macu4™ | Instructions for use

Lumo System

1. Foreword

Valid from: 15.08.2025

- Read this document carefully before using the product.
- Follow carefully the warnings and instructions for use to avoid injuries and product damage.
- Medical personnel should instruct the lay user on the proper and safe use of the product.
- Contact the manufacturer if you have any questions about the product (e.g., commissioning, use, maintenance, unexpected operation or incidents). You will find the contact details on the back.
- Keep this document in a safe place.

These instructions for use provide you with important information on the use, adjustment and handling of the System. **Please notice that in addition to these Instructions for use, there are several explanation videos available. See https://macu4.com/en/application-lumo.**

2. Use

Intended Use

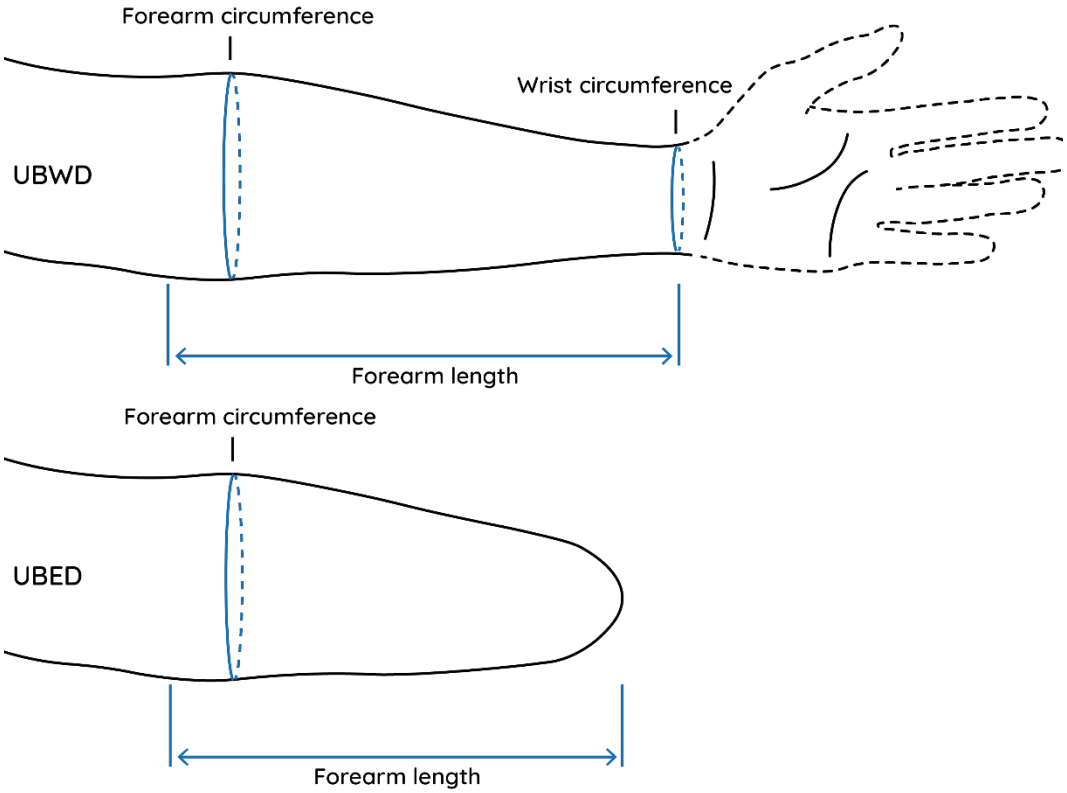
The Lumo System is intended for users with partial or complete loss of hand function due to temporary or permanent weakened hand or hand injury, paralysis, partial hand absence, wrist disarticulation absence or partial forearm and hand absence. By using the Base with a Module, a lack of gripping dexterity, capability or force can be replaced or supported.

Indications

- The system can be used for unilateral amputees from amputation height below the elbow (according to ISO 8549-2:2020).
- The system can be used for unilateral amputees from amputation height below the wrist (according to ISO 8549-2:2020).
- The system can be used for people with unilateral congenital hand or forearm deficiencies (according to ISO 8549-2:2020).
- The system is suitable for persons with impaired or missing gripping function.
- The system is suitable for persons 12 months old and older. An individual evaluation by the specialist is recommended to assess whether the user is physically and mentally in the condition to use the system properly.

Contraindications

- Not indicated for kids under 12 months old. Exceptions: The professional (e.g. doctor, therapist, clinical orthotist prosthetist) can assess whether the user is able to use the system anyway.
- Not indicated for persons with bilateral forearm or hand deficits. Exceptions: The specialist (e.g. doctor, therapist, clinical orthotist prosthetist) can assess whether the user is able to use the system partially despite this.
- Not for persons with cognitive and/or psychological conditions that would not allow for, or only partially allow for, the indicated use of the Lumo system (e.g. dementia, Alzheimer's, psychoses). Exceptions: The specialist (e.g. doctor, therapist, clinical orthotist prosthetist) can assess whether the user is able to use the system partially despite this.
- Not for persons for whom the Lumo system is expected to place too much mechanical stress on adjacent joints due to the indicated user requirements.
- Not for persons with neurological diseases in which learning movements using the Lumo system would be impaired.
- Not for individuals with fresh wounds, allergies or sensitive skin on the arm.
- Not for individuals with a UBWD combined with a forearm circumference below 110 mm (4.33 in) or above 180 mm (7.09 in), or a wrist circumference below 100 mm (3.94 in) or above 135 mm (5.31 in), or a forearm length of less than 120 mm (4.72 in).
- Not for individuals with a UBED combined with a forearm (residual arm) circumference below 140 mm (5.51 in) or above 180 mm (7.09 in), or an arm length below 50 mm (1.97 in).



Anthropometric values definition.

The system may only be used by users who are physically and mentally fit to operate the system properly. If you are unsure whether the physical and/or mental fitness is sufficient, we recommend an individual assessment by a specialist (e.g. doctor, therapist, prosthetist).

Combination possibilities
The system has been tested for combination possibilities of the Lumo Cuff and Lumo Socket with the different Lynk Clic Heads.

CAUTION

3. Warnings

FAILURE TO HEED THESE WARNINGS OR TO FOLLOW THE INSTRUCTIONS FOR USE COULD RESULT IN MALFUNCTION OF THE DEVICE OR PHYSICAL INJURY. IN THE EVENT OF INJURY, SEEK MEDICAL ATTENTION PROMPLY.

Operating conditions - General
Please note that the system is intended exclusively as a medical aid. It is not suitable as a tool and must not be used for other purposes.
The system was specifically developed for everyday, sports, and leisure activities involving low to moderate physical stress. The system must not be used for exceptional activities. Such exceptional activities include, for example, sports with excessive coupling and/or impact loads (push-ups, downhill or mountain biking, etc.) or extreme sports (free climbing, paragliding, etc.).
Furthermore, the system should not be used for operating motor vehicles, heavy machinery (e.g., construction equipment), industrial machines, motor-driven work equipment, or devices with an increased risk of injury—including, but not limited to, firearms, chainsaws, or hedge trimmers.
Always avoid direct contact between the product materials and food. Do not put the product in your mouth.

Notes on unpacking the supplied components

Only open the packaging at the indicated locations with care so that the components inside are not damaged.

General
Carefully inspect your product components before use to ensure that no component is damaged. Always contact support@macu4.com and do not use the component if you suspect or believe, for example, that:

- a component is damaged,
- a component is not suitable for a specific activity,
- a module cannot be easily connected to the cuff or socket,
- the closure mechanism is not working properly or releases unintentionally
- the cuff or socket unintentionally detaches from the arm.

Be sure to watch the instruction video for the component you intend to use. Incorrect use may lead to discomfort, malfunction, or injury to person or property. If you do not find your activity in the provided instruction videos, please contact support@macu4.com or the professional who provided you with the system for instructions before starting the activity.

USE UNDER ADULT SUPERVISION
THE COMPONENTS ARE SUITABLE FOR USE IN CHILDREN AS DESCRIBED IN THE INDICATIONS. BECAUSE CHILDRENS OF THAT AGE ARE NOT ABLE TO USE THE PRODUCT INDEPENDENTLY, THE COMPONENTS MUST ALWAYS BE USED UNDER THE DIRECT SUPERVISION OF A PARENT, LEGAL GUARDIAN, OR RESPONSIBLE ADULT CAREGIVER. SUPERVISION IS REQUIRED AT ALL TIMES DURING USE TO ENSURE SAFETY AND PROPER OPERATION.

Notes on Modules - General
Do not overload the Modules. Always clean the Modules after each use. Remove visible dirt particles so that Modules with flexible modes are not restricted in their function.
Do not use any component as a means to manage objects that are sharp or that could cause damage in case of loss of control (i.e. razor, drill, knives, etc.).
Don't use a Module if the diameter of the object is too large (see Chapter 12). If the diameter of an object is too small, you can increase the diameter slightly by using a soft material around the area where you want to attach the module to the object. For example, when using the Hold Module to hold a fork.
Before using a Module, check if it is compatible with the handle (i.e. bike handle, etc.) or object (i.e. fork, etc.), that the Module is tightly secured on the handle or the grip or the object, and that you have chosen the correct orientation of the Module on the object/handle.

Notes on the SHOVEL Module
Before using the module, be sure that the screw is tightened and did become loose. It may loosen in position when the main part of the module is turned frequently. If it becomes loose, ensure that the screw is engaging with the nut and tighten it. Tighten the screw with a 2.5 Allen key.

Notes on the ROLL Module
Before using the module, make sure that the screw is tighten and did not get loose. It may get loose in position when the main part of the module is turned frequently. When it gets loose than ensure that the screw is engaging with the nut. Tighten the screw with a 2.5 Allen key.

Notes on the HOLD Module
Before using the module, make sure that the screw of the eccentric cam is tighten and did not get loose. It may get loose in position when the eccentric cam was turned too much counterclockwise. When it gets loose than ensure that the position of the eccentric cam screw is engaging with the nut.

Notes on selection of product size

- Do not use a Cuff or Socket size that is too big for your arm. Any excessive tightening can damage the bendable product parts.
- Do not use a Cuff or Socket size that is too small for your arm. It can lead to painful pressure marks and/or impede vascular flow.

Notes on Cuff and Socket

- Do not use the Cuff or Socket when the protective material is missing.

- Be sure that the Cuff or Socket always sits tight on your forearm. If it becomes loose, tighten the Velcro.

Notes on ambient conditions
Always store or use the products in accordance with the information on temperature, UV radiation and humidity as specified in this instruction in Chapter 12. The material properties of the components may change significantly when used and stored at higher or lower temperatures, as stated in this document, and lead to discomfort, malfunction, or injury to person or property.

Notes on storage conditions
Always make sure that the components are well protected during transportation and permanent storage. Do not place weight on a component. It could deform or damage a component. In case of deformation or damage, the component can no longer be used.

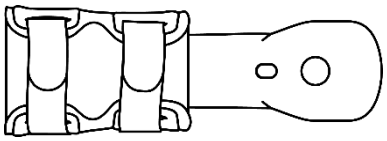
NOTES ON MAGNETS IN THE COMPONENTS
THE CUFF, SOCKET, MODULE CONNECTOR, AND SPACER CONTAIN MAGNETS (SEE CHAPTER 10), KEEP THE COMPONENTS AT LEAST 15 CM / 6 IN AWAY FROM E.G. PACEMAKERS OR DEFIBRILLATORS.

4. Use of the Components

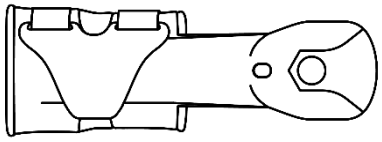
Before using the Lumo components for the first time, familiarise yourself with the instructions for use. The following chapters explain how to use the Lumo Modules together with the Lumo Cuff or Socket.

4.1. How to use the Lumo Cuff

Design and structure of the Lumo Cuff

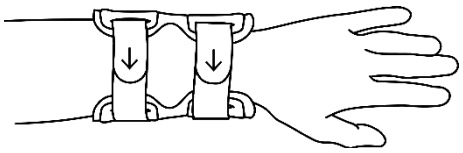


Cuff from the top side equipped with Velcro System



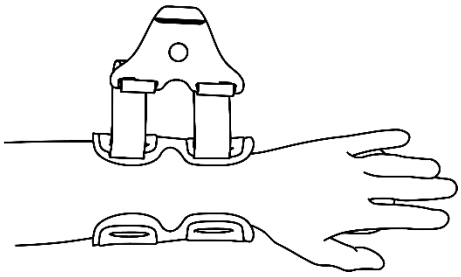
Cuff from the backside (here: with the Hook in its anchoring position)

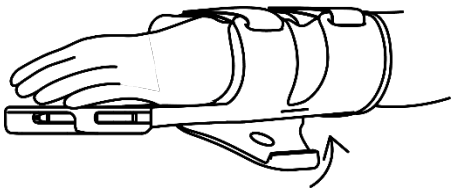
When using the Cuff for the first time
Make sure that the Cuff sits tight and cannot be moved easily. If the Cuff sits too loose on your arm, you should adapt the Velcro straps. The fit of the Cuff on the arm should be snug but not uncomfortable.



Install Cuff | Open the Velcro strap and pull slightly on the Velcro strap to tighten the sit on your arm.

Put on the Cuff





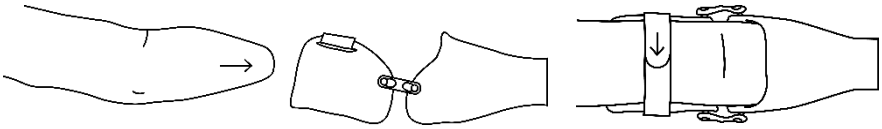
Insert your arm | You can either place the Cuff on a table and insert your arm into it. Or you can use your other hand to hold the Cuff while inserting your arm.

Secure the Cuff on your arm | Place the Hook in front of the Hook Anchoring Holes - the magnets will allow it to click into place. Make sure it is well-positioned and secured by gently moving the Cuff.

4.2. How to use the Lumo Socket

Make sure that the Socket sits tight and cannot be moved easily. If the Socket sits too loosely on your arm, you should adjust the tension of the Laces. The fit of the Socket on the arm should be snug but not uncomfortable.

Put on the Socket



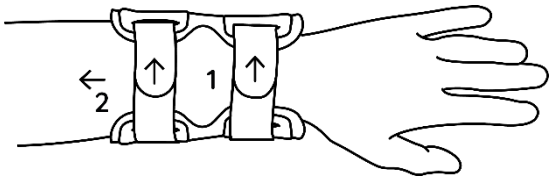
Insert your arm | You can either place the Socket between your legs and insert your arm into it. Or you can use your other hand to hold the Socket while inserting your arm.

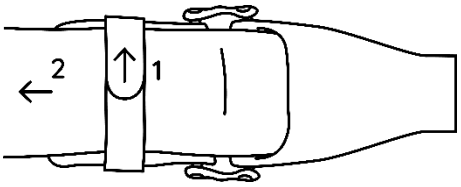
Secure the Socket on your arm | First, pull on the Velcro of the lower shell and, second, on the Velcro of the upper shell. Make sure it is well-positioned and secured by gently moving the Socket.

4.3. Final control

- Check the fit of the Cuff or Socket before you start any activity.
- Make sure it is well-positioned and secured by trying to move the Cuff or Socket gently. The Cuff or Socket should remain firmly in position.
- If the Cuff or Socket is not tight and can be moved, recheck the Velcro System.

4.4. How to remove the Cuff or Socket

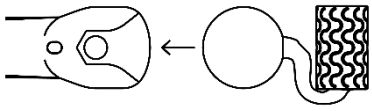




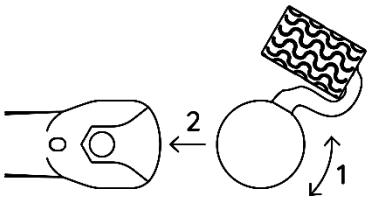
Option for the Cuff | Pull on the Hook. It shall disengage from the Cuff. Once the Hook is free, you can remove the Cuff from your arm.

Option for the Socket | Open the Velcro closure on the upper and lower shells.

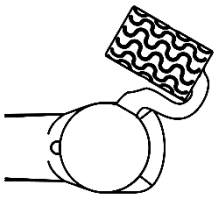
4.5. How to use a Module with the Cuff or Socket



Insert Module | Insert the module into the module receptor. You should hear a small sound.



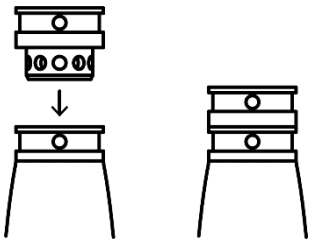
Change position | Remove the Module and insert it in a different orientation.



Final check | Make sure the Module is well-positioned and secured by trying to move it gently. The Module should remain in position.

4.6. How to connect a Spacer to a Socket

A spacer is only used in cases where compensation for the difference between the two arms is necessary and cannot be compensated for by the Module Connector alone.



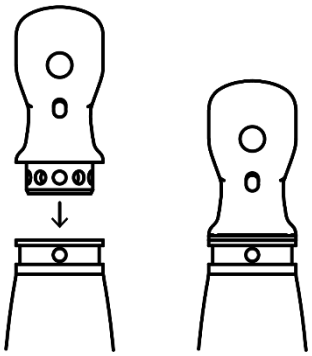
Insert the Spacer | Insert the Spacer into the distal part of the Socket. A magnet will hold it in place.

Change position | Rotate the Spacer to reach the desired orientation. Note that the final orientation is mainly fixed by the Module Connector.

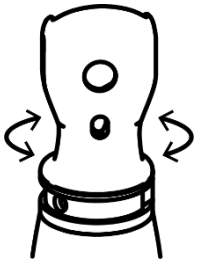
Secure the position | Make sure the holes of the Spacer and the Socket are well aligned. This is necessary to successfully insert the Adapter Pin to lock the orientation. The Adapter Pin shall never protrude.

4.7. How to connect the Module connector to a Socket or a Spacer

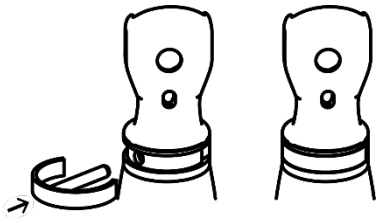
The Module Connector allows the Modules to be connected to the socket.



Insert the Module Connector | Insert the Module Connector into the distal part of the Socket or a Spacer.
A magnet will hold it in place.



Change position | Rotate the Module Connector to reach the desired orientation.



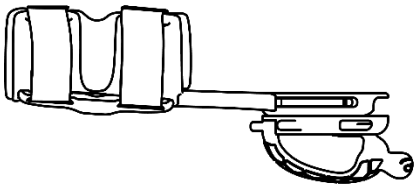
Secure the position | Make sure the holes of the Module Connector and the Socket or Spacer are well aligned, and then insert the Adapter Pin to lock the orientation. The Adapter Pin shall not protrude.

5. Lumo Modules

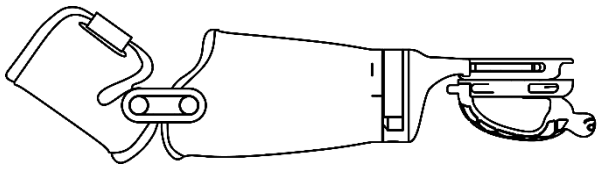
The modules offer no rotation but various locked positions. You can choose between different locked angles.

5.1. CLAMP Module

Design and structure of the Module



Module coupled to the Cuff.



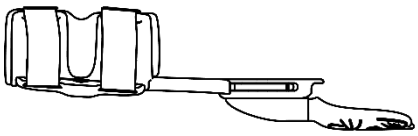
Module coupled to the Socket.

Use case examples with the Module

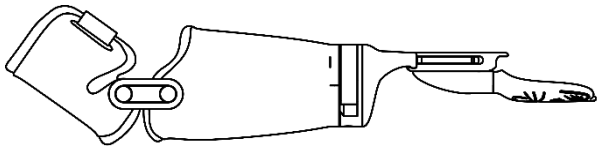
- **Cutting |** Hold a piece of paper to cut it with scissors.
- **Play |** Hold playing cards.

5.2. SHOVEL Module

Design and structure of the Module



Module coupled to the Cuff.



Module coupled to the Socket.

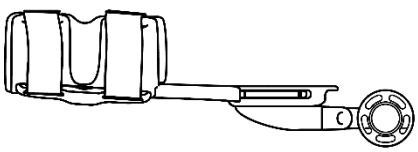
Use case examples with the Module

- **Sand castles |** Play in the Sandbox or at the beach.
- **Support |** Hold objects requiring two arms.

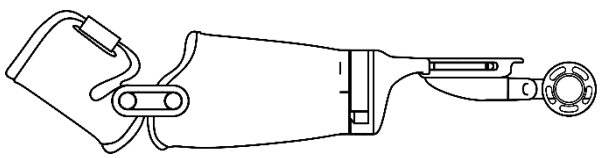
Systematically check that the module has no play at the level of the screw. If this is the case, tighten the screw with a 2.5 Allen key.

5.3. ROLL Module

Design and structure of the Module



Module coupled to the Cuff.



Module coupled to the Socket.

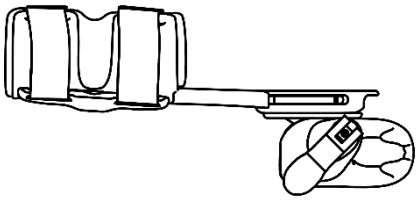
Use case examples with the Module

- **Modelling Clay |** Play and spread the clay with the Roll.
- **Music |** The Roll is a maraca (shaker).

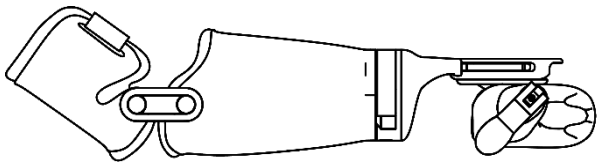
Systematically check that the module has no play at the level of the screw. If this is the case, tighten the screw with a 2.5 Allen key.

5.4. HOLD Module

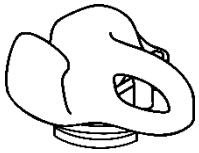
Design and structure of the Module
The Module is provided as one single part with a removable module head element.



Module coupled to the Cuff.

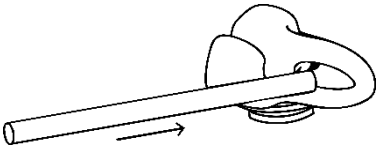


Module coupled to the Socket.

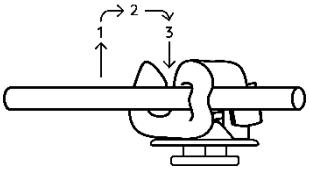


Flexible module head | The module head is a clamp-like element and is made from a flexible material to better conform to objects.

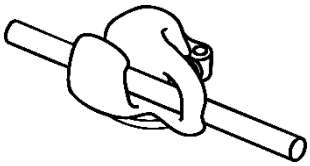
Adaptable orientation | You can turn the module head in various directions to find the desired orientation for your activity by releasing the lever.



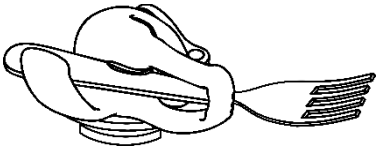
Insert the object | Insert the desired object in the hole as indicated by the arrow. Depending on the geometry of the object, it is possible to insert it from the other side.



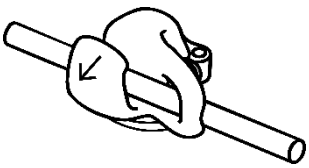
Securing the object | Follow the steps illustrated by first pulling up the object, second rotating it, and third pressing it into position.



The object is secured | To change the orientation, use the lever.



Securing the orientation of flat objects | Use the slits to prevent flat objects from rotating involuntarily.



Pull on the flexible part (here illustrated by the indicator) | The object shall release. You can then take it out.

Use case examples with the Module
Always make sure that objects or handles are properly positioned and secured by lifting the object and shaking it gently. Please consult the website of macu4, where you will find specific explanation videos under the section 'Application'.

- **Pens |** For example a pen with a cylindrical handle.
- **Flat objects |** For example a fork with a flat handle.

6. Storage of product

The product has been specially developed for use with small children. However, it is not a toy and should not be stored or treated as such. To ensure the safety of your child and to maintain the functionality of the product, please observe the following instructions:

- After use, store the product in a clean, dry and safe place – out of the reach of children unless they are under direct adult supervision.
- Store the product away from areas where it could be mixed with other toys or games or otherwise handled improperly.
- Protect the product from dust, water, dirt and mechanical impact.
- Avoid storing in places subject to extreme temperature fluctuations or high humidity.

7. Maintenance

- Remove Dirt Particles: Use a soft-bristle brush to gently remove dirt from any spaces between product components. Do not use water for this step.
- Clean Surfaces: Wipe the product surfaces with a damp (not wet), non-abrasive cloth. Use only cold or lukewarm water.
- Disinfection (if needed): If disinfection is required, use a material specifically suitable for medical devices (risk class I, plastic materials).
- Important: Never put the macu4 medical device in any cleaning appliance or other device (washing machine, dishwasher, microwave, steamer, or similar).

8. Adverse event reporting

Any serious incident related to the device should be reported to the manufacturer and the competent authority of the member state where the user and/or patient is established. Please use the form Please use the Product Experience Report (PER) https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/macu4_GmbH_Lumo/Product_Experience_Report_EN.pdf and send it to by email to support@macu4.com.

9. Legal notice

Limitation or exclusion of liability
Failure to follow these instructions for use, care, maintenance, handling, storage, etc., of this product, or the use of this product in any component combination other than those approved by macu4 GmbH (hereinafter referred to as "Macu") constitutes misuse of the product and invalidates any and all warranties, express or implied, in their entirety as to any consequences of such misuse. In the event of such misuse, Macu disclaims liability for any adverse consequences to the maximum extent allowed by law. Any opening, disassembly, or repair of the products may only be carried out by Macu or with Macu's written permission.

10. Conformity

The product components of the system Lumo with the Basic UDI-DI marking

Lumo Manschette	426242965P030201RF
Lumo Shovel	426242965P030202RH
Lumo Roll	426242965P030203RK
Lumo Hold	426242965P030204RM
Lumo Clamp	426242965P030205RP
Lumo Spacer	426242965P030207RT

Lumo Modul Connector	426242965P030208RV

meet the general safety and performance requirements according to Regulation (EU)2017/745 for medical devices and the Medical Devices Ordinance (MedDO) of 1 July 2020 (812.213).

Other products:

Lumo Socket	Not CE marked and as customization available

Legal manufacturer
macu4 GmbH, Bücklestrasse 3, 78467 Constance, Germany

CE Marking Details
Macu declares that it complies with the relevant European standards for the design, manufacture and supply of orthopedic products. The products meet the requirements of the European Regulation (EU)2017/745 Annex I for medical devices. Based on the classification criteria according to Annex VIII of this regulation, the Cuff has been classified as Class I and all other products as Class I “Accessories”. The declaration of conformity has, therefore, been drawn up by the manufacturer under his sole responsibility in accordance with Annex IV of the Regulation. All products of the System are marked accordingly.

Trademark
All designations mentioned in this document are subject without restriction to the provisions of the applicable trademark law and the rights of the respective owners. All trademarks, trade names, or company names mentioned herein may be registered trademarks and are subject to the rights of their respective owners. The absence of explicit identification of the trademarks used in this document does not imply that a designation is free of third-party rights.

11. Symbols

The table below shows all symbols (according to ISO 15223-1:2021) used on the product and on the label.

CE Mark

This symbol indicates that a manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EEA.

Instructions for use.

This symbol indicates that the user must consult the instructions for use.

Manufacturer

This symbol indicates the manufacturer of the medical device.

Temperature limit

This symbol indicates the temperature limits to which the medical device can be safely exposed.

Date of manufacture

This symbol indicates when the medical device was manufactured.

Batch designation

This symbol indicates the manufacturer's batch code so that the batch or lot can be identified.

Catalog number

REF — This symbol indicates the manufacturer's catalogue number so that the item can be identified.

Medical device

MD — This symbol indicates that the item is a medical device.

Clear device identification

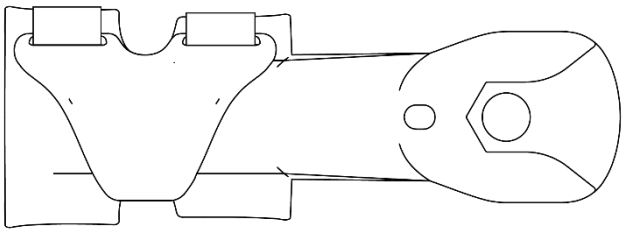
UDI — This symbol identifies a carrier that contains information for unique device identification.

MR Unsafe

This symbol indicates a medical device or other item which is known to pose hazards in all magnetic resonance (MR) environments and should not be brought into the MRI scanner room.

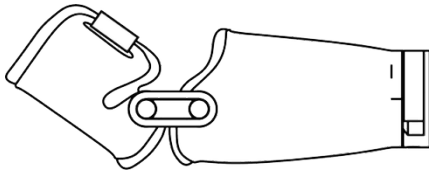
12. Technical data

12.1. CUFF

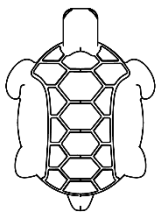
General	
Drawing	 Different versions are available. The present drawing is only informative.
Dimensions (size: STD-SML)	STD-SML-A : 123.8 mm × 56.8 mm × 46.2 mm / 4.87 in × 2.24 in × 1.82 in STD-SML-B : 143.8 mm × 56.8 mm × 46.2 mm / 5.66 in × 2.24 in × 1.82 in STD-SML-C : 163.8 mm × 56.8 mm × 46.2 mm / 6.45 in × 2.24 in × 1.82 in STD-SML-D : 183.8 mm × 56.8 mm × 46.2 mm / 7.24 in × 2.24 in × 1.82 in STD-SML-E : 203.8 mm × 56.8 mm × 46.2 mm / 8.02 in × 2.24 in × 1.82 in
Dimensions (size: STD-MED)	STD-MED-A : 123.8 mm × 62.4 mm × 51.4 mm / 4.87 in × 2.46 in × 2.02 in STD-MED-B : 143.8 mm × 62.4 mm × 51.4 mm / 5.66 in × 2.46 in × 2.02 in STD-MED-C : 163.8 mm × 62.4 mm × 51.4 mm / 6.45 in × 2.46 in × 2.02 in STD-MED-D : 183.8 mm × 62.4 mm × 51.4 mm / 7.24 in × 2.46 in × 2.02 in STD-MED-E : 203.8 mm × 62.4 mm × 51.4 mm / 8.02 in × 2.46 in × 2.02 in

Weight	Depending on product size, between 47 g and 70 g (1.66 oz to 2.47 oz)
Material	Cuff shell: PA2200, coloured with DM standard colour (DyeMansion) Protective material: Alcantara, Velour Velcro: Nylon Magnets: Neodymium–iron–boron (NdFeB), grade 52, Nickel–copper–nickel coating. Dimensions: Ø 9 mm (0.35 in) × 3 mm (0.12 in), tolerance ±0.1 mm (± 0.004 in)
Lifetime of the product	2 years at an average of 120 minutes per day with daily use

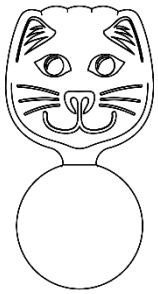
12.2. SOCKET

General	
Drawing	
Dimensions	Varies according to product size
Weight	Depending on product size, between 60g and 120g (2.12 oz to 4.23 oz)
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion) Magnets: Neodymium–iron–boron (NdFeB), grade 52, Nickel–copper–nickel coating. Dimensions: Ø 9 mm (0.35 in) × 3 mm (0.12 in), tolerance ±0.1 mm (± 0.004 in)
Lifetime of the product	2 years at an average of 120 minutes per day with daily use

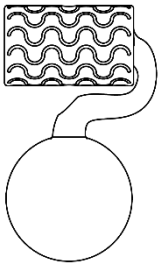
12.3. CLAMP Module

General	
Drawing	
Dimensions	51.9 mm × 70.6 mm × 36.9 mm / 2.04 in × 2.78 in × 1.45 in
Weight	23 g / 0.81 oz
Allowed thickness of objects	From 0.15 mm to 5 mm (0.006 in to 0.20 in)
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion)
Lifetime of the product	2 years at an average of 120 minutes per day with daily use

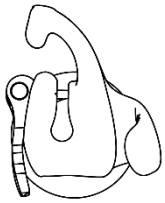
12.4. SHOVEL Module

General	
Drawing	
Dimensions	51.6 mm × 98.8 mm × 20.6 mm / 2.03 in × 3.89 in × 0.81 in Dimensions may vary depending on the orientation of the Module
Weight	20 g / 0.71 oz
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion)
Lifetime of the product	2 years at an average of 120 minutes per day with daily use
Maximum load forces in the Module	
Maximal Pushing force	30 N / 6.74 lbf
Maximum mass allowed in the shovel	0.5 kg / 1.10 lb

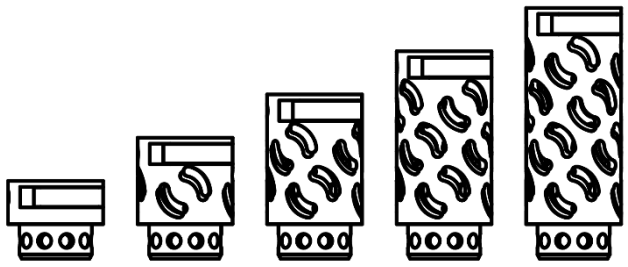
12.5. ROLL Module

General	
Drawing	
Dimensions	53.1 mm × 89.3 mm × 28.0 mm / 2.09 in × 3.52 in × 1.10 in Dimensions may vary depending on the orientation of the Module
Weight	32g / 1.13 oz
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion)
Lifetime of the product	2 years at an average of 120 minutes per day with daily use
Maximum load forces in the Module	
Maximal Pushing force	30 N / 6.74 lbf

12.6. HOLD Module

General	
Drawing	
Dimensions	52.2 mm × 67.3 mm × 41.1 mm / 2.06 in × 2.65 in × 1.62 in Dimensions may vary depending on the orientation of the Module
Allowed diameters for objects	Maximum 15.00mm / 0.59 in
Weight	50 g / 1.76 oz
Material	Module body: PA2200, coloured with DM standard colour (DyeMansion) Module head: Ultrasint TPU01
Lifetime of the Module	2 years at an average of 120 minutes per day / daily use
Maximum conditions the Module can withstand	
Maximum object weight	0.5 kg / 1.10 lb

12.7. SPACER

General	
Drawing	
Dimensions	STD-A : 44 mm × 44 mm × 36 mm / 1.73 in × 1.73 in × 1.42 in STD-B : 44 mm × 44 mm × 51 mm / 1.73 in × 1.73 in × 2.01 in STD-C : 44 mm × 44 mm × 66 mm / 1.73 in × 1.73 in × 2.60 in STD-D : 44 mm × 44 mm × 81 mm / 1.73 in × 1.73 in × 3.19 in STD-E : 44 mm × 44 mm × 96 mm / 1.73 in × 1.73 in × 3.78 in
Weight	Depending on product size, between 25g and 50g (0.88 oz to 1.76 oz)
Material	Spacer body: PA2200, coloured with DM standard colour (DyeMansion) Magnets: Neodymium–iron–boron (NdFeB), grade 52, Nickel–copper–nickel coating. Dimensions: Ø 9 mm (0.35 in) × 3 mm (0.12 in), tolerance ±0.1 mm (± 0.004 in)
Lifetime of the product	2 years at an average of 120 minutes per day with daily use

12.8. MODULE CONNECTOR

General	
Drawing	
Dimensions	44 mm x 44 mm x 94,5 mm / 1.73 in × 1.73 in × 3.72 in
Weight	30 g / 1.06 oz
Material	Connector body: PA2200, coloured with DM standard colour (DyeMansion) Magnets: Neodymium–iron–boron (NdFeB), grade 52, Nickel–copper–nickel coating. Dimensions: Ø 9 mm (0.35 in) × 3 mm (0.12 in), tolerance ±0.1 mm (± 0.004 in)
Lifetime of the product	2 years at an average of 120 minutes per day with daily use

12.9. Environmental conditions

Conditions	
During transport	• Protect from direct sunlight (UV radiation) • Temperature shall be 0 °C to +35 °C / 32 °F to 95 °F
During operation	• Temperature shall be 0 °C to +35 °C / 32 °F to 95 °F
When not in use (e.g. long-term storage)	• Protect from direct sunlight • Max. 70 % relative humidity

13. Allergic reactions

THIS PRODUCT IS FORMULATED FOR GENERAL SKIN COMPATIBILITY. HOWEVER, ALLERGIC REACTIONS MAY OCCUR IN SOME INDIVIDUALS, PARTICULARLY THOSE WITH A HISTORY OF SKIN ALLERGIES OR SENSITIVITY. DO NOT USE IF YOU HAVE A KNOWN ALLERGY OR HAVE PREVIOUSLY EXPERIENCED A REACTION TO ANY OF THE MATERIALS USED IN THIS PRODUCT. DISCONTINUE USE IMMEDIATELY AND SEEK MEDICAL ADVICE IF REDNESS, ITCHING, RASH, SWELLING, OR IRRITATION OCCURS. INDIVIDUALS WITH SENSITIVE SKIN SHOULD REVIEW THE FULL LIST OF MATERIALS AND, IF NECESSARY, PERFORM A PATCH TEST BEFORE FIRST USE. FOR DETAILED INFORMATION ON THE MATERIALS USED IN SPECIFIC PRODUCTS, PLEASE CONTACT MACU. THE TECHNICAL DATA SECTION PROVIDES GENERAL INFORMATION ON MATERIAL USAGE ONLY.

14. Returns

If you suspect or believe there is a problem with your product, please first read this manual carefully before contacting support@macu4.com or your prosthesis manufacturer (unless you purchased the product directly from Macu). Please use the Product Experience Report (PER):
https://25462115.fs1.hubspotusercontent-eu1.net/hubfs/25462115/macu4_GmbH_Lumo/Product_Experience_Report_EN.pdf
Please provide the UDI-DI (starting with "(01) _____") and UDI-PI (starting with "(10) _____") of your Module when requesting warranty repairs or returns. These can be found on the product.
If you return your product to us or your prosthetist, please pack it appropriately; the original packaging in which you received your product is perfectly suitable for this purpose.