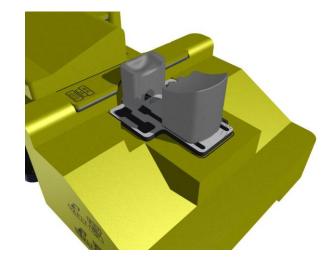


THE AIO SOLUTION® ACCESSORIES PRONE HEAD SUPPORT - ADJUSTABLE





AIO SOLUTION® code: HS-PR-A

Article No.: 29050

A. GENERAL PRODUCT INFORMATION

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

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

B. PRODUCT DESCRIPTION

This ADJUSTABLE PRONE HEAD SUPPORT is a part of the "AIO SOLUTION" PRONE BREAST and HEAD & NECK SETS". It is used in combination with the cushions from these sets, THE AIO SOLUTION" BASE PLATES and the EFFICAST" PRE-CUTS to form a reproducible patient positioning and immobilisation system. The head supports offer the opportunity to position the patient's head in a stable, reproducible way. The sides of the chin cushion are open and there is a tunnel in this chin cushion to have enough breathing space for the patient to feel comfortable.

Information on the EFFICAST® PRE-CUTS and the other parts of the AIO SOLUTION® can be found in the respective 'instructions for use' and on www.orfit.com.

This product consists of a support plate in high pressure laminate with 2 cushions. The cushion for the chin (1) is fixed. The cushion for the forehead and nose (2) can be put in 7 positions to accommodate the patient's size. The cushions are made of coated low density PE foam.

C. PRECAUTIONS FOR USE

Always use this device in combination with the other AIO SOLUTION* PRONE BREAST and HEAD & NECK components on one of the base plates.

The device has two positioning knobs on the bottom that fit into the holes foreseen in the cushions and parts of the different treatment packages (PRONE BREAST – CRANIAL CUSHION, HEAD & NECK BASE PLATE). Always verify that the device is positioned correctly on the other cushions and parts.

Do not expose the cushions of this device to a hot air blower and make sure that no sharp objects can come into contact with the cushions.

D. STORAGE

Always store the product in a safe place to prevent it from getting damaged. Do not put heavy objects on the cushion and prevent hard objects from falling onto it, because these will cause permanent deformations.

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

E. PROPERTIES

E.1. Basic Physical Properties

The following physical properties apply to these cushions:

Dimensions: L 261 mm x W 199 mm x H 95 mm

Weight: 2,63 kg

E.2. Mechanical Properties

The cushions of this device are made of low density PE foam that is covered with a PU coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

The cushions used on the treatment machines are often used more frequently than those on the simulators and during the imaging stages. We therefore recommend rotating the sets between the different machines on a regular base to avoid differences in wear and tear of the cushions.

The maximum deformation measured after 100 uninterrupted pressure cycles with a compression strength of 500N on a surface of 5cm x 5cm is 28.1%. This corresponds to the force of 100 times per day the load of 50 kg applied with the palm of the hand

E.3. Dosimetric Properties

The foam of the head support has the following dosimetric properties **per cm of material** through which the beam passes:

Attenuation (± 0.15%)		Skin build up (± 0.1 mm)
6 MV	15 MV	mm H₂O equiv.
0.48 %	0.25 %	1mm/mm material

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 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. Do not soak the product. 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.

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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Ref. No. 31907 VERSION 7

LAST UPDATE: 01/04/2021 REVISION DATE: 01/04/2023