



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 122500
Instructions for use
English Instructions

MacroMedics® BreastBoards & ThoraxSupports



MacroMedics BV

Oostbaan 670
2841ML Moordrecht
The Netherlands
+31 (0) 182-389777

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 incomplete.
- 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.
- Secure the device properly before positioning the patient.
- The device shall not extend from the cranial side of the couch.
- Do not exceed the allowable maximum patient weight of 150 kilograms.
- Rulers on the devices are only intended for reference of the device positioning of accessories. Rulers shall not replace patient position verification.
- Instruct the patient to lay down calmly and not to reposition themselves after set-up.
- Prevent the formation of closed-loops as they can lead to MRI burns.
Use an isolator between the patient's arms to avoid skin-to-skin contact.
- When used for proton treatment, ensure that the devices are not in the incoming radiation-treatment-beam pathway.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.



2. MRI Safety Information

2.1 MR UNSAFE



- | | |
|---|---|
| • 122100 ThoraxSupport™ | • 122590 BottomStop Adaption |
| • 122300 Upper AS TS/MBLX, set/2 | • 126140 OmniBoard™ BTM-SX-EX |
| • 122320 Rotatable armrest LV, set/2 | • 126160 OmniBoard™ bottomstop |
| • 122330 Cranial AS for BBLX/TS, set/2 | • 172400 BreastBoardSX™, RAS |
| • 122380 Profiles LB1, set/10 | • 172410 BreastBoard SX™ |
| • 122390 Profiles LB1, set/2 | • 172420 Profiles BreastBoardSX™, set/2 |
| • 122520 WedgeThoraxSupport™ | • 172450 BreastBoardSX™, HAS |
| • 122540 HighBridgeSupp. TS/MBLX | • 172110 FlexBoard™ base |
| • 122610 ThoraxSupport™ complete | • 172120 FlexBoard™ BTM-EX |
| • 122650 ThoraxSupport™ short | • 172130 OmniBoard™ BTM-EX |
| • 122670 90D ArmSupports TS | • 173600 OmniBoard™ BTM-LX |
| • 122730 Handpole MBLX-LB1 | • 173660 FlexBoard™ BTM-LX |
| • 122760 Handpoles with armcup | • 174540 OmniBoard™ BTM-SX-RE |
| • 122350 Profiles BreastBoardLX™ set/10 | • 174630 FlexBoard™ BTM-SX |
| • 122360 Profiles BreastBoardLX™, set/2 | • 175010 OmniBoard™ BTM-SX-S |
| • 122500 BreastBoardLX™ | |

2.2 MR CONDITIONAL



- | | |
|--|--------------------------------------|
| • 122150 ThoraxSupport™, MRC | • 122740 Armcup for handpoles, set/2 |
| • 122310 Upper AS TS/MBLX, MRC, set/2 | • 122750 BreastBoard LX™, MRC |
| • 122340 Cranial AS for BBLX/TS MRC, set/2 | • 126190 OmniBoard™ bottomstop MRC |
| • 122660 ThoraxSupport™, short MRC | • 174590 OmniBoard™ BTM-SX-RE, MRC |
| • 122710 Rotatable AS LV MRC, set/2 | • 175060 OmniBoard™ BTM-SX-S, MRC |

The devices labelled as MR Conditional can be safely used in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, **with**
- Maximum spatial field gradient of 2,500 G/cm (25 T/m)
- Maximum force product of 50,000,000 G²/cm (50 T²/m)

Due to size and location of the metallic parts, no clinically significant RF heating is expected. It is the responsibility of the user to ensure that these conditions are met.

2.3 MR SAFE

- 122530 WedgeThoraxSupport™, MR



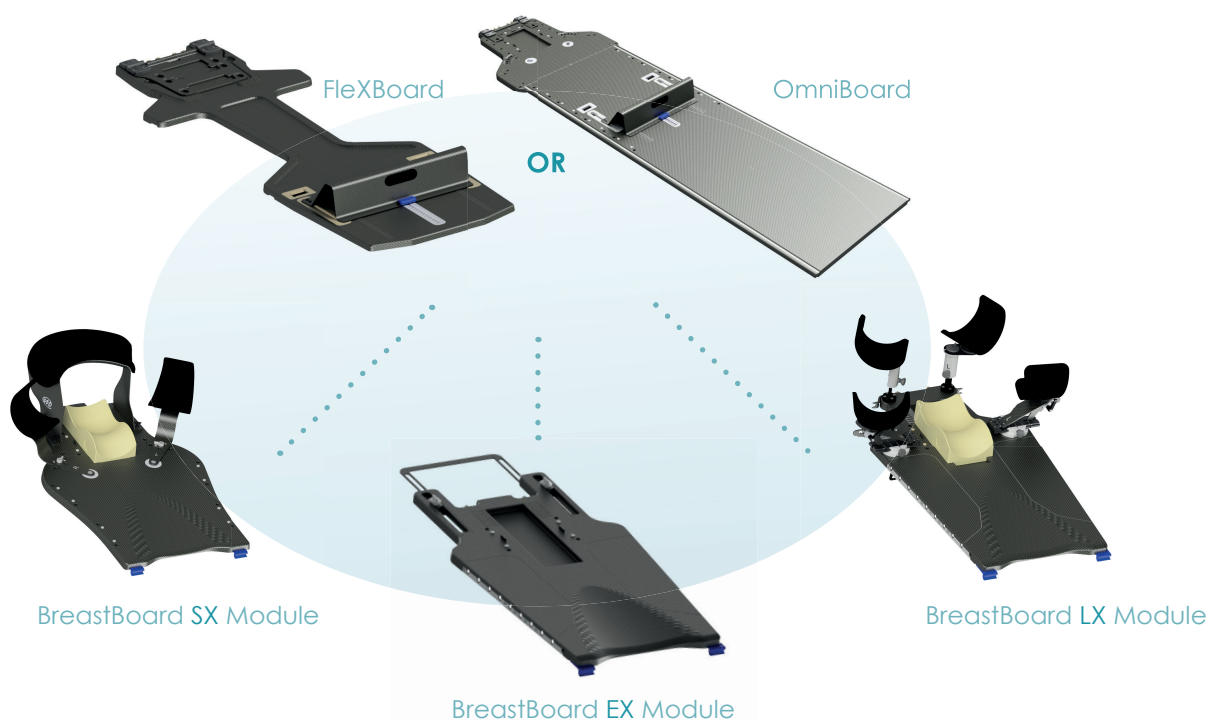
3. Intended Use and Indications for Use

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

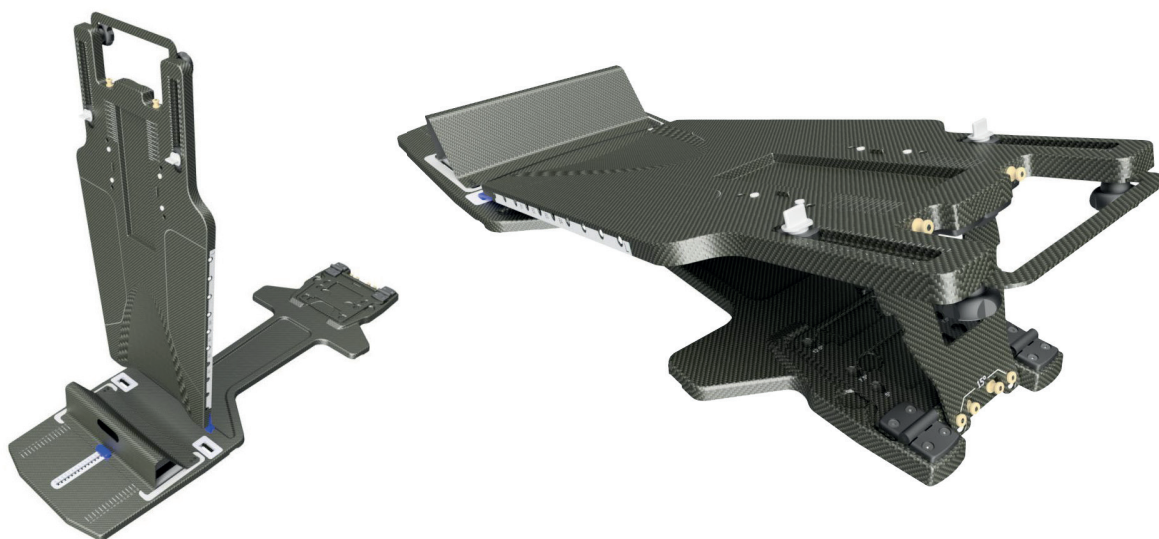
Indications for Use: To aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The devices are also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) imaging systems.

4. Installation Instructions

- I. Instructions for placing the **BreastBoard SX Module**, **BreastBoard LX Module** & **BreastBoard EX Module** on an **OmniBoard** or **FlexBoard**:



Lift the BreastBoard Module and position it vertically above the predestined board. Align the hinge plates at the caudal end of the BreastBoard Module with the slots in the predestined board and slide the BreastBoard in the slots. Carefully lower the Cranial end of the BreastBoard towards the OmniBoard/FlexBoard and the BreastBoard will lock itself. Fix the BreastBoard at an angle using the Angled plates.



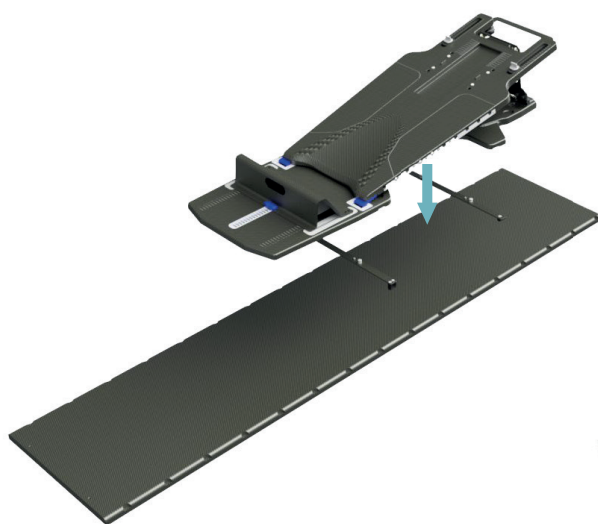
The images above show the attachment of the BreastBoard EX to the FlexBoard. The procedure is the same for attaching the BreastBoard Modules to the OmniBoard.

II. Instructions for placing the **FleXBoard with BreastBoard Module SX, LX & EX**, the **BreastBoard SX & LX** and the **ThoraxSupport** on a **CouchTop**:

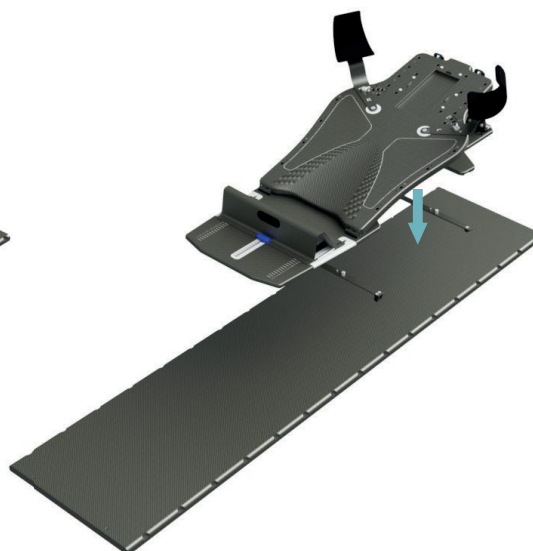
Place the correct Couchstrips on the Couch in indexed positions. Fasten the CouchStrip and make sure that no movement is possible between the CouchStrip and the couch. For more information, refer to IFU147100 - CouchStrips and Sidepieces. The CouchStrips can be screwed onto the baseplate for convenience. (For the usage in a MR environment, use the glass fiber, MR-Safe 3-Pin CouchStrip).

Position the BreastBoard or ThoraxSupport above the Couchtop, align the slots at the bottom of the module with the CouchStrips and carefully place it on the Couchtop.

BreastBoard EX on FleXBoard



BreastBoard SX



BreastBoard LX



ThoraxSupport

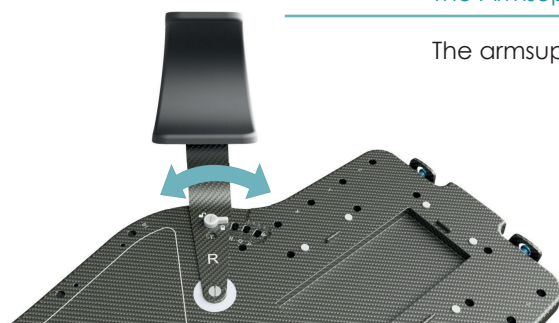


III. Adjusting the components of the BreastBoards & ThoraxSupports

Adjust the components of the BreastBoards and ThoraxSupports for accurate patient positioning and record the positions in the corresponding Set-Up sheet.

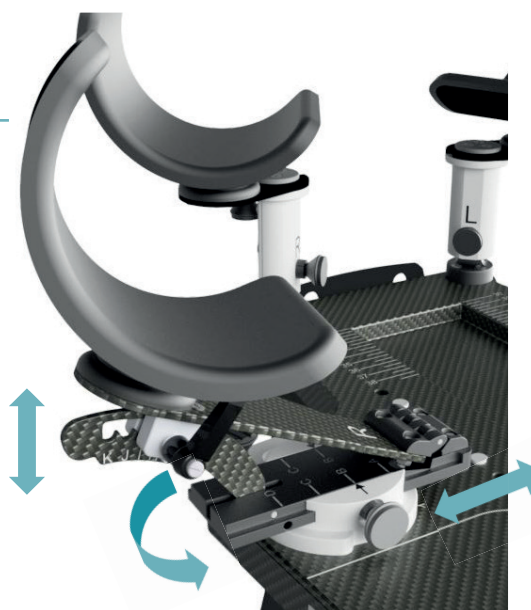
The Armsupports

The armsupports can be adjusted in one direction.



The Upper Armsupports

The upper arm supports can be adjusted in three directions with pushpins.



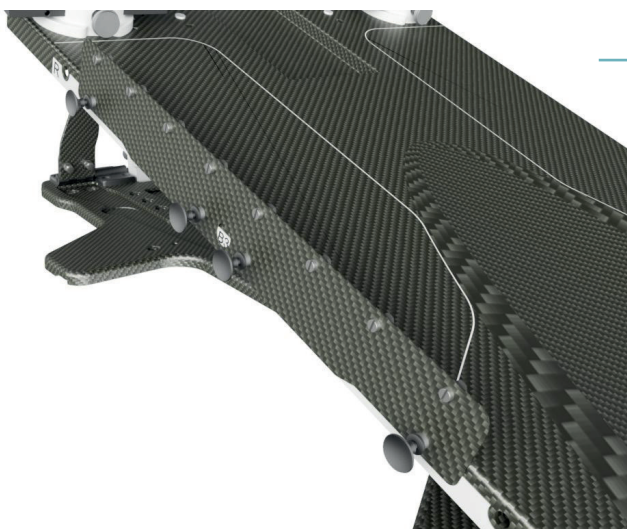
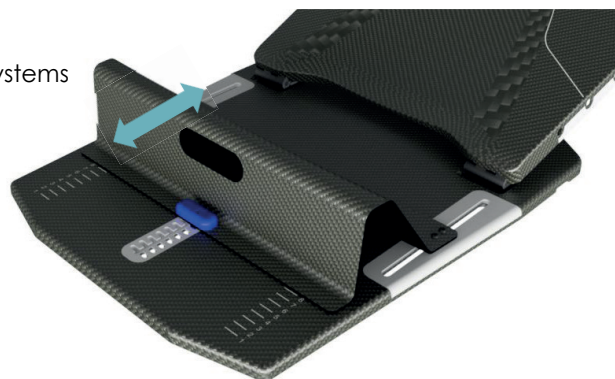
The Cranial Armsupports

The Cranial Arm Supports can be adjusted in two directions.

The BottomStop

Lift the bottomstop on the grip aperture, slide into the desired position and lower into the middle strip.

For the installation instructions of the BottomStop Sliding (174230), please refer to IFU123100 - SBRT Systems

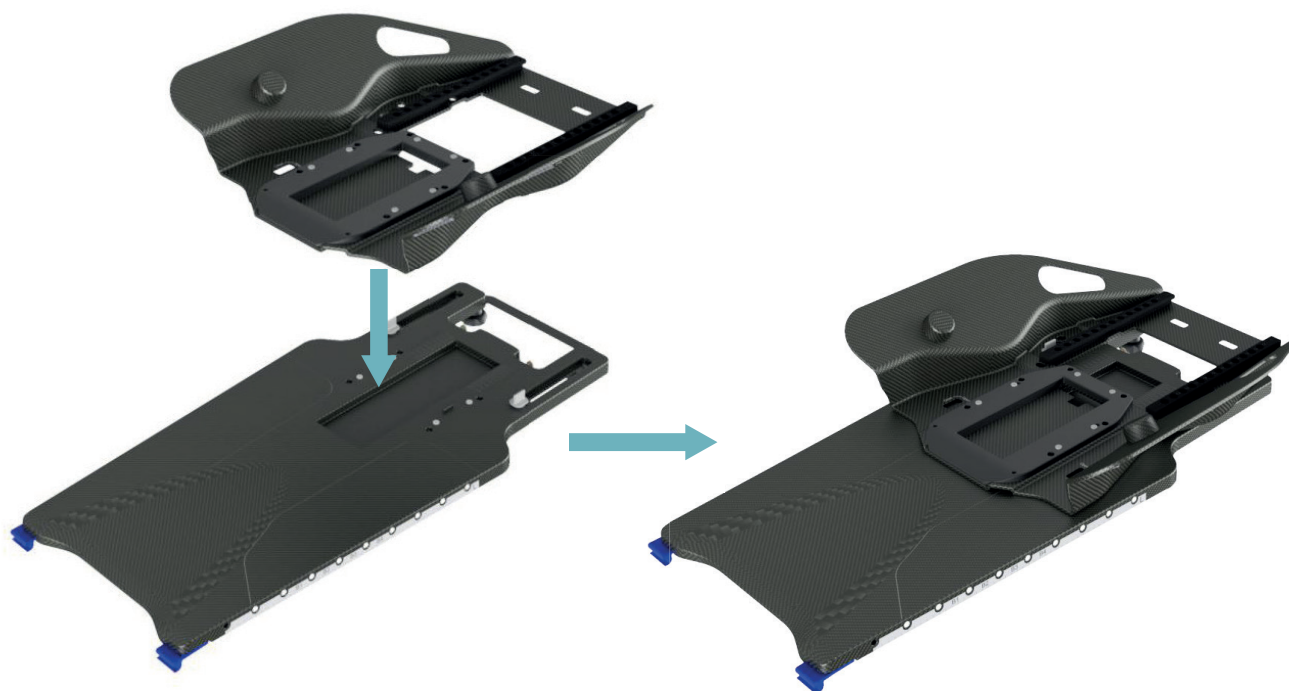


Carbon Fiber L-Profiles

Place the carbon fiber profiles for the Breast Mask in the desired position on the sides of the BreastBoard and lock them with Quickfasteners. Refer to the *Thermoplastic Masks IFU117000* for instructions on profile assembly and Mask heating.

IV. Installation of the EagleBoard 2 on the BreastBoard EX

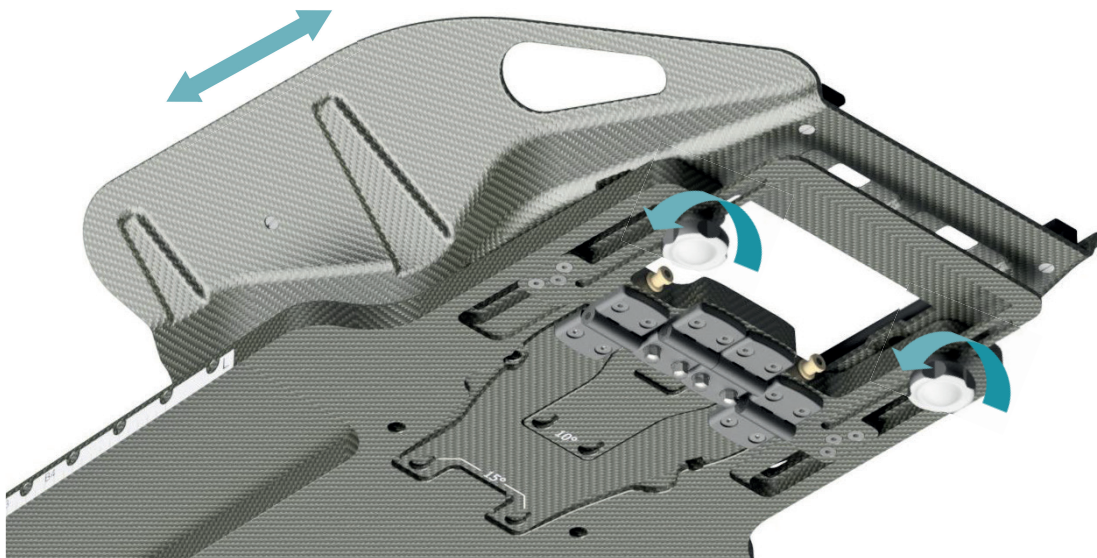
Position the EagleBoard 2 above the BreastBoard EX, align its holes at the bottom with the knobs on the BreastBoard EX and place it carefully on the BreastBoard.



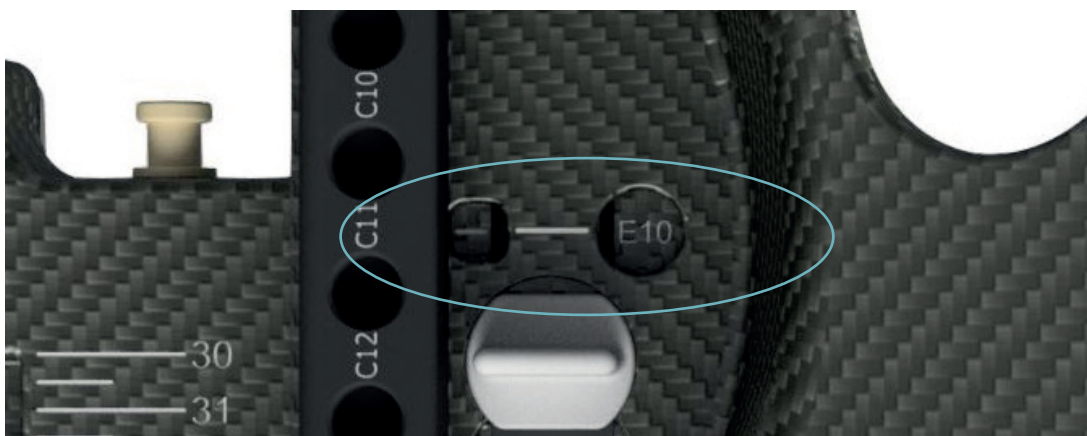
Slide the EagleBoard 2 towards the caudal side and lock it by turning the lock knobs counterclockwise. Turn the lock knobs back in clockwise direction to loosen.



For adjustment of the EagleBoard 2 in longitudinal direction, loosen both of the grip knobs at the dorsal side of the BreastBoard EX.



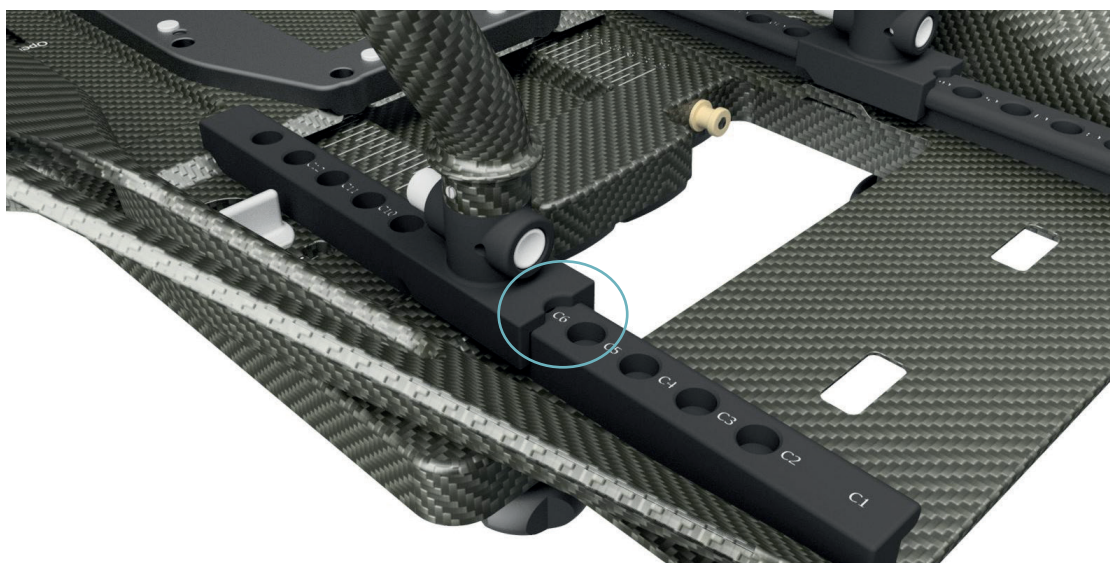
Turn the grip knobs clockwise to lock the EagleBoard 2 on the desired indexed position.



Align the M-Grip with the rails on the EagleBoard 2.
Push the white lock knobs on the M-Grip and
slide it onto the rails.



Place the M-Grip on the desired indexed position and release the lock knobs to fix the M-Grip to the rails of the OmniBoard EX.



Place the HeadSupport in the HeadSupport adaptor.



5. 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 detailed on the bottle 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.

6. 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.

7. 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.

8. 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: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot 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, non-metallic, and nonmagnetic.
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	Prevent Closed Loops	Prevent the formation of closed-loops as they can lead to MRI burns. Use an isolator between the patient's arms to avoid skin-to-skin contact.

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2841 ML Moordrecht
The Netherlands



+31 (0) 182 389 777
info@macromedics.com

www.macromedics.com

(Visit www.macromedics.com for a digital copy of this manual)



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