

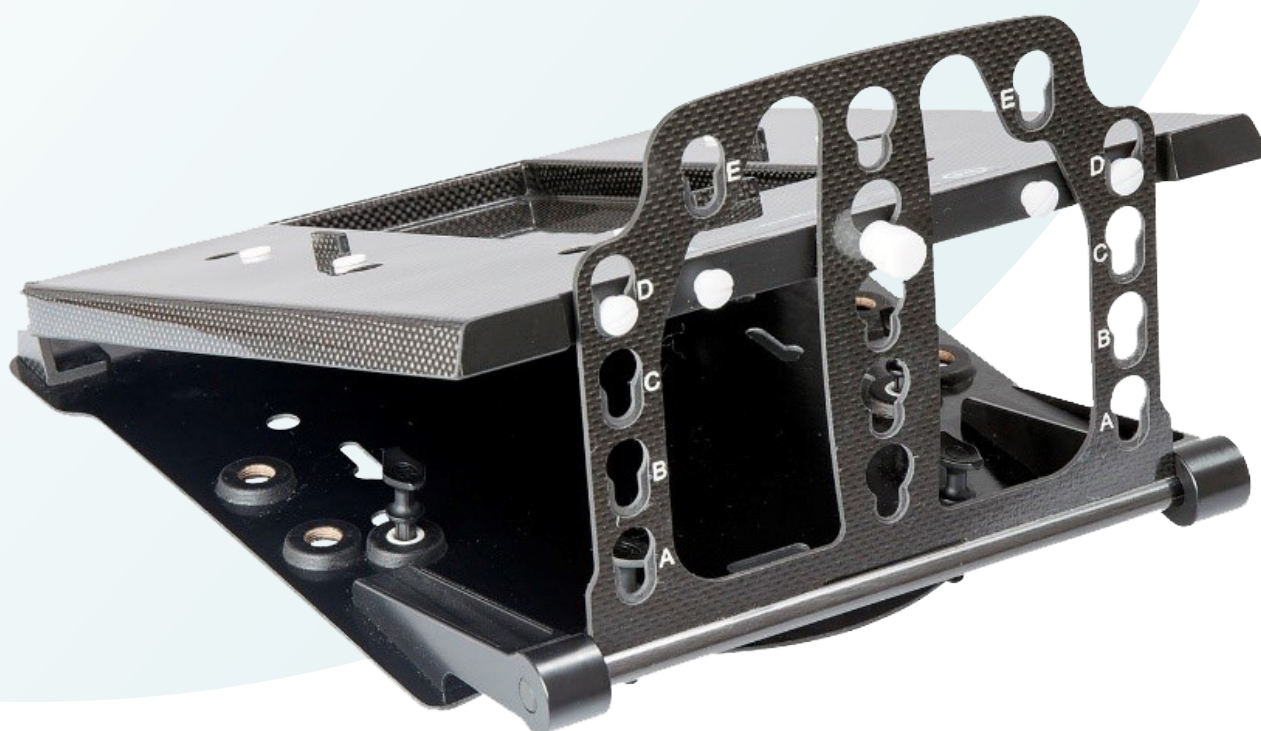


**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 110200  
Instructions for use  
English Instructions

## MacroMedics® ExaTilt & HeadTilt



**MacroMedics BV**  
Oostbaan 670  
2841ML Moordrecht  
The Netherlands  
+31(0)182 389 777  
[info@macromedics.com](mailto:info@macromedics.com)  
[www.macromedics.com](http://www.macromedics.com)

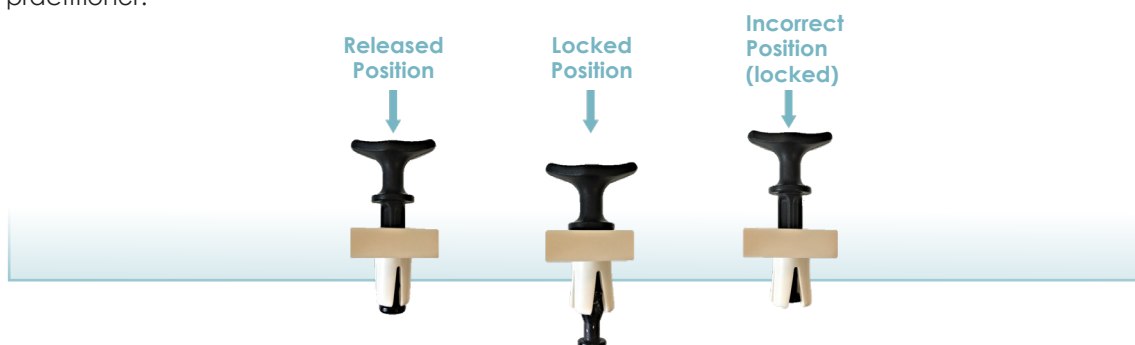
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# 1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or if missing parts.
- Set the inclination position before positioning the patient.
- Secure the device properly before positioning the patient.
- Only use ExaTilt / HeadTilt in inclined position when the angulation is locked with the white knob.
- Do not exceed an equally distributed load of 15 kg.
- Store the Plungers and Quickfasteners in the released position to prevent grommet deformation (see the image below).
- Check individual components on MR-safety when used together in a patient positioning system.
- 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:

- 110200 ExaTilt™, 25
- 110230 ExaTilt™, 35
- 171500 HeadTilt, RE
- 171510 HeadTilt, RE 35
- 171560 HeadTilt, S-Type
- 171580 HeadTilt, S-Type 35



## 2.2 MR SAFE

The following devices are MR safe:

- 110240 ExaTilt™, MR
- 171520 HeadTilt, RE, MR
- 171570 HeadTilt, S-Type, MR



# 3. Intended Use

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

## 4. Installation Instructions

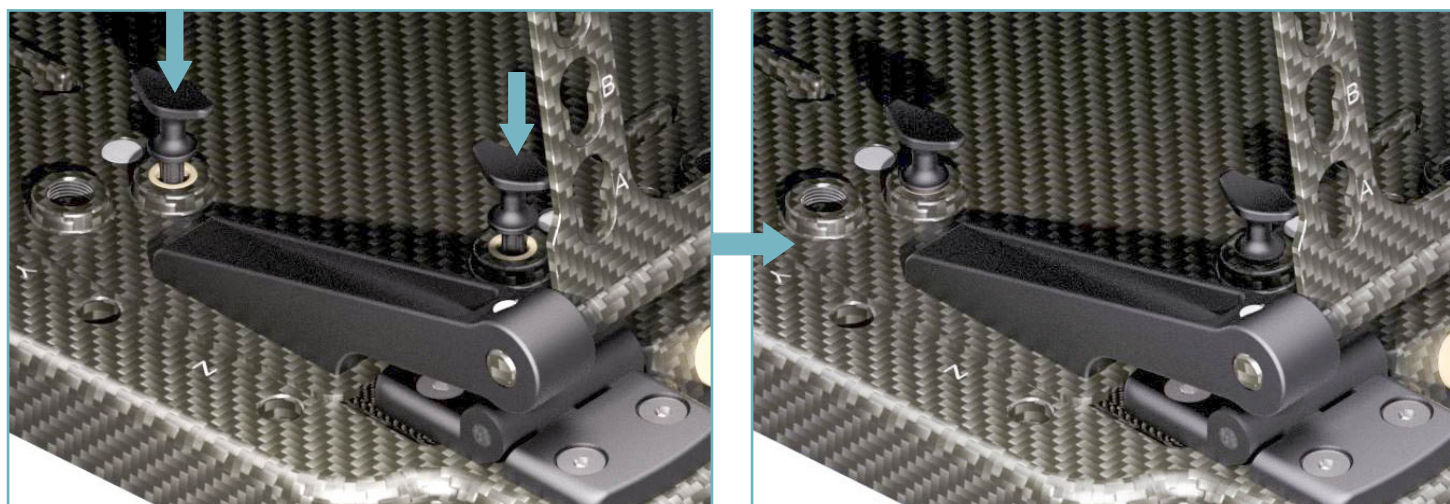
MacroMedics offers different types of head and neck positioning devices . These fit on a variety of MacroMedics baseplates. Contact your local distributor for more information.

### 4.1 POSITIONING AND SECURING

Place the head tilting device at the cranial end of your MacroMedics baseplate as shown in the following image. Align the holes in the base of the head tilting device with the corresponding holes in the baseplate.



All MacroMedics head tilting devices utilise a push-lock system. Push down the Plungers to lock their position, securing the device to the baseplate. To remove the head tilting device from the baseplate, pull the Plungers upwards, back into its released position. You can now lift the head tilting device from the baseplate.

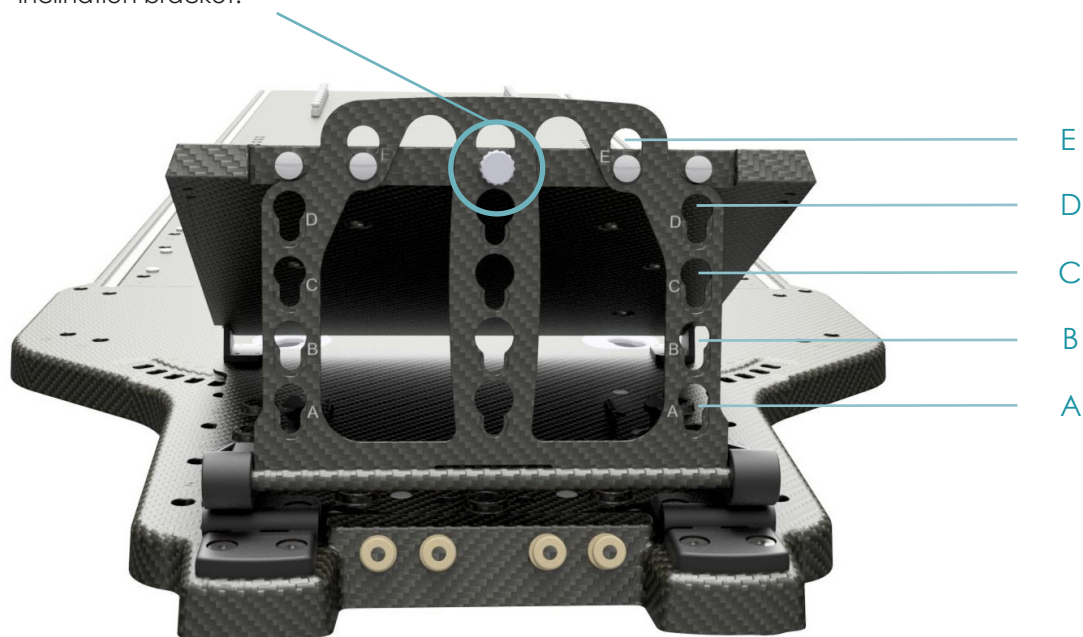


## 4.2 INCLINATION

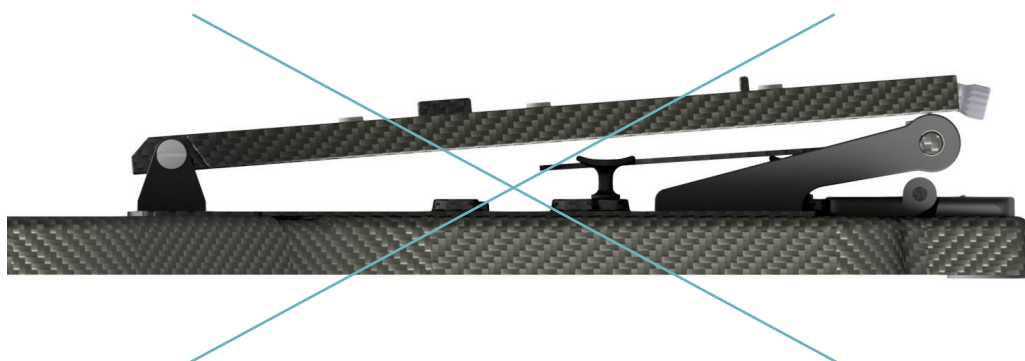
The MacroMedics head tilting devices can incline in 5 different angles: A, B, C, D and E, where position E reaches 25°.

An alternative option is available with an angle of 35°, divided over 6 steps: A, B, C, D, E and F.

Once inclined at the desired angle, tighten the white ribbed knob in the middle to secure the inclination bracket.



Do not use the head tilting device when it is in its horizontal position.



## 5. Cleaning, Storage and Disposal

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- 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

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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

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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.
<b>Rx ONLY</b>	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 Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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