User Guide

For Zeus Users

Version 5.0 / 2025.01.17

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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 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 CPO/CP) 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 CPO/CP.

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**:

- Adults only
- All genders
- Age 18-65

The final decision of fitting Zeus to a patient is taken by a qualified healthcare professional.

Contraindication

Zeus is **not recommended for**:

- Children under age 18
- 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 (finger tip to wrist base)
177 ±2 mm / 6.97in
Palm Width
86mm / 3.38in
Thickness
30.5mm / 1.20in

Device weight with QWD
590 ±15 g / 1.3lbs

Force with closed hand
(static, carrying a bag)
350N
78.68lbf

Closing time
1.2sec

Force on chassis
(static, supporting the hand)
500N
112.40lbf

Grip force
152N / 34.17lbf

Max. weight supported on the knuckles
90 kg / 198 lbs over the knuckles

⚠ Avoid pressure on thumb

Key Features

- **Compliant fingers** to prevent breaking of finger units
- **The strongest bionic hand** (152N grip force)
- **5 Individually motorized articulating digits** allowing for dexterity in movement
- **Opposable thumb**
- **Modular design** all repairs can be done under 30 minutes
- **14 predefined + 3 custom** grip patterns
- **Closing speed 1.2 seconds**
- **Closed loop motor control** sensing finger position and applied force for proportional control

Operating Range

Temperature:
-5°C to +45°C

Pressure:
700 hPa to 1060 hPa

Humidity:
15% to 93% RH (non-condensing)

Storage Range

(at home – between uses)

Temperature:
-25°C to +70°C

Humidity:
Up to 93%

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 152N 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 35kgs, 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.

Custom 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.

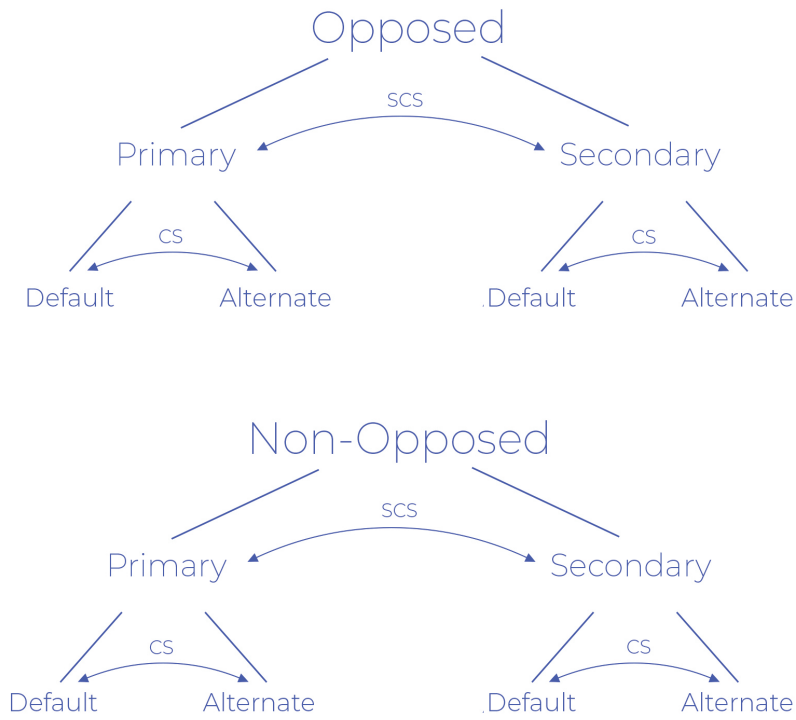
- To switch between the opposed group of grips and the non-opposed group of grips, the user has to move the thumb in the desired position and then provide a Change Signal.
- Using the Primary Change Signal the user can go forward in the loop
- Using the Secondary Change Signal, user can go back in the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



CS - Change Signal
SCS - Secondary Change Signal

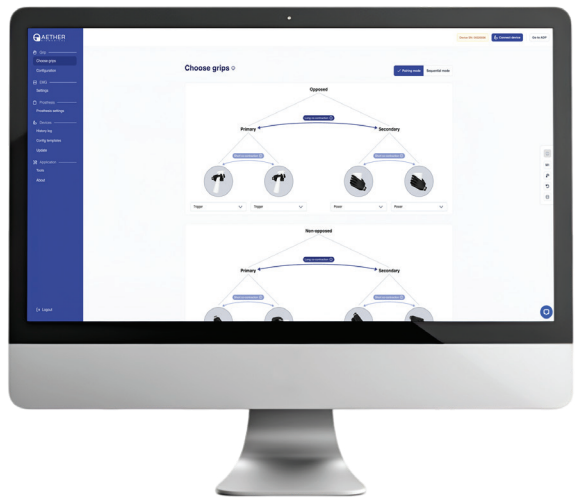
Your clinician will work with you to choose the appropriate grip change mode that works best for you.

Interface Web Application

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

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.

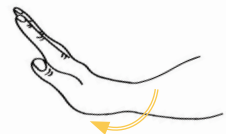
You will have access to the User Part of the software; if you feel your current hand settings are not ideal, please consult your prosthetist about making changes.



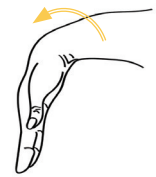
Control Methods

The three types of possible signals detected by sensors include:

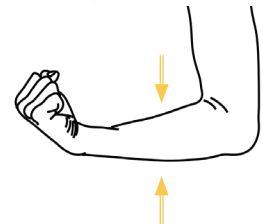
1. Open-contraction of extensor muscles.



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

Different control strategies include:

- Co-contraction - impulse of the co-contraction signal is treated as CS and holding co-contraction for the period specified in so-ftware (default 0.5s) is treated as SCS.

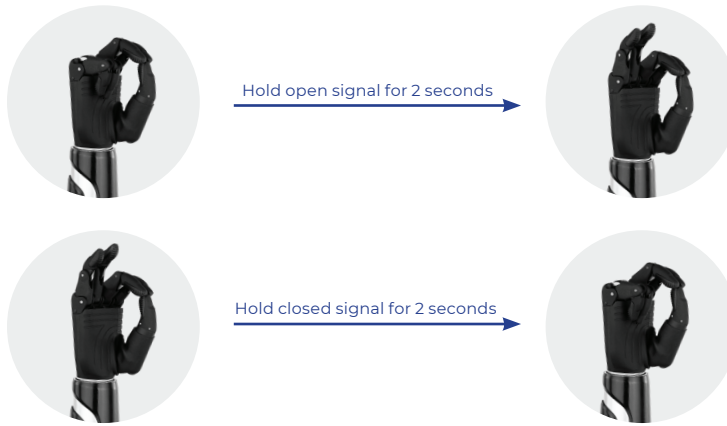
- Open-open - to generate CS, a user needs to make 2 short, con-secutive impulses of the open signal. To generate SCS, a user has to make 3 short consecutive impulses of the open signal.

- Hold-open - holding the open signal above the specified thre-shold 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 tri- pod open, precision closed and precision open, finger point and active index.



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.

Please avoid direct exposure to water and situations where dirt and dust are in direct proximity as these can interfere with or damage the hands performance.

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 purpose of cleaning.

Maintenance

Hand needs to be put to planned maintenance at your prosthetic center every 12 months.
In case of damage please contact your prosthetist.

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.
- You should not attempt to lift or carry objects heavier than 35 kg.
- If a specific activity might subject the prosthesis to excessive impact or force, we recommend discussing this first with the prosthetist.
- You 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 warranty.

- Do not expose Zeus to a naked flame or subject it to excessive heat.
- You 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.
- 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. Likewise, your prosthetist should check the compatibility of any other components (batteries, electrodes, wrist rotators, elbows and so on). Use of non-approved 3rd party components can invalidate the warranty.
- Do 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.
- When closing the hand, ensure that fingers and other body parts are not in the area of the finger joints.
- 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.
- Always check the hand is switched OFF before plugging the hand to the socket.

Troubleshooting

- **Hand does not operate:**
  - Ensure the prosthesis is switched ON at the Power Button
  - Ensure the battery is charged
  - 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 battery is fully charged and plugged in correctly
- **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 a further procedure with your prosthetist.

Regulatory Compliance

The CE mark may be applied on packaging, accompanying instruction or an enclosure, rather than the product itself.

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

Symbols

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.

Manufacturer (adjacent to company website)

AETHER BIOMEDICAL 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)

Zeus should not be thrown away with common household waste.

Serial number

SN Indicates the serial number of the product.

Unique Device Identification

UDI Indicates a carrier that contains unique device identifier information.

Fragile, handle with care

Indicates a medical device that can be broken or damaged if not handled carefully.

Use-by date

Indicates the date after which the medical device is not to be used.

Medical Device

MD The symbol indicates a medical device.

On/off button

Indicates switches with bi-stable positions.

Type BF Applied Part

Indicates a type BF (Body Floating) Part complying with IEC 60601-1.

Temperature Range

This symbol indicates the products temperature range.

Model Number

Indicates the model number or type number of a product.

Date of Manufacture

Indicates the date the medical device was manufactured.

Country of manufacture

To identify the country of manufacture of products.

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.

Caution: Federal law restricts this device to sale by or on the order of a prosthestist.

Indicates the medical device that emit radio frequency (RF) energy.

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.

Table 1 – Compliance level for Immunity tests

Guidance and manufacturer's declaration – electromagnetic immunity			
The Zeus Hand is intended for use in the electromagnetic environment specified below. The user of Zeus Hand should make sure that it is used in such an environment.			
Immunity tests	**EN/IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV Contact discharge ± 15 kV Air discharge	± 8 kV Contact discharge ± 15 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Rapid transient electrical Interferences/bursts acc. to IEC 61000-4-4	Not Applicable	Not Applicable	Not Applicable
Surges acc. to IEC 61000-4-5	Not Applicable	Not Applicable	Not Applicable
Voltage dips, short interruptions and fluctuations of the supply voltage acc. to IEC 61000-4-11	Not Applicable	Not Applicable	Not Applicable
Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50Hz/60Hz	30 A/m at 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital Environment.
Radiated, radio-frequency, electromagnetic field immunity test acc. to IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz *Refer **Table 2** for wireless Proximity RF field test levels	10V/m 80 MHz to 2.7 GHz (in accordance with IEC 60601-1-11)	Refer to **Table 3**
Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6	Not Applicable	Not Applicable	Not Applicable

Table 2 - Test levels for Proximity fields from RF wireless communications

Test Frequency MHz	Band MHz	Service	Modulation	Immunity Test Level V/m	Compliance Test level V/m
385	380 - 390	TETRA 400	Pulse Modulation 18Hz	27	27
450	430 – 470	GMRS 460 FRS 460	FM ± 5kHz deviation 1kHz Sine Wave	28	28
710	704 - 787	LTE Band 13 & 17	Pulse Modulation 217 Hz	9	9
745					
780					
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18Hz	28	28
870					
930					
1720	1700 – 1990	GSM 1800 CDMA 1900 DECT LTE Band 1,3,4,25,UMTS	Pulse Modulation 217 Hz	28	28
1845					
1970					
2450	2400 – 2570	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse Modulation 217 Hz	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	9	9
5500					
5785					

Table 3 - Test levels for Radiated and conducted Immunity Tests

Guidance and manufacturer's declaration – electromagnetic immunity			
The Zeus Hand is intended for use in the electromagnetic environment specified below. The user of Zeus Hand should make sure that it is used in such an environment.			
Immunity tests	**EN/IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF disturbances acc. to IEC 61000-4-6	Not Applicable	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Zeus Hand, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \frac{1.2}{\sqrt{P}}$ Where P is the nominal power of the transmitter in watts [W] according to the information provided by the manufacturer of the transmitter and d is the recommended separation distance in meters [m]. Field strengths from fixed RF transmitters, as determine by an electromagnetic site survey* should be less than the compliance level in each frequency range** $d = 1.2\sqrt{P}$ 80 MHz to < 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to < 2.7 GHz Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF disturbances acc. to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	
NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE:** These guidelines may not apply in all situations. The propagation of electromagnetic quantities is affected by absorptions and reflection from buildings, objects and people.			

*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Zeus Hand is used exceeds the applicable RF compliance level above, the Zeus Hand should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Zeus Hand.

**Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.reflections of buildings, objects, and persons.

Table 4 - Emission class and group

Guidance and manufacturer's declaration – electromagnetic immunity		
The Zeus Hand is intended for use in the electromagnetic environment specified below. The user of Zeus Hand should make sure that it is used in such an environment.		
RF emissions as per CISPR 11	Group 1	The Zeus Hand uses RF energy only for its internal function. The customer or user of the Zeus Hand should make sure that it is used in such an environment. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions as per CISPR 11	Class B	The Zeus Hand is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions as per IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker Emissions as per IEC 61000-3-3	Not Applicable	

Reporting

Any serous incident that has occured in relation to the device should be reported to Aether Biomedical Sp z o.o. and the competent regulatory authority of the country in which user is resident.

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