A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device, used for patient positioning and immobilization in radiation therapy.

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

B. PRODUCT DESCRIPTION

This HP PRO Range Shifter is used to shift the maximum dose depth during radiation therapy. It can be used in combination with immobilization devices like overlay base plates, cushions and immobilization masks to form a reproducible patient positioning and immobilization device. Information on these other parts can be found in the respective ‘instructions for use’ and on www.orfit.com.

C. PRECAUTIONS FOR USE

Carefully follow the instructions for use.

- This is a fragile product, please handle with care.
- Before unpacking, check outside of packaging for severe damages to exclude if the product encountered severe shocks and is damaged as a result.
- The HP PRO Range Shifter must be handled with a minimum of two persons because of its weight and size.
- Always fix the HP PRO Range Shifter securely to the couch before positioning a patient or additional equipment. More information on how to fix this base plate to the couch top can be found in this document (section F).
- Only use in combination with other devices described in this document.
- Check if the size (section E.1.) does not result in collisions with the treatment machine or other components in the room.
- Never load the HP PRO Range Shifter with more, evenly distributed, weight than noted in this document (section E.2.).
- Before first use, check the attenuation of the product to make sure the correct values are used for treatment planning.
- Have the patient sit on the pedestal or couch connection area and then moved towards the extension.
- Carbon fibre is used in the HP PRO Range Shifter which can, when damaged, result in loose fibres with potential skin irritation. When this happens, stop using the base plate to prevent fibres from getting in contact with the patient’s or user’s skin.
- Do not use the HP PRO Range Shifter after it had a hard collision with the ground, wall, door or other devices in the room. A collision might compromise the strength of the internal structure and could result in failure.
- In case there are any uncertainties about the safe use of the HP PRO Range Shifter, contact your distributor.
- Do not exert upward pressure underneath the range shifter during use. This could cause an upward displacement of the range shifter and possible detachment from the treatment couch.
- MR unsafe

D. STORAGE

- Always store the product in a safe place to prevent it from getting damaged.
- Do not hold/place/store it in an upright position unless it is securely fixed.
- Prevent hard or sharp objects from falling onto the composite material surface.
- Store the base plate between +10°C (50°F) and 40°C (122°F). Do not place any items on top of the HP PRO Range Shifter while in storage.
E. PROPERTIES

E.1. Physical properties for HP PRO Range Shifter 25000/19

Dimensions: L 1274,4 x W 549 x H 41,2 mm
             L 50,17 x W 21,61 x H 1,62 inches
Weight: 31 kg / 68,3 lbs

Made from a PMMA core covered with carbon fibre, top and bottom. The interface is made from high grade aluminium with stainless steel reinforcements and bolts.

E.2. Mechanical properties for HP PRO Range Shifter 25000/19

Max. allowed distributed load: 125 kg / 275 lbs

CAUTION

- Prevent point loads at all times!
- Do not lean or sit on the outer end! The allowed load must be distributed over the length of the extension.
- Have the patient sit on the pedestal or couch connection area and then moved towards the extension.
- When using overlays, do not extend them beyond the length of the HP PRO Range Shifter in order not to exceed bending limits or to risk collisions.
- Make sure to take into account the weight of every item placed on top of the HP PRO Range Shifter and add it to the patient’s weight to check that the total distributed weight does not exceed the maximum load limit of the HP PRO Range Shifter. Read the instructions for use of each individual component placed on top to know its weight.

Below sag and creep values are measured without couch induced movement.

Sag (cranial end - distributed weight)

<table>
<thead>
<tr>
<th>Distributed Weight (kg)</th>
<th>25</th>
<th>50</th>
<th>75</th>
<th>100</th>
<th>125</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sag (mm)</td>
<td>1,26</td>
<td>2,76</td>
<td>3,98</td>
<td>5,14</td>
<td>6,45</td>
</tr>
<tr>
<td>Tol. ±13µm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The following formula can be used for an estimation of the sag with any distributed weight:

\[ \text{Sag} = 0,0516 \times \text{weight} + 0,0408 \]

Take into account that a patient does not equally distribute weight onto the HP PRO Range Shifter with his whole body, because the head and neck area might be lighter than the pelvic area for example. This means the sag will be different from what is shown in the table above. Following are some examples of sag values measured with patients.

- 70 kg (154 lbs) = Maximum sag 2,65 mm
- 80 kg (176 lbs) = Maximum sag 2,60 mm
- 101 kg (222 lbs) = Maximum sag 3,5 mm

See below creep data for sag in function of time.

Approximate creep (cranial end - distributed 100 kg)

<table>
<thead>
<tr>
<th>Time (min.)</th>
<th>10 min.</th>
<th>20 min.</th>
<th>60 min.</th>
<th>90 min.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creep (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tol. ±13µm</td>
<td>0,09</td>
<td>0,12</td>
<td>0,18</td>
<td>0,28</td>
</tr>
</tbody>
</table>

E.3. Dosimetric properties

The ‘Water Equivalence’ is 42,35 mm, when measured with protons.

CAUTION

The water equivalence value is only given as reference. The attenuation of the product must be measured by the user before first use. (section C.)

F. ATTACHING TO THE TREATMENT COUCH

The HP PRO Range Shifter ref.no. 25000/19 is made to fit the Civco Universal Couchtop™.

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.
- Carry the HP PRO Range Shifter with minimum 2 persons on either side (15,5 kg / 34,15 lbs
each). The range shifter should be transported by placing both hands on the longest side of the device, as shown on the drawing below.

center of gravity 661 mm

- Recommended is 2 persons on either side and a 3rd person that assists correct positioning.
- Always keep hands on either side of the extension, do not place in between the couch and extension to prevent pinching the fingers.

Before carrying/positioning the HP PRO Range Shifter, verify that the couch interface indexing blocks are mounted and screws are fixed (see below picture).

Insert the HP PRO Range Shifter to the interface couch under a small angle.

Then slide the HP PRO Range Shifter towards the couch until both the couch and HP PRO Range Shifter upper edges meet.

Gently lower the HP PRO Range Shifter until horizontal and the couch takes over the weight.

Verify that the HP PRO Range Shifter is securely fixed by checking if it is flush with the couch (horizontal) and if there is a seam between couch and HP PRO Range Shifter of about 1 mm.

G. USING OVERLAYS

Only use overlay base plates from Orfit Industries which have installation instructions describing the exact fixation devices and specifications related to this HP PRO Range Shifter.

Hereunder is an example using overlay base plate and fixation device.

CAUTION
- Do not extend overlays beyond the length of the HP PRO Range Shifter, unless specified otherwise, in order not to exceed bending limits of the HP PRO Range Shifter. Below example shows the maximum allowed overhang for this specific overlay type (ref.no. 25000/18).

CAUTION
- Make sure to take into account the weight of every item placed on top of the HP PRO Range Shifter and add it to the patient’s weight in order not to exceed the maximum load limit of the HP PRO Range Shifter (see section E.2.).
- Only attach overlay and other accessories to the range shifter once the range shifter is attached to the treatment couch.

H. 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.

**Daily:**
- (micro)cracks in the transparent PMMA core (use flashlight)
- No damages (cracks/dents) of any kind which might indicate a collision occurred.
- No visible defects on the aluminium adapter.
- No delamination of carbon top and bottom layers.

**Monthly:**
- All bolts still firmly in place.

**Every 6 months:**
- Attenuation check

Immediately stop using the HP PRO Range Shifter if a defect is found! **Do not attempt to make repairs yourself.** Contact your distributor if there are any questions or concerns.

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](http://www.orfit.com).