HIPPO MB

INSTRUCTION MANUAL

Man.Hip. EN Rev.1 05/2025

Risposte reali a bisogni speciali

Pro Medicare®

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

INDEX

Please note The illustrations in the following manual may differ from reality; however, the methods of use and operation still apply. All technical data in this manual are approximate and do not constitute specification.

INTRODUCTION

Dear user, thank you for choosing a high-performance Pro Medicare medical device.
HIPPO MB is a comfortable, non-sterile, modular postural pad designed to be used during Horse Assisted Therapy and Hippotherapy session. 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 instructions for the correct and safe use of the modular postural pad. To this end, it is necessary to read the instructions about how to use it carefully, with the express invitation to follow the prescribed directions.
As the manufacturer, Pro Medicare refers to ***professional user*** as a suitably qualified person (member of the rehabilitation team), and to the ***final user*** (or ***lay person***) as the person who is intended the medical device.

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

The characteristics of the device can be found in Annex A *"Technical features"*.
After consulting this manual, for further information, please contact the Technical Sales Department at the number **+39 0831 777840**, from 9 a.m. to 1 p.m. and 2:30 p.m. to 6:30 p.m. on each weekday.
In case of serious emergencies, outside the above hours send an e-mail to **sales@promedicare.it**.
You will be called back as soon as possible.
In order to ensure appropriate after-sale monitoring of devices placed on the market and put service, in the case of accidents resulting from use, you shall proceed according to the instructions given in the appropriate chapter.

USE

HIPPO MB is a comfortable, non-sterile, modular postural pad with a flexible girth and handle adapted for the execution of equestrian rehabilitation treatment. It is designed for use during a session of Horse Assisted Therapy, also known as Equestrian Rehabilitation, which is a form of therapy that uses the movement and gait of the horse as an integral part of the therapeutic program. It is designed and manufactured in compliance with safety standards as resulting from the relevant Regulation (EU) 2017/745. The HIPPO MB modular postural pad, is presented with a multiplicity of configurations capable of following the evolving needs of the end user and the resulting postural adaptations with particular reference to both supine and prone as well as seated positions.
The entire device is designed to allow:

- uniform distribution of pressures;
- postural conrainment and alignment;
- knee flexion and correct leg position when sitting;
- lateral containment of the trunk and pelvic/lumbar spine in supine and prone position;
- head support in the supine and prone position;
- containment of involuntary secondary pathological movements;
- control and guidance for the seated position of the femur-pelvis-rachis relationship system and allow extension and alignment of the trunk.

The combined and harmonious use of each element and subsystem is designed to promote posturally correct and comfortable support for the end user.
It is the duties and responsibility of the professional user to ensure the safe combination according to current standards of the specially made modular postural pad.
Commissioning, subsequent adjustments must exclusively be performer by the professional user. Pro Medicare is contantly dedicated to innovate its own devices; this may result in possible shape and technical changes on the devices and/or related accessory parts, therefore hypothetical complaints on values, images and schemes defined in this manual will not be accepted. Also for complete list of optionable parts and/or accessories, refer to the latest order sheet in effect.
Each component, subsystem and the whole device, are completely modular and independent of each other so that the whole can be plausibly adapted to the anatomical forms of men and women as well as to different morphologies and anthropometric measurements. This peculiarity also makes possible frequent changes and postural adjustments by the professional user.
The entire device is made of polymeric material and combines different characteristics of elasticity, bearing capacity, and shape memory; individual postural elements are covered with antibacterial, biocompatible, nonflammable, breathable, washable, and sanitizable fabric.

1. INSTRUCTION OF USE

1.1 Packaging and transport

The original packaging contains the following components:

1. Upper and lower element of the modular postural pad;
2. Modular positioning elements kit;
3. Any accessories as per the order form;
4. Labelling and instructions for use.

Upon delivery, pleasecheck the integrity of the package. Report any anomalies on the shipping document. Open the package and check the various parts for cracks, deformations or tears or for missing parts. Otherwise note the anomalies found on the shipping document. After performing all the necessary checks, if HIPPO MB is not to be used immediately, it is advisable to repack everything carfully and store it in a dry place. As a rule, the above operations should be carried out by the professional user, who should proceed to combine the modular postural pad.

1.2 Preliminary operations for correct commissioning

Prerequisite for proper functioning of the modular postural pad is proper fit and adjustment of the girth on the horse, the stability of the upper element on the lower one as well as the perfect fit of the modular positioning elements that must be constantly checked. Once the modular postural PAD is attached via the metal buckles present, the entire combination must be stable, supportive and overal safe for the end user.
The HIPPO MB modular postural pad consists of several components (pic. 1):

1) Lower element
2) Upper element
3) Head positioning system
4) Pelvis positioning system kit
6) Push trunk positioning system kit
5) Trunk confortable positioning system kit
7) Abductor insert
8) Femoral condyles positioning guides kit
9) Hand grips kit
10) Knee bend positioning system kit
11) Crupper

pic. 1: *Hippo MB modular postural pad components*

HIPPO MB modular postural PAD does not represent containment designed to prevent falls by the end user. Such operations must be performed by the professional user.

1.3 Adjustments for commissioning and/or subsequent changes

Phase 1. *Lower element positioning (sitting, supine and prone position)*

The lower element (pic. 2) should be the **first** component to be positioned; it is created with a special material that can grip the horse's hair. Once positioned, use the appropriately tightened girth to secure the modular postural pad, preventing it from shifting during rehabilitation treatment.

pic. 2: *Lower element*

Ensure proper operation and fastening of the strap by the metal buckles. These operations should be carried out by the professional user.

Phase 2. *Upper element positioning (sitting, supine and prone position)*

The upper element (pic. 3) should be the **second** component to be positioned. It should be placed on top of the lower element, taking care to visually check that it is perfectly at the center of the latter, with the help of the gray-colored guide borders on both components. Next, apply light pressure to the lateral and transverse areas of the upper element on the lower one to make the clinging systems of the upper element adhere. This operation contributes to the unloading of the end-user's weight on the horse, as well as to greater comfort for the end-user.

pic.3: *Upper element*

Always be careful when placing or removing components to avoid shear and tensile forces. Such operations should be carried out by the professional user.

Sitting position

A) Positioning of the pelvis positioning elements

The entire set is intended to control and guide the sitting position of the femur-pelvis-rachis relation system and to allow the extension and alignment of the trunk. All components can be positioned and oriented independently of each other.

B) Positioning of the abductor insert

It is intended both to guide leg abduction in both sitting, prone, and supine positions and to prevent forward sliding of the end-user.

C) Positioning of the Femoral Condyles positioning guides kit

They consist of a set of 2 positioners to guide knee flexion and are composed of multiple layers in order to be able to adeguate the degree of flexion suitable for the user.

D) Positioning of the hand grips kit

They consist of a set of 2 cylindrical knobs with a wider base to be used as hand supports.

Always take care when placing or removing components to avoid shear and traction forces. It is necessary to verify perfect adhesion, via the fastening tapes on the underside of all positioners, with the upper element of the modular postural pad. These operations should be carried out by the professional user.

Supine/prone position

A) Positioning of the Head positioning system

The contoured head positioning system provides an hollow to accommodate the occiput, its contouring is made of different polymeric foams at different densities, and said contouring is easily adaptable to contain, align and guide the position of the head. The Head positioning system has two detachable elements by means of male-female fastening system to conform around the right and left sides of the neck of the final user in the supine or prone position.

B) Positioning of the Trunk positioning system

The trunk positioner consists of a set of two pairs that are respectively enveloping and convex to laterally contain the trunk and pelvic/lumbar tract.

C) Positioning of the abductor insert

It is intended both to guide leg abduction in both sitting, prone and supine positions and to prevent the final user from sliding forward.

D) Positioning of the Knee bend positioning system kit

They consist of a set of 2 cylindrical guides shaped to direct knee flexion and leg position.

Always take care when placing or removing components to avoid shear and traction forces. It is necessary to verify perfect adhesion, via the fastening tapes on the underside, with the upper and/or lower element of the modular postural pad. These operations must be carried out by the professional user.

Crupper (pic. 4)
Equipped with fastening system along the bottom surface in order to be easily attached along the top surface of the lower element. It is intended to stabilize the pad by preventing it from moving forward.

Always take care when placing or removing components to avoid shear and traction forces. It is necessary to verify perfect adhesion, via the fastening tapes on the underside, with the upper and/or lower element of the modular postural pad. These operations must be carried out by the professional user.

pic. 4: *Crupper*

Accessories

Footrest straps positioning (pic. 5)
Equipped with a hook-and-loop fastening system along the lower surface, in order to be easily attached along the upper surface of the lower element. Along its ends, the straps, will be equipped with two similar adjustable soft and flexible material rings to accommodate the feet of the end user.

Always take care when placing or removing components to avoid shear and traction forces. It is necessary to verify perfect adhesion, via the fastening tapes on the underside, with the upper and/or lower element of the modular postural pad. These operations must be carried out by the professional user.

pic. 5: *Footrest straps*

Storage pocket (pic. 6)
Equipped with a fastening system along the bottom surface in order to be easily attached along the top surface of the lower element.

pic. 6: *Storage pocket*

Hygienic protective cover (pic. 7)
It is composed of a polymer fabric with combined PU/PES composition that is antibacterial, biocompatible, non-flammable, breathable, washable, sanitizable and sterilizable (consumable material). It is equipped with fastening system along the bottom surface in order to be easily attached along the top surface of the bottom element.

Always take care when placing or removing components to avoid shear and traction forces. It is necessary to verify perfect adhesion, via the fastening tapes on the underside, with the upper and/or lower element of the modular postural pad. These operations must be carried out by the professional user.

pic. 7: *Hygienic protective cover*

1.4 Reccomendation of use

In order to ensure safe use and long lasting performance of the device, tips about some ways to use the device are given below:

- Carefully follow the instructions reported in this manual
- Check the conditions of use periodically and never leave the end user alone
- Keep the Device away from hear sources
- Carry out thorough cleaning and sanitization
- Pay close attention to standard maintenance
- Document the occurrence of any skin reactions.

2. GENERAL WARNINGS

The warnings included in this chapter describe conditions and situations that could cause dangerous situations for the end user or third persons and, therefore, should be read carefully before operating the HIPPO MB modular postural pad. For the proper use of the device, certain operations, such as commissioning and adjustments, should be done only by authorized persons.

Warnings for the professional user

If you have any doubts or clarifications, you should contact our Technical Sales Department at the number **+39 0831 777840**

Preliminary operations aimed at proper commissioning: (to be carried out according to the instructions given in *section 1.2*)

- After these operations, make sure that the device, once the buckles are inserted. is secure and functions properly
- Always check that the tightness of the device is suitable for the end user to ensure its safe use.

- Environmental Conditions -

Particularly severe environmental conditions may affect the features of the materials used, the functionality and performance of the device itself, therefore:

- Avoid exposure to extreme temperatures
- Avoid prolonged exposure to sunlight
- Avoid excessively humid places
- Do not use the modular postural unit in a shower, swimming pool or environment in contact with water; some components may be damaged and cause malfunction
- Avoid contact with seawater
- If the device comes in contact with dirty, please carry out immediate and thorough cleaning of the modular postural pad.

- Use -

- If, after a few days of use anomalies are found regarding the tightness of the device, please, contact the manufacturer
- Always verify the proper attachment of the modular postural pad by inserting the hooks present along the girth
- In the event that an accident causes a loss of performance, do not use the device and consult the manufacturer
- Adjustments must be performer only by the professional user
- It is recommended to perform 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 attached product technical sheet.

3. NEGATIVE ADVERSE EFFECTS

Generally, the use of the Hippo MB modular postural pad should not cause any adverse effects such as allergies, skin irritation or redness in both the end user and the horse.
It is necessary in order to avoid dangerous or harmful conditions for the end user to always adopt the prescribed cleaning and sanitization criteria. If side effects and/or adverse health effects to the end user occur under normal conditions of use, it is necessary to discontinue use of the device and consult the manufacturer.

4. RESTRICTIONS OF USE

The HIPPO MB modular postural pad is designed and manufactured to give the end user proper individual postural support during an Assisted Therapy with the Horse session and to facilitate equestrian rehabilitation treatment by increasing the level of safety of positioning in both supine, seated and prone positions. Any use other than that intended may prejudice the safety of the device.

MANDATORY REQUIREMENTS

- Do not use the device in the presence of open flames or sources of high heat
- After each use, it is necessary to disinfect and sanitize the entire device in order to prevent infection
- To ensure proper functionality of the device, make sure the device is properly assembled, snug and stable
- Always ensure that the strap is inserted correctly and tightly
- Ensure that there are no protruding or sharp objects under the modular postural pad
- Contraindications: Some clinical conditions are not suitable for use of this device, and yet not suitable for end users who cannot acquire a sitting, supine, or prone position and for end users for whom horse-assisted therapy is not recommended

- Always apply as directed by the therapist. The use of this device does not exclude, when possible, regular repositioning, posture
- Changes, frequent observation, and constant care of the end user
- Always check that the device has been properly adjusted and that all intended elements do not conflict with each other, as provided in this user manual
- Replacing components or modifying parts of them with non-original parts not approved by Pro Medicare is prohibited in order not to compromise both therapeutic use and safety conditions
- Do not use if the device or its parts are damaged or excessively worn out
- Never leave the end user alone while using the device.

5. STANDARD MAINTENANCE

Periodic inspection and maintenance by the professional user is necessary to ensure proper operation and durability of performance under safe conditions. We recommend careful cleaning and routine maintenance on a fortnightly basis and/or when necessary check all parts of the modular postural pad in order to avoid any discomfort. Hippo MB is a removable product due to the presence of the zipper along the perimeter of the lower element.
Regarding the cleaning of the upholstery, although there is no contact with the skin, in order to avoid possible infections one can simply use a damp cloth or a brush with natural bristles with lukewarm water (max 30°) with the addition of detergent by dabbing with a dry cloth and then air dry, away from heat sources or sunlight; it can also be washed occasionally in the washing machine at 30° with neutral detergent with the precaution of spinning at low speed.
Since the cover is removable, it can be hand-washed with warm water (30°C) and soap and then air-dried. The cover of the postural elements can be sterilized by washing it at 95° and sanitized with the following detergents/disinfectants:

- PERSIL EXPERT coldzyme/HENKEL
- 70% etanol
- PERFORM/Schuelke
- TPH PROTECT/Schuelke
- MIKROZID AF liquid/Oktal pharma
- INCIDIN PLUS/Ecolab
- DESCOGEN liquid/Antiseptica
- MANORAPID/Antiseptica
- PLIVASEPT/Pliva
- sodium hypochlorite products cannot be used

NOTE Symbology valid only for postural element coverings

Do not use dryers to have longer product life.

6. ADAPTATIONS WITH STRUCTURAL CHANGES AND/OR SPECIAL MAINTENANCE

Special maintenance must be implemented when one or more components deteriorate to the point that the performance and safety of end users is affected. In such a case, it is forbidden to use the device and the manufacturer must be consulted immediately. However, it is mandatory to follow the following instructions:

- Breakage or tearing of components: it is mandatory to replace them with original parts supplied by the manufacturer
- Any repair operation is prohibited for all components
- It is recommended to gradually adapt the device to the eventual needs of the end user.

Failure to comply with these requirements will automatically result in the forfeiture of the CE marking. For special maintenance work, the professional user should contact the manufacturer by filling out the appropriate form *"Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* within 24 hours of the request for work.

7. PERFORMANCE AND DURABILITY

Pro Medicare S.r.l. guarantees that the devices have been designed and manufactured in compliance with safety standards as resulting from the relevant Regulation (EU) 2017/745. Therefore, the performance ensured by the abovementioned devices individually or in combination is suitable and responsive to the design purpose aimed at users in the context of effective treatment resulting from proper posturing and stability. The duration of maintenance of performance, under safe conditions, of these devices is defined as 2 years valid under normal conditions of use and proper maintenance according to the instructions provided by Pro Medicare. This value is purely indicative because, although the duration expected at the design stage is far greater, it is strongly conditioned by the mode of use (perhaps demanding, continuous and not foreseeable at the design stage) of the device, as well as by proper use and careful maintenance.
In addition, it is reasonable to consider a slight reduction in performance over time due solely to:

- impacts and accidental events
- natural wear and tear of components.

Both the performance and its duration are, however, conditioned by the verification of the suitability and safety of the combination to be performed exclusively by the professional user. Therefore, provision should be made for periodic re-evaluation by the professional user in order to verify the suitability, safety, and condition of the device.
If deemed necessary, the professional user should carry out retrofitting, proper support, and/or maintenance, if present.
The performance of the device and the relative life span of the device, however, are affected by the number of professional users who have used it and the number of end users to whom it has been applied, so the same, in some cases, may be less than 2 years. Therefore, the performance assured by the device individually or in combination is suitable and in accordance with the design purpose, aimed at end users in the context of effective treatment resulting from proper positioning and stability under the responsibility of the professional user.

8. WARRANTY

Pro Medicare S.r.l. warrants the device functionality for a maximum period of 24 months covering all manufacturing defects from the date of the 1st commissioning and 12 months on coverings and components replaced for extraordinary maintenance from the date of commissioning after treatment to new.
The warranty is valid as long as the device is used as stated in the operating instructions.
The warranty is void in the following cases:

- due to misuse and/or force major cause
- for failures resulting from tampering or incorrect maintenance, including by third parties, which may affect the functionality and safety of the product
- modifications without authorization from the manufacturer
- accidental impacts with deterioration of essential components
- changes and/or evolutions of the end userper
- for professional user see general conditions of sale in case of serious damage caused by transportation
- stolen or loss.

For replacement of the item under warranty, the professional user must contact the manufacturer, completing the appropriate form *"Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* within 24 hours of the request for action. It is essential to send the *Warranty Registration Form* to the manufacturer.

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

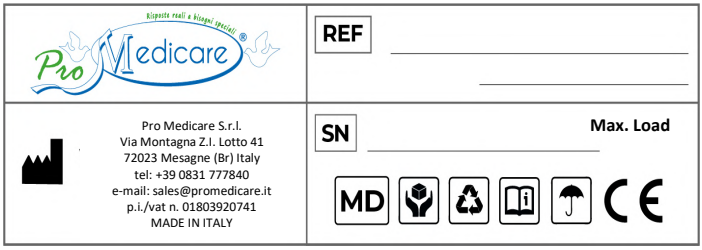
For disposal, follow current local disposal and recycling regulations.
The following is a description of the materials used.
Separation of the various components constituting the accessories of the postural system should be done:

- Polyurethane and polyethylene plastic foams
- Synthetic fabrics polyurethane, polyester
- Plastic and cardboard envelopes for packaging
- Synthetic fabric coverings (polyester, elastane, etc.), padding belonging to the polyethylene foam family or polyurethane, structural kits belonging to polyethylene foam.

If the product is found to be soiled or contaminated with body fluids or other biological product or secretion follow the special waste disposal criteria.

11. LABELLING

The label is attached to the inside of the upper element and is also shown on the second page of this manual. The label contains technical data. For replacement orders or reports, the serial number must be reported. A facsimile of the label is depicted below:



 Manufacturer
MD Medical Device
 Handle with care
 Recovery/Recyclable
 Consult Instruction for Use
 Keep dry
CE CE Mark
SN Serial Number
REF Catalog Number

Annex - A *"Technical characteristics"*

HIPPO MB is a comfortable modular postural pad, non-sterile, equipped with a girth and flexible handle for the hands of the end user suitable for the execution of equestrian rehabilitation treatment. The HIPPO MB modular postural pad comes in a multitude of configurations capable of following the evolving needs of the end user and the resulting postural adaptations with particular reference to both supine and prone positions as well as sitting.
The HIPPO MB modular postural pad consists of several components:

- Lower and upper element;
- Head positioning system;
- Pelvis positioning system kit;
- Push trunk positioning system kit;
- Confortable trunk positioning system kit;
- Abductor insert;
- Femoral Condyles positioning guides kit;
- Hand grips kit;
- Bend positioning system kit;
- Crupper

DIMENSIONS FEATURES

PAD DIMENSIONS HEIGHT X WIDTH (cm)	**105x90**
WEIGHT CAPACITY (kg)	**60**
MODULAR POSTURAL PAD WEIGHT (kg)	**4.5**

Please Note: *Modular postural pad weight as per standard configuration*