Senso

INSTRUCTION MANUAL

SensoCompacto
Positioning Cushion

Man.Cus.Pos.Fle. EN Rev.5 04/2026

Promedicare
Feel the ideal posture

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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 a non-sterile, non-invasive Class I medical device of the Versa range manufactured by PRO MEDICARE S.r.l.
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 ISO 9001 and 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.
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

SENSO COMPACTO is a modular postural cushion designed for wheelchair users. It consists of a flexible base with reinforcing elements inside and equipped with fastening systems (hook-and-loop fasteners), two padded and covered modular elements, also equipped with fastening systems (hook-and-loop fasteners). Inside the two padded elements, a series of inserts with various shapes are included, specifically designed to accommodate the user's pelvis and/or follow its shape.
The SENSO COMPACTO Positioning System in the "7 cm height" version, is intended for users at low/moderate risk of developing pressure injuries. The "9 cm height" version is intended for users at high risk of pressure injury development. Areas with no contact and therefore without pressure can assist in the healing process and support the treatment of existing pressure ulcers.
The SENSO COMPACTO Positioning Cushion switches from an unfolded-use configuration to a folded non-use configuration avoiding removal from the wheelchair.
Its intended use is to manage postural disorders, promote proper pelvic alignment and support, assist in the redistribution of body pressure, and relieve and ventilate all bony prominences and the genital area.
Specifically
The intended use of the SENSO COMPACTO Positioning System is aimed at compensating/supporting/aligning mild pelvic misalignments.
All the devices of the *VERSA* range have been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745.
It is recommended to always ensure the compatibility of the device on the relevant mobility base.
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:

- The SENSO COMPACTO Positioning Cushion consisting of:
  - a flexible base with reinforcing elements inside and equipped with fastening systems (hook-and-loop fasteners)
  - two padded and covered modular elements, equipped with fastening systems (hook-and-loop fasteners) with inside, a series of inserts with various shapes
  - a kit of long triangular-shaped inserts
  - a kit of short triangular-shaped inserts
- 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.

1.2 How to use it

During the installation phase, it is essential to follow several **key instructions** as outlined below:

- Remove the cushion from its packaging and place it on the support surface with the REAR label facing the wheelchair handles (Pic. 1a or Pic. 1b);
- You can now adjust the modular elements, including the elements within them, according to individual needs. Be careful not to position the posterior elements too close to each other and ensure that the labels on the flexible base correspond with those on the padded elements (the two padded elements can be adjusted in width by a total of up to 2 cm).

pic.1a: *unfolded-use configuration with "standard" cover variant for modular elements*

pic.1b: *unfolded-use configuration with "shape" cover variant for modular elements*

- If the wheelchair has a warped seat canvas, a kit of long inserts is provided to be placed in the flexible base. To perform this operation, it is necessary to remove the two polyurethane elements located on the sides and insert the two wedges, making sure to position the thick side of each wedge on the medial part of the base, as shown in figure Pic. 1c.

pic.1c: *inserimento kit inserti lunghi*

- A kit of short triangular-shaped inserts is also supplied, which can be used in various ways, if needed :

  1) to compensate for a pelvic obliquity: insert a single insert into the pocket sewn inside the flexible base, on the side opposite the obliquity, with the thick side of the wedge positioned on the medial part of the base (see Pic. 1d);

pic.1d: *inserimento kit inserti per obliquità pelvica*

  2) to achieve a slight trunk-pelvis angle opening: insert both wedges into the pockets sewn inside the flexible base with the thick side facing outward posteriorly (see Pic. 1e)

pic.1e: *inserimento kit inserti per apertura angolo tronco-bacino*

  3) to achieve a greater opening between the two pads: insert both wedges into the pockets sewn inside the flexible base with the thick side facing the medial part of the base (see Pic. 1f)

pic.1f: *opening between the two pads*

Once compatibility between the cushion and the wheelchair has been confirmed, proceed with installation. It is strongly recommended to carry out installation without the end user seated in the wheelchair. Always exercise caution during use, and verify that the cushion remains securely in place to prevent sliding from the support surface (if the support surface does not already feature hook-and-loop fasteners, appropriate fasteners must be used). Please note that patient body dimensions, seat mobility base dimensions, seat angle, and footrest height can significantly influence load distribution during sitting. Therefore, special care must be taken during the adjustment phase to ensure optimal interaction between the mobility base/wheelchair–cushion–user system.

After use, if necessary, the cushion can be folded without removing the modular components and stored in a dry place (Fig. 2).

pic.2: *folded configuration*

It is essential to regularly inspect the user's skin to monitor for any signs of redness or skin irritation.

1.3 Recommendations for Use

In order to guarantee safe use and a long lasting performance of the SENSO COMPACTO Positioning Cushion, please find below advices on how to use the device:

- carefully follow the instructions reported in this manual;
- keep the Device away from heat sources;
- unauthorised modifications or the use of parts not supplied or approved by the manufacturer, may affect the safety of the Device, may lead to dangerous situations and to the loss of the CE Mark;
- carry out thorough cleaning and pay close attention to the standard maintenance;
- do not use in contact with skin injuries.

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 SENSO COMPACTO Positioning Cushion. For further information, please contact the Technical Sales Department at the following number:

+39 0831 777840

- Always check the Device is properly fixed to the wheelchair base;
- If the device comes in contact with dirt, please carry out an immediate and thorough cleaning of the cover;
- If, after a few days of use, anomalies are found regarding the tightness of the device, please, contact the Dealer (Professional User);
- In the event that an accident causes a loss of performance, do not use the system and contact the Dealer (Professional User);
- It is recommended to perform a thorough cleaning and standard maintenance of the Device every 15 days or if necessary checking all parts of the Device to avoid any inconvenience. For further information about the maintenance and cleaning, please read the desicated section.

Particularly severe environmental conditions can affect the qualities and features of the materials used, the functionality and performance of the SENSO COMPACTO, so:

- avoid the exposure to extreme temperatures;
- avoid prolonged exposure to sunlight (i.e. do not leave the device in a car);
- do not use the device in the shower, pool or environment in contact with water. Some components may be damaged and cause malfunction;
- avoid contact with seawater.

3. NEGATIVE ADVERSE EFFECTS

The use of SENSO COMPACTO should not produce unwanted side effects including allergies, skin irritation or redness when in contact.

Otherwise, please contact both the Doctor and the Dealer (Professional User) immediately. Daily monitor the skin area which is in contact with the Device for evidence of skin redness caused by incorrect or outdated adjustments; in this case it is suggested to suspend the use and immediately contact the Dealer (Professional User).

4. STANDARD MANTEINANCE

All components need to preserve their original integrity and need to be sanitised frequently in order to guarantee a good functioning and long lasting performance in safe conditions. The cover, which is removable, can be washed at high temperatures (60°C) and may be surface-sanitized only with detergents/disinfectants listed below:

- PERSIL EXPERT coldzyme/HENKE
- 70% etanol
- PERFORM/Schuelke
- TPH PROTECT/Schuelke
- MIKROZID AF liquid/Oktal pharma
- DESCOGEN liquid/Antiseptica
- MANORAPID/Antiseptica
- PLIVASEPT/Pliva
- INCIDIN PLUS/Ecolab

Do not use cleaners based on natrium hipo-chlorite. Wash and dry completely after use; surface wrinkles may occur.
Structural parts cannot be washed; The padding cover may be surface-sanitized using the disinfectants listed above.

5. 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. In this case do not use the Device and immediately contact the Dealer (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:

- Components failure: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions
- Components Breakages or tears: they must be replaced with original items provided by the manufacturer
- For all components it is strictly forbidden to perform any repair
- 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.

6. PERFORMANCE AND DURABILITY

PRO MEDICARE S.r.l. ensures that its own production has been designed and produced in compliance with the safety regulations as required by the relevant Regulation (EU) 2017/745.
The performance ensured by these devices is suitable and aligned with their intended purpose, which is to manage postural disorders, promote proper pelvic alignment and support, assist in the redistribution of body pressure, and relieve and ventilate all bony prominences and the genital area. The expected duration of safe and effective performance for the SENSO COMPACTO cushion is approximately 2 years. This 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 the performance and its expected duration are subject to verification of the suitability and safety of the combination with the support surface. The reconditioning of the device is prohibited if not expressly authorized by the manufacturer.

It is strongly recommended to periodically check the skin, gluteal mass, and the pelvic area to be relieved, especially if the device is used continuously throughout the day.

7. 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 covers, paddings and components replaced under special maintenance starting from the date of commissioning after refurbishment.
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
- 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 and/or evolutions of the end user;
- failure or damages during the transportation: the User/Dealer is pleased to refer to the general sales conditions
- stolen or loss.

For warranty replacement of components, the User must refer to the Dealer (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.
It is also essential for the manufacturer to receive a completed *Warranty Registration Form.*

8. 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.

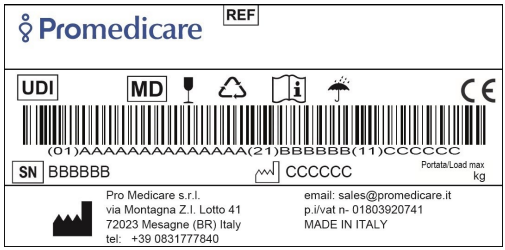
9. DISPOSAL/RECYCLING

Please follow the local law and regulation in matter of disposal and recycling.
Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of the positioning system accessories):

- Padding belonging to the polyethylene or polyurethane foam family
- Synthetic fabrics: polyurethane, polyester
- Plastic bags and cardboard boxes for packaging.

10. LABELING

The label is applied inside the base covering 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

The cushion is available in fourteen sizes

Size (cm)	**3638**	**3642**	**3840**	**3845**	**4040**	**4045**	**4242**	**4245**	**4250**	**4545**	**4550**	**4848**	**4850**	**5050**
Width	36	36	38	38	40	40	42	42	42	45	45	48	48	50
Depth	38	42	40	45	40	45	42	45	50	45	50	48	50	50
min/max wheelchair external tubes width	35/38	35/38	37/40	37/40	39/42	39/42	41/44	41/44	41/44	44/47	44/47	47/50	47/50	49/52
Height	7/9													