



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 123110
Instructions for use
English Instructions

MacroMedics® EAMIS Lite™

(Extra Accurate Modular Immobilization System)



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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.
- Place and fix the device properly before positioning the patient.
- Rulers on the devices are only intended for reference of the device positioning of accessories. Rulers shall not replace patient position verification.
- Handle with care to prevent damage.
- Ensure that the baseplate is correctly secured to the couch prior to use.
- 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

The following devices are MR unsafe:

- 123110 EAMIS™ Lite



2.2 MR SAFE

The following devices are MR safe:

- 123860 EAMIS™ Lite, MR
- 123400 SBRT Secure Arch, size L
- 123500 SBRT Secure Arch, size M
- 123600 SBRT Secure Arch, size S
- 123700 SBRT Secure Arch, size XS



2.3 MR CONDITIONAL

The following devices are MR conditional:

- All Vacuum Cushions distributed by MacroMedics are MR Conditional.



A patient with this device can be safely scanned in an MR system, meeting the following conditions:

- A Static Magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 2,500 G/cm (25T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/Kg (Normal operating mode)

Due to size and location of the metallic parts, no clinically significant RF heating is expected.

3. Intended Use

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

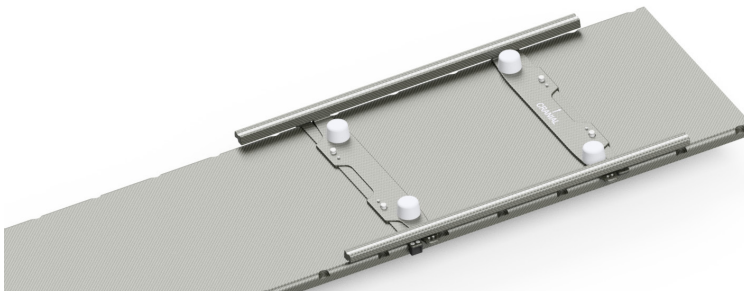
4. Installation Instructions of the EAMIS Lite

I. PLACE THE COUCHSTRIPS

Place the indexing CouchStrip at the cranial end of the CouchTop.
Place the sliding CouchStrips on caudal end of the CouchTop.

II. PLACE THE EAMIS LITE

Place the EAMIS Lite onto the couchstrips.
Make sure that no movement is possible between the EAMIS and the CouchTop.



III. PLACE THE VACUUM CUSHION

Place a Vacuum Cushion onto the EAMIS Lite before positioning the patient. For the moulding of a Vacuum Cushion, refer to IFU155100 - Vacuum Cushions.



IV. POSITION THE PATIENT

Position the patient carefully on the Vacuum Cushion.

V. PLACE THE SBRT SECURE ARCH

Select the appropriate size of SBRT Secure Arch. XS, S, M, L.

Place the brackets carefully over the patient onto the rails of the EAMIS Lite. Be sure to place the SBRT Secure Arch in the right direction: see engravings on the SBRT Secure Arch for cranial/caudal direction.



Rotate and hand-tighten the knobs on each side of the SBRT Secure Arch until the clamps properly fasten onto the baseplate. Do not apply too much force as this may cause damage.



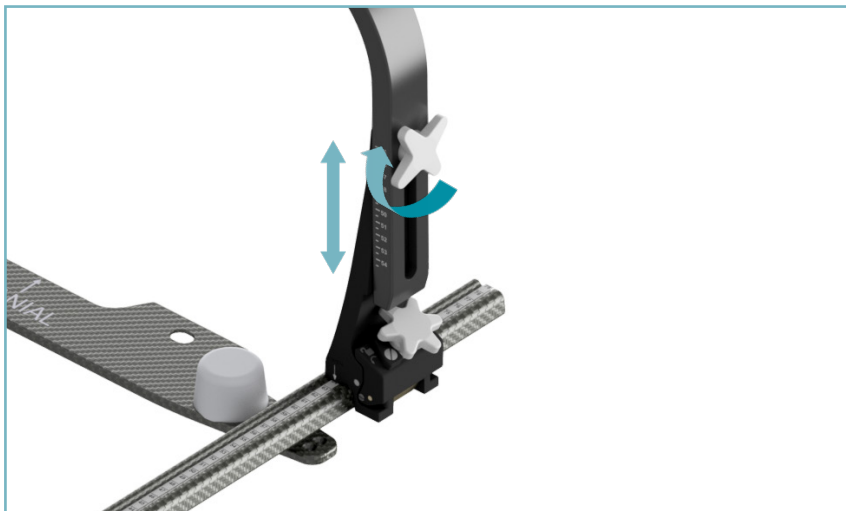
VI. ATTACHING THE RESPIRATORY SUPPRESSION PLATE TO THE SBRT ARCH

To attach the Respiratory Suppression Plate to the SBRT Secure Arch, slot the white pins of the Respiratory Suppression Plate into the holes at the top of the SBRT Secure Arch and slide the white sliding mechanism into the locked position. In the locked position, the arrows (on the Arch and on the sliding mechanism of the Arch) will be in-line with each other.



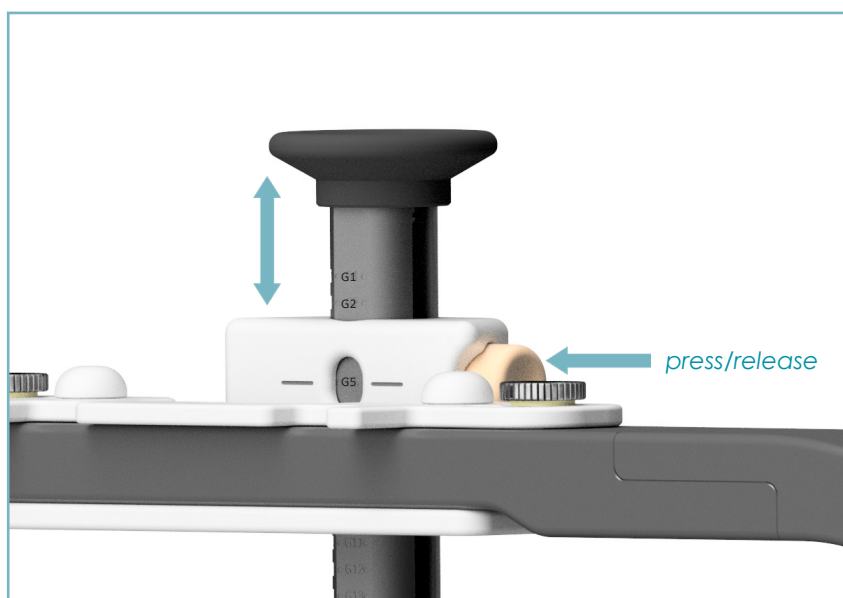
VII. ADJUSTING THE HEIGHT OF THE SBRT SECURE ARCH

Lower the SBRT Secure Arch as appropriate and hand-tighten it in the desired position by turning the knobs on the sides of the arch. Do not apply too much force as this may cause damage.



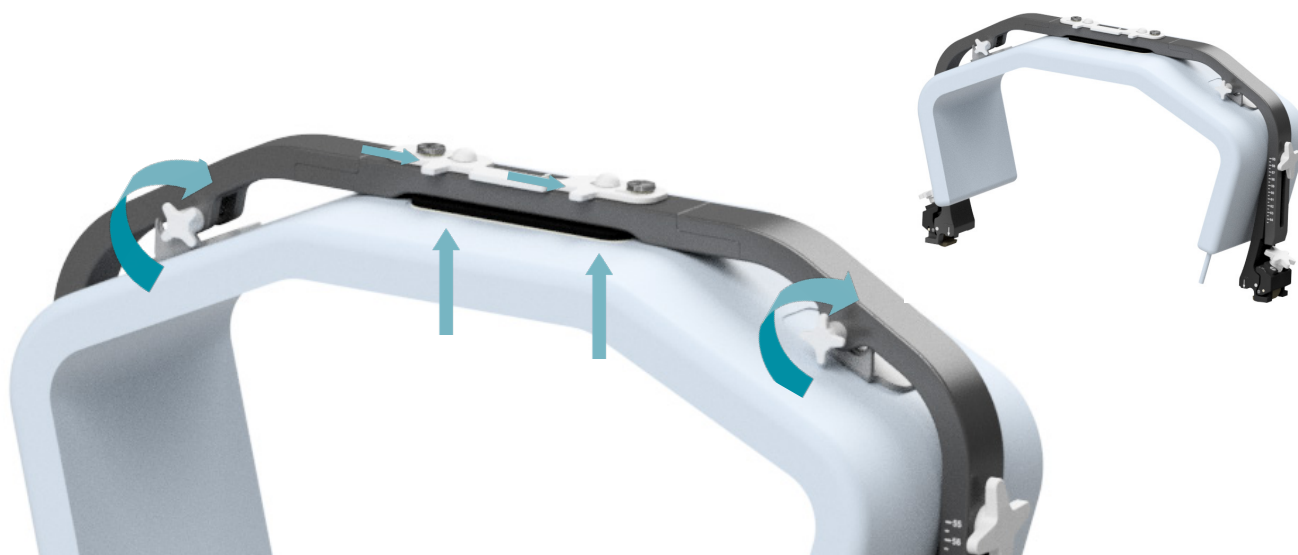
VIII. ADJUSTING THE HEIGHT OF THE RESPIRATORY SUPPRESSION PLATE

To adjust the height of the Respiratory Suppression Plate, press the yellow knob at the side (see the arrow on the right). Move the Respiratory Suppression Plate vertically into a desired indexed position. Release the knob to lock the Plate into position.



IX. ATTACHING THE ABDOMINAL VACUUM CUSHION

To attach an Abdominal Vacuum Cushion to the SBRT Secure Arch, slot the white pins of the cushion into the holes at the top of the SBRT Secure Arch and slide the white sliding mechanism into the locked position. In the locked position, the arrows (on the Arch and on the sliding mechanism of the Arch) will be in-line with each other.



Slide the two hooks of the Vacuum Cushion over the small white knobs of the Arch. Tighten the small knobs of the Arch to secure the Vacuum Cushion in place.

To make a vacuum mould, lower the Secure Arch by turning the knobs on the side of the Arch until the Vacuum Cushion is in tight contact with the patient.

Care should be taken to keep the cushion valve out of the radiation treatment path.

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
	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, nonmetallic, 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.

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