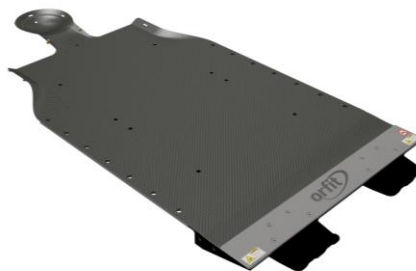


HP PRO® EXTENSION WITH CLAMP INTERFACE – PAEDIATRIC 8-16 YEARS - TYPE 2



Article No. : 25000/29

A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device, used for paediatric patient positioning and immobilisation in radiation therapy. This low density base plate is suitable for proton as well as photon treatments.

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 extension BASE PLATE is the basic element of the ORFIT® PAEDIATRIC HP PRO® SOLUTION. It is used in combination with special 3 and 5 points PAEDIATRIC 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 can be found in the respective 'instructions for use' and on www.orfit.com.

The PAEDIATRIC HP PRO BASE PLATE has a narrow shoulder part specifically designed to immobilise children from 8 to 16 years old in a comfortable and reproducible way.

C. PRECAUTIONS BEFORE USE

- This is a fragile product, please handle with care.
- Use this base plate as an extension only.
- Always fix the extension securely to the couch before positioning a patient or additional equipment. More information on how to fix this extension to the couch top can be found in this document.
- Have the patient sit on the pedestal area first and then slide towards the extension. Make sure the patient is never mounting on the

base plate by sitting on his or her knees. This might damage the base plate.

- Take into account the maximum weight loads.
- 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.
- Do not use the extension after it had a severe collision with the ground, wall/door or other device in the room. A collision might compromise the strength of the internal structure and could result in failure.
- 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.
- In case there are any uncertainties about the safe use of this extension, contact your distributor.

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. Do not place any items on top of the extension while in storage.

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

E. PROPERTIES

E.1 Physical Properties

Outer dimensions : L 1135 x W 530 x H 62,6 mm
 : L 44.69" x W 20.86" x H 2.46"
 Weight : 7,71 kg / 17.00 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. The interface is made from aluminium with stainless steel reinforcements and bolts. Other inserts are made from hardwood/epoxy.

This base plate is labelled 'Not MR Safe' due to the used metallic and carbon fibre materials.



E.2 Mechanical Properties

Max. allowed distributed load: 125 kg / 275 lbs



CAUTION

- Prevent point loads at all times!
- Do not lean or sit on the outer end!
- Have the patient sit on the pedestal area first and then slide towards the extension to lie down. Make sure the patient is never mounting on the base plate by sitting on his or her knees. This might damage the base plate.
- Make sure to take into account the weight of every item placed on top of the extension and add it to the patient weight to check that the total weight does not exceed the maximum load limit of the extension.

E.3. Dosimetric Properties

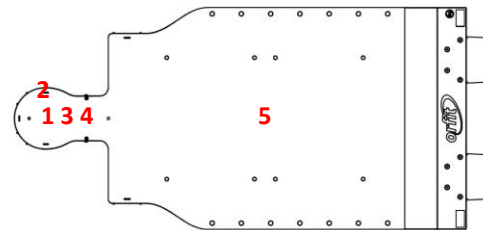
The attenuation and skin build-up depend on the location on the base plate. The values given below are for photon therapy.

Location	Attenuation at 6 MV ($\pm 0.15\%$)	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

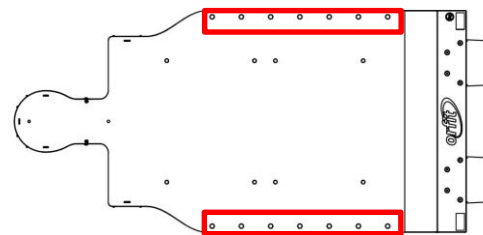
The water equivalence measured with protons is the following:

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

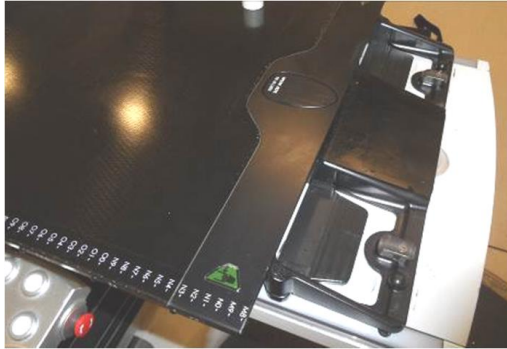
F. ATTACHING TO COUCH

The extension 25000/28 is designed to fit the Civco Universal Couchtop™ with black indexing blocks on the couch support.

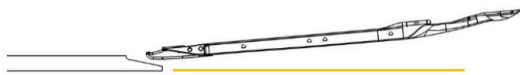
CAUTION

- It is not allowed to be used on another couch than specified in this document.
- Take into account any precautions and instructions described by the couch supplier.

Before carrying the extension, verify that the couch interface indexing blocks are mounted and screws are tightly fixed (see below picture).



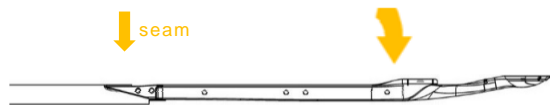
Insert the extension to the interface couch under a slight inclination angle.



Then slide the extension towards the couch until both the couch and extension upper edges meet.



Gently lower the extension until horizontal and the couch takes over the weight.



Verify that the extension is securely fixed by checking if it is flush with the couch (horizontal) and if there is a seam between couch and extension of about 1,5 mm.

G. ACCESSORIES FOR THE BASE PLATE

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

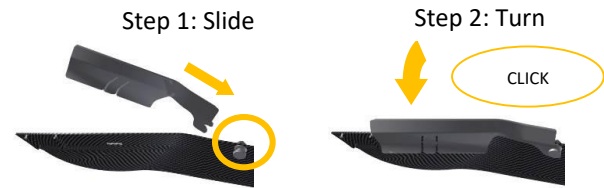
- 25000/6: Cranial Back Stop
- 25000/7: Head Support Indexing Plate
- 25000/17/A and 25000/17/B: Hand Holds

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

H. HP PRO THERMOPLASTIC MASKS

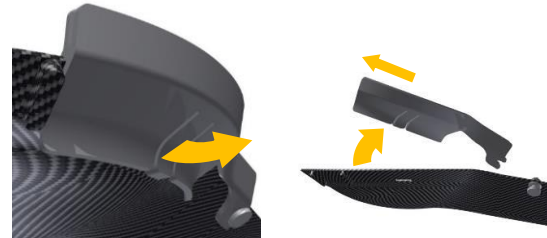
Various paediatric thermoplastic masks are available in a 3-points and 5-points version to immobilise head and neck paediatric patients. To attach the lateral head profiles to the base plate you have to work in a few steps. First slide the caudal side of the profile over the indexing pin and secondly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

Attaching a lateral profile to the base plate:



Removing a lateral profile from the base plate:

Step 1: pull handle Step 2: Turn & slide



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 in Nanor. The profiles are made from Polycarbonate (PC).

I. 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.**

The product can be disposed of with household waste.

Periodic checks of the product should be done to insure safe use.

Weekly:

- No damages (cracks/dents) of any kind which might indicate a collision occurred.
- No visible defects on the aluminium adapter.
- All bolts still firmly in place.
- No delamination of carbon top and bottom layers.

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.

Immediately stop using the extension if a defect is found. **Do not attempt to make repairs yourself.**

Contact your distributor if there are any questions or concerns.

J. **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:

The instructions were written in accordance with the European Directive 93/42/EEC for Medical Devices. It is prohibited to make alterations to this text without prior approval from Orfit Industries.
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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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