the frame only by pushing the pin showed in pic. 5.4. For inserting, squeeze the button and insert the tube by sliding it until the button stops in its housing. Verify the correct operation by ensuring the impossibility of movement or detachment of the device from the frame. See “Standard and fixed version” section to read instructions about the functioning.

pic. 5.4: *Detachable anti tip system*

It is absolutely forbidden using the anti-tip system as pedal for overcoming barriers.

5) Checking the Parking Brake (pic. 6)

To activate the parking brake, push the lever forward until a “click” is audible and the brake is pressing against the tyre. Check that the wheel doesn’t move. Please release the lever to unlock the brake. To ensure that the wheel stops correctly, check that the distance between the brake and the wheel tyre is 6mm. If not, please adjust as follows:
- Unscrew the 2 brake clamp fixing screws
- Adjust the distance between the brake and the wheel tyre (estimated value: 6mm)
- Screw the 2 fixing screws
- Check the wheels stop correctly.

pic. 6: *Activating the brake*

If the wheel is equipped with a drum brake, it is necessary to check for the proper funtion by activating the lever located on the backrest tube. Once the lever is activated, the wheels are locked with no possibility of movement. If the lever is not pressed, the wheels will be able to move freely. These brakes can be used to brake the system while is using. The braking force of the drum brake can be adjusted using the adjusting screw on the brake cable near the brake hub. The braking force can be increased by slightly unscrewing the adjustment screw. Loosen the nut and unscrew the screw until a friction noise is heard in the wheel rotation. Retighten the screw until the friction disappears. Tighten the nut to secure the adjusting screw.

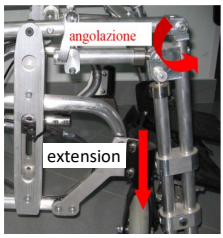
Take care to adjust the drum brakes on both sides of the frame in the same way.

6) Checking the Gas Springs

Verify that the gas springs do not leak oil. Check for the functionality of the tilting mechanism by means of the bigger lever on the backrest handle. Check the elastic reclining mechanism of the backrest by pushing it backward and verify that the shock absorption reclining of the backrest is linear, without kicks and abrupt movements.

7) Checking the Knee Angle elastic mechanism

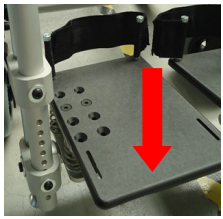
A) Check the functioning of the elastic mechanism for the elevation of the legrest and proceed as follows: hold the frame with one hand and lift the legrest from the end of the footplate with the other (pic. 7). Verify the movement is linear and without kicks.
B) Check the functioning of the elastic mechanism for the extension of the legrest and proceed as follows: hold the frame with one hand and apply a force downwards onto the footplate (pic. 7). Verify the movement is linear and without kicks.



***pic. 7**: Elastic elevation and extension mechanism*

8) Checking the Footplate flexion-extension (where provided)(pic. 8)

Apply downward pressure with your hand on the footplate and verify the movement is linear and without kicks.



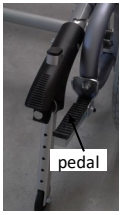
***pic. 8:** Checking the footplate flexion-extension*

9) Checking the tyre pressure

Ensure that the pressure is always as indicated on the tyre because the brake efficiency depends on it.

10) Checking the Pedal (where provided) (pic. 9)

The pedal must only be used to overcome barriers (step); to use it, please perform as follows:
- Push the anti-tip system upwards
- Lower the pedal to a horizontal position
- Push on the pedal with your foot, also using the push handles to overcome the barrier (do this very slowly, gradually and with care)
- Place the pedal in a vertical position to avoid accidental impacts when transporting the user.



***pic. 9**: Pedal*

After overcoming the barrier, please pay attention to handling. 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.

11) Assembling the positioning components

For the correct installation of the seat, backrest and other positioning elements, please, refer to the relevant VERSA and VERSA INSERTO manuals.

After all these operations please ensure that the frame moves easily and all components work properly. 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.

1.3 Adjustments for the first Commissioning and/or subsequent adjustments

The Frame combined with the Positioning System is now ready to be used. Adjustments for the first Commissioning and subsequent adjustments to the changing needs of the end user are possible thanks to multiple adjustment possibilities of the frame. All possible adjustements are described in this chapter.

These operations must exclusively be performed by the Professional User, who is responsible for the safety performance of the combination and/or configuration. The ADACTA KLIM Frame for Positioning System includes elastic movement elements (backrest, legrest tubes and footplates): during adjustments to the user needs take care to avoid entrapments, accidental bumps, and chafing. Also check for the correct posture in various position in order to provide the user comfort.

1) Tilting seat (tilt in space)

The adjustment of the tilt in space is performed by two gas spring by operating the lever on the right hand push handle.
In this way the tilting of the seat is adjustable in a continuous way. When the lever is released, the gas springs will block the seat at the reached position. If this operation is performed with the user seated in the system, it is necessary to hold the push handles with both hands. Then proceed by activating the gas spring and the tilt mechanism.
Please, perform this operation very slowly gradually and with care.

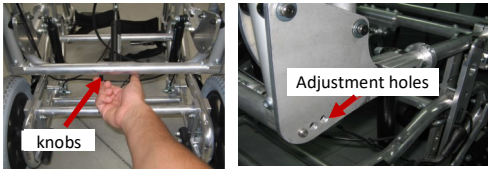
While performing this operation, always ensure that the anti-tip system is fitted and correctly positioned and the user is well seated on the seat by wearing a pelvic belt.
Also ensure that the forearms are positioned on their upper limb supports to reduce the risk of trapping.

2) Adjusting the Push handles position

Push handles must be positioned in order to allow free shock-absorbing movement of the backrest. If not, please, adjust as follows:

- Bring the two knobs located under the transversal tube of the push handle tubes for disconnection from the side plates (pic. 9)
- Position both handles in line with one of the three holes on the side adjustment plate as desired
- Ensure that both knob latches engage properly into the side plate holes.

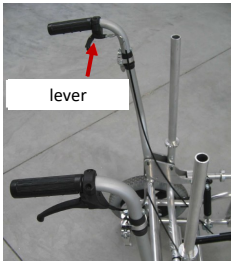
Check the correct positioning by verifying the push handle tubes do not move.



***pic. 9**: Push handles adjustment*

3) Reclining the backrest (pic.10)

This adjustment is performed by the dynamic gas spring. The reclining of the backrest is adjustable in a continuous way by operating the lever on the left hand push handle. When the lever is released, the gas springs will block the backrest at the reached position defining the initial angle of the elastic movement (trunk-pelvis angle at rest).
The shock absorbing movement of the backrest is about 25°; for the correct functioning of the system, the backrest cannot be reclined more than 10°; for higher values please contact the Technical Sales Department.
If this operation is performed with the user seated in the system, it is necessary to hold the push handles with both hands. Then proceed by activating the gas spring and the reclining mechanism.



***pic. 10**: Reclining adjustment*

Please, perform this operation very slowly gradually and with care.

This adjustment is essential for the users posture and must only be performed by the professional user; adjustments not authorized by the professional user may affect its correct functioning. During adjustment, make sure that the anti -tip system is activated.

4) Adjusting the footplates

The footrest can be adjusted in height, depth and angle.

- Height adjustment

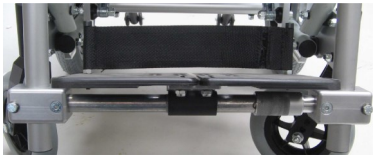
  Footplates version (pic. 11.1):

  - unscrew and remove the button head screw on the back of the support where the footplate ha been inserted
  - move the footplate along the legrest tube to the desired hole and position
  - reinsert and tighten the screw.

pic. 11.1: *footplates adjustment*

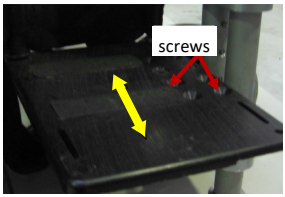
Footboard version (pic. 11.2):

- loosen both the two exagonal head fixing screws located on each side of the footboard
- move the footboard along the legrest tube to the desired hole and position
- tighten the two fixing screws



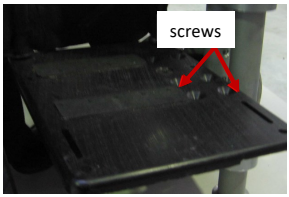
pic. 11.2*: footboard adjustment*

- Depth adjustment (pic. 12):
  - unscrew and remove the 2 countersunk head fixing screws
  - move the footplate back and forth to the desired position
  - reinsert and thighten the screws.

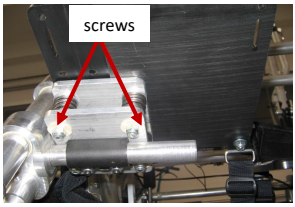


pic. 12: *Footrest depth adjustment*

- Angle adjustment:
  - unscrew and loosen the 2 fixing screws:
    - the countersunk head screws located on the footplates (pic. 13.1)
    - the exagonal head screws positioned between the two aluminum plates of footrest with flexion-extension (pic. 13.2)
  - rotate the footrest clockwise or counterclockwise to the desired position
  - tighten the fixing screws.



pic. 13.1



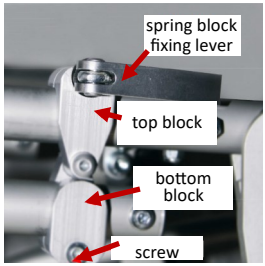
pic. 13.2

After these adjustments, ensure that the footrests do not hit the castors

5) Initial Knee Angle adjustment

This adjustment is performed in a continuous way (pic. 14) proceeding as follows:
- loosen the spring block fixing lever
- Adjust footrest to the desired starting position by sliding the top block along the seat tube
- tighten the spring block fixing lever.

NOTE: If is necessary to increase the adjustment of the initial angle which is possible with the quick adjustment lever, please, perform as follows:
- make sure that the fixing lever is tightened
- loosen the button head screw on the bottom block
- slide the tube to the desired angle
- tighten the button head screw.



pic. 14: *Knee angle adjustment*

During knee angle adjustment it is highly required that the seat is 0° with respect to the top of the base (non-tilted position). The initial knee angle adjustment does not affect he dynamic extension of the legrests.

6) Displacement of the plates

The frame is delivered in its standard features. Depending upon the users needs, it is possible the continuous horizontal displacement of seat with respect to the frame and the continuous displacement of the posterior wheels plates. These adjustments are analysed in detail below:

- Displacement of the seat -

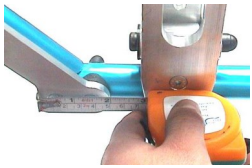
The displacement of the seat with respect to the frame can be done as follows (pic. 15):
1. measure the distance between the tilt-in space plate and the clamp of the gas spring
2. unscrew and loosen the coutersunk screws fixing both plates of the tilting mechanism
3. unscrew and loosen the exagonal head screws fixing both clamps of the gas spring
4. slide the tilt-in-space plates and the clamp of the gas spring along the frame to the desired position. The distance between the tilt-in space plate and the clamp of the gas spring should be the same after adjustment.

pic. 15: *Plate adjustment*

For safe use, displacement must be within the following ranges:

Frame size	XXS, XS, XS1, S	M, M1
Displacement (mm)	from 50 to 70	from 60 to 90

The displacement is detected from the edge of the fork fixing plate to the first edge of the tilt-in space plate, as shown in picture 16:
- position the clamps of the gas spring with respect to the relative tilt-in space plates and in relation to the measure determined in point 1
- screw in and tighten the countersunk head screws of the plates
- tighten the exagonal head screws of the clamps.



pic. 16: *Displacement of the plate*

- Displacement of the posterior wheels plate -

To adjust the rear wheel anchor plates in relation to the backrest tubes, proceed as follows (pic. 17):
- unscrew and loosen the coutersunk screws fixing both plates from the right and left side
- slide the plates along the frame until the desired position is reached.

pic. 17: *Displacement of the plate*

For safe use, displacement of the plate must be within the following ranges:

Frame size	XXS, XS, XS1, S	M, M1
Displacement (mm)	from 350 to 380	from 370 to 410

The displacement is detected from the edge of the fork fixing plate to the edge of the plate, as shown in picture 18:

- screw in and tighten the countersunk head screws
- adjust the position of the parking brake and make sure it works properly
- check the correct functioning of the anti-tip system.

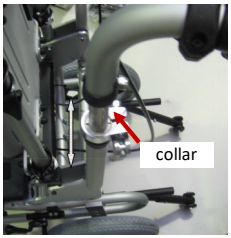
Make sure the screws are properly tightened.

pic. 18: *Displacement of the wheels plate*

7) Push Handles Adjustment

The push handles can be telescopic and can be adjusted in height and angle. This is performed as follows (pic. 19):

- loosen the locking lever of the telescopic push handles (placed on the backrest tube) by lifting it up
- adjust the handles as desired
- close the collar locking lever
- make sure the handles are secure and do not allow any movement.



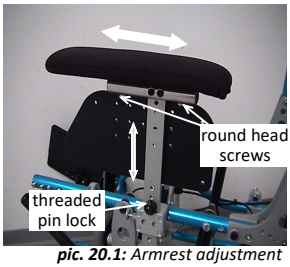
pic. 19: *Push handles adjustment*

8) Multiadjustable kit ABS Laterals with armrest (where provided)

1) *Armrest*

Armrest can be height and depth adjustable (pic. 20.1)

- Heiht adjustment
  1. unscrew the relevant threaded pin lock
  2. adjust the height by moving the vertical bar up and down
  3. once the desired position is achieved, tighten the pin lock in the relevant hole (the holes are placed at a distance of 15mm).
- Depth adjustment
  1. unscrew the round head screw that fix the armrest to the supporting tube
  2. engage the holes under the armrest to adjust the depth (the holes are placed at a distance of 25mm).

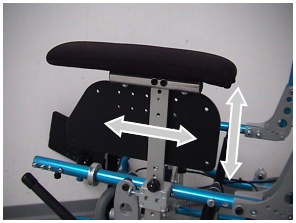


pic. 20.1: *Armrest adjustment*

2) *ABS Lateral*

The ABS lateral is fitted of a row of holes placed at a distance of 25mm which allow a wide range of adjustment both in depth and height (pic. 20.2)

- Depth adjustment
  1. unscrew the 2 countersunk screws located in the inner part of the ABS lateral
  2. adjust the position of the lateral by sliding it horizontally
  3. tighten the screws when the desired position is achieved.
- Heiht adjustment
  1. unscrew the 2 countersunk screws located in the inner part of the ABS lateral
  2. adjust the height of the lateral by sliding it on the vertical bar
  3. tighten the screws when the desired position is achieved.



pic. 20.2: *Depth/height adjustment*

Verify the correct functioning of the ABS lateral:
1) The correct placing of the snap pin
2) The not detachability of the ABS lateral .

9) Calf Support (where provided)

The Calf Support (pic. 21) provides the posterior and lateral containment of the leg. It can be adjustable in height, by engaging the holes (placed at a distance of 25mm) drilled on the hanger, or in depth by engaging the holes drilled on the rear part of the same hanger.

pic. 21: *Calf support*

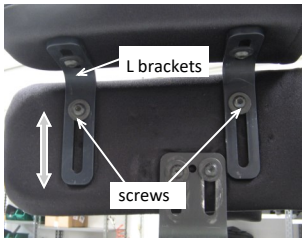
Ensure Calf Supports are properly locked.

10) Arm Supports (where provided)

The arm supports are fixed to the hip guides by means of 2 slotted L brackets. They present 3 rows of threaded holes in order to allow a wide range of adjustments. They can be adjusted in height, width and depth.

- Height adjustment (pic. 22.1)
  1. unscrew and loosen the round head screws fixing the L brackets to the hip guide
  2. move the arm support up and down until the desired position
  3. tighten and fix the round head screws.

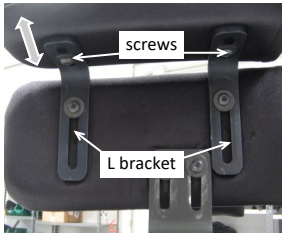
  For a greater movement of the L bracket, it may be necessary that the screws engage a row of holes next to those already engaged (the rows have an interaxis of 25mm).



pic. 22.1: *Height adjustment*

- Width adjustment (pic. 22.2)
  1. unscrew and loosen the round head screws of the L bracket beneath the arm support
  2. move the arm support inward and outward until the desired position
  3. tighten and fix the round head screws.

- Depth adjustment (pic. 22.2)
  1. unscrew and remove the round head screws of the L brackets fixed to the arm support
  2. move the arm support back and forth along the hip guide until the desired position is achieved, by engaging the row of holes under the arm support
  3. punch the cover, insert and fix the round head screws.



pic. 22.2: *Width and depth adjustment*

11) Pelvic belt

To know more about its use, please refer to the relevant instruction manual.

Check the pelvic belt is fitted correctly and is suitable for the function for which it has been chosen. We do not recommend attaching the pelvic belt to the seat and wheelchair. It is not a safety belt and is not intended to be used as such.

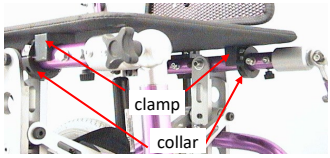
12) Padded/simple Calf Strap

To know more about its use, please refer to the relevant instruction manual.

Do not place the calf strap on any sensitive part.

13) Wooden seat base (where provided)

The wooden seat base (pic. 23) has the purpose to accomodate the positioning system and its accessories.



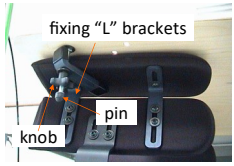
pic. 23*: Wooden seat base*

It can be:
- *Covered in leather flex material*. Along its lateral edges it is featured of rows of threaded holes and 2 interlocking clamps both in the anterior and posterior parts that allow the mounting of the base on the frame.
So that, lay the wooden base onto the tubes by paying attention to the position of the interlocking clamps: for a good installation they should be positioned one in front and one behind the 2 collars mounted on the tubes. This operation impedes the movement of the seat backwards or forwards. The adjustments can be done by sliding the interlocking clamps along the the edges of the seat base or the relevant collars along the tubes of the seat by operating through the screws. After positioning, push the seat on the tubes until you hear a locking click to indicate the 4 interlocking clamps have grafted the tubes. If there are securing clamps, you have to close them tightly on the tube after positioned.
- *Raw (only wood) with mounting kit*. It is featured of 1 row of holes along the lateral edges, where the provided threaded t-nuts have to be inserted. Lay the wooden base on the seat tubes and detect 2 holes both in the anterior and posterior parts where the threaded nuts have to be inserted for the fixing of the interlocking clamps. The threaded nuts have claws that have to be completely embedded in the wood (even with hammer). The interlocking clamps have to be mounted on the face opposite to the threaded nuts. Pay attention to the 4 interlocking clamps and the 2 collars on the tubes: for a good installation the collars have to be mounted in strictly contact with the relevant clamp and be positioned alternatively one in front of the clamp in the anterior part of the base and the other behind the clamp on the opposite side in the posterior part. This operation impedes the movement of the seat backwards or forwards. After positioning, push the seat on the tubes until you hear a locking click to indicate the 4 interlocking clamps have grafted the tubes. If there are securing clamps, you have to close them tightly on the tube after positioned.

Verify the correct mounting of the seat base by checking the impossibility of movement when:
-it is moved back and forth along the seat tubes of the wheelchair
-it is pulled upward.

14) Tray (where provided)
Any shape of tray can be fixed to the armrests or arm supports by detachable or lateral flip mechanism. It is secured as follows:

(option 1) Detachable mechanism (pic. 24)
- verify that the fixing L brackets firmly grip the arm supports/armrests. In a contrary case, please remove the pin and move it a most suitable exagonal shaped hole onto the lateral edges of the tray
- strongly tighten the loching knob
- check the tray is stable.



pic. 24: *Detachable mechanism*

(option 2) Lateral Flip mechanism (pic. 25)
The mounting can be done as follows: (the pic. 25 shows the hardware only):
- mount the guide tube with its clamping knob under the arm support
- insert the rod of the hardware in the guide tube
- tighten the knob firmly
- tigheten and fix the round head screws
- check the tray is stable.


pic. 25: *Lateral flip mechanism*

Verify the correct mounting of the tray by checking it doesn't move when pulled in all directions. Verify its stability.

1.4 How to use it
The frame combined with the 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 caregiver needs to be instructed by the professional user. It will require come degree of training and practice to master all operations in a safe manner. It is good to develop one's own methods for safe use, adapted to the needs.

During daily use it may happen that components and/or accessories become loosen, affecting adjustments, this is why it is recommended to schedule a follow-up to monitor and check the posture. Never make any adjustments or changes without the intervention of the Professional User.

A) 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 frame is locked from movements
√ Ensure the anti-tip device are correctly positioned
√ Put the seat into a horizontal position by operating the tilting lever
√ Loosen any fixing harness
√ Disengage any thoracic supports and hip guides
√ Disengage the legrest by rotating them until they are vertically in contact with the legrest tubes. This reduces the risk of trapping feet during transfer.

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 frame is locked
√ Ensure the anti-tip device are correctly positioned
√ Put the seat into a horizontal position by operating the tilting lever
√ Lift and transfer the user to the system by paying particular attention to this operation
√ Engage any thoracic supports and hip guides
√ Position and adjust the legrests in position by reinserting the locking pin into the slot.
√ 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.

B) Tilting the System

The tilting of the System is performed by activating the gas springs which are controlled by the lever located on the push handle. Adjust the system according to the instructions of the professional user. Tilting must be continuous and, when the lever is released, the springs will lock the system in the position reached. The procedure is described below:

1. Apply the brakes and ensure the frame cannot move
2. Grip the push handles using both hands
3. Press the lever, push the handles down; tilt the frame gently and with slow movements
4. Release the lever when the desired angle of tilt is reached. Int his way the seat will stay in such position.

During the adjustments always ensure the anti-tip system is correctly activated and that the user is well placed in the seat using the pelvic belt. Also make sure that the forearms are positioned on the relative upper limb supports in order to avoid the risk of entrapment.

C) Trasport of the System without occupant

For an easy transportation of the system, it is necessary to proceed with the removal of the Positioning Systems from the Frame by carefully following the steps below:

Pay particular attention to the following 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 by 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.

- Disassemble the Positioning System from the Frame and make it compact for transportation in a vehicle

In order to transport the system in a vehicle, it is necessary to remove the Positioning System from the Wheelchair Base:

1) Apply the brakes ensuring the frame cannot move
2) Remove the seat: follow the instruction reported in the relevant Instruction Manual
3) Remove the backrest: follow the instruction reported in the relevant Instruction Manual
4) Folding down the backrest tubes: disengage the pin at the lower end of the backrest tube that connects the gas spring to the hooking support on the backrest tube and rotate the backrest tube until it is folded down
5) Lowering the push handles: simultaneously press the two pins located below the horizontal tube that connects the two push handles and rotate them towards the base
6) Remove the posterior wheels: release the parking brake by pressing the quick-release axle button and pull out the axle with the wheel

7) Rotate the legrests: disengage the pin located on the side of the legrest tube and consequently rotate it
8) Disengage the anti-tip system.

Now the seat, backrest and frame can be placed in a vehicle.

- Subsequent start-up of the Frame and recombination of the Positioning System with the Frame

At the end of the trip, bring out the frame, the seat and the backrest from the vehicle and preoceed with the following operations:

1) Assemble the posterior wheels: follow the instruction reported on page 5 *point 1*)
2) Apply the parking brake and make sure the frame doesn't move
3) Assemble the backrest tubes: follow the instruction reported on page 5 *point 2.b*)
4) Assemble the legrest tubes: follow the instruction reported on page 6 *punto 3*)
5) Fixing the seat: fix the seat on the base as described in the relevant manual.
6) Fixing the backrest: fix the backrest according to the instructions in the relevant manual.
7) Insert the anti-tip system.

⚠ *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 Frame for Positioning System, please find below advices for the user:

- √ Carefully follow the instructions reported in this manual
- √ Follow the recommendations provided by the Professional User
- √ Keep the Device away from heat sources
- √ Avoid using armrests as a support base for the user
- √ The brake is designed for the parking and not for slowing or stopping the wheelchair while it is running
- √ Carry out thorough cleaning and pay close attention to the standard maintenance
- √ The backrest follows the movements of the user by reclining elastically: it is advisable to leave the anti-tip system inserted while the device is stationary.

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 *section 1.3*)
  - These operations must be performed by authorized people
  - During these adjustments, the anti-tip castors must be positioned to reduce the risk of the System tipping and the structure must not be more than 40mm off the ground
  - After having performed these adjustments, be aware of any noise, vibrations or any changes to the normal conditions of 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

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. The Frame for Positioning System is designed for use on hard surfaces such as asphalt and paving, so:
- Do not take the wheelchair onto sand or rough terrain. This can cause damage to the wheels, axles and other components of your wheelchair
- Use estreme caution and care if you use the wheelchair on wet and/or smooth surfaces.

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 wheelchair 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 wheelchair into a steamy bathroom after a shower)
- Avoid contact with seawater
- If the wheelchair 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 (for example the base, parking brakes, footrests and the positioning system) may overheat.

- Components and Options:

Anti Tip System: This device reduces the risk of the wheelchair tipping backwards in normal conditions of use. If locked in position (downwards) the anti-tip tubes must be at a distance between 25-40mm from the floor; if they are placed too high, they do not reduce the risk of the wheelchair tipping and if too low, they can come in contact with surfaces and obstacles during normal use. Always keep the anti-tipping tubes locked in position unless you are going up or down a sidewalk. In such cases, make sure the anti-tip tubes have been placed upwards. When pushing the frame for positioning system, the anti-tip system, if not turned, may be an obstacle to the caregiver's feet.

***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 wheelchair tipping forwards
- Do not stand or lean on the wheelchair footrest; they may detach from the footrest tubes or break.
- Make sure, after each adjustment, that the footrest does't touch the front wheels.

***Posterior Wheels*:** Every time the wheels are re-inserted please check for the correct assembly. So check:
- the quick-release axle has been activated
- the impossibility of the Wheel to be detached
- that the pressure of the pneumatic tyres is equal to the value indicated on the tyre, as the efficiency of the brakes depends on this.

Armrest: The armrests cannot support the weight of the wheelchair. if used for lifting the chair, 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 wheelchair over uneven ground or obstacles, which if in contact with wheels, they can cause the wheelchair to tilt
- To reduce the risk of a tipping, do not hang bags, backpacks or any other weight on the system
- Maximum accepted gradient : 8.5° without anti-tip system, which is equal to 15%
- 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
- Never perform any adjustment or change without the intervention of the professional user
- In case of malfunctions resulting from other causes, including poor maintenance of the wheelchair, the professional user should be consulted
- For the cleaning operations do not use aggressive products which may affect the oxidation and/or cover
- Frequently check all the connections between the positioning system and the frame and verify for a safe and fully functional operations

- Pay attention to the hands when opening the footrest platforms.

3. NEGATIVE ADVERSE EFFECTS

Generally the use of the system should not cause any adverse effects such as allergies, skin irritations or redness when in contact. Otherwise, please contact the Professional User immediately. Due to the dynamic nature of the moving parts and when the end-user is placed on the device the caregiver should pay special attention when approaching. Refer to the relevant manual for the posture system.
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.

4. RESTRICTIONS OF USE

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

Mandatory Requirements

- When the wheelchair is in tilted position, the anti-tip system should always be in function
- The anti-tip system should never be removed from the wheelchair
- Do not drill or crush the gas spring
- Do not drive the wheelchair with the seat fully tilted on steep slopes
- When the system is not tilted, make sure the user is not too forward in the seat to avoid compromising the stability of the wheelchair
- When the user in on board, avoid lifting the wheelchair by the legrests or any posture accessories. If it is necessary, lift the wheelchair by the sides of the base structure, making sure the seat assembly doesn't move during this operation
- Get help from additional people when you have to lift the wheelchair 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 in the wheelchair, especially in the case of children
- If a stair lift platform is to be used, please contact the Company
- Apply the brakes whenever wheelchair-user is stationary
- Please, pay particular attention when moving on rough or uneven terrain which can damage the system
- It is recommended to never use any type of positioning harness/belt as a safety belt
- Smoking and/or open flames are prohibited
- The Frame for positioning system/Positioning system is not intended to be used on users with injured skin or body surfaces (sores, etc.); therefore, its use is prohibited in such circumstances.

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 addition of detergent, taking care to go over everything with a dry cloth. Mechanisms such as the backrest reclining plate, tilting mechanism, parking brake and anti-tip wheels, should always be checked to remove any dust or dirt that may affect performances. We recommend these operations at least once a month.

- Mechanical Parts Checking -

The following operations have to be performed:
- Daily check the functionality of the brakes
- Weekly check the tyre pressure. Please refer to a qualified professional for inner tube replacement
- Monthly check for tyres wear
  Monthly monitoring of parking brakes efficiency and the initial adjustments performed by the clinical professional or authorised dealer; verify that the distance between the tyre surface and the brake pin is 6mm and the operating force does not exceed 60N
- Monthly inspection the drum brake cable and adjustments

- Monthly inspection the tension of the cable for the proper operation of the gas spring
- Monthly check the screws and their tightening mechanism
- Querterly oiling the quick-release pin of the folding back canes, the hubs and axles of the wheels, the brake pins, the screw of the footrest hangers
- Check the adjustments: it is strictly recommended to respect the program of the checks and monitoring scheduled with the professional user.

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:

- Tyre wear: the tyre can be replaced by qualified professional using one with the same dimensions and features of the original. The professional user should then provide for the adjustment of the parking brakes and their efficiency
- Components failure such as wheels, forks, brakes, anti-tip castors, pushing handles and screws: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions
- Breakages or tears of plates, tubes, linkage components between the various parts of the base and brackets connecting the hip guides to the seat and backrest: they must be replaced with original items 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.

7. PERFORMANCE AND DURABILITY

Pro Medicare S.r.l. ensures that its own production of Frames for Positioning Systems and/or accessories have 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 devices, either individually or in combination, 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.
The realistic life span of the Adacta Frame for Positioning System Range is 5 years, while the realistic life span of Versa Positioning Systems Range is approximately 3 years.
These values are 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 (which may be how it has been used and if it has been used continuously compared to what was intended in the design phase), 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, combination safety and the right System adjustments and have to be exclusively performed by the Professional User; regular reassessment by the professional user should therefore be provided in order to check the suitability, safe and integrity of the system. If the Professional User deems it necessary, he can make adjustments to provide the right support and maintenance.
The reconditioning of the device is prohibited if not expressly authorized by the manufacturer.

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 case:

- 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.*

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.

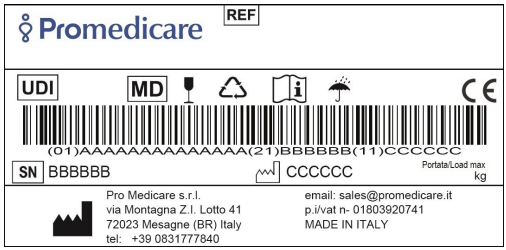
10. DISPOSAL/RECYCLING

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 the Positioning System accessories):

- Aluminium: various type of brackets, tubes, plates, forks, footrest, 500mm posterior wheels
- Steel: screws, threaded inserts, quick-release
- Wood: seat bases, calf support bases, support bases, hip guide bases, trays
- Plastic: internal thoracic support bases, mounting components of the base on the frame, handgrips, castors, 300mm and 400mm posterior wheels, footplate, fixing elements of harnesses, seat/backrest structural kit, various type of padding, packaging
- Synthetic fabric covers (polyester, elastane, etc.) and padding belonging to the polyethylene or polyurethane foam family
- Paper: cartoon or wrapping paper.

11. LABELING

The label is placed on the lower side of the frame 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:



MD Medical Device

SN Serial Number

REF Catalog Number

CE CE Mark

Manufacturer

Manufacturing date

Recovery/Recyclable

Handle with care

UDI Unique Device Identifier

Consult Instruction for Use

Keep dry

Annex - A "Technical Features"

This annex describes the *ADACTA KLIM* frame for positioning system, its technical and functional features. It is an integral part of the instruction manual. For further information please contact our Technical Sales Department at the number **+39 0831 777840.**

The base frames of this range are made of high-strenght aluminium used in the aeronautical industry, without welding and allow significant adjustability and adaptability which ensure a seamless modularity and interchange of components to continually envolve with the users changes. This makes it always adjustable to the user's needs by providing the possibility to periodically change the system, this is a necessary operation especially for developmental disabilities.

The satin finish frame for positioning system can have various colors of plates.

The tilting mechanism is always adjustable by operating the two gas spring lever located on the push handles.

The base frames are equipped with anti-tip wheels to reduce the risk of tipping.

The frame base has the following features:

- Folding down backrest tubes with height and inclination adjustable pushing handles (max. height adjustment: 15 cm)
- Folding and cushioned with gas spring backrest tube (150N) (two types of intensity: weak and strong)
- Continuous tilt in space with gas spring (from 0° to 25°)
- Backrest angle starting recline adjustable from 0° to 20°, elastic recline up to 20°
- Knee angle adjustable up to 15°, and another 20° thanks to the shock-absorbing/elastic extension
- Continuous displacement of the seat with respect to the frame
- Fixed anti-tip wheels
- Continuous displacement of the posterior wheels plates
- Parking brake with lever
- Continuous elevation adjustment of the knee angle
- Shock-absorbing downward extension of the legrest tubes
- Footrest height adjustment
- Footplates/footboard
- Quick release posterior wheels.

This allows an easy transportation of the device during transfers.

Type of wheels:

- posterior wheels: 300mm (poly or pneumatic, with parking brake lever or with drum brake or with drum brake and parking brake lever); 400mm (poly, with parking brake lever or with drum brake or with drum brake and parking brake lever); 500mm (poly or pneumatic with handrims and parking brake lever; pneumatic with handrims and drum brake or with drum brake and parking brake lever)
- castors: 150mm/175mm poly

TECHNICAL FEATURES

Size	XXS	XS	XS1	S	M	M1
Width [cm]*	35	35	38	41	41	44
Depth [cm]**	38	42	46	46	50	50
Width of the backrest [cm]*	35	35	38	41	41	44
Height of the backrest tubes [cm]	53	53	53	53	53	53
Maximum user weight [kg]	50	50	75	75	75	75
Seat-tube height to floor [cm] ***	49 46 43	49 46 43	49 46 43	49 46 43	49 46 43	49 46 43
Overall width with wheels [cm]	53	53	56	59	59	62
Frame weight [kg]*****	20	21	21	21	22	22.5
Positioning system weight [kg]	7.5	8	9.5	10	11	11.5
Max overall length with 90° knee angle [cm]	(I) 77 (II) 88	(I) 80 (II) 90	(I) 82 (II) 93	(I) 82 (II) 93	(I) 85 (II) 96	(I) 85 (II) 96

Note:

* measured from the outside of the tubes
** measured along the seat tube from the connection of the legrest tube to the backrest tube
*** measured with seat tube in 0° horizontal position
**** measured with 90° knee angle and reclined push handles
***** without positioning system
I: with 300mm pneumatic wheel
II: with 500mm pneumatic wheel