



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 164100
Instructions for use
English Instructions

MacroMedics® FluxBoard



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1. Warnings



- Inspect the device prior to use and do not use the product when damage is detected.
- Check individual components on MR safety and MR conditions when used together in a patient positioning system.
- Do not place any load on the extended part other than the patient's head and shoulders.
- Rulers on the device cannot be used as a measurement tool but only for reference for the positioning of accessories.
- Secure the device properly before positioning the patient.
- Place the patient carefully on the device and make sure that they lie down calmly. Instruct the patient to not 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 table top to avoid potential pinch points.
- Do not place any load on the extended part of the device other than the patient's head and shoulders.
- 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

The following devices are MR Conditional:

- 164120 MRIdian FluxBoard Thorax Plate



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

2.2 MR SAFE

The following devices are MR Safe:

- 164110 MRIdian FluxBoard Base
- 164140 The FluxBoard mirrorflex
- 164220 MRIdian H&N mattress
- 164230 MRIdian H&N Base
- 164210 MRIdian Padding
- 164190 MRIdian U-Grip
- 112850 SSPS[®] Cradle-FB MR



3. Intended Use

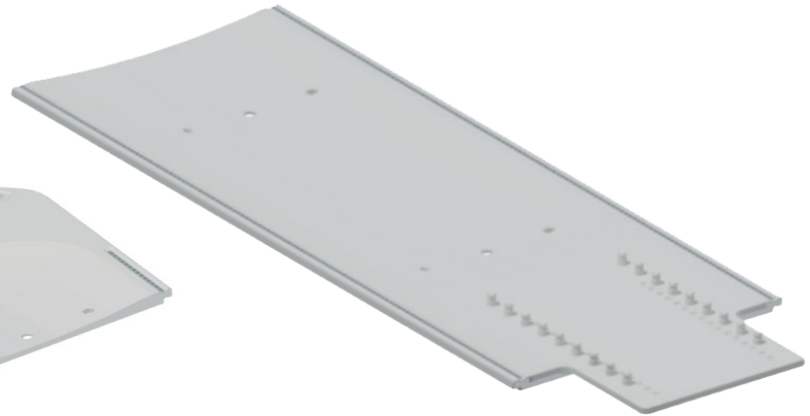
Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

4. Use Instructions

The FluxBoard consists of two separate modules. The Thorax Module and the Treatment Base. Combined, they form the FluxBoard baseplate and can be attached to a CouchTop with the use of CouchStrips.

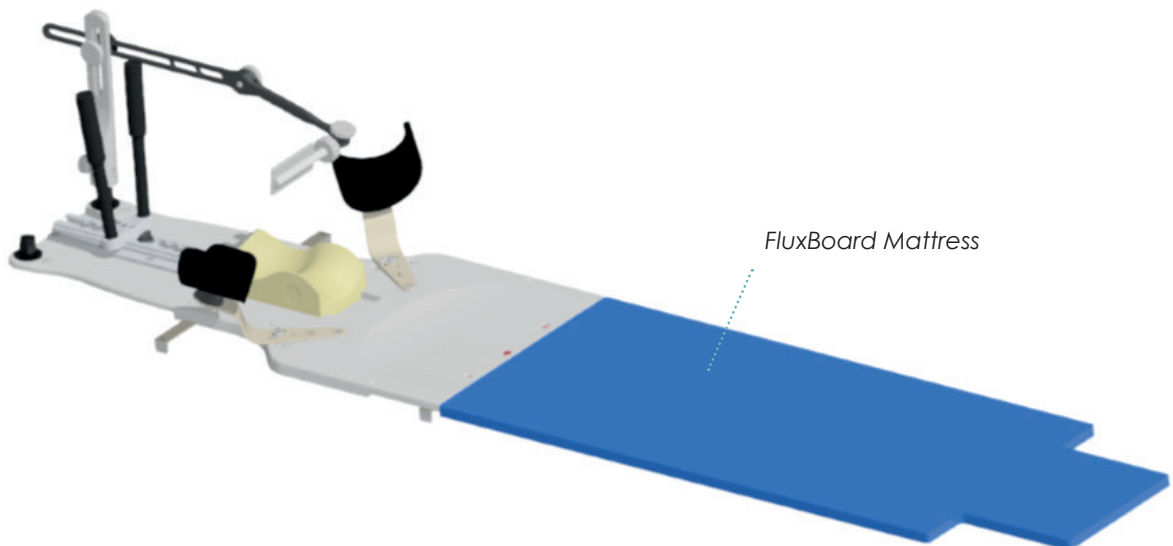


164120 FluxBoard Thorax Module



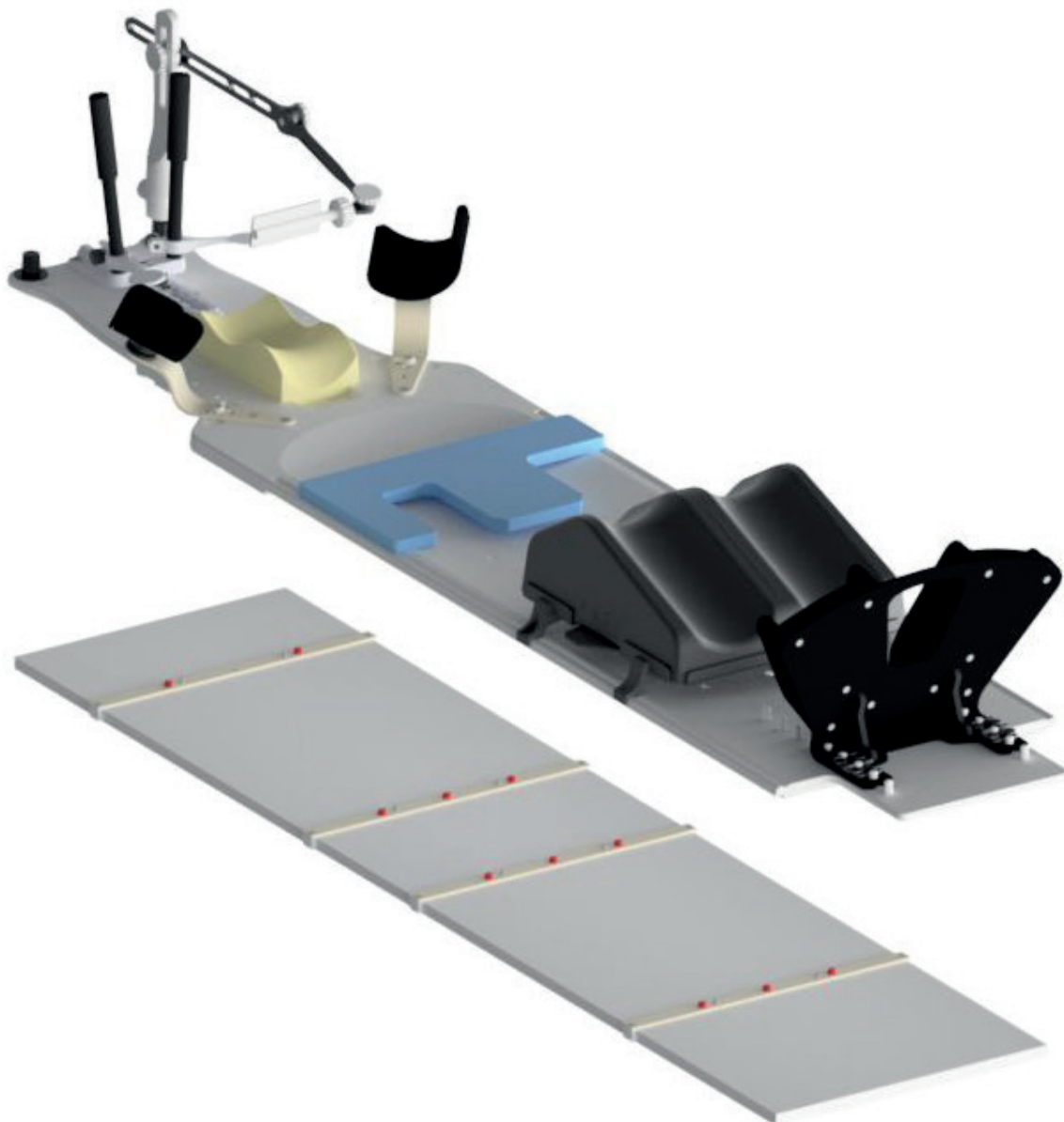
164110 FluxBoard treatment base

When the FluxBoard treatment Base (164110) is not used, the FluxBoard Mattress can be used instead for patient comfort.



4.1 PLACE THE COUCHSTRIPS

Place the CouchStrips on the couch top in designated indexed positions. Place the FluxBoard on the CouchStrips. If desired, the CouchStrip can be mounted on the baseplate with screws.



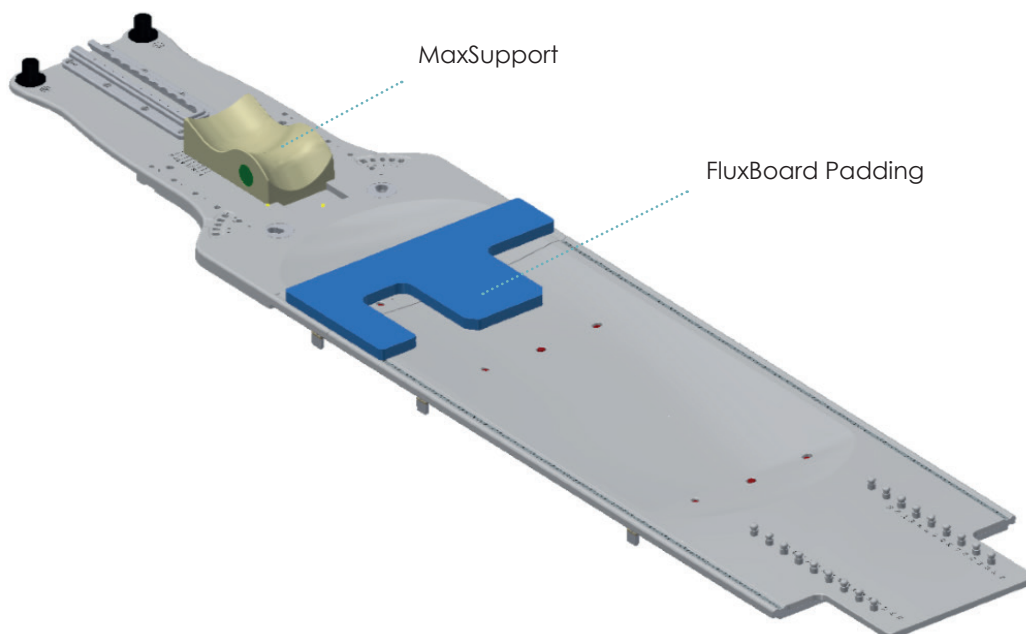
4.3 PLACE THE FLUXBOARD COMPONENTS

I. FLUXBOARD PADDING

The FluxBoard padding is designed to surround the coil to provide more comfort to the patient during treatment.

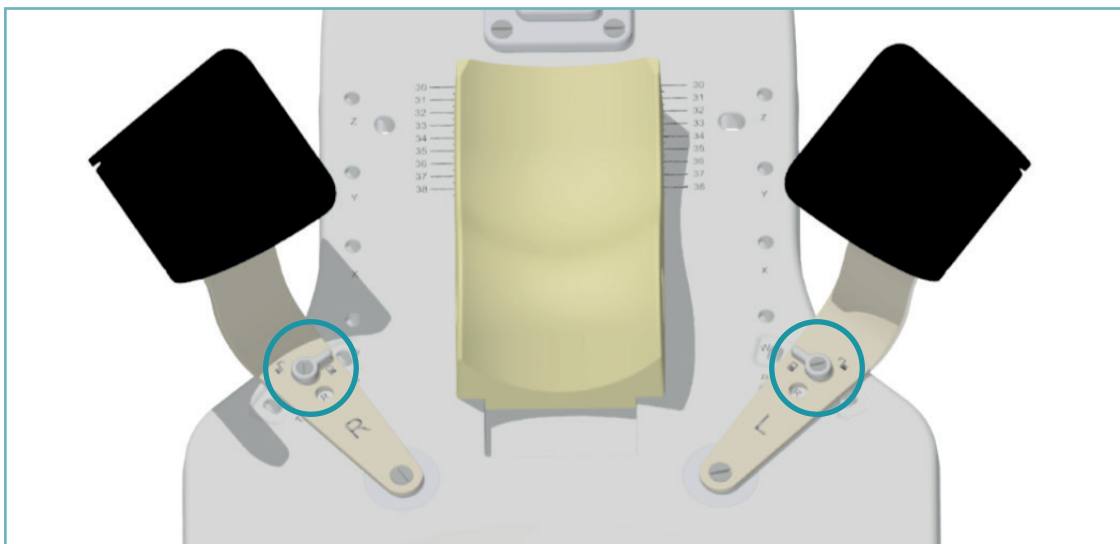
II. MAXSUPPORT 1 - HEADSUPPORT

The MaxSupport 1 supports the patient's head during treatment. Reposition the patient in a more cranial or caudal direction as needed by using the indexation for the MaxSupport.



III. RIGID ADJUSTABLE ARMSUPPORTS

These can be used on the thorax module to support the upper arms. Use the white knob (circled in blue) to lock or release the arm support and put it in one of the five positions.

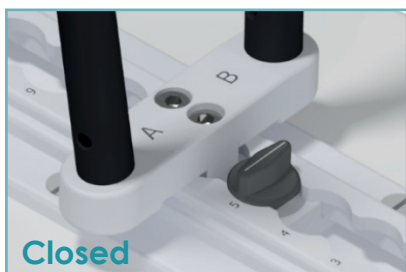


IV. FluxBoard U-Grip

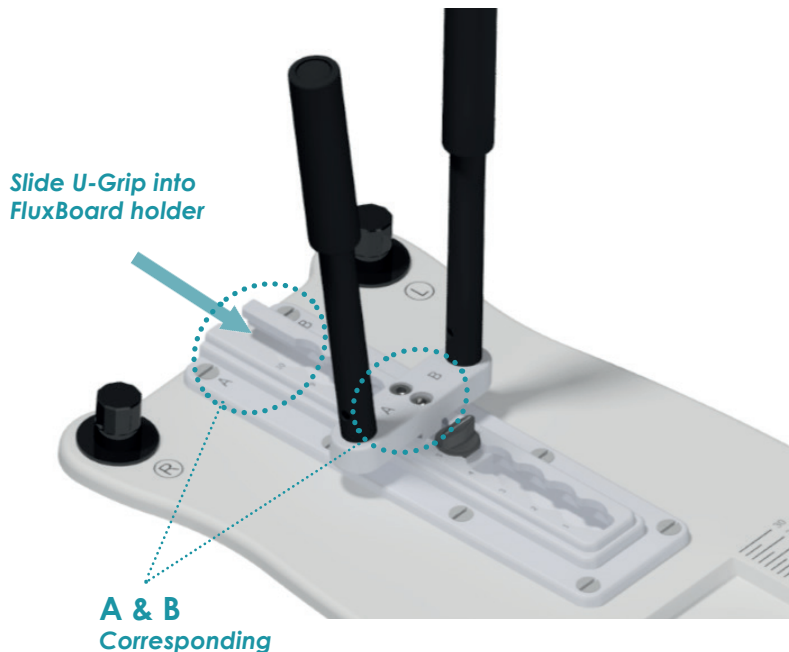
The U-grip can be placed onto the FluxBoard by sliding it into the holder. Ensure that sides A and B on the U-grip align with the corresponding A and B markings on the holder. Keep the black knob in the vertical ('open') position while sliding the U-grip into place. Once positioned, rotate the knob to the horizontal ('locked') position.



Open

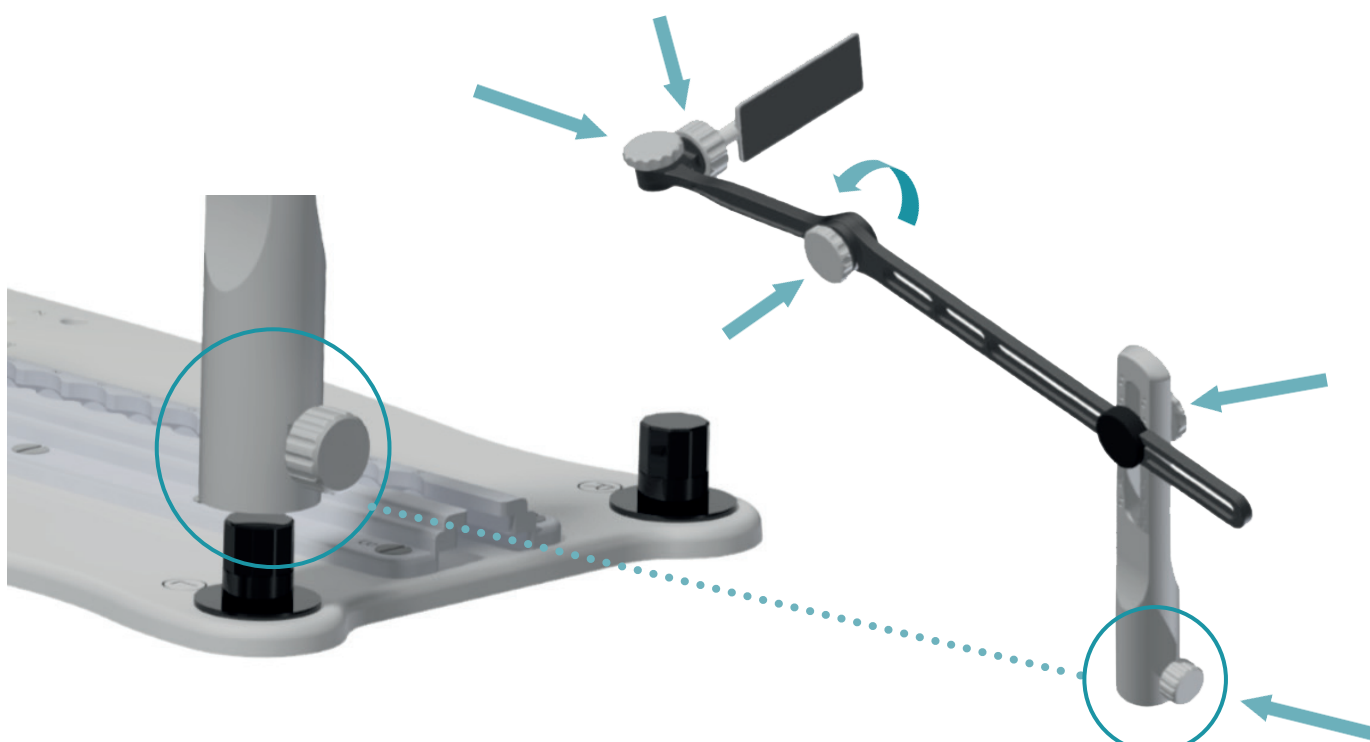


Closed



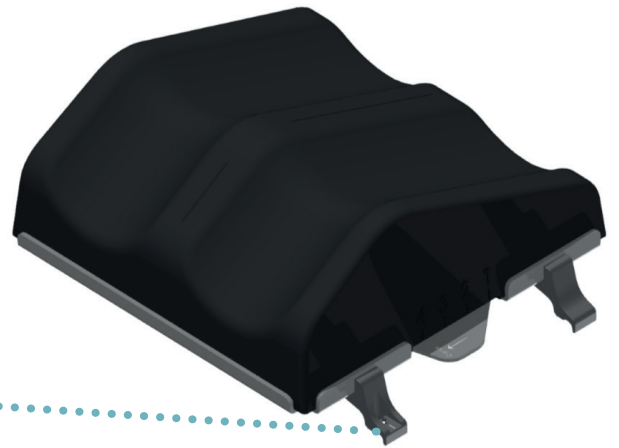
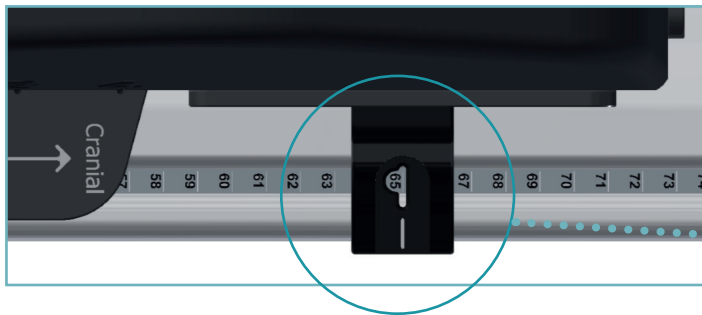
V. FLUXBOARD MIRRORFLEX - (NOT INCLUDED IN CT VERSION)

Place the mirror over the black stud and tighten it with the white knob. The mirror can be placed on the right or left side of the baseplate. By unscrewing the white knobs on the mirror arm, the position of the mirror can be set in every desired position.



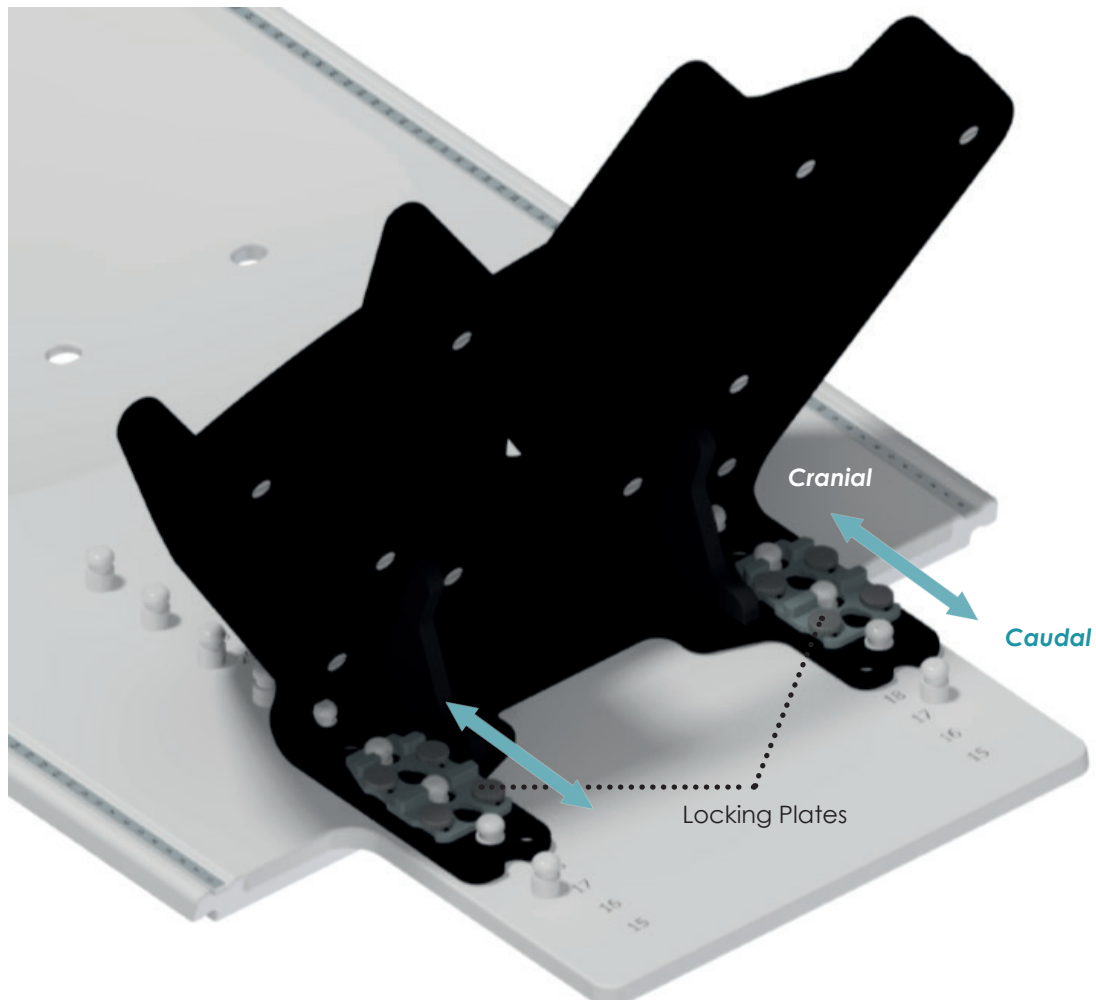
VI. FLUXBOARD KNEESUPPORT BRIDGE

Place the KneeSupport onto the FluxBoard and read the ruler for its position.



VII. FLUXBOARD FEETSUPPORT

Before placing the FeetSupport onto the baseplate, push the locking plates in the cranial direction to unlock the holes. The locking plates are found on the base of the FeetSupport. Place the FeetSupport over the pins on the baseplate. Once in position, pull the locking plates in the caudal direction to lock the FeetSupport to the baseplate.



4.4 PLACE THE FLUXBOARD OPTIONAL ACCESSORIES

I. FLUXBOARD HEAD & NECK MODULE

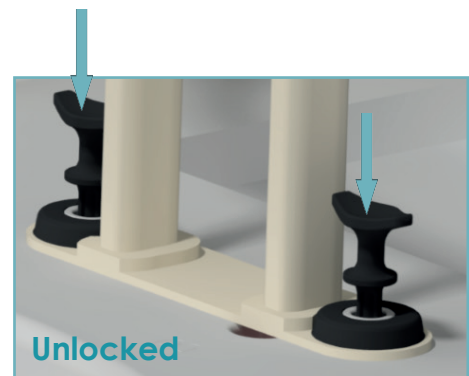
The FluxBoard Head & Neck Module can be placed instead of the FluxBoard Thorax Module and is designed for the usage of the Head & Neck Cradle.



II. FLUXBOARD HEAD & NECK CRADLE

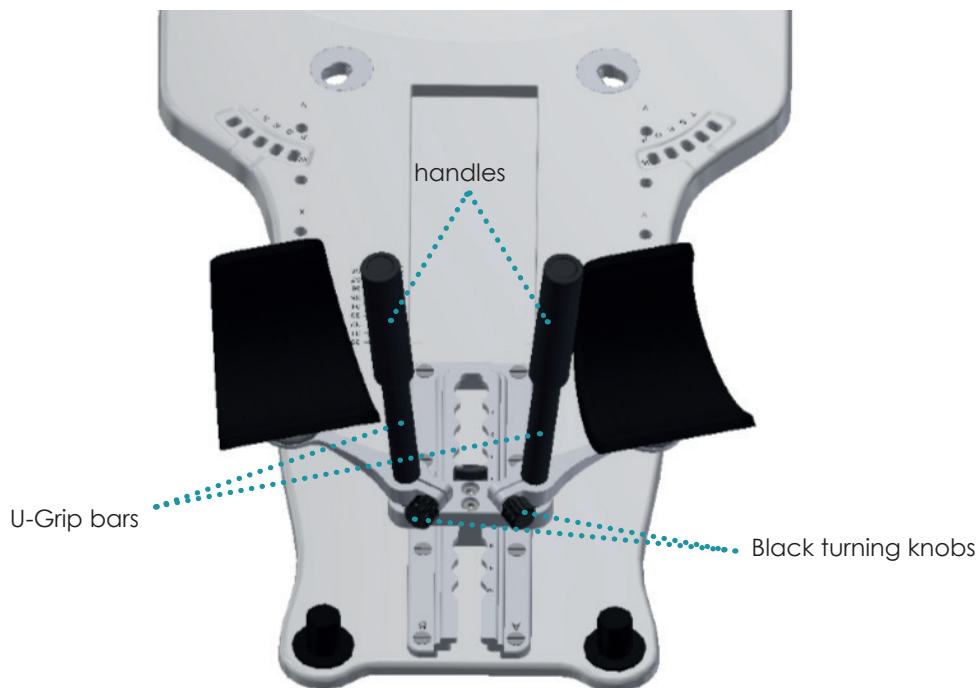
This Cradle can only be used on the Fluxboard Head & Neck Module. The Cradle can be locked with plungers, as shown in the images below.

The cradle can be used in combination with DSPS®. Refer to IFU112100 for instructions on how to mould DSPS® masks.



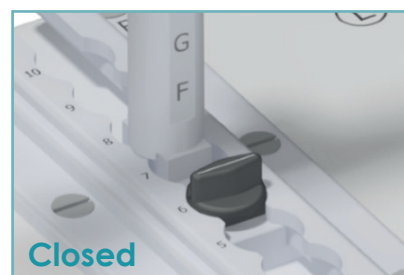
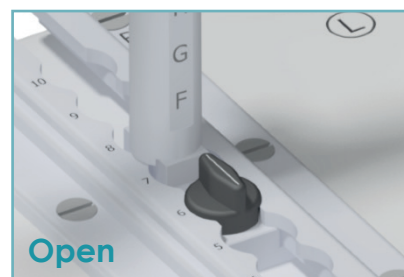
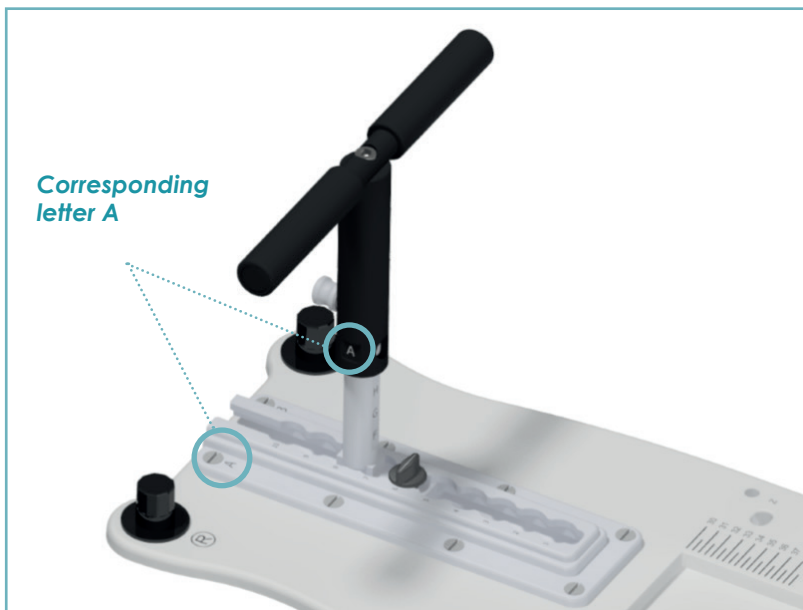
III. WRIST SUPPORT - ACCESSORY OF THE U-GRIP

Unscrew the handles on the U-Grip to mount the wrist supports. Place them over the bars of the U-Grip and tighten them with the black turning knob. Screw the handles back on.



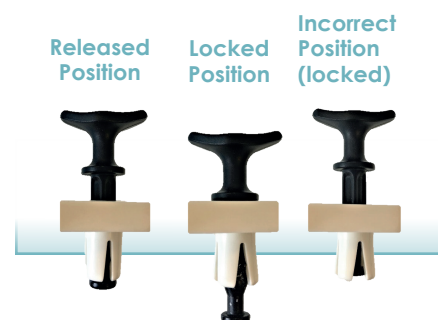
IV. T-GRIP

The T-grip allows height-adjustment in six different positions. The T-grip can be placed by sliding it into the holder. Ensure that sides A and B on the U-grip align with the corresponding A and B markings on the holder. Keep the black knob in the vertical ('open') position while sliding the U-grip into place. Once positioned, rotate the knob to the horizontal ('locked') position.



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 bottle of the cleaning agent.
- Having cleaned the device, perform a visual inspection of the device to ensure that it is thoroughly clean. If it is not, either repeat the cleaning process described above until the device is thoroughly clean upon visual inspection or dispose of the device to prevent the use of a soiled device.
- If unsure about the cleaning fluid, do not use it. Never use Ethanol (Ethyl alcohol), aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.
- The devices are not suitable for sterilization or thermal disinfection.
- Store the device in a clean, ventilated environment.
- Store the products with the Quickfasteners in the released position to prevent grommet deformation.
- 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 Mark	CE marking of conformity
	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 Conditional	An item with demonstrated safety in the MR environment within defined conditions.
	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.

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