INSTRUCTIONS FOR USE



THE AIO SOLUTION® PAEDIATRIC BASE PLATE WITH PAEDIATRIC SHOULDER SLOTS IN CARBON FIBRE LAMINATE



Article No.: 32301-PED/SS

Article No.: 32301-PED/SS/NOLS (without leg separator)

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation in radiation therapy.

This low density plate can be used during both the simulation and the treatment stage.

This product may only be used in combination with immobilisation masks produced by Orfit. Orfit prohibits the use of unauthorised third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

This carbon fibre laminate BASE PLATE is used for the treatment of both children and adults. It is used in combination with THE AIO SOLUTION® CUSHIONS, the RAYCAST® HIGH PRECISION HEAD SUPPORTS and BLOCKS & WEDGES, and with the EFFICAST® PRE-CUTS to form a reproducible patient positioning and immobilisation device.

information on these other parts (and instructions on how to make the masks) can be found in the respective 'instructions for use' and on www.orfit.com.

The BASE PLATE has narrow shoulder slots specifically designed to use EFFICAST* PAEDIATRIC PRECUTS. The shoulder slots extend in the thorax slots. Whether the profile of the mask is attached at the upper or lower part of the slot is determined during moulding. Once the mask is moulded and the EVA block is inserted in the slot, the profile cannot move inside the slot anymore.

C. PRECAUTIONS FOR USE

This is a fragile product, please handle with care. Always place the base plate on a flat surface.

Always fix the base plate securely to the treatment couch before positioning a patient. More information on how to fix this base plate to a couch top can be found on our website http://www.orfit.com/en/fixation-devices/.

If the base plate is used in overhang over the couch a Table Fix (art. no. 35744/6) or iBeam couch fixation (art. no. 32813) needs to be used at the caudal end to secure the base plate to the couch top. This prevents the base plate from falling off the table when the patient moves.

D. STORAGE

Always store the product in a safe place to prevent it from getting damaged. Take care not to damage the edges of the plate when storing it in an upright position. Prevent hard objects from falling onto the plate.

Store the base plate between +10°C (50°F) and 40°C (122°F).

E. PROPERTIES

E.1. Physical Properties

This plate is made of a carbon fibre laminate.

Dimensions: L 1350 mm x W 544 mm x H 30 mm

Weight: 3,630 kg

E.2. Mechanical Properties

Bending:

The bending (sag) Δ Lw of the AIO base plate (measured between the two positioning holes of the head support, at 323 mm from the 'maximum overhang line) can be calculated using the next equation:

Δ Lw = 0,07695W + 0,04889

Where Δ Lw is the displacement of the plate (mm) W is the vertical force (weight), exerted at the measuring point (kg) SD: \pm 0,017 mm

E.3. Dosimetric Properties

The general attenuation factor (\pm 0,15 %) for the Base Plate is as follows:

6 MV	1.4 %
15 MV	1.2 %
Skin build-up	4 mm H₂O equiv.

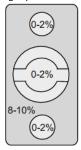
But the Base Plate has some areas where some higher density (±1.4 g/mm³) materials have been used to reinforce some parts like screw inserts, grip pole inserts and the leg separator insert.

The drawing shows these areas and below the corresponding attenuation factors at 6MV are listed.

- .) fixation screw inserts Ø 1 cm: 8-10 %
- 2) grip pole inserts:



- 3) fixation screw inserts (blocks of 30x30x30mm): 8-10 %
- 4) leg separator insert:



- 5) table fix tunnel (runs across the base plate): 4-5 %
- 6) edge of slots: 8-10 %

Note: Base Plate 32301-PED/SS/NOLS doesn't have a hole for the leg separator. As such this part of the Base Plate doesn't contain reinforcement material and the general attenuation factors apply here.

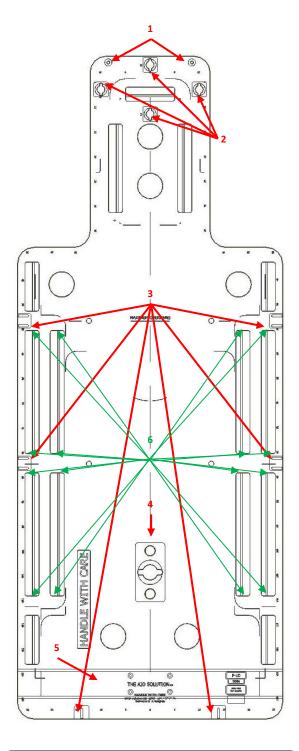
Note: Use these numbers as a guidance only. Perform the measurements again in your department to verify these results.

F. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected by means of soapy water or an isopropanol based disinfectant, applied with a soft cloth. If unsure about the cleaning fluid, do not use. **Never use aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.**

Periodic checks of the product should be done to insure the parts are not worn and require repair or replacement. **Do not attempt to make repairs yourself**. Contact your distributor if there are any questions or concerns.

The product can be disposed of with household waste.



G. ADDITIONAL INFORMATION

For additional information such as distributor contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

Note:

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ORFIT INDUSTRIES

Vosveld 9A | B-2110 Wijnegem | Belgium T (+32) (0)3 326 20 26 welcome@orfit.com

www.orfit.com



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