



Kneuro Protective Cover



Instructions For Use

V1.0.2



EN

These Instructions for Use are intended for the patient (user) and their certified prosthetist.



All images, screenshots, and figures are for reference only and are subject to change.

These Instructions for Use (IFU) provide important information on the use, fitting, and handling of the cover only. Refer to the Kneuro Microprocessor Knee System IFU and installation guide if there are questions related to the general use of the prosthetic.

The BRC4-XX Kneuro Protective Cover is hereinafter referred to as the product or the cover.

Important Information for the Certified Prosthetist

To ensure safe and effective use of the Kneuro Protective Cover and to avoid injury, read the Instructions for Use in its entirety before installing or using the product. The patient should be provided with these Instructions for Use.

If you need help with product setup, use, or maintenance, contact the BrainRobotics support team at +1 (512) 969-2989 or support@brainrobotics.com.

Patient Information

To ensure the cover is used safely and to avoid injury, read the Instructions For Use and follow the information provided by your authorized prosthetist when using the Kneuro Protective Cover.

If you need help with product setup, use, or maintenance, contact your prosthetist or the BrainRobotics support team at +1 (512) 969-2989 or at support@brainrobotics.com.

Any serious incident in relation to the product must be reported to the manufacturer and relevant authorities.

Trademark:

All names described in the documents are unconditionally protected by applicable trademark law and are the property of the respective owners. The brands, trade names, or company names described herein may be registered brands and are the property of the respective owners. Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

Liability Disclaimer:

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorized modification of the cover.

European Directive Declaration of Conformity:

This product meets the requirements of the European Directive 93 / 42 / EEC for medical devices. This product has been classified as class I accessories according to the classification criteria outlined in Annex IX of the directive. The declaration of conformity was therefore created by the manufacturer with sole responsibility according to Annex VII of the directive.

Warranty:

Purchase of this product includes a 6-month warranty covering all manufacturer defects. The warranty is only valid if usage of the product is compliant with the manufacturer's recommendations detailed in these Instructions for Use.



Failure to comply with the Instructions for Use will result in voiding the warranty. An extended warranty and service recommendation is available.

For service or repair, contact BrainRobotics customer support at +1 (512) 969-2989 or support@brainrobotics.com.

Device Description

The Kneuro Protective Cover visually and functionally encloses the Kneuro Microprocessor Knee (MPK) joint. In the covered areas, it protects the knee joint housing against external influences such as scratches and surface contamination.

Key components of the product include:



#	Part
1	Knee Pad
2	Control Button Access
3	Metal Clasps
4	USB-C Port & LED Status Indicator Access

Scope of Delivery and Accessories

	Qty	Item	Qty	Item
	1	BRC4-XX* Kneuro Protective Cover *Colors: Jet Black, Eclipse Blue, Carbon Gray, Sage Green	1	Instructions for Use (for qualified personnel)

Intended Purpose

The Kneuro Protective Cover is intended for physical and aesthetic enclosure of Kneuro Microprocessor Knee System (BR4B/BR4C) for use by lower-limb amputees by providing protection of covered areas of knee joint against external influences (surface contamination) and cosmetic defects during general use. The cover does not come into contact with user's skin and is not intended to alter functionality of knee joint. Knee joint remains fully operational without knee cover; however, the cover is recommended to maintain the device's surface integrity.

Intended Users

This product is intended to be used exclusively by users of the Kneuro Microprocessor Knee System and environments in which the Kneuro MPK is intended for use. See the prosthetic instructions for use for intended user details.

Intended Use Environment

- Indoor/Outdoor Activities – This product is intended to be used with the Kneuro MPK during a variety of activities in various terrains and settings.
- The product is designed for everyday use with the Kneuro MPK. See Kneuro MPK IFU for further details.

Indications

The Kneuro Protective Cover is indicated for users of the Kneuro MPK system for the following:

- Protection of the Kneuro Microprocessor Knee from scratches, scuffs, and minor impacts.
- Prevention of dust or surface debris accumulation on the knee joint housing.
- Aesthetic finishing for lower-limb prosthetic systems.

Contraindications & Limitations

Any use that contradicts or exceeds the specifications described in the sections Indications and General Safety Instructions.

- **Non-Skin Contact:** This product is designed to be installed over the prosthetic structure; it is not intended for direct prolonged skin contact.
- **Compatibility:** Not intended for use with any knee systems other than the Kneuro Microprocessor Knee.
- **Functional Limits:** This cover does NOT provide structural support or impact the mechanical/electronic performance of the microprocessor knee.

Combination Possibilities

The product is compatible with the following prosthetic components:

Knee Joint	Reference Number
Kneuro Microprocessor Knee	BR4B / BR4C

General Safety Instructions



Non-observance of safety instructions

- Personal injury or damage to the product may occur if the product is used in unsuitable situations.
- Observe all instructions and precautions provided in this document.



Improper disassembly, assembly, or handling

- Risk of injury due to pinching of body parts.
- Exercise increased caution during disassembly, assembly, and handling of the product.



Unauthorized modifications

- Injury may occur due to malfunction or improper operation.
- Any changes or modifications must only be carried out by authorized, qualified BrainRobotics personnel.



Mechanical damage

- Damage may result in reduced or lost functionality.
- Handle the product with care.
- If the product is damaged, check it for proper function before use.
- Initiate appropriate measures (e.g. repair, replacement, inspection by the manufacturer's customer service).



Exposure to extreme environmental conditions

- Damage to the product due to thermal stress or deformation.
- Do not expose the product outside the temperature ranges described in Technical Specification section provided in this IFU.
- Ensure relative humidity does not exceed 95% during operation, storage, or transport.

Serious Incident Reporting

Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

'Serious incident' is defined as any incident that directly or indirectly led, may have led, or might lead to any of the following: (a) the death of a patient, user, or other person; (b) the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health; or (c) a serious public health threat. If you have any questions or concerns that were not addressed in this manual, please contact the manufacturer.

Installation Instructions

1. Remove the Kneuro Protective Cover from its packaging.
2. Open the cover by pressing the metal clasps through their openings.
3. Spread the cover open and place it over the knee joint with the BrainRobotics logo on top. Openings in the cover should enable access to the Kneuro control button, USB port, and LED status indicator.
4. Press the cover closure together, by pushing the metal clasps through their respective openings.
5. Ensure the fit of the cover by checking:
 - The protective cover does NOT impede access to the proximal pyramid adapter or the distal tube clamp adapter.
 - The control button, USB port, and LED status indicator are clearly visible and accessible.
 - The cover does not excessively slide or slip when installed on the Kneuro MPK.



Contact your prosthetist or BrainRobotics team if you have concerns regarding the fit of the Kneuro Protective Cover.

Compliance

- **Biocompatibility & Safety:** The mixing silicone used in the product belongs to series verified by SGS for safety.
- **US California Proposition 65:** The product has passed testing requirements for Bisphenol-A, Lead, and Phthalates.
- **EU REACH & RoHS:** The materials and coatings (various colors) are compliant with RoHS Directive 2011/65/EU and Regulation (EC) No 1907/2006 (REACH) regarding Substances of Very High Concern (SVHC).
- **Environmental Resilience:** The device is verified resistant to artificial perspiration and salt spray (48-hour testing).

Maintenance

Regularly inspect the cover for signs of cracks, wear and tear or damage that could snag clothing; replace the unit if structural integrity is compromised to ensure continued protection of the Kneuro MPK System.

If you have questions or concerns, contact BrainRobotics customer support at +1 (512) 969-2989 or support@brainrobotics.com.

Cleaning and Care

To clean the product, dampen a lint-free cloth with warm tap water and wipe down the product and all components. Pat dry. Allow the cover to air-dry to remove any remaining moisture. Clean the cover regularly to ensure continued function.

- **Cleaning:** Clean with a damp cloth and mild detergent. Do not use abrasive chemicals that may degrade the protective material.
- **Safety:** Ensure the cover is securely fastened to avoid it becoming a trip hazard or interfering with the mechanical hinges.

Storage and Disposal

Storage: Store in a dry environment at room temperature.

Disposal: This product may be disposed of as standard waste unless contaminated by biological hazards during use.

Magnetic Resonance (MR) Compatibility



The device is MR Unsafe and should not be worn near or during imaging procedures (i.e. CT scan, MRI, etc.).

Technical Specifications

Product basic parameters	Reference Number	BRC4-XX* Kneuro Protective Cover
	Product Service Life	Wear part, subject to normal wear and tear
	Height	11"
	Material	Silicone, Aluminum
Environmental Conditions	Storage temperature	23°F -86°F (-5-30°C)
	Transportation Temperature	-4°F-140°F (-20-60°C)
	Humidity	Max 95% relative humidity (All modes)
	Air pressure	70-106 kPa (Up to 3000m)
Mechanical Performance	Tensile strength	≥6.0 MPa
	Elongation at Break	≥6.0 MPa
	Hardness	≥6.0 MPa
	Fastner Life	500 snap/unsnap cycles

*Indicates color variations

Symbol Table

Symbol	Definition	Symbol	Definition
	Note		Prescription use only (USA)
	Control button		Warning
	USB plug-in		Serial Number
	Must read Instructions for Use		Indicates device is a medical device

Symbol	Definition	Symbol	Definition
	United Kingdom (UK) declaration of conformity		Catalog number
	Manufacturer		Declaration of conformity according to the applicable European directives
	European Authorized Representative		Country of Origin and date of manufacture
	Unique Device Identifier		United Kingdom UK responsible Person
	Unsafe for MR environment		



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