CaPitis

SUPPORTI PER IL CAPO

INSTRUCTION MANUAL

Man.Ver.Cap. EN Rev.9 04/2026

Promedicare

Feel the ideal posture

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

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

INTRODUCTION

Dear User, thank you for choosing highly performing Pro Medicare medical device.
The *VERSA CAPITIS* Range is the combination of technology and experience in the development of head positioning solutions designed to provide the proper postural support. Thanks to its modularity and different possibilities of adjustment, it allows effective adaptation to the user' needs.
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. 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 1p.m and from 2.30p.m to 6.30p.m.
In case of emergencies outside the working hours, please send an email to: **sales@promedicare.it**
We will call you back as soon as possible.
In order to ensure appropriate After-Sale Monitoring of Devices placed on the market and put into service, or in the event of an incident during the use, please refer to the instructions stated in the relevant chapter.

USE

The *VERSA CAPITIS* Range head positioning solutions have been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745.
The *VERSA CAPITIS* Range head supports are head support positioning solutions; they contribute to the achievement of the proper posture for users with motor disabilities using wheelchair.
The *VERSA CAPITIS* Range head positioning solutions are intended to be used by non-ambulatory users with limited mobility who are sitting and affected by postural insufficiency as a result of various pathologies, such as: infantile cerebral palsy, spina bifida, muscular dystrophy, multiple sclerosis, amyotrophic lateral sclerosis, head trauma, spinal cord injury and stroke.
To ensure the support always suitable to the user's needs, the Range consists of two types of head supports: the Capitis Anatomico Headrest and the Capitis Confort Headrest.
The Capitis Confort Headrest is designed for users with limited mobility who have good head control and do not need lateral support.
The Capitis Anatomico Headrest is designed to provide optimal head positioning for users who need more head lateral control.
Both the versions are equipped with a resistant and multi-adjustable hardware and a system to connect the headrest to the backrest; such hardware can be easily adapted to all the backrest with rigid shell.
The multiple sizes available for both ranges make them suitable for use by children and adults.
We recommend to check the compatibility of the head support with the relevant backrest chosen.
The 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:

- *VERSA CAPITIS* Range Medical Device
- mounting screws
- 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.

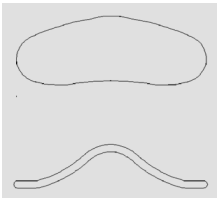
1.2 Preliminary Operations for correct Commissioning

The Commissioning must exclusively be performed by the Professional User.
The *VERSA CAPITIS* Range Medical Device can be used in combination with the positioning system (backrest) if it has a rigid shell for fixing and a set of threaded or other inserts for connecting it.
The professional user and the end user must check, by inspection, that the connecting system of the *VERSA CAPITIS* Range/positioning sistem (backrest) is provided under safe conditions.

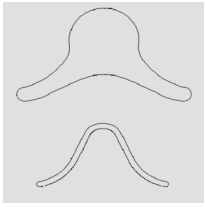
1.3 VERSA CAPITIS Medical Device and backrest shell Combination

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

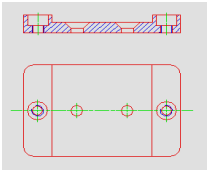
The *VERSA CAPITIS* Range Medical Devices, both in Confort (pic. 1) and in Anatomico version (pic. 2), are connected to the backrest through the attachment shown in pic. 3. For the headrest adjustment can be used a short or a long bracket (pic. 4 and pic. 5). This attachment can be placed on the backrest shell directly by engaging the two central holes, or on a horizontal sliding plate (pic. 6) or on a universal plate (fig. 7) or on the V-Track plate (fig. 8) (for the choice of the type of interface plate please, refer to the order form in use).



pic. 1: *Capitis Confort*



pic. 2: *Capitis Anatomico*

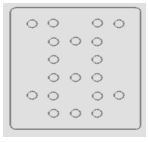


pic. 3: *detachable mounting unit*

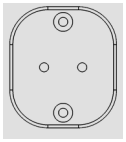
pic. 4: *short horizontal bar*

pic. 5: *long horizontal bar*

pic. 6: *horizontal sliding plate*



pic. 7: *universal plate*

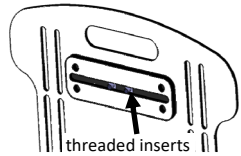


pic. 8: *V-Track plate*

To mount the headrest directly onto the backrest (pic. 8.1), follow the steps below:
- locate the two holes on the back of the backrest
- fix the detachable mounting unit with the screws supplied
- place the device in the mounting unit and tighten the 2 tightening knobs.

pic. 8.1: *mounting example*

To perform the mounting with the horizontal sliding plate (pic. 9) please, proceed as follows:
- place 2 of the 6 threaded components supplied inside the plate as shown in the figure
- position the other 4 threaded components in the 4 holes, making the threaded cylindrical heads come out
- now position the plate on the shell by engaging the 4 cylinders
- tighten everything with the round head screws, remembering to insert the washers first
- secure the detachable mounting unit with the screws supplied
- place the device in the mounting unit and tighten the 2 tightening knobs.



pic. 9: *mounting example with horizontal sliding plate*

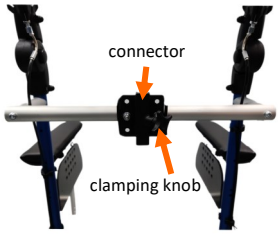
To perform the mounting with the universal or V-Trak plate, please, proceed as follows:
- locate the two holes on the back of the backrest at a suitable distance from the holes on the plate
- fix the plate on the backrest
- fix the detachable mounting unit with the screws provided
- place the device in the mounting unit and tighten the 2 tightening knobs.

After having performed these operations make sure that the Device is secure. 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.

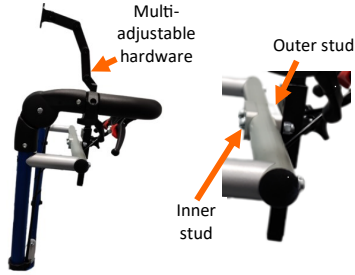
1.4 Combination of the *VERSA CAPITIS* with the wheelchair

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

The devices of the *VERSA CAPITIS* range, both the Confort version (pic. 1) and the Anatomico version (pic. 2), are mounted to the wheelchair by means of the connector shown in figure 10. The multi-adjustable hardware makes the headrest multi-adjustable (pic. 11); it is detachable type and can be removed using the clamping knob.
The mounting can be done as follows:
- take the two supplied studs and place them on the tube between the two push handles near the two holes on the horizontal bar, one on one side and one on the other (the tube must be in the middle between the two studs)
- place the connector on the outer stud (caregiver side)
- insert the two screws and tighten everything with the two nuts provided.



pic. 10: *mounting of the connector*



pic. 11: *multi-adjustable system*

After having performed these operations make sure that the Device is secure. 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.

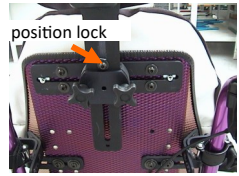
1.5 Adjustments for the first Commissioning and/or subsequent adjustments

The functioning of the device depends on correct adjustment and the correct identification of the device type when ordering. The device is designed and manufactured to allow a wide range of adjustments, so, possible adjustments for commissioning or periodic re-adjustments due to changes in the end user's needs are possible.
The user can be positioned on the device when all adjustments have been performed.

These operations must exclusively be performed by the Professional User.

♦ *System with brackets*

√ Height adjustment (pic. 12)*:*
To adjust the height of the headrest, please, perform as follows:
- loosen the position lock
- unscrew and loosen the clamping knobs of the headrest bracket
- adjust the headrest up and down until the desired height is achieved
- re-tighten the knobs
- secure the position lock.



pic. 12: *height adjustment*

√ Depth and inclination adjustment (pic. 13)**:**
To adjust the depth/inclination of the headrest, please, perform as follows:
- unscrew the cap screws
- adjust back and forth and rotate the superior bracket until the desired position is achieved
- re-tighten the cap screws.

pic. 13: *Depth an inclination adjustment*

√ Angle adjustment of the headrest shell (pic. 14):
To adjust the angle of the shell, please, perform as follows:
- unscrew and loosen the two cap screws that close the collar
- rotate and position the shell as desired
- re-tighten the cap screws.

pic. 14*: angle adjustment*

♦ *Multi-adjustable system (pic. 15)*

√ Height and depth adjustment*:*
Adjustment is performed as follows:
- loosen the securing screws of the multi-adjustable hardware
- move the multi-adjustable hardware to the desired position
- tighten the screws of the multi-adjustable hardware.

√ Angle adjustment:
Adjustment is performed as follows:
- loosen the two screws at the back of the headrest
- adjust the headrest angle to the desired position
- tighten the two screws.

pic.15*: adjustments*

1.6 How to use it/Recommendations for Use

In order to guarantee safe use and a long lasting performance of the *VERSA CAPITIS* Range Positioning Solutions, 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
- unauthorised modifications (if carried out by anyone other than the Professional User) 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.

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.

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 *VERSA CAPITIS* Range devices. 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

- Preliminary Operations for correct Commissioning: (to be performed in accordance with the instructions provided in *sect.* 1.2)
  - After these operations, make sure that the Device is firmly and that it is working properly
  - Check If you hear noise, vibrations or if there are any changes to the normal conditions of use to ensure conditions of safety and suitability for use

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.

- Environmental Conditions

Severe environmental conditions may affect the features of the materials used, the *VERSA CAPITIS* Range Positioning Solutions, their functionality and performance, so:

- Avoid the exposure to extreme temperatures
- Avoid prolonged exposure to sunlight
- Avoid extreme humid places
- Avoid contact with seawater
- If the device comes in contact with dirt, please carry out an immediate and thorough cleaning of the cover.

- Use

- If, after a few days of use, noise, vibrations or any other anomaly is detected, please, contact the professional user
- When using the device, take care not to hang anything on it; this could compromise its functionality, safety conditions and suitability for use
- In the event that an accident causes a loss of performance, do not use the system and contact the Professional User
- Never perform any adjustment to the Device; adjustments may only be performed by the Professional User.

3. NEGATIVE ADVERSE EFFECTS

Generally the use of the *VERSA CAPITIS* Range Positioning Solutions should not cause any adverse effects such as allergies, skin irritations or redness on the head (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 *VERSA CAPITIS* Range Positioning Solutions have 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

- Do not push the wheelchair using *VERSA CAPITIS* devices
- Do not use the VERSA CAPITIS devices as a support for hanging bags, backpacks, etc.
- All replacement parts or adjustments not authorized by the manufacturer are strictly forbidden.

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 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.
The removable cover can be hand-washed with tepid water (max. 30°) and the addition of a light gentle detergent without bleach; dry it away from heat sources.

- *Mechanical Parts Checking* -

The following operations have to be performed:

* 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:

* Components/screws failure: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions
* Connecting brackets breakages or tears: they must be replaced with original items provided by the manufacturer
* Headrest pads breakages or tears: they must be replaced with original items provided by the manufacturer. If the breakages or tears regard the cover only, will be performed the cover replacement only
* 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 *VERSA CAPITIS* Range Positioning Solutions 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 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 and performances in safe conditions of the *VERSA CAPITIS* Range Positioning Solutions is 3 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 performance and relative life span expectancy are however dependent by the periodic verification of the suitability, combination safety 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.
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 of the end user
- failure or damages during the transportation: the Professional User is pleased to refer to the general sales conditions
- stolen or loss.

For warranty replacement of components, the End User must refer to the Professional User who has to send the appropriate form "*Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request of intervention. It is also essential for the manufacturer to receive a completed *Warranty Registration Form*.

9. POST-MARKET SURVEILLANCE AND POSSIBLE INCIDENTS

Pro Medicare S.r.l. ensures that their medical devices have been manufactured within the strict compliance, criteria and requirements established by the relevant applicable standards, guarantee functioning under the safety conditions prescribed by Regulation (EU) 2017/745.
The post-market surveillance system is set up and implemented in accordance with the quality management system adopted by Pro Medicare S.r.l. and is aimed to actively and systematically collect, record and analyse relevant data on the quality, performance and safety of its devices during their whole life, to establish the necessary conclusions and to determine, implement and monitor any preventive and corrective actions (art. 83 MDR).
These activities are also ensured through accurate market surveillance of the medical devices already present on the market, as also included in Art. 84 of the same Regulation (EU)2017/745.
To ensure Post-Market Surveillance, Pro Medicare S.r.l. shall implement all activities together with Professionals and Stakeholders to establish and keep updated a systematic procedure which is useful to collect and promptly analyze the experience gained on devices that have been placed on market, in order to identify any need for improvement or modification.
This surveillance activity also includes any incidents or serious incidents defined by the MDR as:

- "incident": means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (art. 2(64) MDR)
- "*serious incident*": means any incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person; b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; c) a serious public health threat (art. 2(65) MDR).

Serious incidents must be reported to the manufacturer and, through EUDAMED, to the competent authority.
Non-serious incidents, on the other hand, do not have to be reported to the competent authority; they must, however, be documented and taken into account in the manufacturer's quality management system and reported in accordance with the requirements of Art. 88 MDR.
It follows, therefore, that upon the occurrence of both serious incidents and possible non-serious incidents to end users and their companions or to professional users in connection with the use of the device **it is mandatory to send** to **Pro Medicare** a copy of a fully completed "*Annex 2 - Reporting of after-sale incidents*".
Pro Medicare S.r.l., as soon as it receives the aforementioned form, will provide the appropriate communications to the professional/end user, including the possible authorization to repair the damaged device or its replacement, also providing for the adoption of measures within its competence, appropriate to the nature and gravity of the incident detected.
In cases of particular urgency **it is mandatory** to contact the manufacturer at the following number **+39 0831 777840** sending to ***sales@promedicare.it*** the fully completed *Annex 2* as soon as possible.

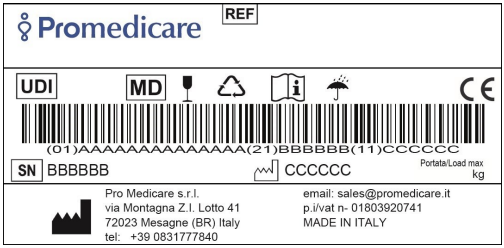
10. DISPOSAL/RECYCLING

Please, follow the local disposal and recycling regulations.
Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of the Positioning System accessories):

- Aluminium: various type of brackets, headrest shells, interface plates
- Steel: screws, threaded inserts
- Plastic: detachable mounting unit
- 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 headrest shell 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:



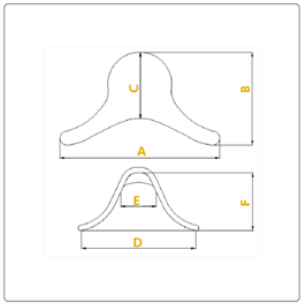
MD Medical Device
SN Serial Number
REF Catalog Number
CE CE Mark
Manufacturer
Manufacturing date
Recovery/Recyclable
Handle with care
UDI Unique Device Identifier
Consult Instruction for Use
Keep dry

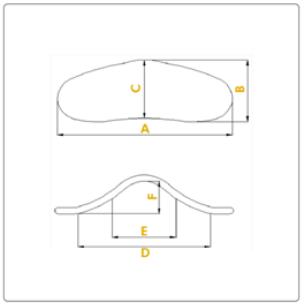
Annex A "Technical Features"

The following annex shows the sizes of the devices of the *VERSA CAPITIS* Range.
It is an integral part of the instruction manual.
For further information, please contact our Technical Sales Department at the following number:

+39 0831 777840

Generally, the *VERSA CAPITIS* Range device supplied by Pro Medicare consists of a padded and covered pad in the anatomico or confort version and mounting hardware in various sizes and shapes to to satisfy the needs.



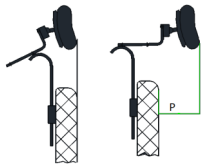


CaPitis *Anatomico*

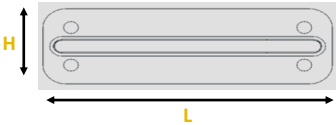
Size (cm)	XP	P	M	G
A	18	24	28	32
B	13	17	19	25
C	08	12	13	16
D	13	19	21	23
E	04	06	08	08
F	02	04	06	08

CaPitis *Confort*

Size (cm)	P	M	G
A	21	30	42
B	14	14	16
C	13	13	14
D	15	24	34
E	8	10	14
F	4	5	7



Size (cm)	Short Bracket	Long Bracket
P*	Min. 0 max 10	Min. 0 max 16
* with a backrest depth of 6 cm		



Size (cm)	P	M	G
L	13	15.5	18
H	5	5	5