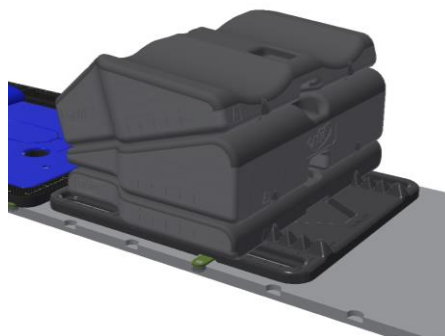


THE AIO SOLUTION® 3.0 KNEE & FEET IMMOBILISATION



Article Nos. :

38126	38204	38210
38127	38205	
38128	38206	

A. GENERAL PRODUCT INFORMATION

These products are medical devices used for patient positioning and immobilisation in radiation therapy. The products can be used during both the simulation and treatment stage, including MRI simulation. These products are also compatible with the Varian Halcyon™ and Ethos™ Radiotherapy systems.

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

B. PRODUCT DESCRIPTION

The AIO Solution® 3.0 Knee & Feet Immobilisation is used to support the knees and feet or ankles in respectively supine and prone position to from a reproducible patient positioning and immobilisation system. The system includes a set of knee and leg positioning cushions, an indexable foot support and 2 extension indexing frames. The system can be used in combination with other AIO 3.0 products. Information on these other parts can be found in the respective 'instructions for use' and on www.orfit.com.

The AIO solution® 3.0 Knee & Leg immobilisation is a modular system of which the cushions can be indexed directly onto the simulation and treatment couch or onto an extension indexing frame.

C. PRODUCT RANGE

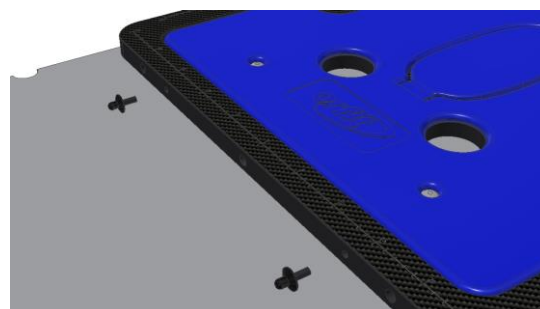
Art. No.	Description
38126	AIO 3.0 – Knee & leg immobilisation cushion - Top
38127	AIO 3.0 – Knee & leg immobilisation cushion – Wedge
38128	AIO 3.0 – Knee & leg immobilisation cushion – Elevation

38206	AIO 3.0 – Indexable foot support
38204	AIO 3.0 – Short extension frame for knee and foot support
38210	AIO 3.0 – Long extension frame for knee and foot support
38205	AIO 3.0 – Knob for short and long extension frame

D. PRECAUTIONS FOR USE

D.1. Set-up with AIO 3.0 base plates

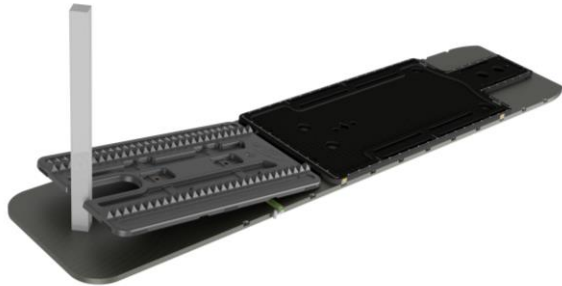
The extension frames for knee and foot support (38204 & 38210) that hold the knee & leg immobilisation cushions and the indexable foot support (38206), can be attached to any of the AIO 3.0 base plates by means of indexing knobs 38205. The indexing knobs are screwed on the caudal end of the base plate.



The extension frames for knee and foot support will drop over the knobs and is at the same time indexed on a 2-pin or 3-pin indexing bar. The extension frames can also be indexed on a 2-pin or 3-pin indexing bar only, without the use of the knobs. The short extension frame can be indexed using 1 2-pin indexing bar while the long extension frame requires 2 pieces of a 2-pin indexing bar.



Both the short and long extension frames can be used in combination with the Varian Halcyon™ and Ethos™ Radiotherapy systems. The long extension frame features a cut-out at the caudal end that can be positioned around the camera pole on the Varian Halcyon™ and Ethos™ Radiotherapy system couch. Ensure that the frame is not overhanging the couch cranially, caudally nor laterally.



All knee & leg immobilisation cushions have notches at the bottom. These notches drop over the triangular knobs provided on the extension plates and the indexing ribs provided on the wedge (38127) and elevation (38128) cushion. We recommend to use the elevation first and then index the wedge on top of the elevation cushion.



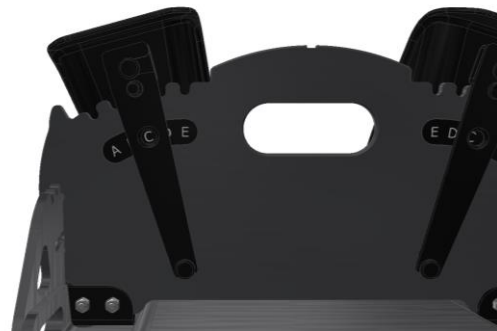
The AIO 3.0 foot support also has notches at the bottom that drop over the triangular knobs provided on the extension frames for knee and foot support. It's recommended to use the long extension frame (38210) when the AIO 3.0 foot support is used to make sure both the knee & leg positioning cushions and foot support fit on the frame.

The foot support can be tilted at three different angles. To tilt the device, the foot support should be lifted by the handle in the middle and dropped in the desired position (1, 2 or 3). The position can be read at each side of the indexable foot support. Always verify that the indexable foot support is correctly locked by verifying if the marking colour

is green. It will appear red when the indexable foot support is not properly locked.



The foot support cups can also be rotated at five different angles. To rotate the foot support cups, each cup should be lifted and dropped in the desired position (A, B, C, D or E). The position can be read at the caudal end of the foot support. Always verify that the foot support cups are correctly locked.



If necessary, the foot support cups can be removed from the indexable foot support by removing the latch at the back of the foot support.

The foot support serves as a reference point for the feet of the patient. Make sure no pressure is applied on the foot support when repositioning a patient as this will lead to a damaged foot support and/or extension frame.

Always verify that the knee & leg cushions and indexable foot support are correctly positioned on the other cushions or the extension indexing frame. Make sure to write down for each patient which combination of cushions is used and the position on the frame. The position on the frame is indicated by numbers on one side of the frame.

D.2. Set-up without AIO 3.0 base plate

All knee & leg immobilisation cushions have holes that accept a 2-pin or 3-pin indexing bar and as such can be indexed directly onto the simulation or treatment couch.



Always verify that the cushions are correctly positioned on the other cushions or the indexing bar. Make sure to write down for each patient which combination of cushions is used and the position on the indexing bar. The cushion can be indexed at 5 different positions.

The indexable foot support is not 2-pin or 3-pin bar compatible and can only be used with one of the extension frames for knee and foot support.

The extension frames for knee and foot support can also be used as a standalone product to index the knee & leg cushions and indexable foot support without the use of an AIO 3.0 base plate. In this case the extension frame is indexed on the couch by means of a 2-pin or 3-pin indexing bar.

The knee & leg immobilisation cushions and the indexable foot support can be combined with the other AIO 3.0 immobilisation sets to create a comfortable and reproducible position of the patient. More information on these other sets can be found in the respective 'instructions for use'.

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.

Note: these cushions cannot be used in combination with the 1st or 2nd 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 it 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 accessories in such a way that they cannot fall or bump against anything.

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

F. PROPERTIES

38126: AIO 3.0 – Knee & leg immobilisation cushion - Top

Physical properties:

Dimensions: L 400 mm x W 540 mm x H 155 mm
L 15.75" x W 21.26" x H 6.10"

Weight: 760 g

Density foam: 50 kg/m³



This product is made entirely of electrically non-conductive, 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.

38127: AIO 3.0 – Knee & leg immobilisation cushion - Wedge

Physical properties:

Dimensions: L 400 mm x W 540 mm x H 163 mm

L 15.75" x W 21.26" x H 6.42"

Weight: 750 g

Density foam: 50 kg/m³



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

Mechanical properties:

The AIO 3.0 cushions are made of low a 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 same dosimetric properties apply as cushion 38126, see above.

38128: AIO 3.0 – Knee & leg immobilisation cushion - Elevation

Physical properties:

Dimensions: L 400 mm x W 540 mm x H 83 mm

L 15.75" x W 21.26" x H 3.27"

Weight: 370 g

Density foam: 50 kg/m³



This product is made entirely of electrically non-conductive, 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 same dosimetric properties apply as cushion 38126, see above.

38206: AIO 3.0 – Indexable foot support

Physical properties:

Dimensions: 507.5 mm x 245 mm x 445 mm

19.98" x 9.65" x 17.52"

Weight: 3.5 kg



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

Mechanical properties:

The AIO 3.0 indexable foot support is made of a material which keeps its dimensions overtime and under conditions of frequent use.

Dosimetric properties:

This product is not intended to treat through. The product is not located in the treatment area.

38204: AIO 3.0 – Short extension frame for knee and foot support

Physical properties:

Dimensions: 550 mm x 485 mm x 43.5 mm

21.65" x 19.1" x 1.71"

Weight: 275 g



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

Mechanical properties:

The AIO 3.0 short extension frame for knee and foot support is made of a material which keeps its dimensions overtime and under conditions of frequent use.

Dosimetric properties:

This product is not intended to treat through. The product is not located in the treatment area.

38210: AIO 3.0 – Long extension frame for knee and foot support

Physical properties:

Dimensions: 812 mm x 485 mm x 43.5 mm

31.97" x 19.1" x 1.71"

Weight: 1080 g



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

Mechanical properties:

The AIO 3.0 long extension frame for knee and foot support is made of a material which keeps its dimensions overtime and under conditions of frequent use.

Dosimetric properties:

This product is not intended to treat through. The product is not located in the treatment area.

38205: AIO 3.0 – Knob for short and long extension frame

Physical properties:

Dimensions: 27.5 mm x 18 mm x 18 mm
1.08" x 0.71" x 0.71"

Weight: 10 g



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

Mechanical properties:

The AIO 3.0 knob for short and long extension frame is made of a composite material which keeps its dimensions overtime and under conditions of frequent use.

Dosimetric properties:

This product is not intended to treat through. The product is not located in the treatment area.

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 [Orfit Cleaning Guidelines](#).

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. The product 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 www.orfit.com.

Note:

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