

MAMMORX® - new design CARBON FIBRE BREAST BOARD SOLUTION BUNDELS

Article Nos.: **CFB-001/EU** **CFB-003/EU**
CFB-004/EU **CFB-005/EU**
CFB-006/EU



A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation (Breast) in radiation therapy. This low density plate can be used during both the simulation and the treatment stage.

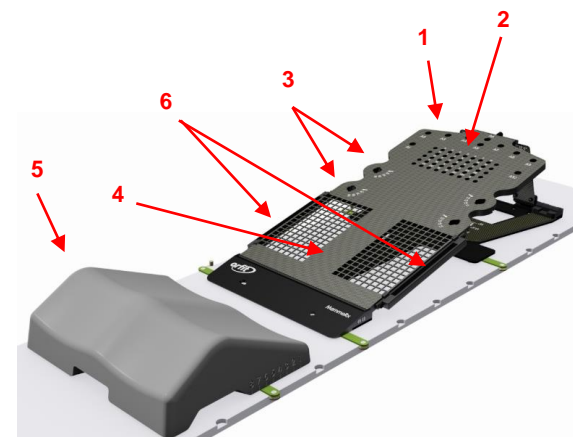
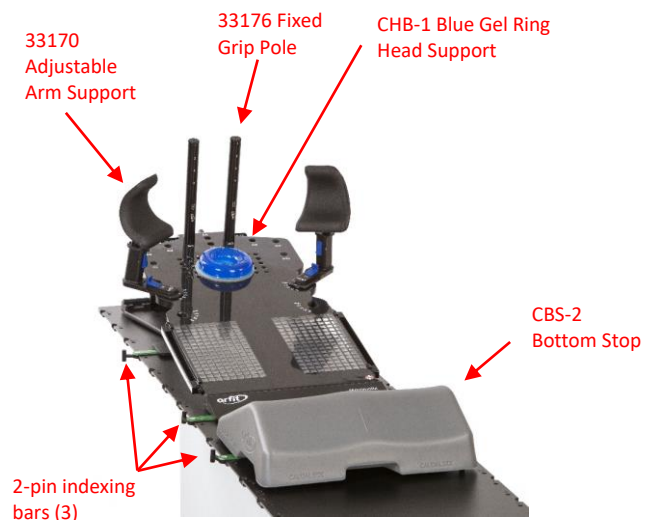
This product may only be used in combination with immobilisation masks produced by Orfit. Orfit prohibits the use of unauthorized third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

The MammoRx Breast Board with accessories provides the immobilisation and positioning system necessary to accurately set up and reproduce a breast patient's position for simulation and treatment. The board is crafted from a core of high strength foam covered with a thin skin of carbon fibre. This makes it light weight, strong and radiographically transparent. There are several options to support the head, arms, hands and wrists. The board can be elevated in different angles from 0° to 22.5°. For increased precision the set-up can be combined with an Orfit thermoplastic EFFICAST mask. Information on these other parts and instructions on how to make the masks can be found in the respective 'instructions for use' and on www.orfit.com.

Indications for Use: The MammoRx Breast Board is a positioning and immobilisation system to set-up and reproduce the supine position of a breast patient during radiation therapy.

The following pictures illustrate how the accessories can be combined with the MammoRx Breast Board.

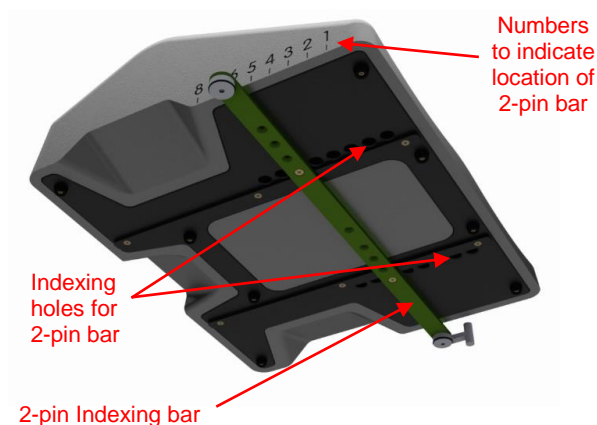


1. 10 wrist support indexing holes
2. Head position indexing holes
3. Upper arm support indexing holes and locking slots(both sides)
4. Tilt board
5. Bottom stop cushion with 8 indexing positions (on 2-pin bridge bar)
6. Slots for fixation of thermoplastic mask

The breast board is fixed to the couch top by means of 2 two-pin indexing bars. Then the appropriate angle for the patient is chosen. The tilt board is mounted in a 5°, 7.5°, 10°, 12.5°, 15°, 17.5°, 20° or 22.5° angle by inserting the angle support ladder into the slot. Make sure the board is secured by checking if the plunger is locked into the angle support ladder.



The bottom stop can be indexed on a separate 2-pin bar in 8 positions. To change the position of the bottom stop cushion, lift the cushion by using the handgrips and move the cushion forwards or backwards. Choose a comfortable position for the patient and one that stops the patient from sliding down the board.



The upper arm support can be inserted into the lower or upper hole by pulling the red trigger and placing it in the highest position. Then rotate it downwards to the desired position. The upper part of the board has 10 indexing holes to put hand or wrist supports in place. The head support can be placed directly onto the baseplate or by using an adapter plate (for Orfit HP, Timo and Silverman head supports). Information on the MammoRx Breast Board Accessories can be found in the respective 'instructions for use' and on www.orfit.com.

All the indexing holes are marked with a letter or number to reposition the bottom stop, head support, arm support and hand or wrist supports in the same place for simulation and treatment.

Positioning note: position the patient as low as possible on the MammoRx Breast Board to avoid treating through high density areas located around the arm support indexing holes.

After the patient is in the correct position on the board and her arms are raised, a 2 points thermoplastic EFFICAST mask with L-shaped profiles can be moulded to immobilise the chest of the patient. Information on how to make the masks can be found in the respective 'instructions for use' and on www.orfit.com.

C. PRECAUTIONS FOR USE

This is a fragile product, please handle with care. Always place the breast board on a flat surface and make sure that it is fully supported by the treatment table. Clear the treatment table on any debris before positioning the breast board.

Always fix the breast board securely to the treatment table before positioning a patient. More information on how to fix this breast board to a couch top can be found on our website <http://www.orfit.com/en/fixation-devices/>.

Make sure the angle support ladder is positioned properly in the slot and the plunger is locked into the angle support ladder safely before positioning a patient. Watch out when moving the angle support ladder as moving parts can crush or cut.

Warning: Do not apply point loads on the grid structure when positioning a patient.

This breast board is constructed to be light in weight and to have superb dosimetric properties. When handled roughly, it may get damaged and fibres may come off. When this happens, stop using the breast board to prevent fibres from getting in contact with the patient's or user's skin. Periodic checks of the products should be done to insure the parts are not worn and require repair or replacement. **Do not attempt to make repairs yourself**, but contact your distributor if there are any questions or concerns. Always check the product before the first use to detect any damages.

A millimetre scale is attached to both sides of the breast board. Deviations between breast boards may occur. Verify accuracy of the scales with the in-room lasers before using them as a reference mark.

A patient set-up form is available on the Orfit website:
<https://www.orfit.com/app/uploads/MammoRx-Redesign.pdf>.

D. STORAGE

Always store the product in a safe place to prevent it from getting damaged or falling onto other objects. Take care not to damage the edges of the board when storing it in an upright position. Prevent hard objects from falling onto the board.

Store the breast board between +10°C (50°F) and 30°C (86°F).

E. PROPERTIES

E.1. Physical Properties

Board:

Dimensions: L 100.1 cm x W 43.1 cm x H 3.6cm
 L 39.4" x W 16.9" x H 1.4"

Weight: 5.75 kg
 12.68 lbs

Materials: Carbon fibre, low density foam, RENY, phenolic, polyurethane, glass fibre reinforced polyamide

There are no metal components in CT scan areas.



The board is labelled 'Not MR Safe' due to the used metallic and carbon fibre materials.

Bottom stop cushion:

Dimensions: L 40 cm x 49 W cm x H 15.3 cm
 L 15.7" x W 19.3" x H 6"

Weight: 1.53 kg
 3.37 lbs

Material: EVA foam with PE skin.

This product is labelled as 'MR safe'.



The following images show the breast board in a 700mm and 800mm bore. When placed in a 700mm bore the highest angle that can be used is 10° with the height of the arm supports at position 2. In a 800mm bore the highest angle that can be used is 20° with the height of the arm supports at position 5.



MammoRx Breast Board at 10° in a 700mm bore. Height arm supports: position 2



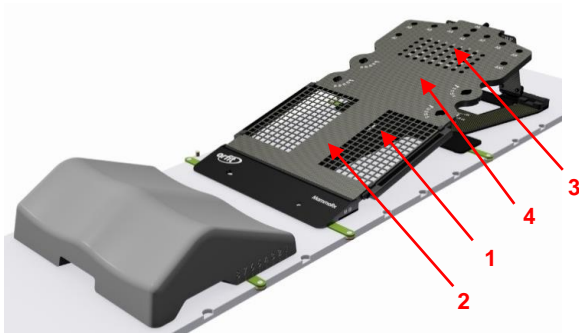
MammoRx Breast Board at 20° in a 800mm bore. Height arm supports: position 5

E.2. Mechanical Properties

The maximum patient weight is 158 kg/348 lbs. This was tested with the breast board tilted at 22.5°.

E.3. Dosimetric Properties

Position	Attenuation (± 0.15 %)	Skin build-up (± 0.1 mm)
	6 MV	mm H ₂ O equiv. (15MV)
1 (grid)	0.4 %	1.6 mm
2 (centre spine)	5.25 %	14.5 mm
3 (head rest indexing)	6.17 %	17.4 mm
4 (centre of board)	5.21 %	14.5 mm



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

F. UNPACKING AND INSTALLATION

The MammoRx Breast Board is designed to be ready for use following removal from their packing container.

When you receive your breast board, inspect all shipping containers for evidence of physical damage. If there are any dents, scratches, or other evidence of physical damage to the boxes, note the damage on the shipper's copy of the bill of lading and file a claim against the shipper.

In the case of shortages or malfunctions, notify your distributor immediately to arrange for replacement or repair. Save all packing containers and materials for the MammoRx Breast Board in case it needs to be returned to Orfit Industries for replacement or repair.

If you will be using thermoplastic masks in combination with the breast board, the slots to attach the mask in will need to be attached to the

breast board. Two screws are provided with each slot to attach the slot to the side of the breast board. The lowest number of the millimetre scale should be facing cranial.

G. MAINTENANCE AND WASTE MANAGEMENT

An adhesive backed Mylar grid cover may require replacement after a period of use. The Mylar may be removed by pulling it from the grid. A replacement grid cover may be made from locally obtained adhesive backed clear Mylar (H10285) or ordered from Orfit Industries or your distributor.

Periodic checks of the entire 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.

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.**

Be careful when cleaning the millimetre scale on the breast board. Aggressive cleaning products might remove the scale. Only use water and soap.

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:

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. MAMMORX® and EFFICAST® are registered trademarks of ORFIT INDUSTRIES N.V.



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