Zeus Bionic Hand Small

Instruction for use

For Qualified Personnel

Version 1.0 / 2025.06.23

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WARNING

- We highly recommend reading this document carefully before using the prosthesis.
- This document contains information about the proper and safe use of the prosthesis.
- We highly recommend keeping this document for the whole period of using prosthesis.
- If you have any questions about the product please contact us on info@aetherbiomedical.com

ZEUS

Zeus V2: Zeus Bionic Hand Small (Zeus S) is a multi-articulating myoelectric hand combining ease of control with an elegant, robust design. The fingers and thumb provide a firm grasp to perform everyday tasks with ease. The fingers stall individually, allowing them to conform to the shape of the object, regardless of shape or size.

Read this document carefully before fitting Zeus.

INTENDED USE

Zeus is a prosthetic hand intended to be used alone or with other appropriate upper limb components to form a complete arm prosthesis, to be fitted only by qualified and certified clinicians. It should be used **only by upper limb amputees** and by people with **congenital absence of an upper limb.** Zeus is suitable for 3 amputation levels: below-elbow, above-elbow and shoulder disarticulation, but the final decision whether Zeus should be used belongs to qualified medical personnel. Its functionality covers most hand movements.

Zeus, including the socket (made by professionals) is designated for only one person during the whole lifetime of the prosthesis.

Fitting of the product to the patient's upper limb may be exclusively done by a qualified and certified clinician/prosthetist.

Zeus is designed for mild to moderate activities.

Indications

- Amputation level below-elbow, above-elbow and shoulder disarticulation
- For unilateral or bilateral amputation
- Congenital limb deficiency of the forearm or upper arm
- The patient must be able to understand usage and safety messages and put them into practice

PATIENT POPULATION

Zeus is **recommended for:**

- All genders
- Age 14-75

Contraindication

Zeus is not **recommended for:**

- Children under age 14
- People with cognitive deficits

SAFE USAGE

- Please avoid use in situations with heavy loads, vibrations or impacts.
- Zeus is developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill. mountain biking) or extreme sports (free climbing, paragliding, etc.).
- Furthermore, the Zeus should not be used for the operation of motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment.
- The prosthesis is intended exclusively for use on one patient. Use of the product by another person is not approved by the manufacturer.

TECHNICAL SPECIFICATION

Height (fingertip to wrist base)	159±2mm / 6.26±0,08in
Height (from fingertip to the end of EQD)	182±2mm / 6.77±0,08in
Palm Width	72mm / 2,83±0,08in
Device weight QWD	480g ±10g / 1.05lbs
Closing time	0,8 s
Grip force	120N / 26.98lbf
Max. weight supported on the knuckles	90kg / 198lbs over the knuckles
Force on chassis (static, supporting the hand)	500N / 112,4lbf
Force with closed hand (static, carrying a bag)	200N / 44.97lbf
Operating range: Temperature	-5°C to +45°C
Operating range: Pressure	700 hPa to 1060 hPa
Operating range: Humidity	5% to 93% RH (non-condensing)
Storage range (at home-between uses): Temperature	-25°C to +70°C
Storage range (at home-between uses): Humidity	Up to 93%

- Key Features
  - **Compliant fingers** to prevent breaking of finger units
  - **5 Individually motorized articulating digits** allowing for dexterity in movement
  - **Opposable thumb**
  - **Modular design** all repairs can be done under 10 minutes
  - **14 predefined + 3 selectable** grip patterns

SCOPE OF DELIVERY

Zeus V2 is available in left and right-hand configurations.

- Zeus V2 hand – Left: [model no. A02L-SF0B]
- Zeus V2 hand – Right: [model no. A02R-SF0B]

ZEUS GRIPS

You can choose from 14 grip patterns. The hand has two selectable thumb positions: opposed and non-opposed.

- Opposed thumb in opposition to the fingers on the hand allows choosing grips like Tripod and Power.
- Non-Opposed thumb parallel with the fingers of the hand allows grips like Key and Finger Point
- The speed and force applied by the fingers can be modulated on the basis of EMG signal.

Opposed Grips

Power Grip

In this grip, the thumb is opposed, while all of the fingers can be closed until they meet the object or no further close signal is given. The strong grip provides 120N of force spread over all four fingers and thumb. This multi-purpose grip allows you to open a door or shake hands. Individual finger stalling means the grip conforms to the shape of the object so that you can lift things such as a wine glass. Thanks to advanced sensors, the hand optimizes the force applied to the object.

Trigger Grip

This grip is useful for operating appliances which require trigger mechanisms like sprays. The hand grasps the object and conforms to the shape of the object The index finger and middle finger are controlled proportionately to operate the trigger mechanism. The speed and force applied by the index finger can be modulated on the basis of EMG signal.

Precision Open Grip

In this grip, the thumb moves to a mid-point and stops. The index finger can be controlled proportionally to form a pinch. Middle, ring and little fingers remain open. This grip can be used for picking up small delicate objects and various precise activities.

Precision Closed Grip

In this grip, the thumb moves to a mid-point and stops. The index finger can be controlled proportionally to form a pinch. Middle, ring and little fingers close fully. This grip can be used for picking up small objects from a table.

Tripod Closed Grip

The grip allows you to hold medium sized objects such as a pen, car keys and eggs. The thumb assumes a midpoint position while the index and middle finger move proportionally to reach the tip of the thumb. The ring finger and little finger close fully.

Tripod Open Grip

This grip allows you to hold a variety of daily life objects like a pen, car keys and eggs. The thumb assumes a mid-point position while the index and middle finger move proportionally to reach the tip of the thumb. The ring finger and little finger remain open.

Rest opposed Grip

Resting position of a hand with a thumb in opposed position. Good for long periods of inactivity.

Non-opposed Grips

Key Grip

This is a commonly used grip for picking up thin flat objects, holding a key or turning a page. The four fingers assume a position to provide a flat platform for the thumb. The thumb can be controlled proportionately to open and close.

Hook Grip

This grip is used for lifting up heavy objects like briefcases, shopping bags and gym equipment. Because of the self-locking nature of Zeus, the fingers have a static grip capacity of 20 kgs, allowing you to lift heavy objects with ease. This grip can also be used to provide support when getting up from a seated position.

Active Index

The index finger is active and in a pointing position with the rest of the fingers open. This can be used for working on computer keyboard, typing.

Open Palm

The hand opens to the extent where it provides a slight curvature to support plates, bowls and books. The rubberized palm provides a flat, non-slippery surface to confidently carry objects in this grip.

Finger Point

The index finger is active and in a pointing position with the rest of the fingers closed. This can be used for pushing switches and buttons.

Mouse Grip

This grip is used to operate a computer mouse. The hand assumes the position of the mouse. The index finger and the ring finger can be controlled to push left and right buttons respectively. After grip is set, the thumb position can be adjusted to securely hold the mouse.

Counting Grip

This grip can be used to show a number from 1 to 5 using the fingers. Pulses of the opening signal increase the count, pulses of the closing signal decrease it. Count can be reset to 0 by holding a closing signal.

Configurable grips

In addition to the predefined grips up to 3 custom grips can be used. They can be used in both opposed and non-opposed position of the thumb. Active fingers and positions of all the digits can be freely configured for those grips.

Moving the thumb

To move the thumb from the non-opposed to the opposed position, please hold the thumb at its base with your free hand and push it steadily inwards in a controlled manner.

To move the thumb from the opposed to the non-opposed position, please hold the thumb at its base with your free hand and push it steadily outwards in a controlled manner.

Changing grips

There are 2 different modes to change grips

Sequential mode

In the sequential mode you can cycle between the grips in the loop. The grips are split into two groups: when the thumb is in the opposed position, the opposed group of grips is active and when the thumb is in the non-opposed position, the non-opposed group of grips is active.

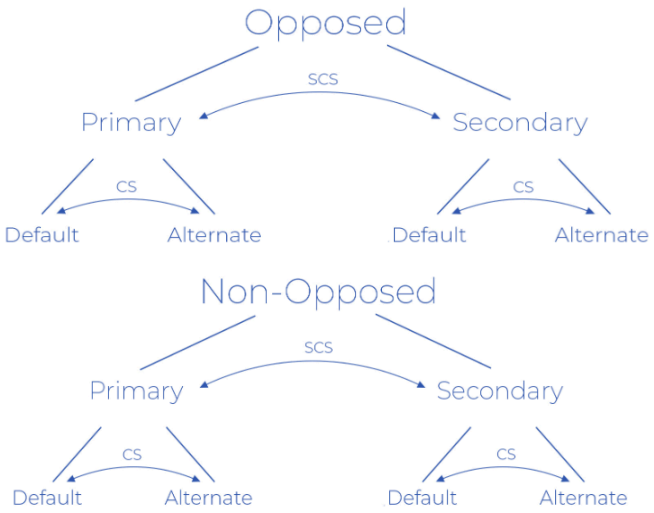
- To switch between the opposed group of grips and the non-opposed group of grips, the user has to move the thumb in the desired position and then provide a Change Signal.
- Using the Primary Change Signal the user can go forward in the loop.
- Using the Secondary Change Signal, users can go back in the loop.

Pairing mode

In the pairing mode, the grips are arranged in a hierarchical manner, allowing for quick access. The first level of division is based on the position of the thumb. When the thumb is in the opposed position, the opposed group of grips is active and when the thumb is in the non-opposed position, the non-opposed group of grips is active.

- To switch between the opposed group of grips and the non-opposed group of grips, the user has to move the thumb in the desired position and then provide a Change Signal.

- Within each group of grip, there are two subgroups - the primary group and the secondary group. Each subgroup has two grips within it, the default grip and the alternate grip.
- To switch between the default grip and the alternate grip, provide a Change Signal.
- To switch between the subgroups, primary group and the secondary group, provide a Secondary Change Signal.
- The grip pairings can be represented as follows:



INTERFACE WEB APPLICATION

Clinicians are granted access to the web Zeus configuration application.

The software is designed for prosthetists to make changes in the Zeus setting to fine-tune functions for users.

The Interface software is designed for use only by qualified and Zeus certified prosthetists. Users of the prosthesis are not allowed to make any changes in it.

Using this application the practitioner is able to: control the EMG settings for controlling Zeus, choose grips available to the user, modify the finger positions for each grip and activate more advanced functions of the prosthesis.

Prosthetists should refer to the Software instructions (DMR-5) provided by Aether Biomedical to use the software and to understand the process of connecting the device with a computer.

CONTROL METHOD

The three types of possible signals detected by sensors include:

1. Open-contraction of extensor muscles.
2. Close-contraction of flexor muscles.
3. Co-contraction - Contraction of both flexor and extensor muscles simultaneously. It can be compared to making a fist, or trying to open and close the hand at the same time if the sensors are placed on the forearm of the user.

The 2-channel sensor system might be placed differently, depending on the user accessibility.

The table below shows what type of signal is treated as primary Change Signal and Secondary. Change Signal in different grip switching modes.

Grip switching mode	**Primary Change Signal**	**Secondary Change Signal**
Co-contraction	Co-contraction	Long co-contraction

Open-open	Open-open	Open-open-open
Hold-open	Hold-open	Long hold-open
Single electrode – alternating	Double impulse	Triple impulse
Single electrode - slope	Hold open	Long hold-open

Zeus actively measures the EMG signal to look for the grip Change Signal (CS) and the grip Secondary Change Signal (SCS). These signals are used to switch between chosen grips. The practitioner can select which action is treated as the CS and the SCS by selecting grip switching mode from the following options in the web application:

- Co-contraction - impulse of the co-contraction signal is treated as CS and holding co-contraction for the period specified in software (default 0.5s) is treated as SCS.
- Open-open - to generate CS, a user needs to make 2 short, consecutive impulses of the open signal. To generate SCS, a user has to make 3 short consecutive impulses of the open signal.
- Hold-open - holding the open signal above the specified threshold for longer than 1.5s (possible to change in the software) when the grip is fully opened is treated as a CS. Holding the open signal above the specified threshold for longer than 3s (possible

to change in the software) when the grip is already fully opened is treated as a SCS.

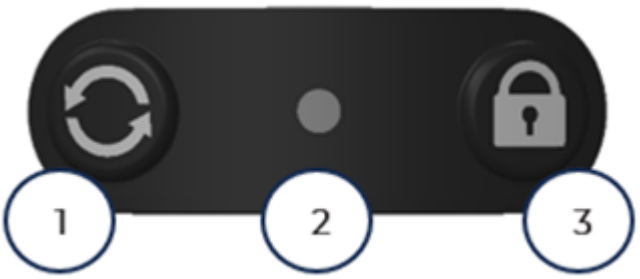
- Single electrode - alternating - this grip switching mode works with a one channel sensor system. It treats 2 short, consecutive impulses of the signal as CS and 3 short, consecutive impulses of the signal as SCS.
- Single electrode - slope - this grip switching mode works with a one channel sensor system. It chooses the movement direction based on how fast the signal rises above a threshold. To change a grip, produce an opening signal and hold it as in ”Hold-open” mode.

Also you can quickly switch between the grips tripod closed and tripod open, precision closed and precision open, finger point and active index.

Button panel

There is a button panel on the hand with the following functions:

1. Change grip button. Works as a secondary change signal
2. LED visual indicator
3. Freeze mode button – enables or disables the freeze mode



Alarms and Signals

Visual indicators

LED visual indicator from the hand button panel is used to convey different information:

Indicator	Meaning
Green light on for 8s	Power turned on
Cyan (turquoise) light flashing	Freeze mode enabled

Auditory indicators

Indicator	Meaning
Two beeps while holding signal	About to enable/disable freeze mode
Long beep	Freeze mode enabled
One beep (while holding opening signal)	Hold open
One beep (while no signals are present)	Movement direction change (single electrode)
Two beeps repeated every 30s	Low battery alarm (low priority)
Three beeps repeated every 5s	Low battery alarm (medium priority)

Low battery alarm

There are two levels of low battery alarm: low and medium priority. Low priority alarm is triggered at higher voltage than the medium priority one. Threshold voltage should be adjusted be the clinician to match specific battery characteristics.

When a medium priority alarm is triggered, the hand enters a mode where only opening of the hand is possible and it is performed at reduced speed. This ensures that operation of the motors won't cause a reset of the depleted battery.

WARRANTY AND COMPATIBILITY

Compatibility

- The hand is compatible with most industry standard sensor systems:
  1. Dual channel EMG
  2. Single channel EMG
  3. Switch
- The hand is also compatible with 7.2V battery systems and a variety of wrist rotators and elbows. Please refer to the compatibility manual DMR-25 v 1.0.

Warranty

The Zeus hand comes with a 2-year-standard warranty from Aether Biomedical Sp. z o.o. In addition, extended warranty packages are available. The Zeus hand must be serviced every 12 months.

The warranty includes:

- Free of charge repair* of the prosthesis hand
- Free of charge replacement unit for the period of repair and maintenance in case of warranty

* Superficial damage and damage resulting from negligence or improper use are not included.

Warnings:

⚠ Please avoid direct exposure to water, excessive dirt and dust as these can damage the hand or affect its performance.

⚠ The user should clean Zeus with cleaning wipes based on isopropanol.

Cleaning

⚠ Do not spill or spray any liquid directly on the prosthesis. It is advised to soak a wipe instead and use that soaked wipe for the purpose of cleaning.

Maintenance

In case of damage, please contact the manufacturer or your local distributor.

SAFETY AND WARNINGS

⚠ The user must avoid subjecting the arm to excessive loads or impacts - the prosthesis is not recommended for interacting with heavy loads.

⚠ The user should not attempt to lift or carry objects heavier than 20 kg.

⚠ If using a hand with a flexion wrist module, the user should not attempt to lift or carry objects heavier than 15 kg. However, for a hand fitted with a flexion wrist module positioned at 30° or -30°, the user should not attempt to lift or carry objects heavier than 5kg.

⚠ If a specific activity might subject the prosthesis to excessive impact or force, we recommend discussing this first with the prosthetist.

⚠ The user must not submerge the prosthesis in water - it should be kept away from moisture at all times. Zeus is not water resistant. If any water reaches the internal components of the hand or arm there is a risk of damage and failure. Water damage is not covered by the standard 24 months warranty.

⚠ The user must not expose Zeus to a naked flame or subject it to excessive heat.

⚠ The user should store Zeus carefully in the provided case while not using it. The storage temperature should be between -25°C and 70°C, out of direct sunlight and water.

⚠ The user should use Zeus in the temperature range between -5 °C and +45 °C. Use at extreme temperatures can affect the functionality of the device.

⚠ Any attempt by non-Zeus accredited parties to repair or modify the hand invalidates the warranty. No modifications of any kind should be attempted; this invalidates the warranty.

⚠ The user should not use the prosthesis while batteries are charging.

⚠ The product must not be used for handling firearms.

⚠ Ensure that no body parts are between the fingertips when using the product.

⚠ Dropping the hand may damage the hand. Impact caused by the dropping of the device may cause permanent damage or improper functioning of the hand.

⚠ Do not connect/disconnect the hand from the socket without first switching the power supply off.

⚠ User should always check the hand if the power switch is OFF before plugging the hand to the socket.

⚠ The user must avoid excessive exposure to UV radiation.

⚠ The user must avoid using the bionic hand with hazardous items (e.g., hot beverages).

⚠ The user must avoid reaching for small children and animals.

⚠ The touchscreens may only be operated using the index finger.

⚠ The product contains trapping zones - the user must avoid exposing body parts to contact with the surfaces of the bionic hand.

⚠ The user must avoid Strong cleaning agents and solvents (e.g. acetone, gasoline, isopropyl alcohol), acids, alkalis and industrial oils.

⚠ The user must not expose the bionic hand to strong magnetic fields and devices emitting high voltage or electromagnetic interference.

Troubleshooting

- Hand does not operate:
  - Ensure the prosthesis is switched ON at the Power Button
  - Ensure the battery is charged
  - Ensure the electrodes are making good contact with the skin by checking the EMG signal graph in the software
  - Ensure the hand is properly attached at the wrist
- Fingers are not moving/responding to my signals:
  - Ensure the Power Button is ON
  - Ensure the electrodes are making good contact with the skin by checking the EMG signal graph in the software
  - Ensure the battery is fully charged and plugged in correctly
  - Ensure that the selected grip mode enables the fingers to move
- Digits open when a closed signal is activated:
  - Either switch the electrodes or simply select inverted electrodes on the software.
- Fingers are moving erratically:
  - We recommend removing the EMG electrodes, cleaning with an alcohol wipe and reattaching to Zeus.
- Water splashes on Zeus:
  - Immediately switch off and remove the prosthesis and urgently contact your prosthetist to check the prosthesis. If possible, pour the water out of the Zeus hand and try to dry it with a cloth and leave it unused until you have agreed to a further procedure with your prosthetist.

Regulatory Compliance

CE The CE mark may be applied on packaging, accompanying instruction or an enclosure.

All individual products are marked indicating that they comply with the requirements of the Medical Device Regulation MDR 2017/745.

Applicable EU Harmonised Regulation:

- MDR 2017/745
- RoHS Directive 2011/65/EU
- WEEE Directive 2012/19/EU

EU DECLARATION OF CONFORMITY with the Medical Device Regulation we, Aether Biomedical Sp. z o.o. Mostowa 11, Poznań Poland 61-854 SRN (Single Registration Number): PL-MF-000005368 under the sole responsibility of the manufacturer declare that for the following products are in conformity with the European Medical Device Regulation (EU) 2017/745 amended by Regulation (EU) 2020/561 in effect as of 26th May 2021. Aether Biomedical Medical Product Family: Zeus V2 Technical file/Product group No: 1104_TF MDR Annex II and III MDR classification: I MDR Rule: 13.

SYMBOLS

CE	CE Mark This mark indicates the product conforms with the essential requirements and provisions of MDR 2017/745.
	Refer to operating instructions This mark indicates the user should read the operating instructions before use.
	Manufacturer (adjacent to company name) This mark indicates the manufacturer.
AETHER BIOMEDICAL	Manufacturer (adjacent to company website) This indicates www.aetherbiomedical.com
	Manufacturer (adjacent to company website) This indicates www.aetherbiomedical.com
	Protect from water This symbol indicates the product should be protected from water.
	Electronic Equipment: Dispose of Properly (WEEE Compliance) Aether Battery System should not be thrown away with common household waste.
SN	Serial Number Indicates the model number of the product.
UDI	Unique Device Identification Indicates a carrier that contains unique device identifier information.
	Temperature Range This symbol indicates the product's temperature range.
	Date of Manufacture Indicates the date the medical device was manufactured.
	Country of manufacture Indicates the country of manufacture of products.
	Type BF applied part To identify a type BF applied part complying with IEC 60601-1.
QTY	Quantity Indicates the quantity.
	Atmospheric Pressure Limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Humidity Limitation Indicates the range of humidity to which the medical device can be safely exposed.
	Single patient multiple use Indicates a medical device that may be used multiple times (multiple procedures)

	on a single.
℞ Only	Caution: Federal law restricts this device to sale by or on the order of a prosthetist.
UKRP	UK Responsible Person (UKRP) and Importer Indicates identification of UKRP and Importer on UK market.
	Label ISO 7010-M002 Indicates read the IFU before use.

EMC LABELLING INFORMATION

Electromagnetic Compatibility

Electromagnetic compatibility, or EMC, means that a device's electromagnetic (EM) environment does not cause interference, and the device does not emit levels of EM energy that cause electromagnetic interference (EMI) in other nearby devices. Rules and regulations set by international standards and agencies minimize interference between electronic devices.

The Zeus hand complies with the requirements of the standard IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Note: The emission characteristics of this electronic equipment make it suitable for use in professional healthcare as well as residential environments (CISPR 11 Class B). This equipment offers adequate protection to radio communication service. In the rare event of interference to the radio communication service, the user might need to take mitigation measures, such as relocating or reorienting equipment.

- ⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
- ⚠ Use of accessories, electrodes, cables other than those recommended by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- ⚠ Portable RF transmitters should be used no closer than 30 cm (12 inches) to any part of the device. Otherwise, degradation of the performance of this equipment could result.
- ⚠ Fitting a patient with Zeus may only be carried out by a prosthetist who has been authorized by Aether Biomedical after completion of a corresponding training course.

REPORTING

Any serious incident that has occurred in relation to the device should be reported to Aether Biomedical Sp z o.o. via email info@aetherbiomedical.com and the competent regulatory authority of the country in which the user is resident.

www.aetherbiomedical.com

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