VersaTitti

SISTEMA DI POSTURA INTEGRATO

# INSTRUCTION MANUAL

Man.Ada.Ver.Tit. EN Rev. 12 04/2026

Promedicare

Feel the ideal posture

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## INDEX



**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.
*TITTI* is an Integrated 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, *TITTI* 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 frame.
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.
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

*TITTI* Integrated Positionign System represents the valid and careful combination between the ADACTA Frame for Positioning System and the INSERTO SEAT Pelvis Positioning System together with the INSERTO BACK Trunk Positioning System of the VERSA Range. Their combination have been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745.
*TITTI* is intended to be used by children and teenagers affected by low, medium and high postural insufficiency as a result of various pathologies and it is handled by an accompanier both indoors and outdoors. In particular, it allows the customisation and adaptation during the trial phase, delivery and post-delivery monitoring for users affected by: asymmetries, wind-swept, pelvic obliquity, pelvic retroversions and anteroversions also combined, scoliosis, lordosis and kyphosis. The Inserto Positioning Systems can be simply adapted to the user as needed. They can be customized, shaped and modified as written prescription, they can be fitted and adjusted to the anatomy and morphology of the User, by taking the body measurements and carrying out direct checks, in order to obtain a made-to-measure positioning for the perfect reconstruction of their anatomical shapes, for the support and compensations of the deformities and to provide the body pressure distribution.
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. Any removal and/or changes of the standard configuration, and configuration for the specific user based on the prescription, must exclusively be performed by the Professional User and make it a custom-made Device. 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:

- Adacta Liga Light Frame for Positioning System (rigid or folding) with backrest canes folded down, posterior wheels, footrest and wooden rigid base detached
- the Positioning System, as per Professional User form, in particular:
  - INSERTO SEAT Pelvis Positioning System
  - INSERTO BACK Trunk Positioning System
  - CAPITIS Headrest
  - FIXATIS Harnesses
  - Accessories (if requested)
- 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

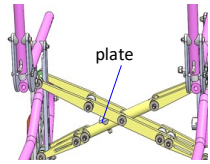
The Frame for Positioning System and the Positioning System are disassembled; before proceeding to their combination it is necessary to perform the following operations:

### 1.2.1 Operations for the "Commissioning of the Frame for Positioning System"

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

**1) Unfolding the Frame for Positioning System (folding model)**

Push down the cross brace until the two arms come into contact with the plate as shown in the picture (pic. 1).
Verify the correct opening of the frame by checking:
- the impossibility of movement of the cross brace
- the complete contact of the central bars on the supporting plate.

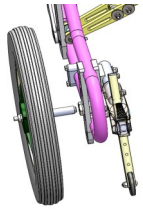



***pic. 1:*** *cross brace*

*Be careful not to trap the fingers in the cross brace.*

**2) Assembling the posterior wheels**

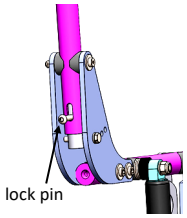
To assemble the posterior wheels, insert the quick-release axle in the special bush fixed in the mounting plate (pic. 2), by pressing and then releasing the button.
Verify the correct inserting of the wheel by checking:
- the release of the button of the quick-release axle
- the impossibility of movement of the wheel.



***pic. 2:*** *Assembling the posterior wheels*

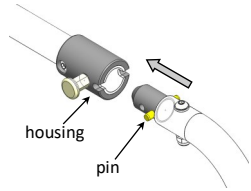
**3) Unfolding backrest tubes**

Pull the backrest tubes by the push handles and bring them in upright position until you hear a click indicating the engagement of the lock pin (pic 3).
Verify the correct positioning of the backrest tubes by checking they are stable and do not move.




***pic. 3****: Backrest tubes*

**4) Inserting the legrest tube** (such operation is valid for any chosen legrest tube)
Insert the extremity of the footrest hanger tube in the seat tube (pic 4).
Push the tube until the pin locks in its housing.
Verify the correct positioning by checking the hanger is in position and doesn't come off.

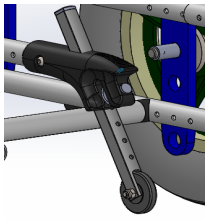



***pic. 4:*** *Inserting the legrest tube*

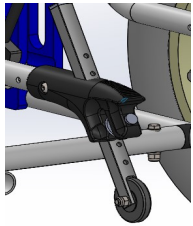
**5) Checking the tyre pressure** (where provided)
Ensure that the pressure is always as indicated on the tyre because the brake efficiency depends from it.

**6) Checking anti-tip system**

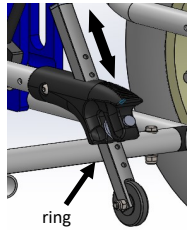
* Standard and fixed version:
This component reduces the risk of the structure tipping over under normal conditions of use.
The anti-tip system works properly (pic. 5.1) if they are between 25mm and 40mm from the floor; if they are positioned too high they do not reduce the risk of tipping, if they are 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***

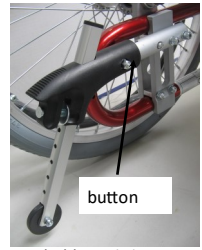


***pic. 5.2***




***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, both in the standard and detachable versions, as pedal for overcoming barriers.*

**7) 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.
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.


***pic. 6****: activating the parking brake*

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.*

**8) Checking the Gas Springs**

Verify that the gas springs do not leak oil. Check the functionality by activating the tilt mechanism ever located on the backrest tube.

*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.*

**9) Checking the pedal** (where provided) (pic. 7)

The pedal must only be used to overcome barriers (step); to use it, please perform as follows:
- push the anti-tipping 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 back in an upright position to avoid accidental impacts when transporting the user.

*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.*


***pic. 7**: Pedal*

### 1.2.2 Operations for the "Commissioning of the Positioning System"

The Frame for Positioning System is now ready to be combined with the Positioning System. For the correct mounting and positioning of the INSERTO SEAT Cushion, of the INSERTO BACK backrest with all its accessories, of the VERSA CAPITIS Range Headrest and VERSA FIXATIS Range Harnesses or Pelvic Belt, please follow carefully the instructions reported in the relevant Instruction Manuals here attached. Eventual supporting accessories, if any, are supplied separate from the seating system.
For their mounting, please refer to the relevant section reported in the Chapter *1.3: Adjustments for the first Commissioning and/or subsequent adjustments*. Only for the INSERTO cushion, the combination with the frame takes place through the wooden seat base, whose mounting on the wheelchair is done by following the instruction below.

*Mounting the wooden seat base* (pic. 8)

It has rows of holes with threaded inserts along its side edges and 2 clamps at the front and rear, which allow it to be fixed to the seat tubes of the base. Place the base on the seat tubes. Pay attention to the position of the clamps: for the correct mounting they have to be positioned strictly in contact and alternatively one in front and one behind of the blocking collars fixed onto the tubes. In this way the sliding back and forth of the seat is avoided. For additional adjustments, it is possible to slide the clamps along the wooden base or the collars along the tubes of the seat by operating on the screws. After having achieved the correct positioning, press the seat towards the tubes until the click snap is heard to indicate the engagement of the 4 clamps of the seat on the tubes. If there are securing clamps, tighten by the provided knob once positioned.

***pic. 8**: Mounting the wooden seat base onto the tubes*

Verify the correct mounting of the seat at the correct position by:
a) moving it back and forth along the guiding tubes of the wheelchair
b) moving it upward.

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

*After having performed these operations make sure that the Frame combined with the Positioning System is secure, 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.*

## 1.3 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. All possible adjustements are described in this chapter.

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

### 1.3.1 "Frame for Positioning System" Adjustments

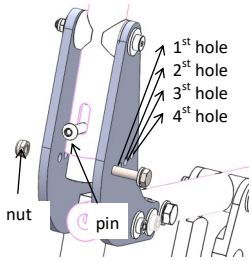
**1) Tilting seat** (tilt in space)

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) Reclining the backrest**

This adjustment is performed by engaging the desired hole located on the backrest tubes connecting plates. In particular (pic. 9):
- Lift the pin of the backrest tubes folding system placed on the lower end of each tube. This operation will make the backrest tubes free
- Unscrew the bolt that joins the two connecting plates of the backrest tubes.
- Depending on the desired reclining value, insert the screw in the appropriate holes in the plate and screw it in without tightening the self-locking nut; the regular tightening is achieved by checking that the screw exits the thread from the plastic ring of the self-locking nut. The holes allow the following values with respect to the vertical position:
  - 1st hole = 3°
  - 2st hole = 9°
  - 3st hole = 15°
  - 4st hole = 22°
- Pull the backrest tubes and bring them in vertical position until you hear a click indicating the tube has been locked in position.



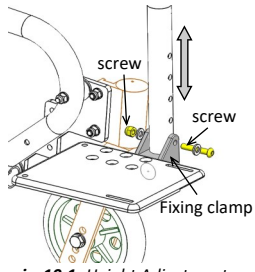
***pic. 9:*** *Reclining the backrest*

⚠ *Verify the correct position of the backrest tubes by checking they do not rotate.*

**3) Adjusting the Footplates**

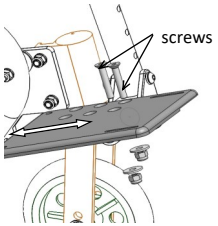
The footplates can be adjusted in height, depth and angle.

- Height Adjustment of the footplates (pic. 10.1):
  - unscrew and remove the exagonal head fixing screw
  - move the fixing clamp along the hanger until the destre position is achieved
  - reinsert the screw in the appropriate hole and thighten without screwing the self-locking nut; the regular thightening is achieved when the screw exits from the thread of the plastic ring of the self-locking nut.



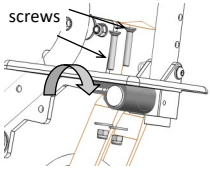
***pic. 10.1:*** *Height Adjustment*

- Depth Adjustment of the footplates (pic. 10.2):
  - unscrew and remove the 2 countersunk head fixing screws
  - move the footplate back and forth until the desired position is achieved
  - reinsert and thighten the screws.




***pic. 10.2:*** *Depth Adjustment*

- Angle Adjustment of the footplates (pic. 10.3):
  - unscrew and loosen the 2 countersunk head fixing screws
  - rotate the footplate clockwise or counterclockwise until the desired position is achieved
  - reinsert the fixing screws and thighten securely




***pic. 10.3:*** *Angle Adjustment*

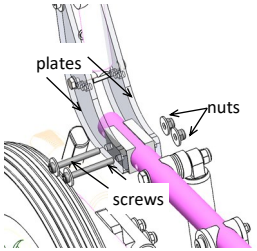
*After these adjustments, ensure that the footrests do not hit the castors.*

### 4) Frame Depth Adjustment

The frame is delivered in its standard configuration. Depending on the user's needs, it is possible to adjust the depth of the frame as follows:
- Posterior part of 50mm, with a gap of 25mm, by moving the backrest tubes
- Anterior part of 30mm by moving the legrest tube block.

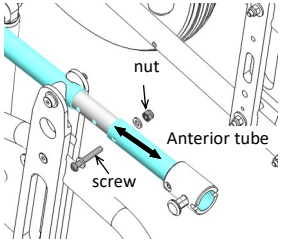
- *Posterior part depth adjustment (pic. 11.1):*
  - unscrew an remove the 2 fixing screws of the plates on the longitudinal tube
  - slide the plates along the tube by engaging the relevant holes of the desired value
  - insert the fixing screws and tighten to a torque level of 13.5Nm.

  Once this adjustment has been carried out, it is strongly recommended to perform a reposition of the posterior wheels in order to avoid unsafe tipping situations.
  It is sufficient to perform a slide movement of 15-20mm in the same direction of the depth adjustment by following the instructions reported in the section **6) Displacement of the plates** on pages 11, 12.




***pic. 11.1:*** *Posterior part depth adjustment*

- *Anterior part depth adjustment (pic. 11.2):*
  - unscrew and remove the fixing screw of the telescopic anterior tube
  - slide the plates along the anterior tube by engaging the relevant hole to the desired value
  - insert the fixing screw and tighten to a torque level of 13.5Nm.



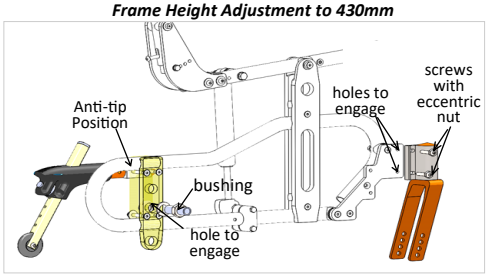

***pic. 11.2:*** *Anterior part depth adjustment*

## 5) Frame Height Adjustment

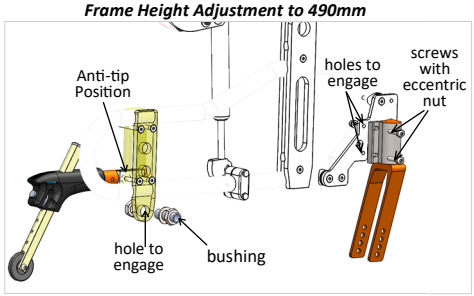
The Frame Height Adjustment to 430 mm and 490 mm can be performed both with the 300mm and 500mm posterior wheels; please refer to the following schemes to switch from one height to the other in function of the wheels provided.

### √ 300mm WHEELS

***Frame Height Adjustment to 430mm***

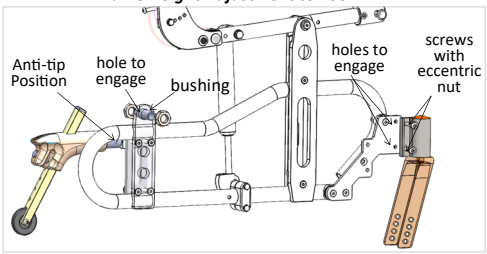



***Frame Height Adjustment to 490mm***

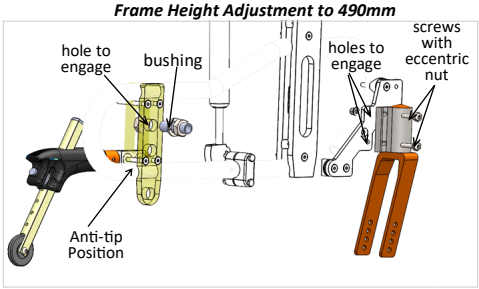



### √ 500mm WHEELS

***Frame Height Adjustment to 430mm***




***Frame Height Adjustment to 490mm***




Once this adjustment has been made, it is strongly recommended to perform a reposition of the posterior wheels plates and seat sliding plates in order to avoid unsafe tipping situations. It is sufficient to perform movements by following the instructions reported in the section ***6)*** **Displacement of the plates** on pages 11, 12.

To change the Frame Height, please perform as follows:

**A) *Change the position of the RH and LH forks***

- unscrew the two rounded head screws with eccentric nut connecting the fork to the plate
- engage the two relevant holes as reported in the scheme. Pay attention to the position of the eccentic nut: it has to be such that the fork axis is horizontal. Thighten at torque level of 13.5Nm.

**B) *Repositioning the posterior wheels bushing***

- disengage the wheels mounted on the frame
- disengage the parking brakes
- remove the wheel drive bushing
- unscrew and loosen the 4 countersunk screws locking the wheel plates
- if needed, rotate 180° the outer plates of the wheels
- mount the bushings by engaging the relevant hole as shown in the scheme
- firmly thighten the two nuts, placed one with washer outside to the plate and the other inside.

**C) *Repositioning the Anti-tip System***

- remove from the inner plate the Anti-tip System with the relevant interface stud
- mount the Anti-tip System with the relevant stud by engaging the holes as shown in the scheme
- screw and tighten the 4 countersunk screws of the plate at torque level of 13.5Nm.

**D) *Mounting the posterior wheels***

Verify the correct functioning of the wheels by checking:

- the release of the quick release axis button
- the impossibility of the wheel to be detached.

**E) *Mounting the parking brake***

For the correct parking of the wheels, adjust the distance between the brake pin and the tyre of the wheel by operating as follows:

- unscrew the 2 fixing screws of the brake clamp
- adjust the distance between the brake pin and the tyre of the wheel (estimated value 6mm.)
- tighten the 2 fixing screws
- verify the parking of the wheels.

⚠ *After having performed these operations make sure that the Frame is 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.*

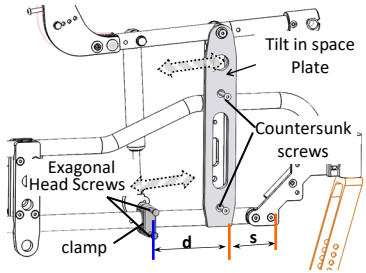
## 6) Displacement of the plates

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 (*Folding model*) -

The displacement of the seat with respect to the frame can be done as follows (pic.12.1):

- measure the distance *d* between the tilt-inspace plate and the clamp of the gas spring
- unscrew and loosen the coutersunk screws fixing both plates of the tilting mechanism
- unscrew and loosen the exagonal head screws fixing both clamps of the gas spring
- slide the tilt-in-space plates along the frame until the moving value *s* in the picture
- move the clamps of the gas spring in the same direction of the tilt-in-space plates until the previously detected value of the distance *d* is restored
- tighten the countersunk screws of the tilt-in-space plates to a torque level of 13.5Nm
- tighten the exagonal head screws of the gas spring clamp to a torque level of 13.5Nm.

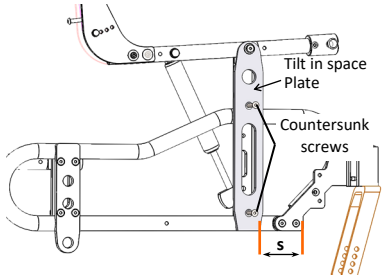



***pic. 12.1:*** *Displacement of the seat (Folding model)*

- Displacement of the seat (*rigid model*) -

The displacement of the seat with respect to the frame can be done as follows (pic. 12.2):

- unscrew and loosen the countersunk screws fixing both tilt-in-space plates
- slide the tilt-in-space plates along the frame until the moving value *s* in the picture
- tighten the countersunk screws of the tilt-inspace plates to a torque level of 13.5Nm.




***pic. 12.2:*** *Displacement of the seat (rigid model)*

**Moving value *s* for the displacement of the seat**

√ **430mm Frame Height** (with 300mm and 500mm wheels) and **450mm Frame Height** (with 400mm wheels)

| Frame Size | US, XXS | XS, XS0 |
|---|---|---|
| **Displacement (mm)** | From 50 to 60 | From 60 to 70 |

√ **490mm Frame Height** (with 300mm e 500mm wheels) and **470mm Frame Height** (with 600mm wheels)

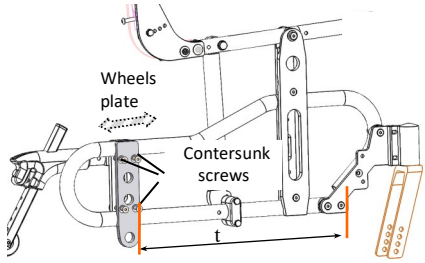
| Frame Size | US, XXS | XS, XS0 |
|---|---|---|
| Displacement (mm) | From 60 to 70 | From 70 to 80 |

The displacement *s* is detected from the edge of the fork fixing plate to the first edge of the til-in-space plate.

*After each operation check the position of the brakes and, if needed, perform adjustment as reported on page 6* ***point 7****. After having performed these operations make sure that the Frame is 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.*

- Displacement of the posterior wheels plate -

The displacement of the posterior wheel plates can be done as follows (pic.12.3):
- unscrew and loosen the countersunk screws of the wheels plates
- slide the plates along the frame to the moving value *t* in the picture
- tighten the 4 countersunk screws of the plates to a torque level of 13.5 Nm.




***pic. 12.3:*** *Displacement of the posterior wheels plate*

**Moving value *t* for the displacement of the seat**

√ **430mm Frame Height** (with 300mm and 500mm wheels ) and **450mm Frame Height** (with 400mm wheels)

| Frame Size | US, XXS | XS, XS0 |
|---|---|---|
| Displacement (mm) | From 360 to 380 | From 370 to 390 |

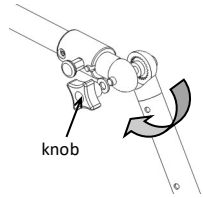
√ **490mm Frame Height** (with 300mm e 500mm wheels ) and **470mm Frame Height** (with 600mm wheels)

| Frame Size | US, XXS | XS, XS0 |
|---|---|---|
| Displacement (mm) | From 370 to 390 | From 380 to 400 |

The displacement *t* is detected from the edge of the fork fixing plate to the first edge of the wheel plate.

*After each operation check the position of the brakes and, if needed, perform adjustment as reported on page 6* ***point 7****. After having performed these operations make sure that the Frame is 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.*

**7) Knee Angle Adjustment** (where provided) (pic. 13)
- unscrew and loosen the fixing knob
- rotate the hanger until the desired position is achieved
- tighten the knob gradually so as the teethed mechanism engages and blocks the position of the hanger.



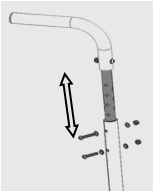

***pic. 13:*** *Knee Angle Adjustment*

**8) Push Handles Adjustment** (where provided)

Push Handles adjustment by pin (pic. 14.1)

The push handles of the backrest tubes can be height adjusted by pin (max course 100mm with gap of 25mm) as it follows (pic. 14.1):

- unscrew the two round head screws
- adjust the height of push handles as desired by engaging the relevant holes
- tighten the two round head screws.



***pic. 14.1:*** *Push handle adjustment by pin*

Telescopic Push Handles with Lever Block (pic. 14.2)

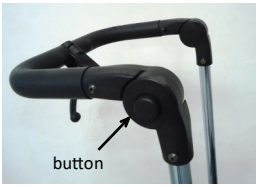
- loosen the locking lever of the telescopic push handles (placed on the backrest tube) on the uprights by lifting it up
- adjust the height and/or orientation of the handles as desired
- close the collar locking lever
- make sure the handles are secure and do not allow any movement.

(The same operations can be performed in case of the single handlebar)

***pic. 14.2:*** *Telescopic Push Handles with Lever Block*

Angle-adjustable single handlebar for rigid frame (pic. 14.3)

- press the side buttons on the handlebar
- adjust the orientation of the handlebar as desired
- Release the side buttons
- make sure that the two side buttons have been released.




***pic. 14.3:*** *Angle-adjustable single handlebar*

### 1.3.2 Adjustments of the Positioning System

The adjustments of the INSERTO SEAT cushion, the INSERTO BACK backrest with related thoracic supports, when provided, the VERSA CAPITIS Range headrest, and VERSA FIXATIS Range harness and/or pelvic belt, can be performed as reported in their own instruction manuals. Following you can find the instructions to adjusti the supporting accessories of the positioning system.

*These Operations must exclusively be performed by the Professional User; he will check the safety conditions, the suitability for use and the effectiveness of the Device.*

**A) Wooden Seat Base**

The adjustments of the wooden seat base are the following:

- *Depth Adjustment*

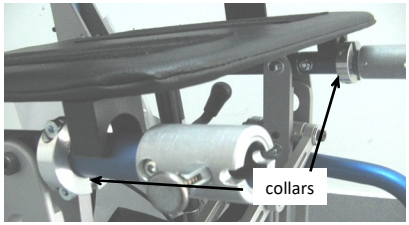
The wooden seat base is mounted on the seat rails of the wheelchair by means of 4 snaplock clamps and it is secured against movements by 2 collars mounted on the tubes of the base. The collars are positioned, alternatively, one in front and one behind the anterior snaplock clamps. The depth adjustment is performed as follows (pic. 15):

1. unscrew and loosen the collars fixing screw placed on the tubes of the base
2. slide the wooden seat base along the tubes to the desired position
3. tighten the screws of the collars.

It may be also necessary to move the snaplock clamps along the lateral edges of the wooden seat base.

In this case, plese perform as follows:

1. unscrew and remove the countersunk screw of the snaplock clamp
2. slide the snaplock clamp along the lateral edge of the wooden seat base to the desired position, in relation to the holes placed along the lateral edge of the seat itself (with a gap of 25mm)
3. Punch the cover, insert and fix the countersunk screw.




***pic. 15****: Collars for depth adjustment*

*Make sure that the collars are fixed alternatively one in front and one behind the relevant snaplock clamps in order to avoid undesired sliding of the seat base.*

• *Width Adjustment*

This kind of adjustment is possible only with the hip guides; in that case follow the instruction reported in the relevant section *B*) *hip guides*.

**B) Hip Guides** (where provided)

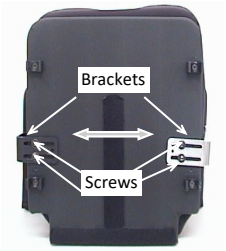
The hip guides are fixed to the seat by the brackets. They present rows of threated holes in order to allow a wide range of movements and adjustments. The distance between the two hip guides determines the width of the seat, which is adjustable. It is also possible to adjust the depth and the height of the hip guides.

• *Seat width adjustment* (pic. 16.1)

The width adjustment is made by changing the position of the hip guides, acting on the brackets, by means of which the hip guides are fixed to the seat base:

1. Unscrew and loosen the round head fixing screws of the bracket to the seat
2. Move the hip guide inward and outward of the seat until the desired position is achieved
3.Tighten the round head fixing screws.

For the movement of the 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. 16.1:*** *Seat width adjustment by the hip guides brackets*

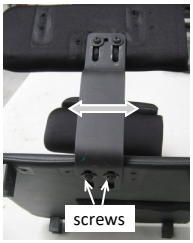
• *Hip guides depth adjustment*

It can be performed in two ways:

*A) By Moving the bracket of the hip guide along the seat (pic. 16.2)*

By operating on the round head screws of the bracket, located beneath the seat:

1. unscrew and remove such screws
2. move the hip guide back and forth along the edge of the seat base until the desired position is achieved
3. punch the cover, insert and fix the round head screws.




***pic. 16.2:*** *Bracket adjustment*

*B) By Moving the hip guide along the bracket (pic. 16.3)*

By operating on the round head screws connecting the bracket to the hip guide:

1. unscrew and loosen such screws
2. slide the hip guide back and forth, until the desired position is achieved by engaging the relevant row of hole on the same hip guide
3. punch the cover, insert and fix the round head screws.

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

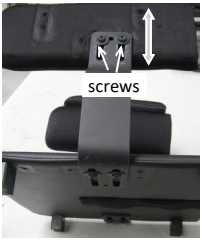

***pic. 16.3:*** *Hip guide adjustment*

• *Height adjustment* (pic. 16.4)

By operating on the round head screws connecting the bracket to the hip guide:

1. unscrew and loosen the round head screws fixing the hip guide to the bracket
2. move the hip guide up and down to the desired position
3. Retighten and fix the round head screws.

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



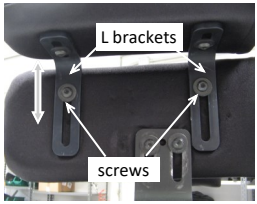

***pic. 16.4:*** *Height adjustment*

**C) Arm Supports** (when 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 movements and adjustments. They can be adjusted in height, width and depth.

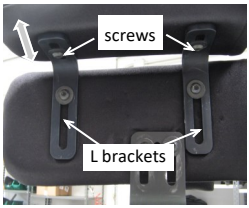
- *Height adjustment* (pic. 17.1)
  1. unscrew and loosen the round head screws fixing the L brackets to the hip guide
  2. move the arm support up and down until the desired position
  3. tighten and fix the round head screws.

  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).



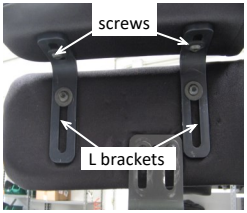
***pic. 17.1:*** *Height adjustment*

- *Width adjustment* (pic. 17.2)
  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.



***pic. 17.2:*** *Width adjustment*

- *Depth adjustment* (pic. 17.3)
  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.



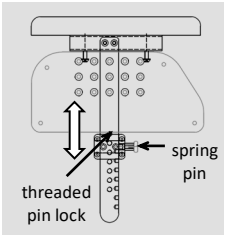
***pic. 17.3:*** *Depth adjustment*

**D) Kit ABS Laterals with armrest** (where provided)

The armrest fixed bracket, can be height adjustable (pic. 18):

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)

*Verify the correct functioning of the ABS lateral:*
*1) The correct placing of the spring pin*
*2) the impossibility of detachment of the ABS Lateral*



***pic. 18****: ABS Lateral*

**E) Calf Support** (where provided)

The Calf Support (single or separate) (pic. 19) 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.

*Ensure Calf Supports are properly locked.*


***pic. 19****: Calf Support*

**F) Padded 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
4) adjust the padding of the Calf Strap by using the fastening system to give a correct support to the leg.

⚠ *Check that the front parts are not too tight to avoid problems with foot circulation. Always check the fastening for better functionality of the calf strap. 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.*

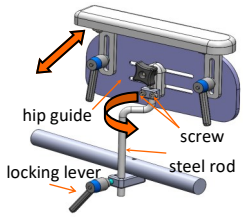
**G) Multiadjustable Kit** (where provided)

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

A) *Pelvis*

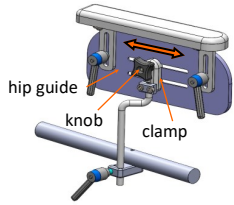
Possible adjustments are: in width, depth, height e adduction/abduction:

- Width and/or adduction/abduction adjustment (pic. 20.1)
  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.



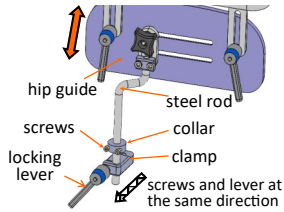

***pic. 20.1:*** *Width adjustment*

- Depth adjustment (pic. 20.2)
  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




***pic.20.2*** *Depth adjustment*

- Height adjustment (pic. 20.3)
  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.

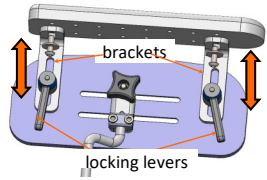



***pic. 20.3:*** *Height adjustment*

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.

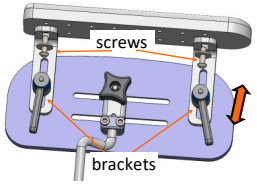
- Height and/or tilt adjustment (pic. 20.4)
  1. loosen the two locking levers to ensure the sliding of the brackets which are fixed to the arm support
  2. move the arm support vertically or tilt it until the desired position
  3. tighten the locking lever to block the arm support.




***pic. 20.4:*** *Height and/or tilt adjustment*

♦ Width and internal/external rotation adjustment (pic. 20.5)
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. 20.5)
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. 20.5:*** *Width and internal/external rotation and 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.*

**H) Abductor Wedge** (where provided)
The Abductor Wedge, which can be removed with lever or block, is mounted to an L shaped Bracket and it is locked under the seat with a clamping knob.

√ Abductor Wedge removal
- unscrew and loosen the clamping knob
- slide the bracket.

√ Abductor Wedge inserting
- place the bracket under the seat, taking care to slide the slot along the round head screws
- screw the clamping knob
- verify the right inserting by checking the impossibility of movement.

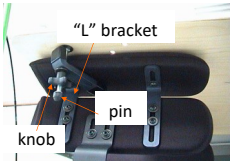
√ Height adjustment (pic. 21)
- unscrew and loosen the Abductor Wedge fixing round head screws to the Bracket
- slide the Abductor Wedge up and down until the desired position is achieved
- tighten and fix the round head screws.

√ Abductor Wedge lateral adjustment (pic. 21)
The Abductor Wedge can be mounted laterally in relation to the rows of holes located under the wooden base along the front edge. For the adjustment, please perform as follows:
- unscrew the fixing round head screw
- slide the bracket to the right or left and in relation to the rows of holes as shown in the picture, until the desired position is achieved
- punch the cover, insert and fix the round head screw
- insert the clamping knob. For correct functionality, the knob needs to be be positioned behind the round head screw.


***pic. 21:*** *Abductor Wedge lateral adjustment*

**I) 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. 22)
- 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. 22:*** *detachable mechanism*

**(option 2) Lateral Flip mechanism** (pic. 23)
The mounting can be done as follows: (the pic. 23 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. 23:*** *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) Use of the Frame Components*

- **Backrest Tubes: installation/removal** (pic. 24)

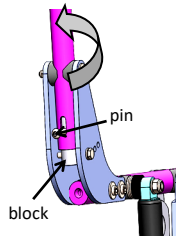
*Installation*

Pull the backrest tubes by the push handle in vertical position until you hear a click indicating the engagement of the lock pin.

Verify the correct position of the backrest tubes by checking they are stable and do not move/rotate.

*Removal*

Lift the pin of the backrest folding system placed on the lower end of each backrest tube. This operation will make the tubes free to be folded.




***pic. 24:*** *Backrest Tube*

- **Anti Tip System: installation/removal**

Please, follow the instruction reported on page 6 *point 6.*

- **Unfolding the Frame for Positioning System** (folding model)

Please, follow the instruction reported on page 5 *point 1.2.1.*

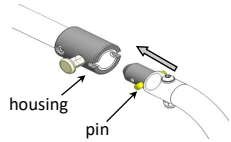
- **Legrest Tubes: installation/removal**

*Installation* (pic. 25.1)

Insert the edge of the legrest tube into the seat tube.

Push the tube until the lockin pin stops in its relevat housing.

Verify the correct assembling by checking the Legrest tube is in place and doesn't move or rotate.

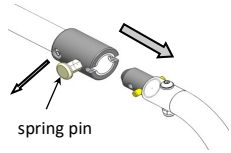



***pic. 25.1:*** *Installation of the paediatric size*

*Removal* (pic. 25.2)

Pull the spring loaded locking pin outward.

Remove the Legrest tube.




***pic. 25.2:*** *Removal of the paediatric size*

- **Parking brakes**

The frame is provided with two parking brakes. To activate the brake, press the lever downward until you hear a blocking noise inticating the engagement of the brake; check that the wheel doesn't move. To unlock the brake, pull the lever in its original position. The brakes are designed to be used as parking brake and do not have to be used while the frame is running.

For the correct parking of the wheel, check that the distance between the brake peg and the wheel tire is equal to 6mm. In a contrary case please refer to the professional user for its adjustment. If the wheel is equipped with a drum brake there will be two lever located on the backrest tubes. Once the levers are activated, the wheels will be blocked without possibility of movement; if the levers are released the wheels will be free to move. These brakes can be used to stop the system while it is running.

*When the frame is running and the drum brake has to be activated, it is necessary to operate both levers at the same time. The adjustment of the levers must be performed by the professional user.*

- **Tyres**

Check that the pneumatic wheels are inflated as the value reported on the side edge of the tire. Improper pressure can influece the performance of the Frame: low values can affect the manoeuvrability and action of the brake; high values can cause the tyre to burst. The replacement of the inner tube and/or tyre is like any bicycle wheel. Also check the tire profile: excessive wear can reduce the action of the parking brake.

**- Pelvic Belt**

The positioning system involves the use of a pelvic belt of the FIXATIS range. To know more about its use, please refer to the relevant instruction manual.

*Before using the system, make sure that the pelvic belt is fastened. 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.*

**- Kit ABS Lateral** (pic. 26) (where provided)

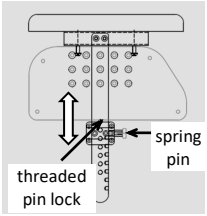
*Installation*

- pull the spring loaded pin
- insert the bracket in the relevant receptacle and make it slide until it stops
- release the spring loaded pin that blocks the bracket.

*Removal*

Pull the spring pin that blocks the bracket and detach the ABS laterals kit.

*Verify the kit ABS lateral is blocket in a proper way by checking:*
*1) the correct insertion of the spring pin*
*2) the impossibility of detachment of the Kit ABS lateral.*




***pic. 26**: Kit ABS Lateral*

### *B) 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
√ Release or swing-away the footrests, and flip them into an upright position, which is in relation with the footrest tubes. This reduces the risk of entrapment of the feet with the footrest during the 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 footrests
√ 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.*

### *C) Tilting the System*

The tilting of the System is performed by activating the gas springs which are controller by the lever located on the push handles of the backrest. Adjust the seat according to the instructions of the professional user. Tilting must be continuous and, when the lever is released, the springs will lock the seat 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.*

## 1.5 Transportability

When traveling in a vehicle is strongly recommended to transfer the user from the wheelchair to the vehicle seat (when possible) and use the vehicle's seat belts, storing the wheelchair in the trunk. The vehicle seat provides the highest level of safety, as it is mounted to the chassis of the vehicle and is designed for that purpose.

### 1.5.1 Trasport of the System without occupant

For an easy transportation of the system, it is necessary to proceed with the removal of the Positioning System 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 Inserto Seat cushion: if there are 2 snaplock clamps, loosen and pull the seat with the wooden base upwards until it clicks, indicating that the seat clamps are detached from their relative tubes
3) Remove the Inserto Back backrest: follow the instruction reported in the relevant Instruction Manual
4) Remove the Kit ABS Lateral (where provided)
5) Folding down the backrest tubes; follow the instruction reported on page 18
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) Remove the legrest tubes: follow the instruction reported on page 18
8) Disengage the anti tip system: follow the instruction reported on page 6
9) Fold the foldable Frame for Positioning System (where provided); pull the string placed on the cross brace upwards; bring the two frame tubes of the base closer until they stop.

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) Unfold the Frame for Positioning System (where provided): follow the instruction reported on page 5
2) Assemble the posterior wheels: follow the instruction reported on page 5
3) Assemble the backrest tubes: follow the instruction reported on page 18
4) Assemble the legrest tubes: follow the instruction reported on page 18
5) Apply the parking brake and make sure the frame doesn't move
6) Fix the wooden seat base onto the frame: lay the seat base down on the tubes. Pay attention to the snaplock clamps: for a correct installation they have to get in contact with the appropriate collars on the tubes, one in front and one behind. in this way the wooden seat base will not move.
7) Fix the Inserto Seat cushion on the wooden seat base; please, follow the instruction reported in the relevant instruction manual
8) Assemble the Kit ABS Lateral (where provided)
9) Fix the Inserto Back backrest: follow the instruction reported in 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.*

### 1.5.2 Transport of the System with occupant (when equipped with car transport kit)

Please note that in cases where is not possible to transfer the user to the vehicle seat the wheelchair is designed in accordance with the requirements of ISO 7176-19:2008 and can be used as a seat for transport in a motor vehicle by complying with the following instructions:

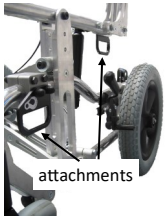
*The risk of serious injury or death increases dangerously if the following recommendations are ignored. In the event of an accident or crash, please, send the wheelchair and posture system to a Pro Medicare dealer in order to check its integrity for subsequent reuse.*

1. Ensure that the vehicle has the proper equipment for transporting a seated passenger in a wheelchair and make sure that the vehicle access arrangements are suitable for the type of wheelchair. The vehicle floor must have the strength to support the total weight of the user, wheelchair and accessories.
2. Sufficient space must be available around the wheelchair to allow easy access to attach, tighten and release the wheelchair anchor straps and user restraint straps.
3. The occupied wheelchair must be facing forward (pic. 27) and secured with the wheelchair anchor strap and user restraint straps (WTORS "Wheelchair Tie-down and Occupant Restraint System" that meet the requirements of ISO 10542 or SAEJ2249) in accordance with the WTORS manufacturer's instructions. Use of the wheelchair in other positions within a vehicle has not been tested. Therefore, never transport the wheelchair facing sideways (pic. 28).


***pic. 27:*** *Forward-facing wheelchair*


***pic. 28:*** *Sideways-facing wheelchair*

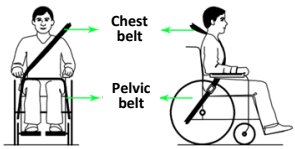
4. The wheelchair should be secured with a 4-point restraint system in accordance with ISO 10542 with non-adjustable front straps and adjustable rear straps usually equipped with Karabiner clips/S-hooks and fasteners with buckle and tab.
Such systems usually include 4 separate straps that are each to be attached to a corner of the wheelchair in the appropiate attachments (pic. 29). The presence of a label indicates the correct position for attachment (pic. 30).



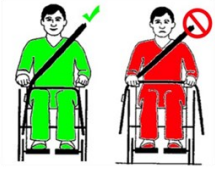

***pic. 29:*** *left front and rear attachment*


***pic. 30:*** *label*

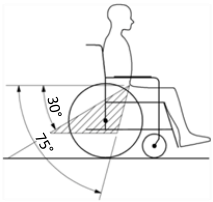
5. The anchored restraint system must be attached to the main frame of the wheelchair where indicated by the manufacturer. The system should never be attached to wheelchair components or accessories, e.g., to wheel spokes, brakes, or footrests.
6. Attach the anchor straps so that the angle is as close to a 45° angle as possible and tighten them securely following the manufacturer's instructions.
7. Do not make changes or replacements to the attachment points or to the structure, frame, or components of the wheelchair without consulting the manufacturer.
8. Use both the pelvic belt and the thoracic belt to secure the user and minimize the user's movement during impact, to reduce the impact with parts of the vehicle and the resulting serious risk of injury to the user and other occupants of the vehicle (pic. 31).
The restraint belts should not wrap around wheelchair components, such as armrests or wheels, because they would then not adhere to the body (pic. 32).
The chest belt should be attached to the vehicle pillar and should not go over the neck; the pelvic belt should be placed immediately above the pelvic bones.
Vehicle restraint belts should be positioned on the user so that the pelvis belt is at an angle between 30° and 75° to the horizontal plane. It is preferable for the belt to have a pronounced angle, but not more than 75° (pic. 33).




***pic. 31***

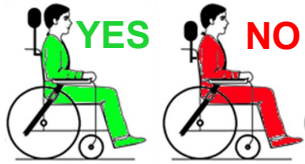


***pic. 32***




***pic. 33***

9. Install a suitable headrest for transport and always position it properly during transport (pic. 34)




***pic. 34***

10. Do not use user postural supports (pelvic straps, pelvic belts) as restraints in a moving vehicle that are not labeled according to the requirements specified in ISO 7176- 19:2008 standard.
11. Pay close attention when positioning anchor straps so that their buckle release button cannot come in contact with any other component of the wheelchair during a crash.
12. To reduce the potential risk to vehicle occupants, remove any moving parts of the positioning system and store them in a safe place (e.g., tray)
13. When transporting the occupied wheelchair, if there is an elevating footrest, it should not be used in an elevated position.
14. If the backrest is reclined bring it to vertical position.
15. If the seat is "tilting" type, bring it to its minimum inclination.
16. The brake must be activated.

### 1.6 Recommendations for Use

In order to guarantee safe use and a long lasting performance of the Integrated Positioning System, please find below advices for the end 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.

## 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 the 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 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 these adjustments, the anti-tip castors must be positioned to reduce the risk of the System tipping
  - 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 when the end user is left alone on the base, when the system is running, make sure that the anti-tip tubes have been placed upwards.

***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 wheelchair, 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
- Max accepted gradient: 7°
- 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 (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.

## 4. RESTRICTIONS OF USE

The Integrated 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
- 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 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
- Components breakages or tears such as plates, tubes, linkage components: 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 Integrated Positioning Systems 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 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.*

## 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.

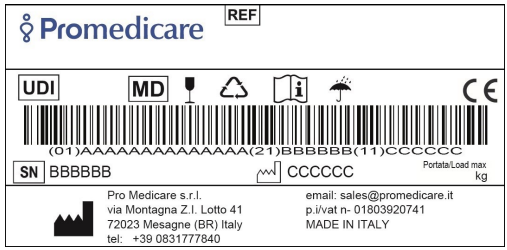
## 10. DISPOSAL/RECYCLING

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 Integrated Positioning System accessories):

- Aluminium: headrest hardware, various type of brackets, tubes, plates, forks, footrest, backrest shell, 500mm and 600mm posterior wheels
- Steel: screws, threaded inserts, headrest shells, quick-releases
- Wood: seat bases, calf support bases, support bases, hip guide babses, trays, abductor wedge base
- Plastic: internal thoracic support bases, mounting components of the base one the frame, handgrips, castors, 300mm and 400mm posterior wheels, footplate, fixing elements of harnesses, seat/back 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 wheelchair base, 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 bases of this range are made of high-strenght aluminium used in the aeronautical industry, 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 Frame for Positioning System enables the continuous tilt in space between +2° and +35° which is always and easily adjustable by operating the two gas spring lever located on the push handles. By means of an aluminium plate between the seat rails and the backrest tubes it is possible to recline it in a fixed position of 3°, 9°, 15°, 22°.

Furthermore, due to a particular type of fixing plates it is possible to:

- seat depth adjustment (for a total of 80mm)
- sliding of the seat with respect to the sub-frame
- sliding of the posterior wheel plates
- frame height adjustble:
  - 430/490mm (only with 300mm and 500mm posterior wheels)
  - 450mm (only with 400mm posterior wheels)
  - 470mm (only with 600mm posterior wheels).

The positioning system can be easily installed or removed from the frame. The frame, which can be rigid or folding, has the following features:

- folding down backrest tubes
- detachable footrest hanger: 90°; 75°; elevating
- quick-release 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 or without handrims with parking brake lever; pneumatic with drum brake or with drum brake and parking brake lever); 600mm (pneumatic with handrims and parking brake lever), not available on size US
- castors: 150mm/175mm poly

This enable an easy transportation of the device during transfers.

## TECHNICAL FEATURES TABLE

| Titti Size | | Max Load *(kg)* | Frame Weight* *(kg)* | Weight of the heaviest Postural component** *(kg)* | Pivot Width *(mm)* | Seat Tube Height*** *(mm)* | Maximum overall width/length (with 90° knee angle and footplate positioned all the way forward) *values expressed in mm* | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | 300 wheels strd. | 300 wheels with Drum Brake | 400 wheels strd. | 400 wheels with Drum Brake | 500 wheels strd. | 500 wheels with Drum Brake | 600 wheels |
| **US** | *Rigid* | 50 | 14.1 | 1.9 | 690 | 430/490 with 300/500mm posterior wheels and 150/175mm castors<br>———<br>450 with 400mm posterior wheels and 150/175mm castors<br>———<br>470 with 600mm posterior wheels and 150/175mm | 480/960 | 490/960 | 500/990 | 530/990 | 500/1010 | 530/1010 | / |
| | *Folding* | 50 | 14.9 | 1.9 | | | | | | | | | |
| **XXS** | *Rigid* | 50 | 14.4 | 2.3 | 690 | | 530/960 | 540/960 | 550/990 | 580/990 | 550/1010 | 580/1010 | 550/1040 |
| | *Folding* | 50 | 15.3 | 2.3 | | | | | | | | | |
| **XS** | *Rigid* | 50 | 14.7 | 2.6 | 720 | | 530/990 | 540/990 | 550/1000 | 580/1000 | 550/1020 | 580/1020 | 550/1070 |
| | *Folding* | 50 | 15.6 | 2.6 | | | | | | | | | |
| **XS0** | *Rigid* | 50 | 15.4 | 2.6 | 750 | | 560/990 | 570/990 | 580/100 | 610/1000 | 580/1020 | 610/1020 | 580/1070 |
| | *Folding* | 50 | 15.9 | 2.6 | | | | | | | | | |

* Only Frame weight including wheels, knee angle and footrest as per standard configuration

** EFFECTO Backrest

*** taken outside to outside seat tube at the tilt in space plate

Maximum weight and dimensions of the frame with decoupled posture, folded backrest tubes, footrest and posterior wheels detached

| **Titti Size** | | **Frame Weight** *(kg)* | **Overall dimensions** *values expressed in mm* | | |
|---|---|---|---|---|---|
| | | | width | lenght | height* |
| **US** | *Rigid* | 11.4 | 420 | 660 | 650 |
| | *Folding* | 12.2 | 300 | | |
| **XXS** | *Rigid* | 11.7 | 480 | 660 | 650 |
| | *Folding* | 12.6 | 300 | | |
| **XS** | *Rigid* | 12 | 480 | 680 | 660 |
| | *Folding* | 12.9 | 300 | | |
| **XS0** | *Rigid* | 12.7 | 510 | 680 | 660 |
| | *Folding* | 13.2 | 300 | | |

*fixed push handles

**NOTE**: The length dimensions, referred to the average values, are subjected to variations due to the displacement of the plates. The values reported are intended for the standard configuration.