INSTRUCTIONS FOR USE



THE AIO SOLUTION® 3.0 CARBON FIBRE BASE PLATES FOR VARIAN HALCYON™ & ETHOS™ RADIOTHERAPY SYSTEMS



Article No.: 38009 & 38014

A. GENERAL PRODUCT INFORMATION

These products are medical devices used for patient positioning and immobilisation in radiation therapy. The products can be used during both the simulation and treatment stage and are compatible with the Varian Halcyon™ and Ethos™ Radiotherapy systems.

To attain an optimal result, it is recommended to use these products in combination with Orfit immobilisation products.

B. PRODUCT DESCRIPTION

The AIO 3.0 base plates for the Halcyon™ and Ethos™ Radiotherapy system are the basic element of the AIO Solution 3.0. The base plates are used in combination with the AIO Solution 3.0 cushions and accessories, the Raycast® High Precision Head Supports and Blocks & Wedges, and with the Efficast® Pre-cuts to form a reproducible patient positioning and immobilisation device in the field of radiotherapy. 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 products are designed in such a way that they can be mounted on the Varian Halcyon™ and Ethos™ Radiotherapy system couches using fixation blocks 38212 and/or 2-pin bar 32166 without overhanging the cranial, caudal or lateral edges. More information on the fixation devices can be found in the respective 'instructions for use'.

Base plate 38009 comes with holes to index a leg separator (high or low) while base plate 38014 comes without leg separator holes.

C. PRECAUTIONS FOR USE

These are fragile products, please handle with care. Always place the base plates on a flat surface. Clear the treatment table of any debris before positioning the base plates. Always fix the base plates securely to the treatment couch before positioning a patient. More information on how to fix these base plates to a couch top can be found in the 'instructions for use' of the fixation devices mentioned in the above paragraph.

Ensure that the base plates are not overhanging the couch top either cranially, caudally nor laterally when used on a Halcyon™ or Ethos™ Radiotherapy system couch.

The carbon fibre base plates are constructed to be light in weight and have superb dosimetric properties. When handled roughly, they may get damaged and fibres may come off. When this happens, stop using the base plates to prevent fibres from getting in contact with the patient's or user's skin. Contact your distributor.

Do not place the products in direct sunlight.

D. STORAGE

Always store the products in a safe place to prevent them from getting damaged or falling onto other objects. Take care not to damage the edges of the base plates when storing them in an upright position. Prevent hard objects from falling onto the base plates.

Store the base plates between +10°C (50°F) and 40°C (104°F).

E. PROPERTIES

Physical properties:

These base plates are made of carbon fibre laminate.

Dimensions: L 1298 mm x W 530 mm x H 21 mm

L 51.10" x W 20.87" x H 0.83"

Weight: 3.77 kg



These products are MR unsafe and cannot be used in a MRI scanner.

Mechanical properties:

Maximum allowed patient weight: 200 kg

Do not use the base plates in overhang on a Varian Halcyon™ or Ethos™ Radiotherapy System.

Dosimetric properties:

| Position | Attenuation (± 0.15 %) (6MV) | Attenuation (± 0.15 %) (15MV) | Skin build-up (± 0.1 mm) (15 MV) |
|----------|------------------------------------|-------------------------------------|--|
| | % | % | Mm H₂O equiv. |
| 1 | 1.8 | 1.1 | 4.1 |
| 2 | 4.5 | 2.8 | 10.7 |
| 3 | 1.8 | 1.2 | 4.3 |
| 4 | 3.8 | 2.5 | 9.3 |
| 5 | 1.9 | 1.2 | 4.3 |
| 6 | 1.1 | 0.7 | 2.3 |
| 7 | 1.1 | 0.7 | 2.6 |
| 8 | 1.1 | 0.7 | 2.4 |
| 9 | 3.7 | 2.4 | 8.9 |
| 10 | 2.2 | 1.4 | 5.0 |

The drawing below shows the corresponding positions. The AIO 3.0 base plate 38009 for Halcyon™ and Ethos™ Radiotherapy system in CFL has areas where higher density materials have been used to reinforce parts like screw inserts and the leg separator insert. The base plate has low attenuation and skin build-up values in the treatment areas.



Note: Use these numbers as a guidance only. Perform the measurements again in your department according to the applied treatment techniques and treatment systems.

Note: Base plate 38014 does not have holes for the leg separator (position 9). As such, this part of the base plate does not contain reinforcement material and the general attenuation factors apply here.

F. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned and disinfected by means of 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.** Further cleaning instructions can be found in the <u>Orfit Cleaning Guidelines</u>.

Periodic checks of these products 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.

These products 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.

THE AIO SOLUTION® is a registered trademark of Orfit Industries. Halcyon™ and Ethos™ are trademarks of Varian Medical Systems.

