

1. Background

This guide provides you with inclusion and exclusion criteria for the macu4™ Explorer socket. It serves you to determine whether it is suitable for your client. The socket is a pre-defined design that is custom-made for each client (user) based on 8 parameter values and the assembly technique.

Consult the instructions for use with regards to the purpose, indication(s), contraindication(s), operating condition(s), and other aspects that are relevant to you before you make your decision. Note that socket length is determined by the residual arm length. Any arm length difference is compensated by a spacer that is attached to an activity module and depending on the activity module type.

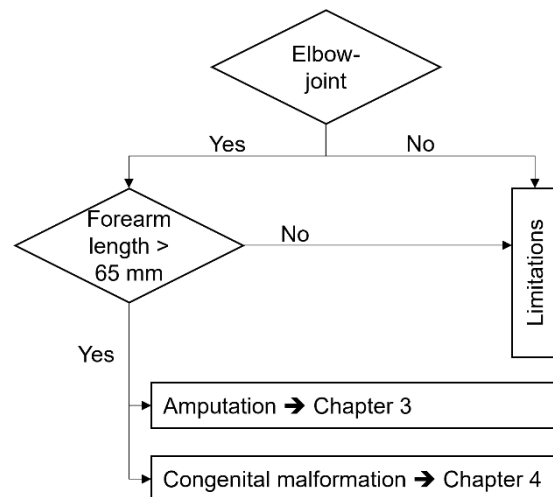
2. General criteria

The socket is not indicated for individuals with

- bilateral forearm deficits, who have musculoskeletal limitations (e.g., stiffness in the shoulder joint).
- fresh wounds.
- allergies or sensitive skin on the arm.

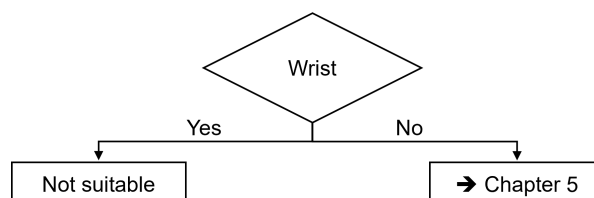
The current socket design has limitations or may not be suitable when it is used for people

- with no elbow joint.
- when the length of the residual arm (L_4) is shorter than 65mm (consult chapter 4.2).



3. Criteria for people with an amputation

In case of an amputation, the socket is not suitable if the wrist is still present because this would result in a significant overlength of the prosthesis system. If it is not the case, continue to chapter 5. Further information concerning pressure sensitivity in the case of amputation is specified in chapter 4.2.



4. Criteria for people with congenital malformation

4.1. Stepwise assessment

Step 1: Length of non-affected arm

On the non-affected arm, measure parameter L_5 . It is the distance between the Epicondylus Medialis and the palm of the hand as described in the measurement instructions.

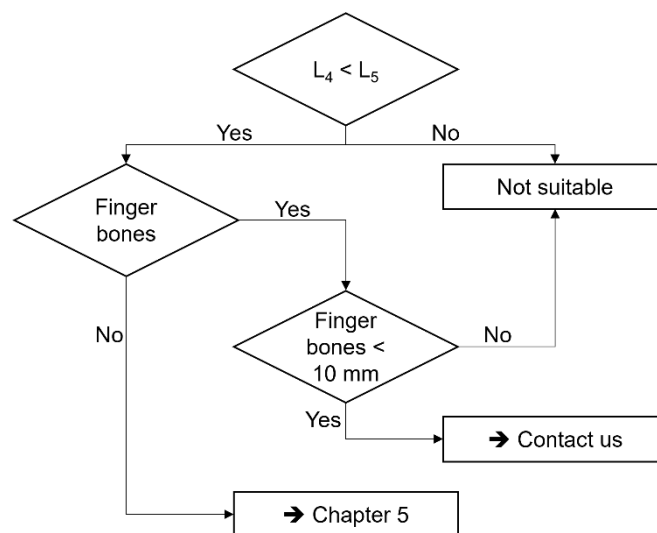
Step 2: Length of affected arm

On the affected arm, measure parameter L_4 . It is the distance between the Epicondylus Medialis and the distal arm end as described in the measurement instructions.

Step 3: Compare both L_4 and L_5 .

If L_4 is smaller than L_5 , control the presence of finger bones.

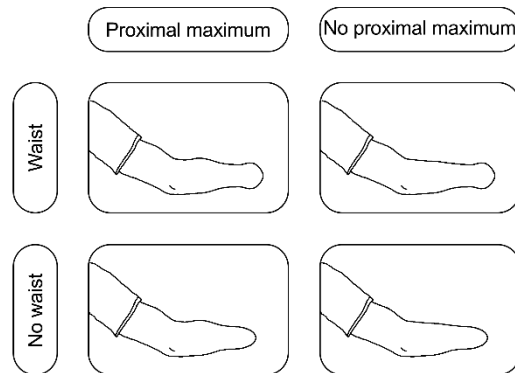
- If there are no finger bones, continue directly to chapter 5.
- If there are finger bones, they should be smaller than 10 mm and facing/positioned distally. Please contact us at support@macu4.com.



4.2. Supplementary considerations

Consideration 1: Arm shape without Proximal Maximum and without Waist

Different groups of potential users were identified to facilitate the measurement process. The groups are determined over two main criteria: the presence of a waist and the presence of a proximal maximum. The socket may slip off the residual arm easier when there is no waist and no proximal maximum.



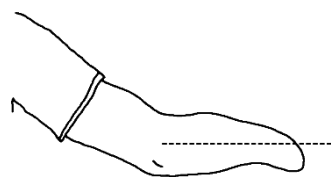
A waist corresponds to an area where the arm presents a local minimal circumference, i.e., a thinner section than the sections after and before it. A proximal maximum is considered a thicker section than the elbow section, which is present distal from the elbow and before (proximal to) the waist, if there is any. The measurement instructions provide more explanations.

Consideration 2: Short arms

Short arms imply a lower surface of contact between the arm and the socket. It can lead to a loss of adhesion and stability. However, we have demonstrated with several users that these limitations can be overcome by considering additional customisations. Please contact us at support@macu4.com for supplementary recommendations.

Consideration 3: Curved arm shape

The case where the residual arm presents a curved shape is also covered. A curved shape is considered if the arm's shape deviates distally significantly from being rotationally symmetric around the axis (dashed line) determined by the arm proximally. For such cases, the socket can be considered to be suitable if the special measurement process is evaluated to be adequate. Please consult the measurement instructions.



Consideration 4: Soft tissues

The socket design enables handling cases with a lot of moving soft tissues, especially fat. The closing system distributes pressure uniformly on the arm once it is completely inserted. Additional considerations can help to take advantage of soft tissues. Please contact us at support@macu4.com.

Consideration 5: Pressure sensitivity

Depending on the user's sensitivity in the distal area of his arm, the geometry of the distal part of the socket can be adapted to place additional cushioning material. Please consult the measurement instructions.

5. Additional considerations

Additional considerations regarding the overall overlength when the socket is used with the activity modules should be taken into account. Note that the arm length difference between the two arms will be compensated for each activity module with the help of a spacer when needed. Have a look at our Instructions for Use of the macu4™ Explorer socket and modules to know more.

The table below provides you with the offset generated by the design for the socket and also for a combination of a module with the socket. Additionally, the maximum arm lengths difference that can be covered by a spacer is given. Note that the offset corresponds to the difference between the area of interest of the module (e.g. the location where the Bike module is attached to the handlebar) and the palm of the hand. For the socket, it only corresponds to the added length without any module (surface of coupling interface).

	No overlength, if $\Delta L = L_5 - L_4$ (mm) is bigger than:	Maximum arm difference covered with a spacer (mm)
Socket only	29	Not applicable
Ball Module	70	265
Bike Module	64	259
Swim Module	70	265
Twin Module	53	248

6. Contact data

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7. Document history

Version	Date	Description
1.0	06.10.2023	-