

HeadActive®

TECHNICAL DATA AND INSTRUCTIONS OF USE



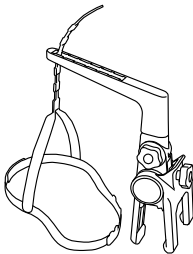
Manufactured by: Onlywise Unipessoal Lda.
Calle Santa Caterina nº 124 Porto (Portugal)
PT510797725

HeadActive®

HeadActive® is a product designed to improve the quality of life for users with hypotonia in the neck muscles and for their carers and families. HeadActive® significantly increases the user's relationship with the environment, facilitating feeding and making different therapies accessible. HeadActive® facilitates natural rotation of the head providing an increase in a user's concentration and improved intellectual performance.

FEATURES

- Universal
- Easy adjustment and adaptation
- Ergonomic
- Made of lightweight and durable materials.
- Easy to mount
- Offers safety and comfort
- Latex Free



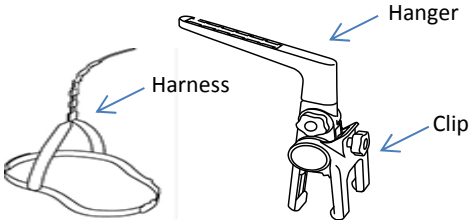
The cephalic HeadActive® system control is available in 4 models for maximum ease and adaptability.

HeadActive® Standard

Given its versatile design, the Standard Model is simple and easy to install, adjust and use.

The Standard Model consists of 3 elements:

- Clip
Adaptable to any type of support or semi - rigid headboard with a thickness of 10-80 mm.
- Hanger
Angle and depth adjustable
- Head-Harness
1 standard size and 1 small size

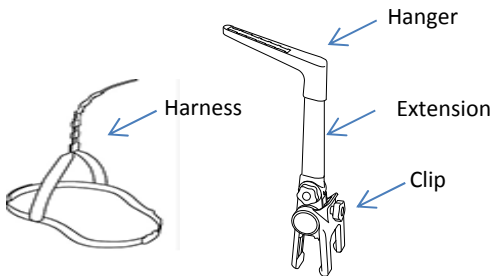


HeadActive® Tower

This is particularly suitable for users whose support system has a short back height and who have reduced control of their cervical spine.

The Tower Model consists of 4 elements:

- Clip
Adaptable to any type of support or semi - rigid headboard with a thickness of 10-80 mm.
- Extension of 15 cm
- Hanger
Adjustable depth and angles
- Head-Harness
1 standard size and 1 small size

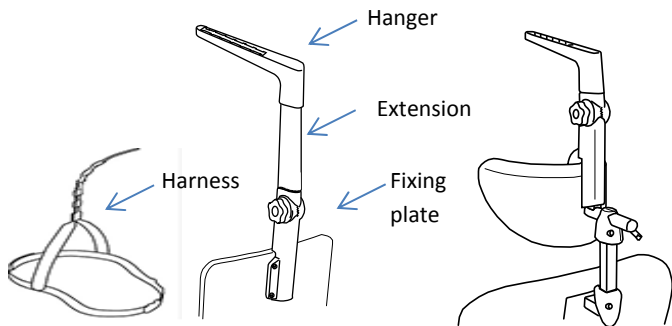


HeadActive® Fix

Fits to the back of the support surface leaving the front of the support free from attachments.

The Fix Model consists of 4 elements:

- Fixing plate with two possibilities:
 - Direct fixing to back
 - Mounting onto 15x15mm square tube present as standard on some postural support systems.
- Standard Extension piece of 15 cm
- Hanger
Adjustable depth and angles
- Head-Harness
1 standard size and 1 small size

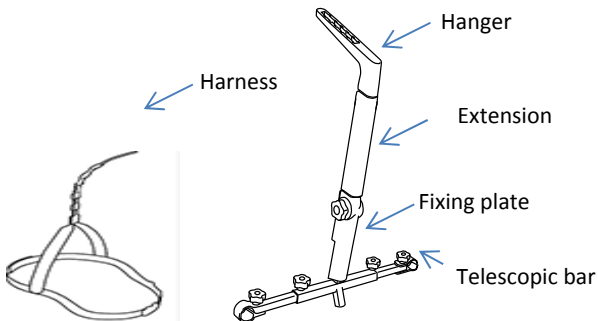


HeadActive® Soft

Specially designed for use with support systems with soft or flexible backrests e.g. Wheelchairs.

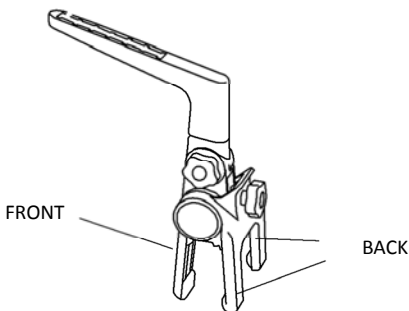
The Soft Model consists of 5 elements:

- Telescopic Horizontal Bar
Attaches to the handles of a wheelchair.
- Fixing plate
- Extension of 15 cm
- Hanger
Adjustable depth and angles
- Head-Harness
1 standard size and 1 small size

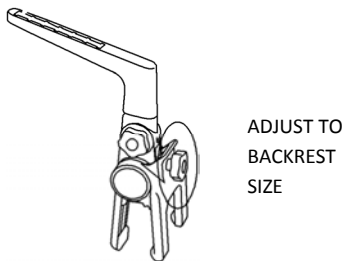


DIRECTIONS

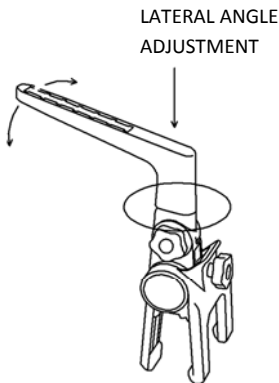
HeadActive® Standard



1. Place the bracket over the back so that the front of the clip (1 prong) is in the area of patient contact with the backrest and the back of the clamp (2 prongs) is behind the backrest. It is important that all three prongs are parallel to the base of the clamping surface to allow greater clamping efficiency .
2. Tighten the clamping screw by turning clockwise.



3. Adjust the angle of the hanger as required.



4. The angle of the support column can be adjusted forwards or backwards using the screw on the right hand side of the base of the support column. This adjustment can be used to regulate the centre of gravity to accommodate kyphotic postures and variable backrest angles.

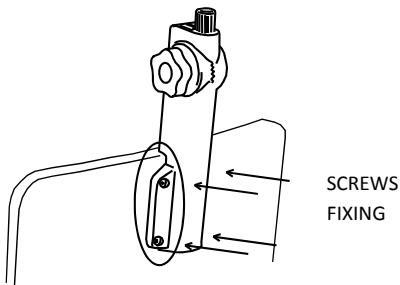
HeadActive® Tower

As for the standard model with the addition of an extension piece to give additional height where required.

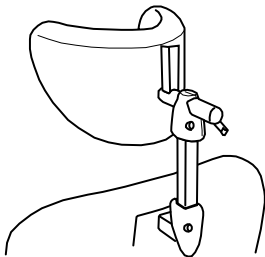
HeadActive® Fix

1. Fixed model can be attached in two ways:

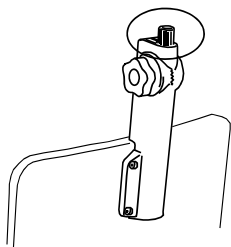
a) Place the fixing plate on the back of the backrest, existing headrest or interface plate so that the screws line up with the existing holes. If you need to create new holes ensure the anchor piece will sit level. Screws for this type of fixing are not included but must be suitable to the type of material.



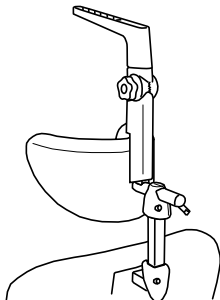
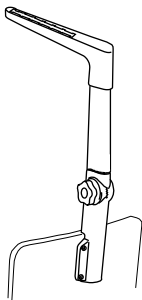
b) Place the fixing plate on a square tube 15x15 mm (not included) that can be attached to the back of the headboard.



2. Where the fixing plate is fixed directly to the rear of the support system the angle of the support column should not exceed 20 ° from upright. Excessive angles may compromise the user safety.

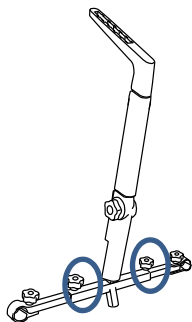


TOOTHED RIM FOR
LATERAL ANGLE
ADJUSTMENT

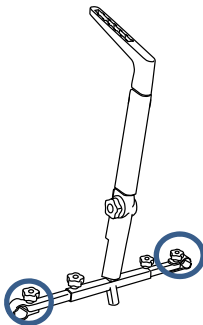


HeadActive® Soft

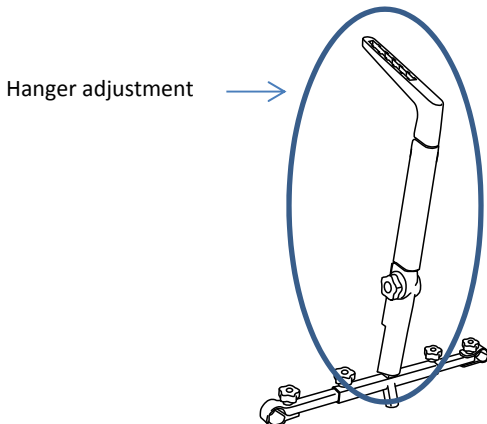
1. To attach loosen the screws on the inner side of the telescopic bar, and adjust the length to suit the width of the bars of the chair you are going to place the system. Once in place, tighten the screws to set the correct length.



2. Once the correct length has been set loosen the two outer screws to open the clamps at either end of the telescopic bar. Place the open clamps around the frames they are to be clamped to and tighten securely to fix in place. It is important that the two ends of the bar are exactly parallel – an uneven setting can affect the safety and function of the HeadActive®.



3. Finally fixing bracket, extension and the hanger, onto the protruding 15 x 15mm square mounting piece on the telescopic bar. Please note the telescopic bar can be mounted in two ways to adjust the angle of the mounting piece which will affect the orientation of the harness.



SET UP FOR USER

To set up the HeadActive® for the user, you should work in a quiet environment, free from distractions.

It is advisable to fully explain to the user all the steps that are going to be taken in the setup whenever possible.

Do not use sharp or dangerous items near the user.

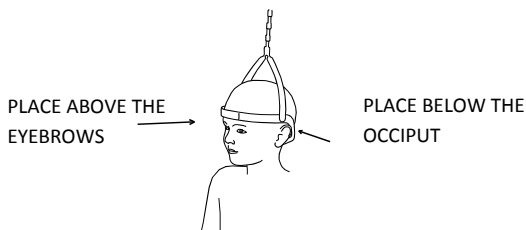
Do not place the user at risk or in dangerous positions.

Safe set up of the HeadActive® requires two people – one to hold the user's head with both hands from back to front, the other to fit the harness around the users head from the front.

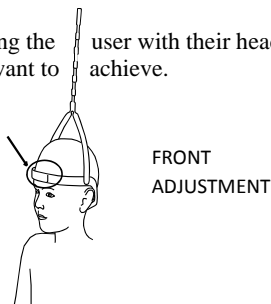
Do not over-tighten the harness on the head contour.

Do not place the harness over the eyebrows.

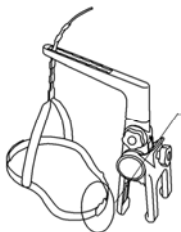
Do not place the harness over the ears.



1. Start by keeping the user with their head in the position you want to achieve.

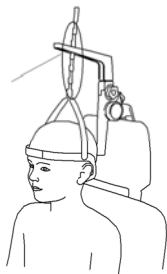


2. Place the harness around the user's head. The harness has Velcro adjustments at the front (front adjustment) and back (back adjustment). Adjust at both points to get the curves on both sides of the harness aligned with the ears. When this position has been achieved the diameter of the harness is adequate to sustain head without being over tightened due to the dimensions of the skull.



BACK
ADJUSTMENT

3. Attach the harness to the hanger using the toothed strip (Height adjustment) which comes with the harness. The height of the fixing position depends directly on the desired position for the user so that a better height, better cephalic clamping and better tendency to extension are achieved.



HEIGHT
ADJUSTMENT

The HeadActive® system operates best between the recommended angle ranges of 0° (upright) to 20° (reclined). Please consult with your local HeadActive® representative if you are intending to set up the system for use outside of these recommendations.

If you change the angle of the support column you will also need to adjust the central strip to achieve optimum head position and range of movement for the user. **NB: adjusting the angle of the support column will cause further extension of the neck and is contraindicated for users with high level cervical injury.**

In users who rotate, it is recommended to position the hanger rotated to the opposite side to that preferred by the user except in cases of untreated torticollis.

The side screw can alter the angle of the support column to facilitate secure and suitable support for users with a kyphosis.

BENEFITS

The HeadActive® has the following advantages:

- The ability to achieve alignment of the Frankfurt line parallel to the ground
- The ability to align the coronal axis with the cervical line
- The ability to align the centre of mass relative to the sagittal suture
- Proper positioning for optimizing the temporomandibular jaw joint (TMJ) and facilitation of mastication.
- Facilitating oropharyngeal swallowing and breathing through verticalisation of the neck.
- High level of support with minimal intervention for the user.
- Immobilization of the lower cervical segment in all three planes of motion.
- Ideal for extreme muscle action to facilitate and improve physiological spatial positioning.
- Minimises dangerous movements (e.g. lashing) during transit.
- Latex free.
- Minimize the contact areas for improved proprioception.
- Provides stability in the sagittal and coronal planes, leaving the transverse free for natural movement.

INDICATIONS

When used correctly the HeadActive® system gives innovative head support by providing stability in the coronal and sagittal planes while still allowing for complete freedom of motion in the transverse plane.

HeadActive® works by controlling the cervico-cephalic structures but still allowing mobility. This is achieved via active suspension of the cranial segment against gravity.

HeadActive® can be used in therapy programmes to provide element alignment, for neuromuscular disorders, cephalic/cranial/sagittal drop as well as muscular deficits, cervical flexion stress in extension, and cephalic rotation lateralisation.

The underlying conditions that may benefit from HeadActive® system are:

- Hypotonic cerebral palsy.
- Mitochondrial diseases with hypotonic component.
- Neuromuscular diseases.
- Torticollis secondary to treatment.
- Deficits of visual fixation
- Axial trunk spasticity with cervical impotence.
- Scapular Dyskinesia
- High humeral head alignment.
- Mechanical difficulties in swallowing as a result of postural abnormality..

LIMITATIONS

Intended users with any of the following conditions should be evaluated by experienced personnel. If the following conditions occur, consultation with a clinical specialist familiar with the care of the individual in question is recommended:

- Incomplete cranial sutures.
- Atlanto-odontoid instability.
- Arnold Schiari syndrome.
- Syringomyelia.
- Fractures or bone deformities in the area between the skull base and C3 vertebra.
- Hydrocephalus.
- Global Dystonia with flexor component.
- Global Dystonia with extensor component.
- Cervical spasticity.
- Damaged meniscoids.
- Cervical and cranial tumors.
- Structural kyphosis.
- Scoliosis at D8 above.
- Dysphagia associated with neurodegenerative diseases (e.g. ALS, MS)

SIDE EFFECTS

No side effects have been reported with the use of HeadActive® system.

This product has been listed as " Medical Device Class I" in accordance with Directive 2007/47/EC of the European Parliament on medical devices, and as such complies with the essential requirements that are applicable, and must be used under the supervision of specialist effectiveness in achieving its therapeutic purpose and safety in use, ie, their use does not pose any health risk to the user.

MANTENANCE

Wash HeadActive® different parts with warm water and mild soap. Do not use bleach. Do not expose to temperatures exceeding 75 ° C.

PACKAGING AND STORAGE

Product packaging ensures protection to avoid damage during transport and storage, provided that they are conducted in sanitary and environmental conditions and avoids exposure to chemical contaminants. Store in a clean, dry place.

REUSE

Given its therapeutic purpose, it is not recommended to reuse this product for someone else.

CHANGES

Any modification made to the original product manufacturer without consent relieves it from any liability that may arise from its use.

WARRANTY

HeadActive® is guaranteed for a period of 2 years for defects in materials or workmanship after purchase.

The warranty does not cover the proper use of the product or normal wear and tear.

| | |
|--|---------------------------|
| Reference: | |
| Lot Nr.: | |
| Purchase date: | |
| Signature and stamp of the orthopaedic shop: | Place, Date and Signature |

Has to be presented to validate the warranty



Date of last review:05/2014