

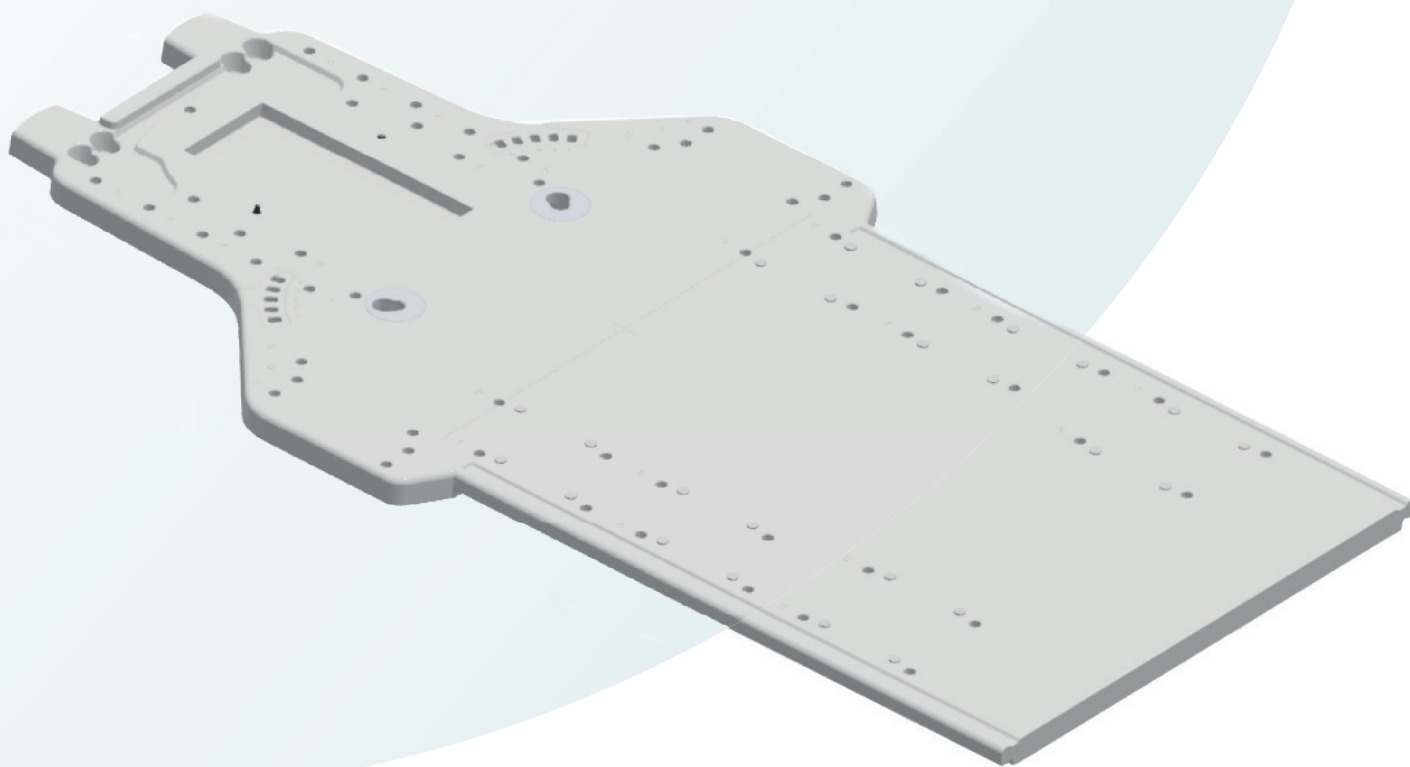


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SOLUTIONS IN RADIOTHERAPY

MANUAL 175170
Instructions for use
English Instructions

MacroMedics® OmniBoard™ MR



MacroMedics BV

Oostbaan 670
2841ML Moordrecht
The Netherlands
+31(0)182 389 777

info@macromedics.com
www.macromedics.com

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1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or if missing parts.
- Check individual components on MR-safety when used together in a patient positioning system.
- Do not use MR unsafe items in an MR environment.
- Prevent the surface from damage and scratching.
- Take extra care when securing the baseplate to the couch to not damage the products.
- Ensure that the baseplate is correctly secured to the couch prior to use.
- Do not exceed an equally distributed load of 200 kg on the baseplate.
- If the cranial end of the board is extended past the couch, do not exceed a load of 15 kg in this area.
- Place the patient carefully on the device and make sure that they lie down calmly. Instruct the patient not to reposition themselves after set-up
- Rulers used on the devices are only intended for reference of the device positioning of the accessories. Rulers shall not replace patient position verification.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. MRI Safety Information

MR SAFE

The following devices are MR safe:

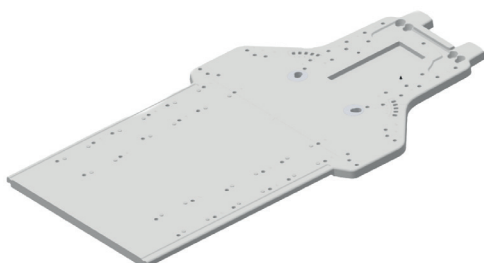
- 126860 OmniBoard™ H&N EXF MR
- 174620 OmniBoard™ H&N RE MR
- 175080 OmniBoard™ H&N S-Type MR
- 175090 OmniBoard™ MR Lower base
- 175170 OmniBoard™ S-Type P FS MR
- 175180 OmniBoard™ S-Type HN P FS MR
- 175910 OmniBoard™ 2.0 caudal MR



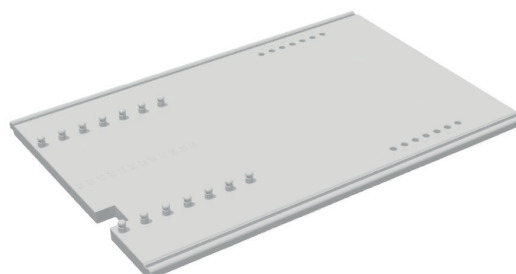
3. Intended Use

Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

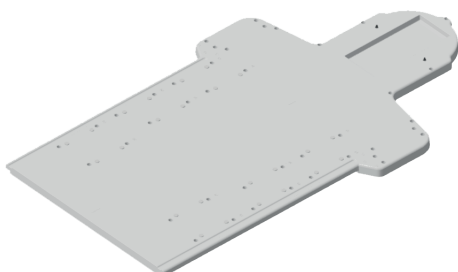
4. Types of OmniBoards MR



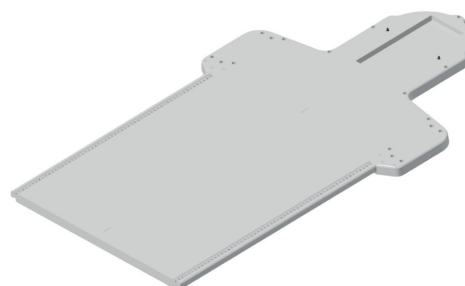
175170 – OmniBoard S-Type Pediatric MR



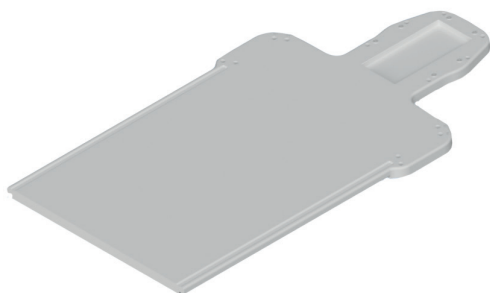
175090 – OmniBoard MR Lower Extremities



175180 – OmniBoard S-Type H&N Pediatric MR



175080 – OmniBoard S-Type H&N base GF



174620 – OmniBoard™ H&N RE MR



126860 – OmniBoard™ H&N EXF MR

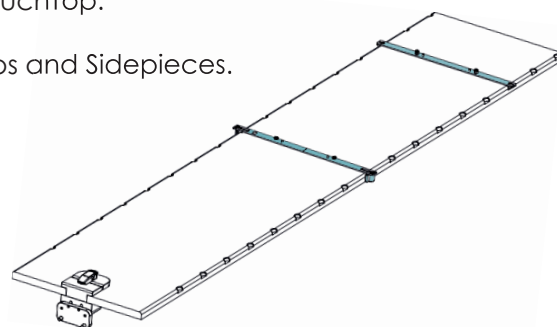


175910 OmniBoard™ 2.0 caudal MR

5. Installation Instructions - OmniBoard MR

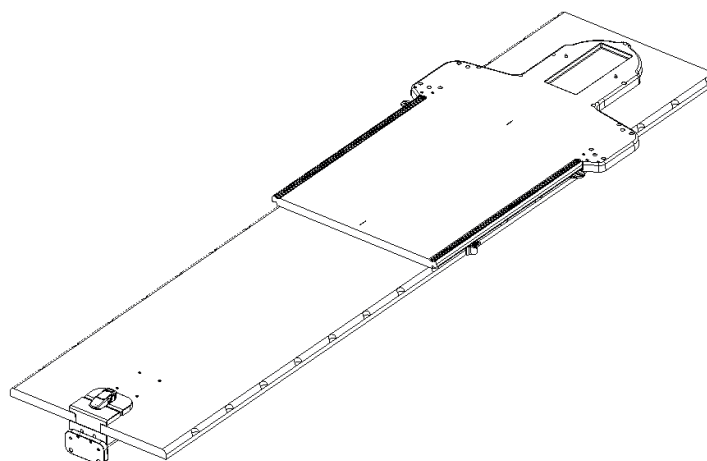
5.1 PLACE THE COUCHSTRIPS

Place indexing CouchStrip at the cranial end of the CouchTop.
Place a sliding CouchStrip on caudal end of the CouchTop.
Fasten properly without play.
For more information, refer to IFU147100 - CouchStrips and Sidepieces.



5.2 PLACE THE OMNIBOARD

Place the OmniBoard onto the CouchStrips. Make sure that no movement is possible between the baseplate and the CouchTop.



5.3 PLACE THE ACCESSORIES

Place accessories when desired. Use the instructions for use for the individual devices for a proper set-up of the patient.

5.4 POSITION THE PATIENT

Place the patient carefully on the baseplate. Use the instructions for use for the individual accessories for a proper set-up of the patient.

6. Cleaning, Storage and Disposal

- Clean the device before and after every use with 70% Isopropanol or soapy water, applied with a soft cloth. Rinse with water and dry properly. Follow the cleaning precautions provided by the manufacturer of the cleaning agent.
- If unsure about the cleaning fluid, do not use it. Never use Ethanol (Ethyl alcohol), aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.
- Make sure that there is no residue of the cleaning agent left on the device prior to use.
- The devices are not suitable for sterilization or thermal disinfection.
- Store the device in a clean, ventilated environment.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

7. Warranty

The MacroMedics products are warranted to be free from defects in manufacturing, material and construction. The warranty is for 1 year starting from the date of delivery.








Product warranties remain valid provided the product was installed and/or used according to the instructions. Defects, malfunctions or failures caused by nature, misuse, abuse and unauthorised alteration or repair are not warranted.

This warranty is limited to the repair and/or replacement at the sole discretion of MacroMedics.

8. Notices

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is established.

9. Glossary of Symbols

Symbol	Symbol Name	Description of Symbol
	European Conformity	EC declaration of conformity by manufacturer.
	Manufacturer	Indicates the medical device manufacturer.
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
 GS1 Code: (21)	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Consult Instruction for Use	Indicates the need for the user to consult the instructions for use.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
Rx ONLY	Prescription Only	Devices for sale to physicians or trained healthcare providers only.
	MR Safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.



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