HP PRO® SOLUTION OVERLAY BASE PLATE COMPATIBLE WITH THE ELEKTA HEXAPOD™ EVO RT SYSTEM

Article No. : **25000/26**

A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device, used for patient positioning and immobilisation in radiation therapy. This low density plate can be used during both the simulation and the treatment stage. The base plate has a cut-out which makes it compatible with the HexaPOD™ evo RT system.

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 BASE PLATE is the basic element of the ORFIT HP PRO SOLUTION. It is used in combination with special 3 and 5 point HP PRO masks, a cranial stop and a personalised head rest 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.

C. PRECAUTIONS FOR USE

- This is a fragile product, please handle with care. Always place the base plate on a flat surface. Clear the treatment table of any debris before positioning the base plate.
- Always fix the base plate securely to the treatment couch before positioning a patient. More information on how to fix this base plate to the couch top can be found on our website: www.orfit.com/en/fixation-devices.
- When a robotic arm is used to transfer the table onto a stretcher with the base plate attached to it, the base plate should be fully supported at all times. For safety reasons the base plate cannot hang over the table past the 'maximum overhang line' at the level of the shoulders. Always verify that the base plate is attached safely to the table before performing the transfer.
- The base plate contains a cut-out which limits the use of the hand holds. Positions A0 until A26 are not available.
- The carbon fibre base plate is constructed to be light in weight. When handled roughly, it may get damaged and fibres may come off. When this happens, stop using the base plate to prevent fibres from getting in contact with the patient's or user's skin. Contact your distributor.
- The article number and lot number can be found on the back of the base plate. They are mentioned on the bottom side of the plate in between 2 indexing holes at the edge.
- The maximum patient weight is 180 kg / 397 lbs.
- Make sure the patient is never mounting on the base plate by sitting on his or her knees. This might damage the base plate.

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 30°C (86 °F).

E. PROPERTIES

E.1. Physical Properties

Dimensions (± 0,2 mm):
L 1250 mm x W 540 mm x H 49,5 mm
L 49.21'' x W 21.26'' x 1.95''
Weight (± 0,05 kg): 2.5 kg/5.51 lbs

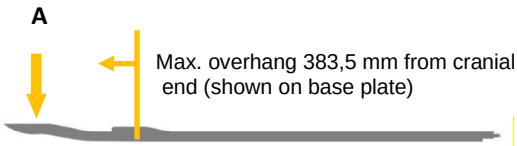
The thin head shell is made from carbon fibre with epoxy. Starting from the neck, the thickness gradually increases to 30 mm using a foam core

covered with carbon fibre and epoxy. Edges are epoxy resin. Other inserts are made from hardwood/epoxy.

This base plate is labelled 'MR Unsafe' due to the used carbon fibre materials. This is visualized by the following label:

E.2. Mechanical Properties

Max. allowed load at point A (lowest point of head shell): 35 kg/77lbs

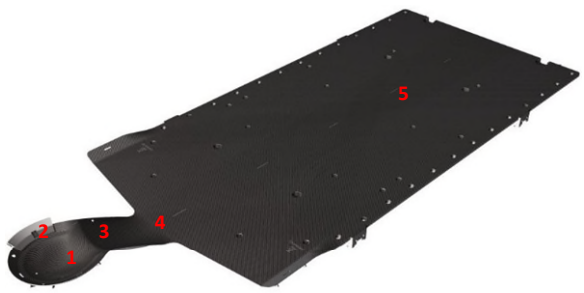


Always take into account the maximum weight loads!

E.3. Dosimetric Properties

The attenuation and skin build-up depend on the location on the base plate. The values given below are for photon therapy.

Location	Attenuation at 6 MV (± 0.15 %)	mm H2O equivalence (± 0.1 mm)
1	0.98 %	2.2 mm
2 (with profile)	1.52 %	3.3 mm
3	0.81 %	2.9 mm
4	0.45 %	2.9 mm
5	1.07 %	3.5 mm



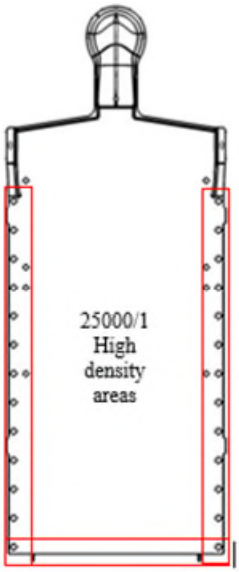
Note: The picture shows base plate 25000/1 instead of base plate 25000/26. The same dosimetric properties apply.

The water equivalence measured with protons is the following:

Location	mm H2O equivalence (± 0.1 mm)
1	2.64 mm
3	4.10 mm
5	3.01 mm

The attenuation factor for high energy proton beams will be negligible. It is so small that it cannot be measured.

The Base Plate has areas where higher density (± 1.4 g/mm³) materials have been used. The following image shows these areas inside the red lines. Attenuation factors at 6 MV of the non-metal inserts range from 8 to 10 %.



Note: The picture shows base plate 25000/1 instead of base plate 25000/26.

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

F. ACCESSORIES FOR THE BASE PLATE

Various accessories can be used in combination with the HP PRO base plate, such as:

- 25000/6: Cranial Back Stop
- 25000/7: Head Support Indexing Plate
- 25000/17/A and 25000/17/B: Hand Holds
  The base plate contains a cut-out which limits the use of the hand holds. Positions A0 until A26 are not available.

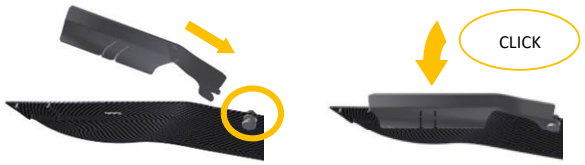
Information on these accessories can be found in the respective 'instructions for use' and on www.orfit.com.

G. HP PRO THERMOPLASTIC MASKS

Various thermoplastic masks are available in a 3-points and 5-points version to immobilise head and neck patients.
To attach the lateral head profiles to the base plate you have to work in a few steps. First slide the caudal side of the profile over the indexing pin and secondly swivel the profile inwards until it clicks over the base plate.

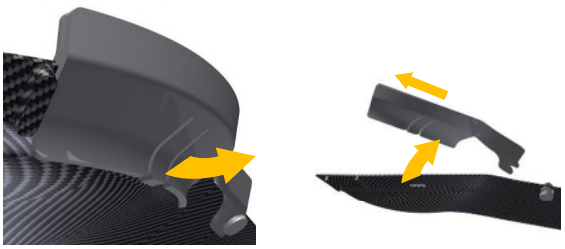
Attaching a lateral profile to the base plate:

Step 1: Step 2: Turn



Removing a lateral profile from the base plate:

Step 1: pull handle Step 2: Turn &



The cranial head profile and the shoulder profiles simply click onto the base plate.
If the patient has medium to long hair it is helpful to add a hair cover. This will automatically clear the areas where the mask profiles must be attached. It provides more time to mould the mask and prevents hair getting stuck in between the mask profile connection.

Different shapes and sizes are available both in Efficast and Nanor. The profiles are made from Polycarbonate (PC).

H. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected by means of an ethanol or 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 Orfit Cleaning Guidelines.
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.

Periodic checks of the following parts is extremely important in order to safeguard a good fixation of the mask to the base plate:

- The holes where the mask profiles click into.
- The guidance ribs to position the mask profiles.
- The pin to attach the inferior part of the profile to the base plate.
- The profile of the mask.

I. 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.

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Ref. No. 50158
VERSION 5
LAST UPDATE: 05/10/2021
REVISION DATE: 05/10/2023