macromedics
SOLUTIONS IN RADIOTHERAPY

MacroMedics® - SBRT™ Systems

[This page is intentionally left blank]

Table of Contents

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.
- Ensure that the baseplate is correctly secured to the couch prior to use.
- Do not lean on the OmniBoard HXP Rail System.
- Secure the device properly before positioning the patient.
- Ensure to gently attach the iGUIDE Reference Frame.
- Ensure that the patient's hands, arms and limbs do not hang over the side of the baseplate to avoid potential pinch points.
- If the cranial end of the board is extended past the couch, do not exceed a load of 15 kg in this area.
- Do not exceed an equally distributed load of 200 kg on the baseplate.
- Take extra care when securing the baseplate to the couch to not damage the products.
- Prevent the surface from damage and scratching.
- Rulers used on the devices are only intended for reference of the device positioning of accessories. Rulers shall not replace patient position verification.
- Keep the vacuum cushion valve out of the radiation treatment path.
- Do not inflate the vacuum cushion above 100 Mbar.
- Please be aware not to deform the cushion whilst the patient is being (re)positioned.
- Place the patient carefully on the device and make sure that they lie down calmly. 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 CONDITIONAL
Non-clinical testing has demonstrated the following devices are MR Conditional:

123450	Vacuum Cushion, abdom. S	
123470	Vacuum Cushion, abdom. XL	
125310	Rigid UAS MRC set/2	
125350	Adjust. UAS MRC set/2	
130250	FeetSupport™, fixed	
130260	FeetSupport™, rotatable	
130460	FeetSupport ™, rotatable 2.0	
130450	FeetSupport ™, fixed 2.0	

126890	OmniBoard™ 2.0 base, EXF MRC
174260	OmniBoard™ 3.0 base,RE, MRC
174550	OmniBoard™ base MRC
174990	OmniBoard™ 2.0 S-Type MRC
175050	OmniBoard™ Base, S-Type MRC
175150	OmniBoard™ Base short S-Type MRC
175890	OmniBoard™ 2.0 S-Type Base 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 the 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.

2.2   MR UNSAFE
The following devices are labelled MR Unsafe:

- 120360   Low Bridge Support
- 120370   High Bridge Support
- 123110   EAMIS Lite™
- 125110   VacuumCus.Pos.DSCP™
- 125130   MultiBoard™ baseplate
- 125160   MultiBoard™ base-O
- 125300   Rigid UAS set/2
- 125320   Adjust. UAS set/2
- 125410   MultiBoard™ base ExaFix HexaPod
- 125420   MultiBoard™ base Type-O HexaPod
- 125450   MB HXP Rail System
- 125460   MB HXP Rail System Caudal
- 126110   OmniBoard™ HXP Base, EXF
- 126120   OmniBoard™ baseplate
- 126800   OmniBoard™ 2.0 base, EXF
- 126810   OmniBoard™ 2.0 HXP base, EXF
- 126250   OMB EXF HXP Rail System, set/2
- 126250R OMB HXP EXF Rail System right
- 126250L OMB HXP EXF Rail System left
- 173510   Low Bridge Support, RE

- 173520   VacuumCus.Pos.DSCP™RE
- 173530   HighBridgeSupport RE
- 174210   OmniBoard™ 3.0 base,RE
- 174230   OmniBoard™ bottomstop sliding
- 174360   MultiBoard™ base I RE mouldroom
- 174460   MultiBoard™ base I RE
- 174510   OmniBoard™ HXP base, RE
- 174520   OmniBoard™ baseplate,RE
- 174900   OmniBoard™ 2.0 base,RE
- 174910   OmniBoard™ 2.0 HXP base, RE
- 175000   OmniBoard™ Base, S-Type
- 175130   OmniBoard™ HXP Base, S-Type
- 175140   OmniBoard™ Base,S-Type P.Thorax
- 175160   OMB HXP Rail System, set/2
- 175160L OMB HXP Rail System left
- 175160R OMB HXP Rail System right
- 175410   OmniBoard™ 3.0 base, S-Type
- 175800   OmniBoard™ Base, S-Type 2.0
- 175810   OmniBoard™ Base HXP, S-Type 2.0

2.3   MR SAFE
The following devices are MR Safe:

- 123320   DSCP™ KS indexstrip
- 123400   SBRT Secure Arch, size L
- 123460   SBRT Secure Arch, size L HXP
- 123500   SBRT Secure Arch, size M
- 123530   Respiratory Suppr. Plate, S
- 123540   Respiratory Suppr. Plate, L
- 123550   PelvMidBlock EAMIS/UTB
- 123560   SBRT Secure Arch, size M HXP
- 123600   SBRT Secure Arch, size S
- 123660   SBRT Secure Arch, size S HXP
- 123700   SBRT Secure Arch, size XS
- 123760   SBRT Secure Arch, size XS HXP
- 123860   EAMIS Lite™ MR

- 125190   PelvMidBlock UTB Type-O
- 125230   MultiBoard™ Mouldroom
- 125260   MultiBoard™ base-O, GF
- 126260   Handgrips for DSCP™ set/2
- 130100   KneeSupport™
- 130120   KneeSupport™ LiftBlock™
- 130130   KneeSupport™ low,plastic
- 130140   KneeSupport™, plastic
- 130160   KneeSupport™ PelvMidBlock
- 173540   Low Bridge Support, RE, MR
- 173720   VacuumCus.Pos.DSCP™ RE MR
- 174270   OmniBoard Bottomstop Sliding, MR
- 174480   PelvMidBlock UTB RE
- 174430   MultiBoard™ base I RE MR

3. Intended Use

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

4. Caution

Ensure that the patient's hands, arms and limbs do not hang over the side of the baseplate to avoid potential pinch points.

5. Installation Instructions - ALL BASEPLATES, EXCEPT HXP.

I.   **Place the CouchStrips**

Place an **indexing** CouchStrip on the cranial end of the couchtop.
Place a **sliding** CouchStrip on the caudal end of the couchtop.

For more information, refer to IFU147100 - CouchStrips and Sidepieces.
For use in MR, use a glass fiber, MR Safe 3-Pin CouchStrip.

Note: for OmniBoard 3.0, place an indexing CouchStrip on the
caudal end of the couchtop and a sliding CouchStrip on the
cranial end of the couchtop.
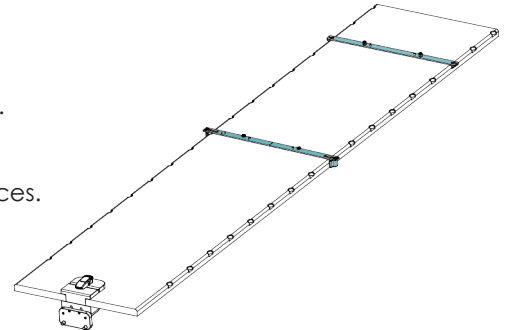
II.   **Place the SBRT Baseplate**

Align the SBRT baseplate with the Couchstrips and slot it into place. Make sure that no
movement is possible between the baseplate and the couch.

III. **Place the Accessories**

Place the designated accessories on the baseplate. Make sure that no movement is possible between
the baseplate and the accessories.

IV.   **Position the patient**

Place the patient on the SBRT baseplate.
Use the instructions for use for the individual devices for a proper patient set-up.

6. Installation of Accessories

6.1   Placing the SBRT Secure Arches

I.   Select the appropriate size of SBRT Secure Arch.
The SBRT Secure Arch is available in sizes; XS, S, M and L.

II. Place the brackets over the patient onto the SBRT baseplate sides.
To place the SBRT Secure Arch correctly, check the engravings on the SBRT Secure Arch for the cranial/caudal direction.
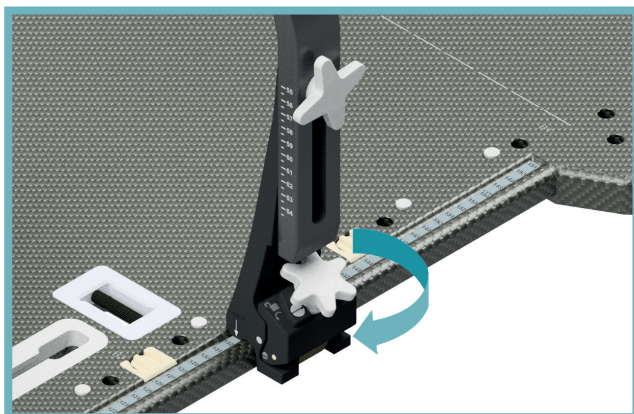

III. Rotate the knobs on each side of the SBRT Secure Arch until the clamps properly fasten onto the baseplate. Do not apply too much force as this may cause damage.

6.2   Placing the Respiratory Suppression Plate

I.   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.

II. Lower the SBRT Secure Arch 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.
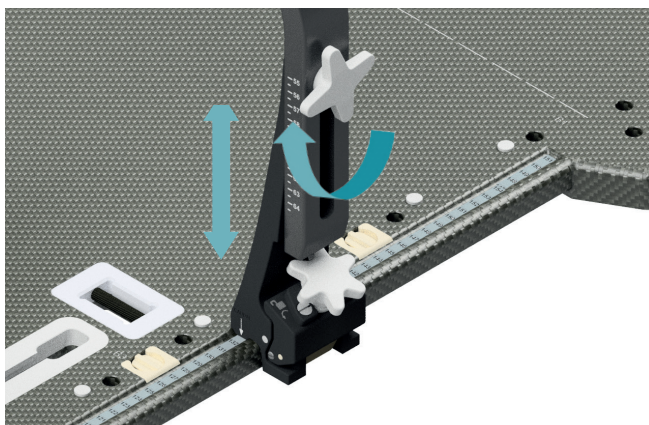

press/release

III. To adjust the height of the Respiratory Suppression Plate, press the yellow knob at the side. Move the Respiratory Suppression Plate vertically into a desired indexed position. Release the knob to lock the Plate into position.
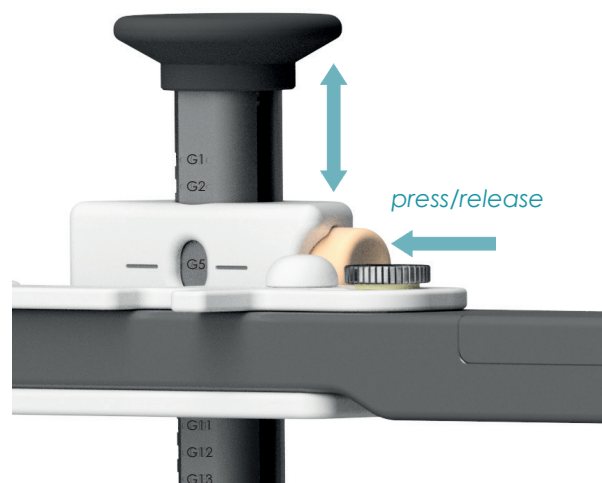
6.3   Placing the abdominal Vacuum Cushion

I. 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.
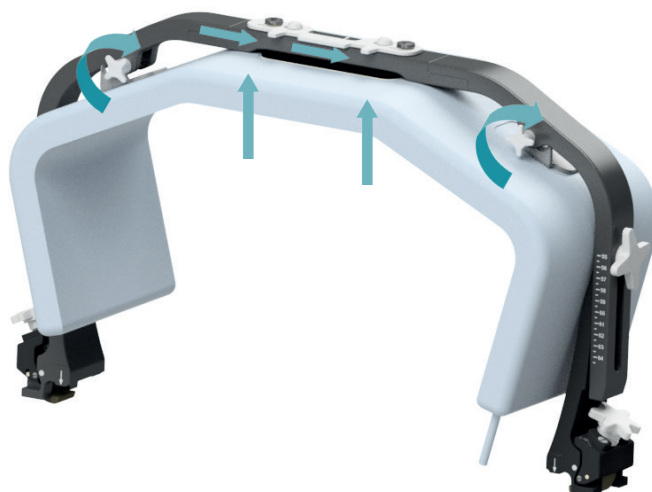
II. Make sure that the arrows on the black attachment components of the cushion are in-line with the arrows on the arch (pointing in the cranial direction).

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

IV.   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.

V.   Make a vacuum mould.

VI.   Lower the bridge again and fasten it in the desired position.

VII.   Make sure to keep the cushion valve out of the radiation treatment path.

6.4   Attaching the BottomStop Sliding to the OmniBoard 3.0

To unlock the bottomstop, rotate the two knobs in anti-clockwise direction. You can now slide the bottomstop along the baseplate. Rotate the knobs in clockwise direction to lock the bottomstop in the desired position. Please watch out to not overtighten the knobs
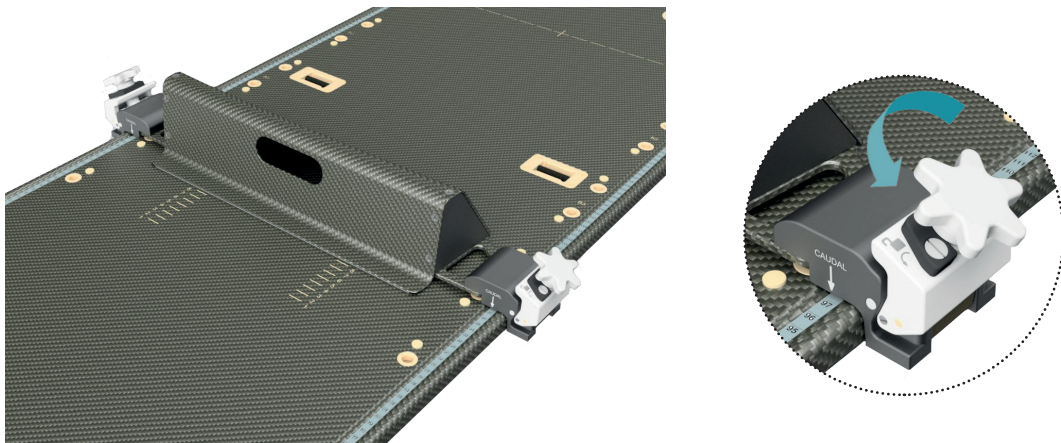
7. Installation Instructions - HXP BASEPLATES.

7.1   Securing the OmniBoard HexaPod to the Couch

I.   Placing the CouchStrips
Place an **indexing** CouchStrip on the cranial end of the couchtop. Place a **sliding** CouchStrip on the caudal end of the couchtop.
For more information, refer to IFU147100 - CouchStrips and Sidepieces.

II.   Placing the OmniBoard
Align the Omniboard with the CouchStrips and slot it in place.
Make sure that no movement is possible between the baseplate and the couch.

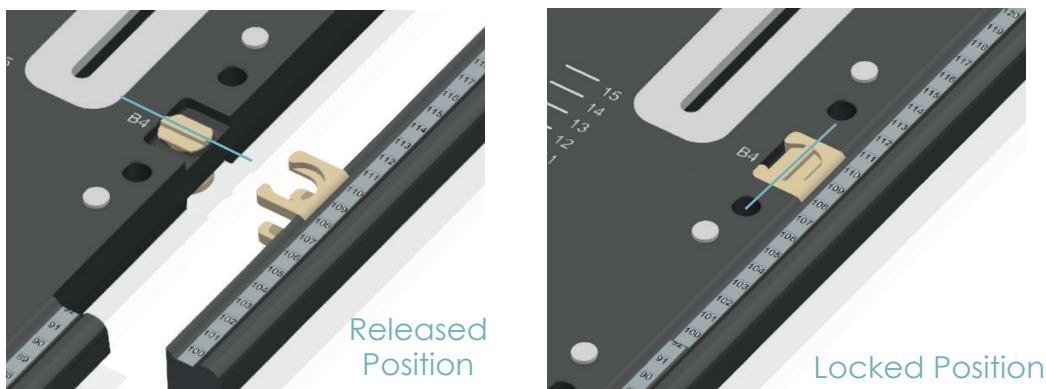## 7.2   Attaching and detaching the OmniBoard HXP Rail System

OMB HXP Rail System consists of a right and left rail that can be attached to either side of the OmniBoard HXP baseplate.

To attach the rail:
Ensure that the locking mechanism on both sides of the OmniBoard HXP baseplate is in the released position, as shown on the image below. Ensuring that the rulers are facing up, slide the rails' hooks onto the baseplate's locking mechanism. Turn the knobs 90 degrees to secure the rails in place.

To detach the rail:
Rotate all locking mechanisms 90 degrees to the released position. Pull on the rail to detach it from the baseplate.

Released Position

Locked Position

7.3   Attaching and detaching the MultiBoard HXP Rail System

The MultiBoard HXP Rail System can be attached to the MultiBoard HXP baseplate. Align the bottom of the MultiBoard HXP baseplate with the rail system and slot it in place.
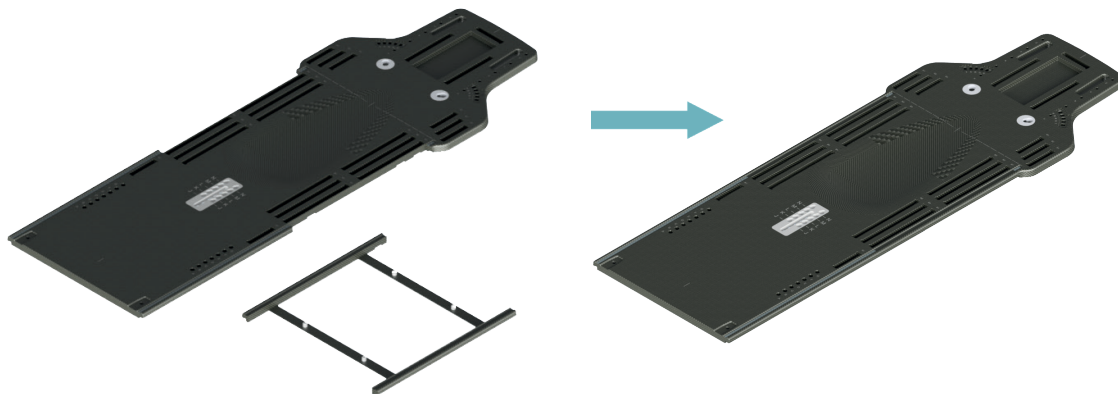
7.4   Securing the MultiBoard HexaPod to the Couch

I.   Placing the CouchStrips
Place an **indexing** CouchStrip on the cranial end of the couchtop.
Place a **sliding** CouchStrip on the caudal end of the couchtop.
For more information, refer to IFU147100 - CouchStrips and Sidepieces.

II.   Placing the MultiBoard
Align the MultiBoard with the CouchStrips and slot it in place.

7.5   PLACING THE ACCESSORIES

I.   Placing the dedicated Secure Arches.
Note: the HXP baseplate secure arches differ from the secure arches for regular baseplates.

1. Select the appropriate size HXP Secure Arch. The available sizes are; XS, S, M and L.
2. Check the correct orientation of the HXP Secure Arch by looking at the engravings for the cranial and caudal alignment. Once correctly orientated, place the HXP Secure Arch over the patient, aligning the clamps of the arch with the holes in the iBEAM couchtop.
3. Rotate the knobs on each side of the HXP Secure Arch until the clamps properly fasten onto the couchtop. Do not apply too much force as this may cause damage.
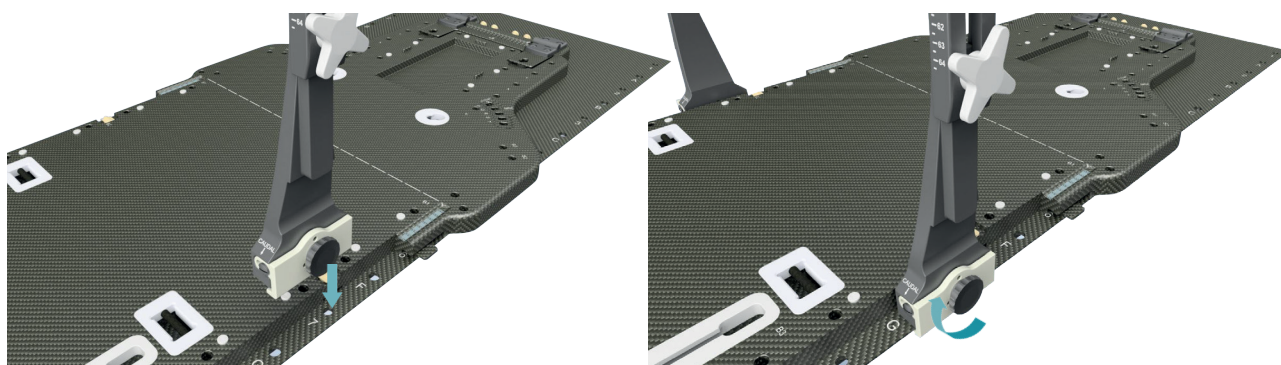
II.   Placing other accessories

Attach the required accessories following their instructions for use.
Check the latest MacroMedics' catalogue or contact your distributor for further information on available accessories.
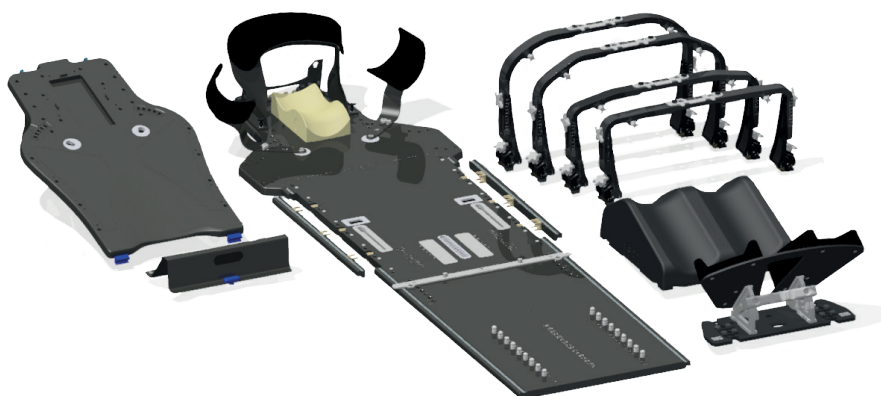
7.6   PATIENT POSITIONING

Follow the department protocol and the Instructions for Use of the individual accessories for patient set-up.

8. 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.
- Make sure to store the foam knee supports so that no mechanical pressure is applied to them.
- Make sure to store the foam knee supports in a dry environment, away from direct sunlight and heat sources.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

9. 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.

10. 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.

11. 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.
SN GS1 Code: (21)	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
📖i	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.
☂	Keep Dry	Indicates a medical device that needs to be protected from moisture.
☀	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources.
MR	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.
MR	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	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.

[This page is intentionally left blank]

[This page is intentionally left blank]

macromedics

SOLUTIONS IN RADIOTHERAPY

MacroMedics BV
Oostbaan 670
2841ML 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)

04112024V34IFU123100