MANUAL 161100
Instructions for use
English Instructions

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SOLUTIONS IN RADIOTHERAPY

# MacroMedics ® OmniCouch™

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# 1. Warnings

- Do not place hands underneath the OmniCouch on the caudal side.
- Check individual components on MR-safety when used together in a patient positioning system.
- Do not use MR unsafe items in an MR environment.
- It is the user's responsibility to take into account the attenuation, absorption and build-up effects.
- It is the user's responsibility to take into account the deflection or sagging.
- Any rulers used on the device are only intended for reference of the device position. Rulers shall not replace patient position verification.
- Do not exceed maximum distributed static load of 200 kg.
- Test the device on your system without a patient before treatment.
- Place and fix the device and any components properly before positioning the patient.
- Make sure that the patient lies down calmly.
- It is the user's responsibility to ensure that collision does not occur between the Linear Accelerator and the device, including any components.
- Do not lift the OmniCouch without caution; the OmniCouch shall not be lifted by one person only.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

# 2. MRI Safety Information


MR UNSAFE
The following devices are MR unsafe:

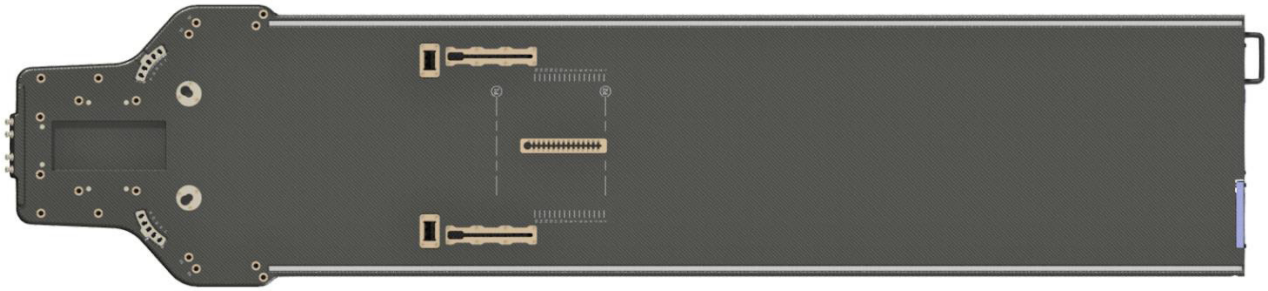
- 161100 OmniCouch for Elekta, RE

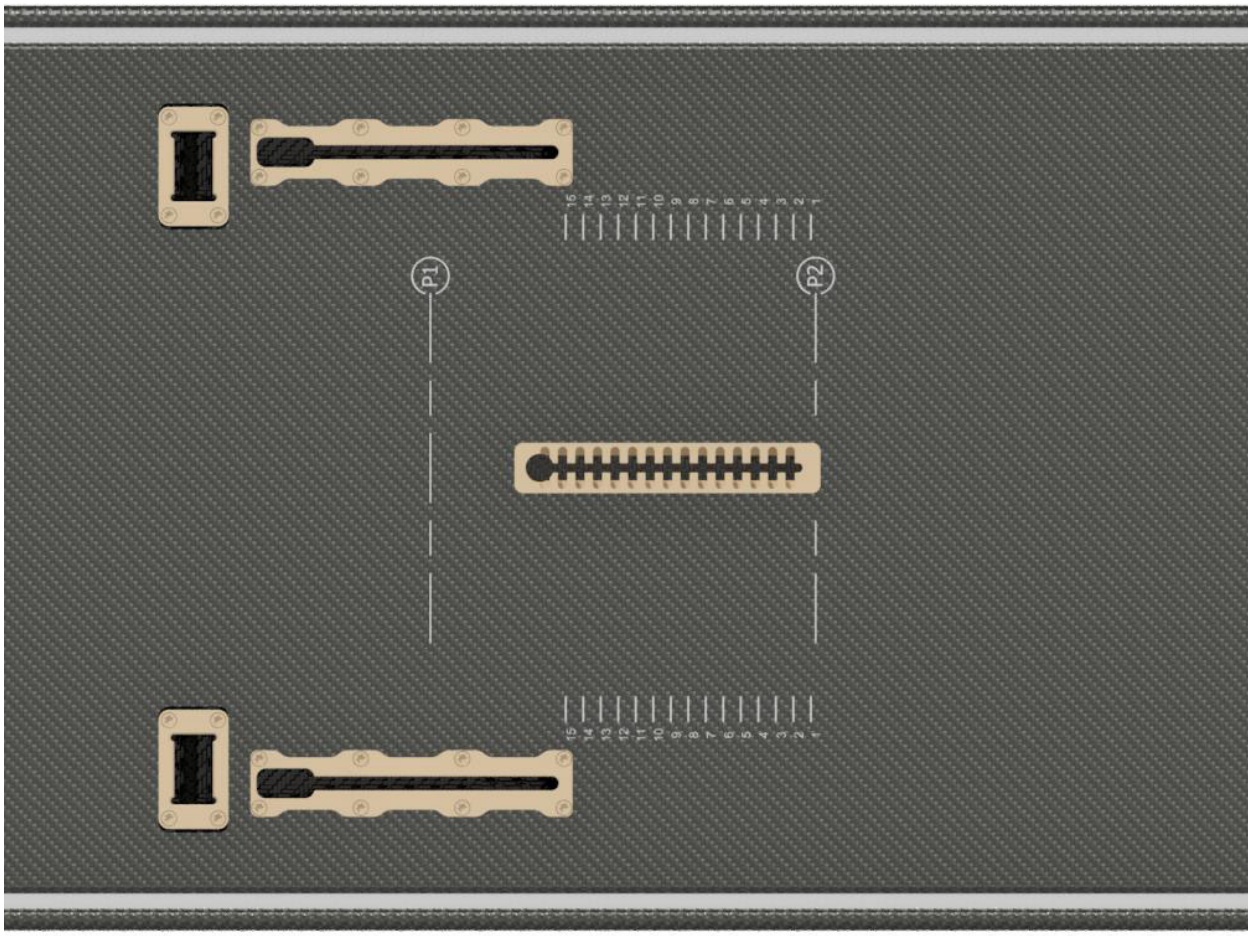
# 3. Intended Use

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

# 4. Installation Instructions

I. The OmniCouch offers a wide range of treatment area with its integrated travel range system. The following instructions explain how range is achieved by moving the OmniCouch couchtop in two discrete positions, P1 or P2.





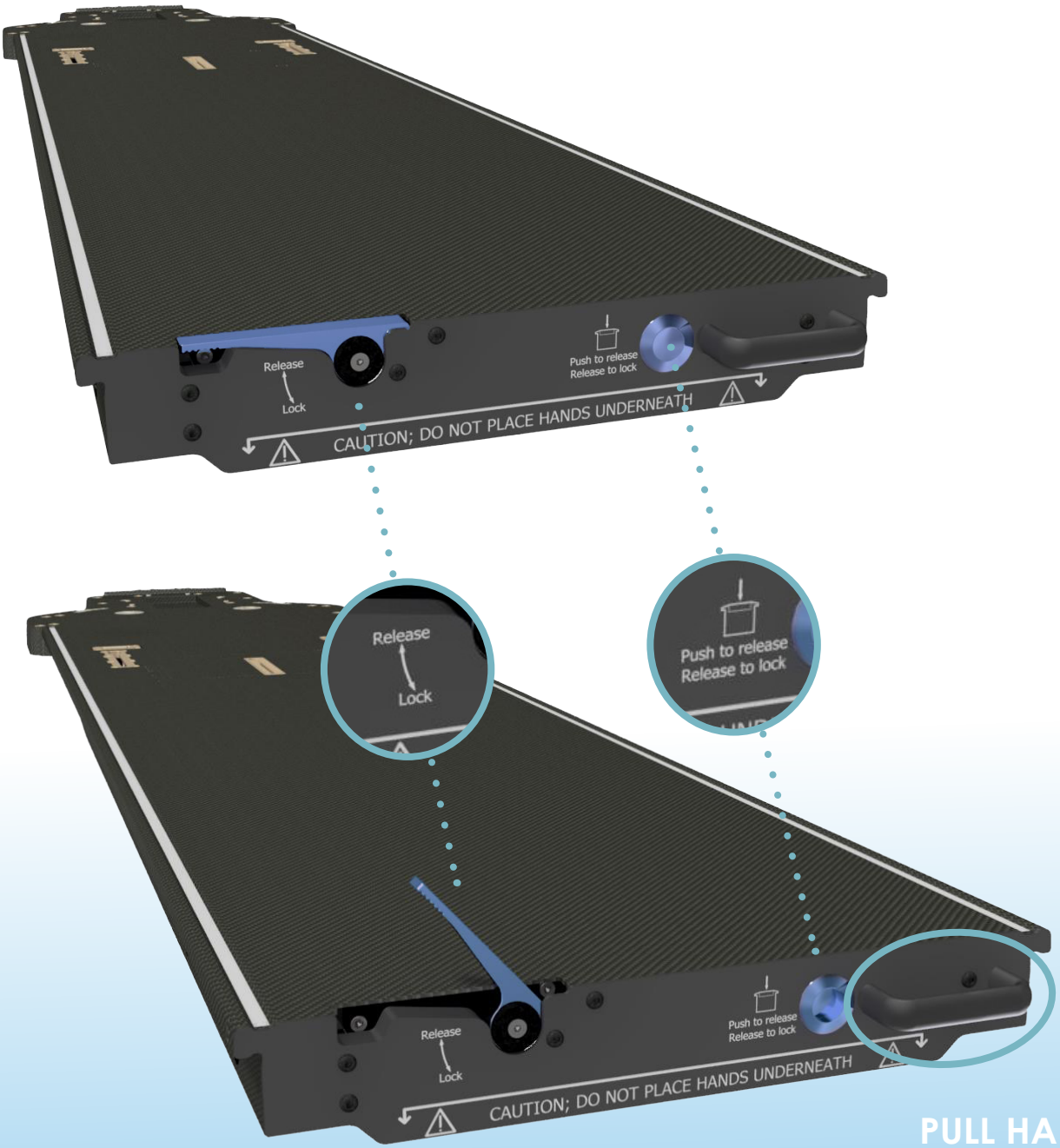
II. It is possible to read the active position on the top surface and on the side of the OmniCouch. See the figures below:


In position P1, an optimal travel range is offered towards the cranial section of the radio translucent part of the OmniCouch Couchtop. In position P2, an optimal travel range is provided towards the caudal section of the radio translucent part of the OmniCouch couchtop.

There are two operating instruments located at the caudal side of the OmniCouch. To move the OmniCouch couchtop from position P1 to position P2 or vice versa, complete the following steps:

- To unlock the Couchtop from its locked position, raise the blue handle upwards.
- To move the OmniCouch, press the blue round button. This releases the second locking mechanism.
- To move the OmniCouch into the desired position, push or pull the black handle. In the newly set position, the blue locking handle will automatically spring back into its closed position and the blue round button should be released. Please see the following images.

The transfer of the OmniCouch couchtop to the desired discrete position can only be achieved with proper operation.




**PULL HANDLE**

# 5. Cleaning, Storage and Disposal

## REGULARLY

- Clean the device before and after every use with soapy water, rinse with clean water and dry properly. Or use isopropanol-based 70 % disinfecting alcohol, applied with a soft cloth. Do not use ethanol-based alcohol.
- Inspect for damage or wear before every use. Do not use when damaged.
- Store the device in a flat position in a safe place.

## PERIODICALLY

- Plastic PEEK parts and apertures.
- To clean the PEEK plastic parts and underlying apertures, remove the PEEK parts and use a clean cloth and soap to wipe clean the part and apertures.
- Carbon fiber surfaces.
- Use a clean cloth and soap to wipe clean the carbon fibre surfaces.
- Metal components.
- Use a clean cloth and soap to wipe clean the aluminium parts on the cranial side of the OmniCouch.

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 standard warranty is for 1 year starting from the date of delivery.

Product warranties remain valid provided the product was installed and used conform the instructions. Defects, malfunctions or failures caused by nature, misuse, abuse and unauthorized 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. |
|  | 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. |
|  GS1 Code: (17) | Use-by Date | Indicates the date after which the medical device is not to be used. When the graphical symbol is used, the date is expressed in the format: YYYY-MM-DD. On the other hand, when expressed next to the GS1 Code (17), the date is in the format: YYMMDD. |
|  | MR Safe | An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment. |
|  | MR Unsafe | 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. |

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