

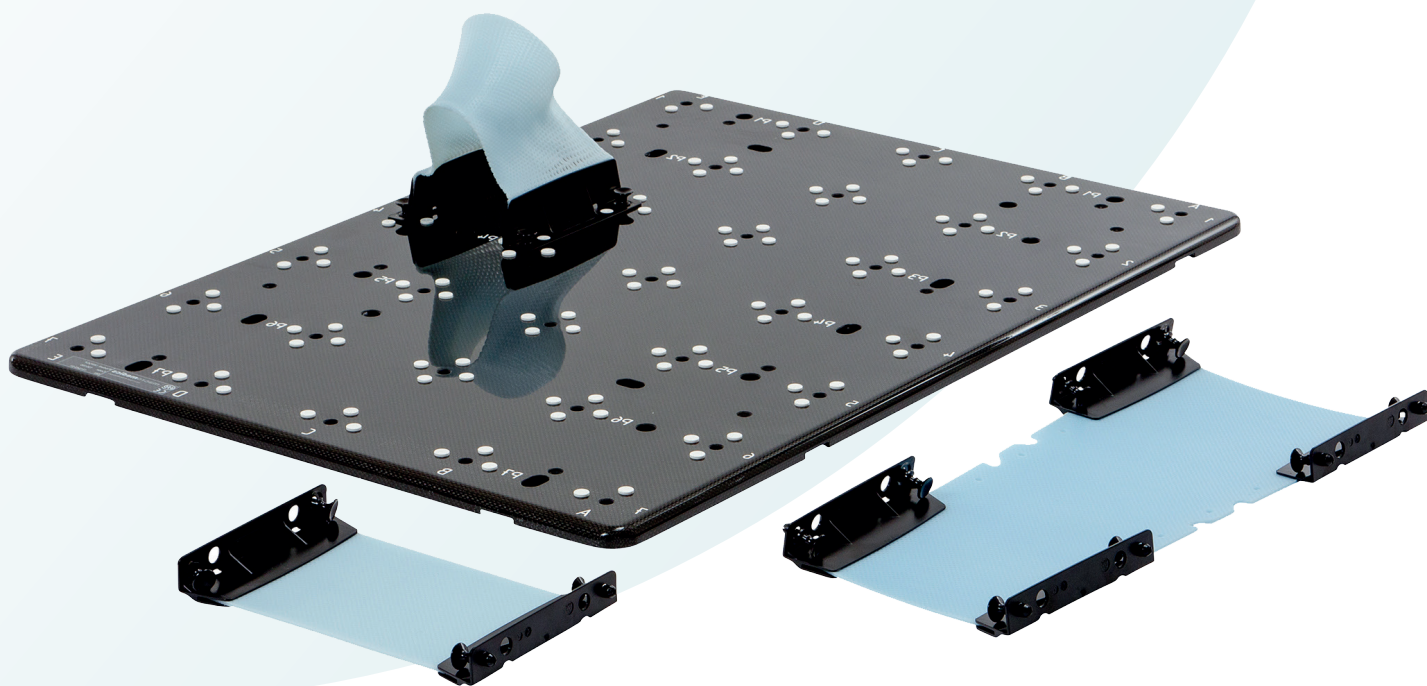


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SOLUTIONS IN RADIOTHERAPY

MANUAL 135100
Instructions for use
English Instructions

MacroMedics® UniqFix



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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.
- 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.
- Ensure there is no possibility for collision between gantry and device.
- Ensure that the patient's hands, arms and limbs do not hang over the side of the baseplate to avoid potential pinch points.
- Secure the device properly before positioning the patient.
- 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:

- 135100 UniqFix



2.2 MR SAFE

The following devices are MR Safe:

- 135150 UniqFix MR

3. Intended Use

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

4. Installation procedure - UniqFix Positioning System

I. PREPARATION OF THE TREATMENT AREA

Ensure the treatment area is ready and that all necessary components are available:

- UniqFix baseplate
- Couchstrips
- Thermoplastic mask
- Positioning cushion (if needed)
- UniqFix Set-Up Sheet (for recording positions)

II. PLACING THE COUCHSTRIPS

- Place the couchstrips onto the treatment couch according to the required configuration for the body part being treated.
- Make sure the couchstrips are level, firmly placed, and aligned with any couch reference markers if available.

III. PLACING THE UNIQFIX BASEPLATE

- Position the UniqFix baseplate on top of the couchstrips.
- Ensure there is full contact between the baseplate and the couchstrips, with no movement possible.
- Lock or secure the baseplate to the couch, if applicable.
- Test stability by gently pressing on different areas of the baseplate.

IV. PLACING THE UNIQFIX BASEPLATE

- Place the affected body part (limb) onto the UniqFix baseplate.
- Use a cushion or support block if necessary to achieve the correct positioning.
- Ensure the patient is in a relaxed but stable position.

V. CREATING AND POSITIONING THE THERMOPLASTIC MASK

- Prepare the mask following IFU117000 – Thermoplastic Masks.
- Mold the thermoplastic mask over the target body part to ensure a secure and precise fit.
- Ensure the mask interfaces properly with the UniqFix baseplate without causing discomfort or pressure points.

MASK POSITION REGISTRATION

Record the exact mask fixation points on the baseplate:

- Horizontal position: select from A / B / C / D / E
- Vertical position: select from 1 / 2 / 3 / 4 / 5 / 6 / 7

Example: Mask attached at positions C3 and D4

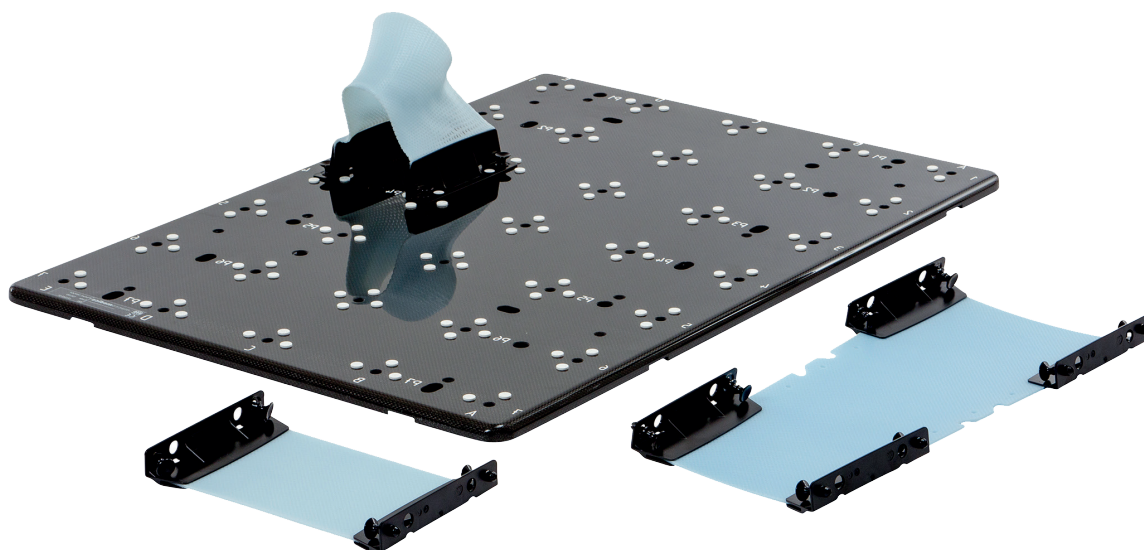
Write down these positions clearly on the UniqFix Set-Up Sheet to ensure accurate reproducibility for future treatments.

VI. FINAL CHECKS

Review the full setup:

- Is the baseplate securely fixed to the couch?
- Is the mask properly molded and comfortable for the patient?
- Are couchstrip and mask positions clearly documented?

Once all elements are verified, proceed with patient alignment.



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 product.
- 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: (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 Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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