



INSTRUCTION MANUAL

 **Promedicare**

Feel the ideal posture

Pro Medicare S.r.l.

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

INTRODUCTION

Dear User, thank you for choosing highly performing Pro Medicare medical device.

EOLO is a multifunctional high chair intended to be used in maintaining the sitting position of a user with limited mobility to maintain sitting position. Thanks to its modularity and different possibilities of adjustment, *EOLO* 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 for positioning system; to this end, it is important to read the information about how to use it carefully, with the express invitation to follow the prescribed indications.

As a manufacturer, Pro Medicare refers to the Professional User as the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), and to the End User (or lay person) as the person who is intended to use the Device (caregivers, family members, etc.).



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

The Technical features of the device are reported in the Annex A "Technical Features".

After consulting this manual, for further information, please contact the Technical Sales Department at the number **+39 0831 777840**, Monday to Friday from 9 a.m. to 1 p.m. and from 2.30 p.m. to 6.30 p.m.

In case of emergencies outside the working hours, please send an email to **sales@promedicare.it**

We will call you back as soon as possible.

In order to ensure appropriate After-Sale Monitoring of Devices placed on the market and put into service, or in the event of an incident during the use, please refer to the instructions stated in the relevant chapter.

USE

EOLO highchair has been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745; because it is modular, *EOLO* is able to follow the evolution of somatic growth and the consequent adaptations of the user.

EOLO is intended to be used in indoor spaces, for personal use only and with the assistance of caregivers.

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

The CE Declaration of Conformity refers exclusively to the Medical Device prepared and provided by the manufacturer, "as-is", when the Device is unchanged with respect to the standard configuration. Pro Medicare is constantly dedicated to innovate its own Devices; This can entail changes in form or technique on the devices and/or related accessories. Therefore, hypothetical complaints on values, images and schemes defined in the this manual, will not be accepted. Furthermore, for the complete list of the optional parts and/or accessories, 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:

- EOLO highchair
- any accessories as per the order form
- labeling and Instruction Manual.

Upon delivery, please check for the integrity of the package and immediately note any damages or anomalies on the shipping document. Then open up the packaging and check that the various parts do not show dents, drippings, deformations or tears. Otherwise note the anomalies found on the shipping document.

After performing these checks and if the product has not to be put into immediate use, we recommend to repack and store it in a dry place.

The above operation will be carried out by the Professional User.

1.2 Preliminary Operations for correct Commissioning

The professional user and the end user must check, by inspection, that the tightness of the seat on the base is always in a safe condition (check that the screws securing the seat to the base are always well tightened).

Highchair comes in compact version with the removable components disconnected; it must be put into operation.



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

1.2.1 Operations for the “commissioning of the device”

The EOLO high chair, in its standard configuration, consists of:

- Indoor frame high-low height-adjustable and tilting by gas spring (-5° to +30°) with multi-adjustable push handle and equipped with 4 swivel castors, 2 of which have a parking brake.
- An anatomical seat width and depth adjustable
- An anatomical backrest with extension, adjustable in height and reclining by gas spring (-3° to +20°)
- Armrests adjustable in width, height, depth and tilt
- Pelvis side panels adjustable in width, height, depth and tilt
- Fixed flat thoracic supports adjustable in height, depth and tilt
- Tilting wooden tray with edge and self-levelling supports
- Footboard with containment adjustable in height, tilt and flexion-extension.

The seat and backrest padding provides maximum softness and comfort. The cover is available in different colors, it is fire retardant, breathable, latex-free and with a low risk of skin irritation, it is commonly used in medical devices. Furthermore, depending on the particular needs and clinical conditions of the user, the high chair can be equipped with contoured thoracic supports, harnesses, pelvic belt, headrest, padded abductor wedge, padding for footboard and for tray, head cover, seat cover, armrest cover, thoracic support cover.

The components are reported below:

1) Seat/pelvic side panels/armrest

The seat is an anatomic shape cushion placed on the metallic plate through hook and loop system. The depth adjustment can be done via the fastening inserts located under the seat (pic. 1); the width adjustment can be done via unscrewing the screws located under the pelvis side panels hardware as showed in pic. 1. Furthermore both the pelvis side panels and the armrests have numerous holes allowing different adjustments such as height, depth, tilt activated by unscrewing and re-tightening the screws on the pelvis side panels (pic. 2).



pic. 1: Depth adjustment of the seat



pic. 2: Pelvis side panels/armrests adjustment

2) Backrest/Thoracic Supports

The metal shell of the backrest consists of two segments that slide over each other and the upholstered part, on the other hand, consists of a single, slightly contoured piece. The upholstered part is positioned on the metal shell with hook and loop tapes.

Height adjustment of the backrest is possible through fastening inserts positioned on the rear side of the metallic shape (pic. 3); Thoracic supports allow width adjustment, this is possible by unscrewing and retightening the screws on the positioned on the rear side of the thoracic supports hardware as showed in pic. 4.

Furthermore, thoracic supports have several holes that allows different adjustments such as height, depth, tilt; simply unscrew and retighten the screws as showed in pic. 4.

The backrest can be reclined activating the lever positioned at the gas spring lower end (pic. 5). Reclining is continuously adjustable by activating the lever. Once released the lever, the spring will block the backrest to the position reached. If the adjustment is done with the user seated in the system, it is necessary to hold the backrest until the gas spring lever is released. Proceed slowly, gradually and pay careful attention.



pic. 3: Backrest adjustment



pic. 4: Thoracic supports adjustment



pic. 5: Reclining adjustments

Ensure safe and correct functioning by checking:

- 1) tightening of levers and screws
- 2) the impossibility of detachment of pelvis side panels/armrests/thoracic supports.



Once adjustments have been made, it is advisable to seat the user for at least an hour and to examine any possible areas of pressure overloads; if so, it will be necessary readjust, while if not, the product will be ready to be used.

3) Tray

The Tray provides proper forearms support, it allows the discharge of the trunk and arms weight from ischial tuberosities and promotes residual activities/abilities.

The locking of the Tray is performed by inserting the Steel Rod into its housing which is located under the tray and tighten the Knob (pic. 6).



pic. 6: Tray



Verify the tray is assembled properly by checking the impossibility of movements. Check the stability of the tray.

Be careful not to hit the user when moving the tray.

Do not adjust the depth of the tray too forward, as this may cause the tray to tip over when a weight is placed on it.

4) Footboard

It is possible to adjust:

- the knee angle elevation, through the holes in the aluminium plates located below the seat
- the footboard angle, this is possible by unscrewing and retightening the screws located on the footboard plate
- the footboard height, through the holes located on the tube.



pic. 7: Footboard

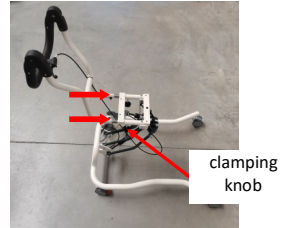
5) Base frame

Handlebar insertion

Connect the handle (pic. 8) only by inserting the tubes into the guides on the base and tighten all with the knobs provided



Check for correct tightening.



pic. 8: Handlebar insertion

Orbital handlebar adjustment

- Push the side handlebar buttons (pic. 9)
- Adjust the Handlebar direction as desired
- Release the side handlebar buttons
- Make sure the two side buttons have been released.

High-low height adjustment (pic. 10)

Press the pedal with foot at the posterior wheels, hold the handle and lift the positioning system mounting interface.

Checking the brake (pic. 11)

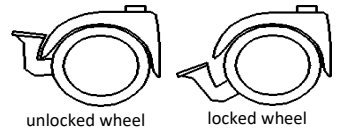
Apply and release the brake on the two posterior wheels and check that the device is properly locked.



pic. 9: Orbital handlebar adjustment



pic. 10: High-low height adjustment



pic. 11: Brake application

6) Headrest (if required)

The headrest is designed to provide head support and horizontal view wherever possible. It is multiaadjustable (pic. 12) and it is firmly anchored to the backrest structure; its height adjustment can be done by acting on the fixing screws of the arms, while its angle adjustment can be done by acting on the fixing screws of the spherical headrest housing.



pic. 12: Headrest

7) Harness (if required)

The Dynamic butterfly harness (pic. 13) provides stability of the trunk and shoulders allowing to keep the position, accompanying small movements; must be anchored to the back of the backrest, using the screws for adjusting the height of the backrest for the upper part of the harness and the screws for anchoring the backrest reclining plate for the lower part. Furthermore the harness is equipped with easy-to-operate release buttons.



pic. 13: Harness



Always use a pelvic belt to stabilise the pelvis. Monitor that the user does not slip (risk of strangulation).

8) Pelvic belt (if required)

The pelvic belt (pic. 14) provides the pelvis stabilization by preventing it from moving forward on the seat and by adjusting its position on the sagittal plane.

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



pic. 14: Pelvic belt

1.3 How yo use it

EOLO high chair after the Professional User has performed the commissioning, is ready to be used.

Daily operations such as the transfer from and to the high chair, must normally be performed by parents or caregiver.

Following there are all modes of use. Before to start any operation the professional user needs to educate the parent or caregiver about use. It will require to practise all daily operations and manoeuvre the high chair in areas where it should be used.

It is good to develop one's own methods for safe use, adapted to the needs.



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

During the removal of pelvic belt, thoracic supports or tray pay attention to avoid collisions against the user.

A) End-user transfer from/to the high chair

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 high chair

- √ Ensure the brakes are on, and the high chair is locked from movements
- √ Put the seat into a horizontal position
- √ Loosen any fixing harness
- √ Disengage any detachable elements (i.e. tray, thoracic supports, retractor)

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

Transfer to the high chair

- √ Ensure the brakes are on, and the high chair is locked from movements
- √ Put the seat into a horizontal position
- √ Lift and transfer the user to the high chair by paying particular attention to this operation
- √ Insert any detachable elements
- √ Fasten any fixing components
- √ Make sure that the user is in his normal seating position.



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

B) Transporting the high chair

To transport the high chair alone, its structure must be compacted by lowering the seat and removing the removable elements.



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

Subsequent start-up

At the end of the trip, bring out the highchair EOLO and detachable elements and proceed with commissioning of this one by proceeding with the operations described in the instruction manual.



After having performed these operations make sure that the highchair with the detachable elements 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.

1.4 Recommendations for Use

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

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

2. GENERAL WARNINGS

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

2.1 Warnings for the Professional User

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

+39 0831 777840

- Max. Load: See Annex A “*Technical Features*”

- Preliminary Operations for correct Commissioning: (to be performed in accordance with the instructions provided in *sect. 1.2*)
- * After having performed these operations make sure that the Frame combined with the Positioning System is stable, easy to move and that all components work in harmony
 - * Check for noise, vibration, or changes to the normal conditions of use to ensure safety conditions and the suitability for use.

- Adjustments:

- These operations must be performed by authorized people
- After having performed these adjustments, be aware of any noise, vibrations or any changes to the normal conditions of use to ensure the safety conditions and suitability for use
- Unauthorized modifications or the use of parts not supplied or approved by the manufacturer may affect the safe and operational integrity of the system and be cause of danger.

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.** Contact with water and excessive moisture can cause components of the structure to oxidise and start to show signs of decay, so:
- Do not use the system in the shower, pool or environment in contact with water. Some components may be damaged and cause malfunctions
 - Avoid extreme humid places (for example: do not bring the system into a steamy bathroom after a shower)
 - Avoid contact with seawater
 - If the device comes in contact with water or dirt, please carry out an immediate and thorough clearing.
- b.** Severe environmental conditions may affect the features of the materials used, the functionality and performance of the structure, so:
- Avoid the exposure to extreme temperatures
 - Avoid prolonged exposure to sunlight. Some parts may overheat.

- **Components and options**

Footboard: The portion of the high-low base closest to the floor is the footboard, so avoid passing over obstacles that may collide with the footboard and cause damage. Furthermore:

- be sure that feet do not 'hang' or get trapped
- do not place any weight on the footboard to prevent the high chair from tipping forward
- do not tilt the high chair on the footboard, the footboard may detach from its tubular frame and break
- be sure before installation and after each adjustment that the footboard do not collide with the front wheels.

Pelvis side panels: The pelvis side panels cannot support the weight of the high chair. The device must not be lifted by the pelvis side panels, otherwise the latter could detach or break off.

- **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 high chair over uneven ground or obstacles, which if in contact with wheels, they can cause the system to tilt

- To reduce the risk of a tipping, do not hang bags, backpacks or any other weight on the system
- In the event that an accident causes a loss of performance, do not use the system and consult the professional user
- In the case of a sudden deterioration in performance, do not use the system and consult the professional user
- In case of malfunctions resulting from other causes, including poor maintenance of the system, the professional user should be consulted.
- Frequently check all the the fixing of the seat on the fram base and verify for a safe and fully functional operations

3. NEGATIVE ADVERSE EFFECTS

Generally the use of the high chair *EOLO* should not cause any adver effects such as allergies, skin irritations or redness when in contact (the cover is latex-free, is at low risk of irritation to the skin and it is commonly used in medical devices). Otherwise, please contact both the Doctor and the Professional User immediately. Daily monitor the skin area which is in contact with the Device for evidence of pressure sores caused by incorrect or outdated adjustments; in this case it is suggested to suspend the use and contact the Professional User.

4. RESTRICTIONS OF USE

EOLO high chair has been designed and manufactured to provide the end user correct mantainement of sitting position during normal daily life activities into indoor spaces. Any other use may compromise safety.



Mandatory Requirements

- Do not drill or crush the gas spring
- When the high chair is not tilted, make sure the user is not too forward to kepp the system stable
- When the user is on board, avoid lifting the high chair by the legrests or any posture accessories. If it is necessary, lift the high chair by the sides of the structure, making sure the seat doesn't move during this operation
- Get help from additional people when you have to lift the high chair over obstacles or down stairs
- All replacement parts or adjustments not authorized by the manufacturer are strictly forbidden
- For safety, never leave the user alone on the system, especially in the case of children
- When the high chair is stationary, activate the brakes
- Take particular attention, as a matter of safety, when moving on uneven floors so as not to cause structural damage
- Do not use any belt/harness as a safety belt system
- The use is not permitted for users who need shock-absorbing/dynamic seating systems
- Smoking and/or open flames are prohibited
- The high chair is not intended to be used on users who have injured skin or body surfaces (sores, etc.); therefore, use in such circumstances is prohibited.

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. regular maintenance consists of two parts: cleaning and mechanical parts checking.

- Cleaning -

The metal and plastic parts can be cleaned with a damp cloth with cold water without the addition of detergent, taking care to go over everything with a dry cloth. All mechanism, such as the the backrest inclination, Thoracic support brackets and Headrest hardware should always be checked to remove any dust or dirty that may affect the performances. We recommend to perform these operations at least once a month. Regarding the cleaning of the padding, even if it is not in prolonged direct contact with the skin, we recommend to clean it in order to avoid infections. The cleaning can be performed with a damp cloth or a brush with natural bristles and tepid water (max 30°). It can be used a light gentle detergent. Wipe out the excess of water from the padding with a dry cloth. Then dry it away from heat sources. Do not dry with exposure to direct sunlight. It is advisable to perform the cleaning procedure at least once a week or when it is necessary.

For a more accurate cleaning it is suggested to remove the cover. The cover can be hand-washed with tepid water (max. 30°) and the addition of a light gentle detergent without bleach, then it can be air dry.

The removable cover can be washed at 30° with neutral detergent and sanitized with the following detergents/disinfectants:

- PERSIL EXPERT coldzyme/HENKEL
- 70% etanol
- PERFORM/Schuelke
- TPH PROTECT/Schuelke
- MIKROZID AF liquid/Oktal pharma

- DESCOGEN liquid/Antiseptica
 - MANORAPID/Antiseptica
 - PLIVASEPT/Pliva
 - INCIDIN PLUS/Ecolab
- Sodium hypochlorite-based products cannot be used.

- Mechanical Parts Checking -

The following operations have to be performed:

- Daily general check to ensure that screws, nuts and knobs are not loosen, that there are no signs of wear and tear on covers, on parts with velcro and on metal parts, that the seat is firmly attached to the frame and that any accessories are firmly mounted to the structure
- Monthly check for wheels wear
- Monthly check the screws and their tightening mechanism
- Check the adjustments: it is strictly recommended to respect the program of the checks and monitoring scheduled with the professional user.

6. ADAPTATIONS WITH STRUCTURAL CHANGES AND/OR SPECIAL MAINTENANCE

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

The instructions below must be followed at all times:

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

The non observance of the above clauses will automatically void the CE mark.

For special maintenance, the End User must refer to the Professional User who has to send the appropriate form "*Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance*" to the manufacturer within 24 hours of the request for intervention.

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

7. PERFORMANCE AND DURABILITY

Pro Medicare S.r.l. ensures that its own production of EOLO High Chair has been designed and produced in compliance with the safety regulations as required by the relevant Regulation (EU) 2017/745. The benefits provided by the above mentioned medical device, are therefore suitable and respond to the project's purpose, which is the mobility of users with disabilities.

The duration of maintenance of performance, under safe conditions, is said to be 5 years, while for the seat part (padding) it is defined as 2 years.

These value is purely indicative because, even if the duration expected in the design phase is much greater, it is significantly determined by the way the device is used (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, safety and the integrity of the system and have to be exclusively performed by the Professional User. If the Professional User deems it necessary, he can make the morphological, dimensional readjustment, the right support and maintenance.

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 months 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.

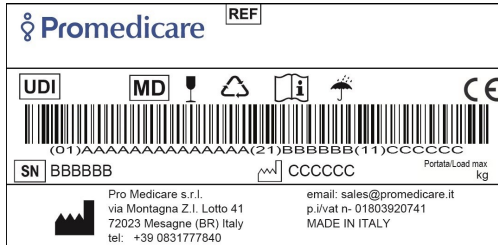
Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of Positioning System accessories);

- **Aluminium**: seat and backrest shells, legrest tubes connecting brackets
- **Steel**: fixing point; screws, headrest shell and hardware, base of the indoor frame
- **Plastic**: handgrips; footplates; harness fixing elements; plastic bags
- Synthetic fabrics PU/PES and padding belonging to the polyethylene or polyurethane foam family
- **Paper**: cartoon or wrapping paper.

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

11. LABELING

The label is placed on the lower part of the positioning system and it is also stuck 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”

		Size 1	Size 2	Size 3
EOLO	Seat width (cm)	17-24	22-29	27-34
	Seat depth (cm)	19-26	22-34	31-43
	Trunk height (cm)	26-38	33-45	41-53
	Trunk width (cm)	bracket A 19-25	bracket A 22-28	bracket A 27-33
		bracket B 14-20	bracket B 17-23	bracket B 22-28
	Distance Popliteal Cable-Footboard (cm)*	10-21	10-26	10-36
	Armrest height (cm)	14-19	20-26	20-26
	Reclining backrest (°)	-3+20	-3+20	-3+20
	Eolo max load (kg)	25	35	50
Eolo weight (kg)	18	21	26	



