# INSTRUCTIONS FOR USE



# THE AIO SOLUTION<sup>®</sup> 3.0 PRONE BREAST BOARD

Article Nos. :

38110	38112	38114	38219
38111	38113	38115	

### A. GENERAL PRODUCT INFORMATION

These products are medical devices used for positioning and immobilisation of breast patients treated in prone position in radiation therapy. The products can be used during both the simulation and treatment stage, including MRI simulation.

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

#### B. PRODUCT DESCRIPTION

This AIO Solution<sup>®</sup> 3.0 Prone Breast Board is used for the treatment of prone breast patients. The system includes a set of prone breast positioning cushions. It is used in combination with the High Precision Prone Head Support (ref. 38226) and Blocks & Wedges, Comfort head rest (ref. 29051) and 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 <u>www.orfit.com</u>.

The AIO solution<sup>®</sup> 3.0 Prone Breast Board is a modular system of which the cushions can be indexed onto all AIO 3.0 carbon fibre and fibreglass base plates or directly onto the simulation and treatment couch using the indexation cushion for use without base plate (ref. 38219). This allows the system being suitable for use in small bore CT and MRI scanners.



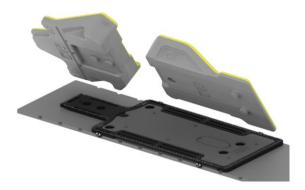
#### C. PRODUCT RANGE

Art. Description	
No.	
38110	AIO 3.0 – Prone Breast Board - Cranial
	Cushion
38111	AIO 3.0 – Prone Breast Board - Caudal
	Cushion
38112	AIO 3.0 – Prone Breast Board - Cranial
	Elevation Cushion
38113	AIO 3.0 – Prone Breast Board - Caudal
	Elevation Cushion
38114	AIO 3.0 – Prone Breast Board - Comfort
	Wedge for Contralateral Breast
38115	AIO 3.0 – Prone Breast Board - Bridge
	Plate for Contralateral Breast
38219	AIO 3.0 – Prone Breast Board –
	Indexation Cushion for use without Base
	Plate

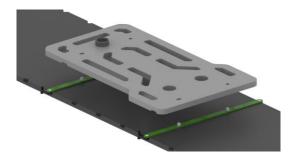
#### D. PRECAUTIONS FOR USE

The cushions can be used in combination with the AIO 3.0 carbon fibre and fibreglass base plates or they can be indexed directly onto the simulation and treatment couch.

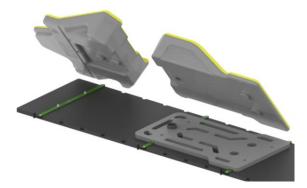
When the prone breast cushions are being used in combination with an AIO 3.0 base plate, always make sure that the base plate is fully supported by the simulation and treatment couch. The AIO 3.0 base plates cannot be used in overhang in combination with the AIO 3.0 prone breast cushions. Also, the 0° cushion (ref. 38101) should be in place on the AIO 3.0 base plates before positioning the AIO 3.0 prone breast cushions. The 0° cushion fits in the cut-out provided in the AIO 3.0 base plates. The cranial (ref. 38110) and caudal (ref. 38111) cushion can be indexed on the 0° cushion by fitting the knobs provided on the bottom side of the cushions, in the positioning holes provided in the 0° cushion and the AIO 3.0 base plates.



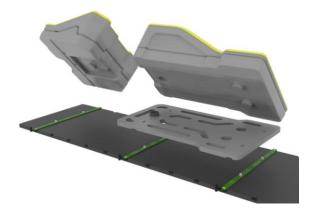
The cranial and caudal cushions can also be indexed directly onto the simulation and treatment couch without using an AIO 3.0 base plate. The cranial cushion is indexed by means of a 2-pin or 3pin indexing bar. The caudal cushion can be indexed by using the indexation cushion for use without base plate (ref. 38219). This indexation cushion will compensate for the height difference between the cranial and caudal cushion when used without AIO 3.0 baseplate. The indexation cushion for use without base plate can be indexed to the simulation or treatment couch by means of 2 2-pin or 3-pin indexing bars.



The indexation cushion has 2-holes and 1 knob to index the caudal cushion (ref. 38111).



For patients with large and pendulous breasts, the cranial and caudal elevation cushions (ref. 38112 & 38113) can be used. These cushions will increase the total height of the set. The cranial and caudal elevation cushions fit in exactly the same way on the AIO 3.0 base plates or directly onto the simulation or treatment couch as the standard cranial and caudal cushions (ref. 38110 & 38111).



The bridge plate for the contralateral breast (ref. 38115) is mounted in between the cranial and caudal (elevation) cushions. The bridge plate can be mounted as such for both left- and right-sided treatments. A soft comfort wedge for the contralateral breast (ref. 38114) is indexed on top of the bridge plate to support the contralateral breast in a comfortable way.



To position the head of the patient, an AIO 3.0 prone head support (ref. 38226) or comfort head rest (ref. 29051) can be used. The prone head support 38226 offers the opportunity to position the patient's head in a stable and reproducible way. The AIO 3.0 prone head support contains 2 round knobs on the bottom that fit into the round cut-outs provided in the cranial cushion (ref. 38110). There are 2 different positions to index the AIO 3.0 prone head support to the cranial cushion marked by numbers 1 and 2. The AIO 3.0 prone head support can be combined with blocks and wedges to ensure a comfortable position of the head. The comfort head rest (ref. 29051) is a soft head support in the form of a ring that allows for a comfortable positioning of the head in prone position or sideways. The comfort head rest is positioned on top of the cranial cushion (ref. 38110) and cannot be indexed.

The grey AIO 3.0 knee & leg immobilization cushions (ref. 38126, 38127 & 38128) and indexing frames (ref. 38204 or 38210) can be combined with the AIO 3.0 prone breast solution to support the ankles and lower legs of the patient in a comfortable way. More information on these other parts can be found in the respective 'instructions for use'.

More information on these other parts can be found in the respective 'instructions for use' and on <u>www.orfit.com</u>.

Maximum distributed patient load: 180 kg / 396 lbs.

Always verify that the cushions are correctly positioned on the base plates or the simulation and treatment couch.

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

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

Do not use tape on the cushions.

Applying marks on the cushions with ink or other substances are at your own risk.

<u>Note</u>: these cushions cannot be used on the  $1^{st}$  or  $2^{nd}$  generation AIO base plates.

A patient set-up form is available on the Orfit website.

## E. STORAGE

Always store the products in a safe place to prevent them from getting damaged or falling onto other objects. Do not put heavy objects on the cushions and prevent hard objects from falling onto them to prevent permanent deformations. Avoid pressure points on the cushions during storage as these can cause imprints in the cushions. The imprints will disappear overtime when the pressure is released. Store the system between +10°C (50°F) and 40°C (104°F).

#### F. PROPERTIES

38110: AIO 3.0 – Prone Breast Solution - Cranial Cushion

Physical properties:

Dimensions: L 580 mm x W 536 mm x H 171 mm L 22.83" x W 21.10" x H 6.73"

Weight: 1400 g

Density foam: 50 kg/m<sup>3</sup>



This product is made entirely of electrically nonconductive, non-metallic and non-magnetic materials and is MR safe.

#### Mechanical properties:

The AIO 3.0 cushions are made of a low density foam that is covered with a coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

#### Dosimetric properties:

The attenuation and skin build-up at 6 MV and 15 MV per cm of material:

Attenuation (± 0.15%)		Skin Build-	up (± 0.1 mm)
6 MV	15 MV	6 MV	15 MV
0.25%	0.15%	0.6 mm	0.6 mm

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

# 38111: AIO 3.0 – Prone Breast Solution - Caudal Cushion

Physical properties:

Dimensions: L 754 mm x W 467 mm x H 150 mm L 26.69" x W 18.39" x H 5.91"

Weight: 1600 g

Density foam: 50 kg/m<sup>3</sup>



This product is made entirely of electrically nonconductive, non-metallic and non-magnetic materials and is MR safe.

Mechanical properties:

The AIO 3.0 cushions are made of a low density foam that is covered with a coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

Dosimetric properties:

The attenuation and skin build-up at 6 MV and 15 MV per cm of material:

Attenuation (± 0.15%)		Skin Build-	up (± 0.1 mm)
6 MV	15 MV	6 MV	15 MV
0.25%	0.15%	0.6 mm	0.6 mm

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

# 38112: AIO 3.0 – Prone Breast Solution – Cranial Elevation Cushion

**Physical properties:** 

Dimensions: L 409 mm x W 511 mm x H 112 mm L 16.10" x W 20.12" x H 4.41"

Weight: 760 g

Density foam: 50 kg/m<sup>3</sup>



This product is made entirely of electrically nonconductive, non-metallic and non-magnetic materials and is MR safe.

Mechanical properties:

The AIO 3.0 cushions are made of a low density foam that is covered with a coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

#### Dosimetric properties:

The attenuation and skin build-up at 6 MV and 15 MV per cm of material:

Attenuation (± 0.15%)		Skin Build-up (± 0.1 mm)	
6 MV	15 MV	6 MV	15 MV
0.25%	0.15%	0.6 mm	0.6 mm

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

# 38113: AIO 3.0 – Prone Breast Solution – Caudal Elevation Cushion

# Physical properties:

Dimensions: L 740 mm x W 464 mm x H 78 mm L 29.13" x W 18.27" x H 3.07"

Weight: 1100 g

Density foam: 50 kg/m<sup>3</sup>



This product is made entirely of electrically nonconductive, non-metallic and non-magnetic materials and is MR safe.

Mechanical properties:

The AIO 3.0 cushions are made of a low density foam that is covered with a coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

# Dosimetric properties:

The attenuation and skin build-up at 6 MV and 15 MV per cm of material:

Attenuation (± 0.15%)		Skin Build-	up (± 0.1 mm)
6 MV	15 MV	6 MV	15 MV
0.25%	0.15%	0.6 mm	0.6 mm

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

## 38114: AIO 3.0 – Prone Breast Solution - Comfort Wedge for Contralateral Breast

Physical properties:

Dimensions: L 260 mm x W 210 mm x H 110 mm L 10.24" x W 8.27" x H 4.33"

Weight: 350 g

Density foam: 50 kg/m<sup>3</sup>



This product is made entirely of electrically nonconductive, non-metallic and non-magnetic materials and is MR safe.

Mechanical properties:

The AIO 3.0 cushions are made of a low density foam that is covered with a coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

### Dosimetric properties:

The attenuation and skin build-up at 6 MV and 15 MV per cm of material:

Attenuation (± 0.15%)		Skin Build-up (± 0.1 mm)	
6 MV	15 MV	6 MV	15 MV
0.25%	0.15%	0.6 mm	0.6 mm

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

# 38115: AIO 3.0 – Prone Breast Solution – Bridge Plate for Contralateral Wedge

Physical properties:

Dimensions: L 425 mm x W 336 mm x H 47.5 mm L 16.73" x W 13.23" x H 1.87"

Weight: 750 g



This product is made entirely of electrically nonconductive, non-metallic and non-magnetic materials and is MR safe.

# Mechanical properties:

This AIO 3.0 cushion is made of a low density foam reinforced with a fibreglass insert, covered with a coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

# 38219: AIO 3.0 – Prone Breast Solution – Indexation Cushion for use without Base Plate

Physical properties:

Dimensions: L 740 mm x W 465 mm x H 39 mm L 29.13" x W 18.31" x H 1.54"

Weight: 500 g



This product is made entirely of electrically nonconductive, non-metallic and non-magnetic materials and is MR safe.

Mechanical properties:

This product is made of a low density foam that is stable and that keeps its dimensions overtime and under conditions of frequent use.

### G. 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. Do not soak the products.** Further cleaning instructions can be found in the <u>Orfit Cleaning Guidelines</u>.

The AIO 3.0 cushions are made of a closed-cell foam and will not absorb any cleaning agent. 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.

H. ADDITIONAL INFORMATION

For additional information such as distributor contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website <u>www.orfit.com</u>

Note:

It is prohibited to make alterations to this text without prior approval from Orfit Industries. THE AIO SOLUTION\* is a registered trademark of Orfit Industries.

CE

ORFIT INDUSTRIES Vosveld 9A | B-2110 Wijnegem | Belgium T (+32) (0)3 326 20 26 welcome@orfit.com



Ref. No. 50280 VERSION 3 LAST UPDATE: 06/03/2024 REVISION DATE: 06/03/2026