macromedics
SOLUTIONS IN RADIOTHERAPY

MANUAL 122800
Instructions for use
English Instructions

MacroMedics® EagleBoard™

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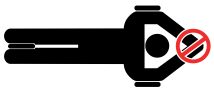
Table of Contents

1. Warnings....4
2. MRI Safety Information....4
3. Intended Use and Indications for Use....4
4. Installation Instructions....5
5. Cleaning, Storage and Disposal....6
6. Warranty....6
7. Notices....6
8. Glossary of Symbols....7

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.
- 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.
- Make sure that the patient lays down calmly.
- Handle with care to prevent damage and surface scratching.
- Instruct the patient not to reposition themself 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



- 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

- 122930 EagleBoard™-2 Base
- 122940 EagleBoard™-2 M-Grip

2.2 MR SAFE

- 122850 EagleBoard™ MR
- 122860 T-Grip for EagleBoard™ MR
- 122870 U-Grip for EagleBoard™ MR
- 122950 EagleBoard™-2 Base MR
- 122960 EagleBoard™-2 Adaptor HS RE
- 122970 EagleBoard™-2 M grip 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) and Magnetic Resonance (MR) imaging systems.

4. Installation Instructions

I. Place the correct CouchStrip on the couch in indexed positions.
(For the usage in a MR environment, use the glass fiber, MR safe CouchStrip).

II. Position the EagleBoard above the Couchtop, align the slot at the bottom of the EagleBoard with the CouchStrip and carefully place the EagleBoard on the Couchtop.

III. Place a HeadSupport and a HandGrip onto the EagleBoard.
When working with the EagleBoard-2, a vacuum cushion can be used to define the ideal patient position.

IV. Position the patient.

EagleBoard-2 with M-Grip

EagleBoard with U-Grip

EagleBoard with T-Grip

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 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.

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.

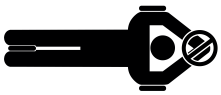
Product warranties remain valid provided the product was installed and/or used according to the instructions. Defects, malfunctions or failures caused by nature, misuse, abuse and unauthorised alteration or repair are not warranted.

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
CE	European Conformity	EC declaration of conformity by manufacturer.
	Manufacturer	Indicates the medical device manufacturer.
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT GS1 Code: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot 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.
	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.

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