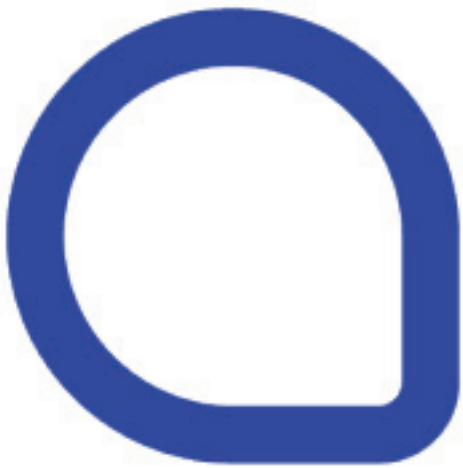


AETHER DIGITAL PLATFORM
WEB APPLICATION INSTRUCTIONS

For Professional Use

Version 5.0 / 2025.01.28

TABLE OF CONTENTS

Release Notes

⚠ Warning!

Date of the last update of this Software instruction: 2025.01.28

- We highly recommend reading this document carefully before using the software.
- This document contains information about the proper and safe use of the software.
- This document is regarding Aether Digital Platform v. 1.9.0 web software application [W-ADP].
- We highly recommend keeping this document in a safe place.
- If you have any questions about the product, please use the contact form on our website: www.aetherbiomedical.com

⚠ Warning!

Clinicians certified by Aether Biomedical can connect with the Zeus prosthetic hand by opening the Zeus Configurator function within the Aether Digital Platform. Do not use any third party software to connect with the Zeus hand.

⚠ Warning!

Only certified clinicians can us the Aether Digital Platform to make changes in the Zeus hand settings.

1 GENERAL INFORMATION

- Aether Digital Platform software is compatible only with the Zeus hand. All required functions are available in the Aether Digital Platform application. There is no requirement to download anything from a website to launch the program.
- The Aether Digital Platform must be accessed via Google Chrome web browser (version 131 or higher) or Microsoft Edge web browser (version 131 or higher).
- Bluetooth Low Energy 4.0 or higher version is necessary to connect to the Zeus hand.
- The Aether Digital Platform allows clinicians to set up accounts, invite other medical professionals, patients, adjust various settings and parameters of the Zeus hand remotely, allowing clinicians to customize the device for their patients.

The Aether Digital Platform allows clinicians to remotely connect with the patient through the patient mobile application (The Aether Digital Platform Mobile [M-ADP]).

The patient mobile app can be downloaded from the Apple Appstore or Google Play store.

Another functionality of the Aether Digital Platform is to render usage data of the Zeus hand and enable clinicians to adjust settings according to patient needs.

2 INTENDED USE

The Aether Digital Platform is intended to monitor the Zeus device (prosthetic hand class I device) and remotely connect with the patient.

- The Aether Digital Platform is designed to be used solely by clinicians certified by Aether Biomedical. Patients, as the users of the prosthesis, do not have access to this web based software. However, patients will have access to a mobile application.
- The software provided by Aether Biomedical is designed exclusively for the Zeus hand.
- The Aether Digital Platform enables clinicians to remotely connect with patients through the Aether Digital Platform Mobile (M-ADP) application. The app is available for download on the App Store and Google Play Store.

2.1 Contraindication

The Aether Digital Platform is not recommended for Clinicians who have not been trained by Aether Biomedical.

3 KEY FEATURES

The Aether Digital Platform (ADP) contains a web application for Clinicians and a Mobile App for Patients. The mobile App is available in both iOS and Android.

The ADP web application:

- Clinician to log into their account (if already created).
- Set up their account and login credentials for the first time. This is secure and includes two factor authentication.
- Set up a patient profile and invite the patient to the mobile app.
- Assign a Zeus hand to the patient, configure and adjust the settings of the hand to suit the personal situation of the patient.
- Allow the Clinician to set up a local, remote or asynchronous session with the patient and adjust parameters of the Zeus hand via these sessions These sessions allow the clinician to make parameter changes to the Zeus hand and send these changes to the hand via a range of sessions either locally, asynchronously or remotely.

- **Note:** previous settings can be restored simply by loading previously saved configurations from the history logs

- Invite a fellow medical professional via the platform feature “Invite a new Medical Professional”
- The clinician can view the user’s EMG muscle contractions in real-time graphs and adjust the activation levels/ thresholds.
- Integrated within the application is the Zeus Configurator feature that allows the Clinician to input options, sites, define the hand control strategy, grip changes, grip switching modes etc.

3.1 BLE connection

The Zeus hand uses BLE (Bluetooth Low Energy) to communicate with the Zeus Configurator.

- To start configuring the Zeus, it is necessary to have the Bluetooth on your computer enabled/ switched on.

Note:

If your device does not come with an inbuilt Bluetooth modem, you can use a BLE dongle. You will need to install its drivers according to the provider’s instructions.

If you are using a Chromebook device running ChomeOS then the app may not work properly. Problems may occur when trying to connect the application using BLE.

4 ACCESSING THE ADP APPLICATION

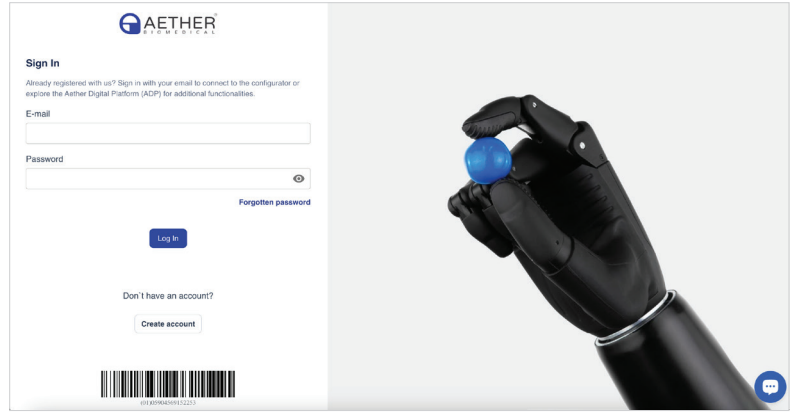
For the best experience, we recommend using Google Chrome or Microsoft Edge. The application is compatible with systems running Windows (version 11 or higher) or Mac OS (version 14 or higher). An internet connection is required.

If you are a clinician certified by Aether Biomedical open the Aether Digital Platform at the following URL in the chosen web browser: https://zeushand.com

4.1 Login or Setup account

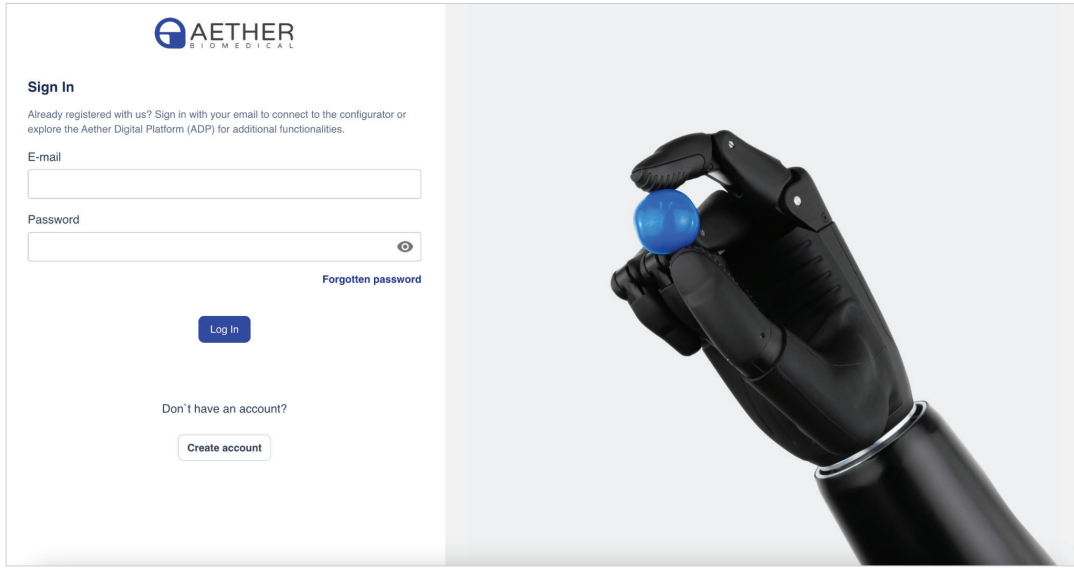
From the landing page, the Clinician has the following options:

1. Sign in if the user already has an account setup
2. Create an account
3. Reset their password if forgotten



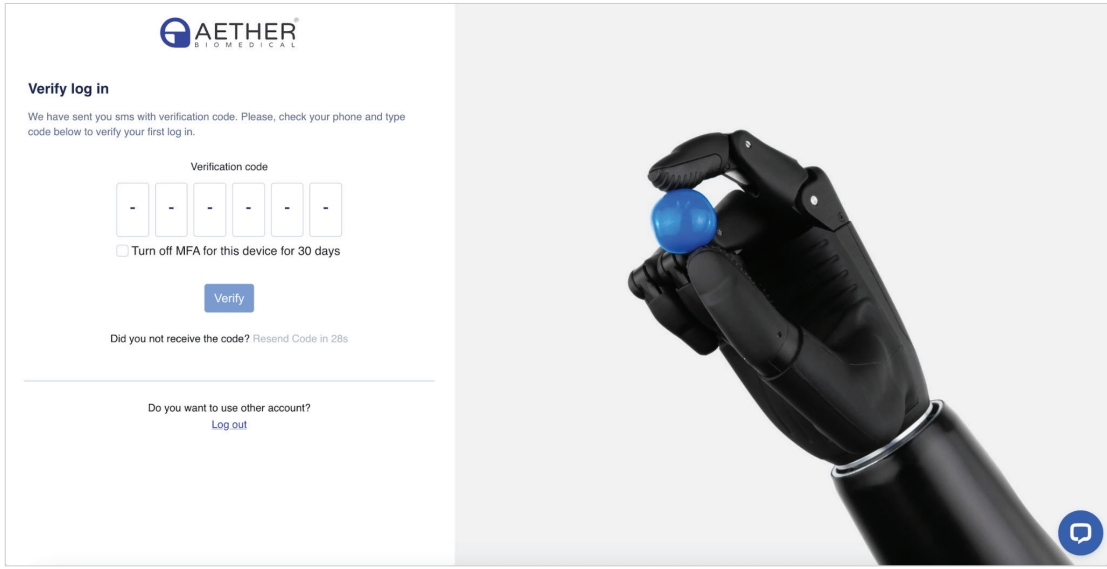
4.1.1 Sign in to your account page

If you already have an account setup, follow the screen below to log into your account.

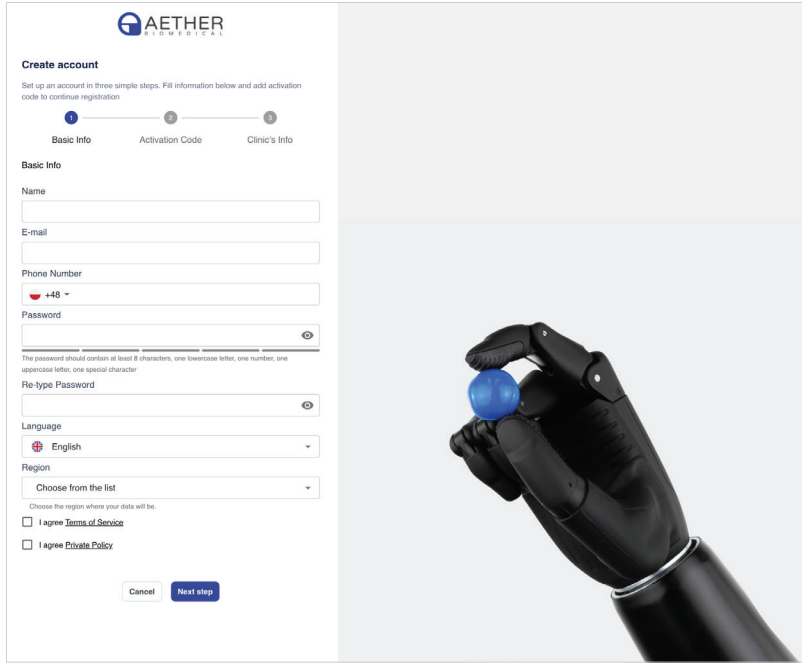


4.1.1.2 Login Second Step

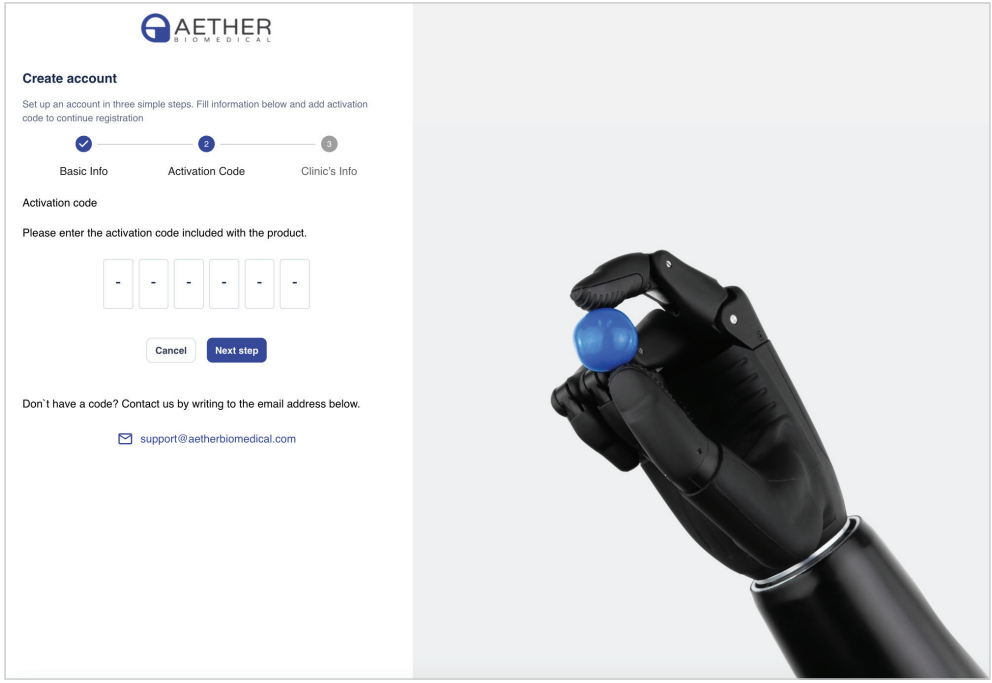
For users who have enabled Two-Factor Authentication (2FA), the second step of the login process requires entering a verification code. This code is sent to your verified mobile device or email, depending on your selected authentication method.

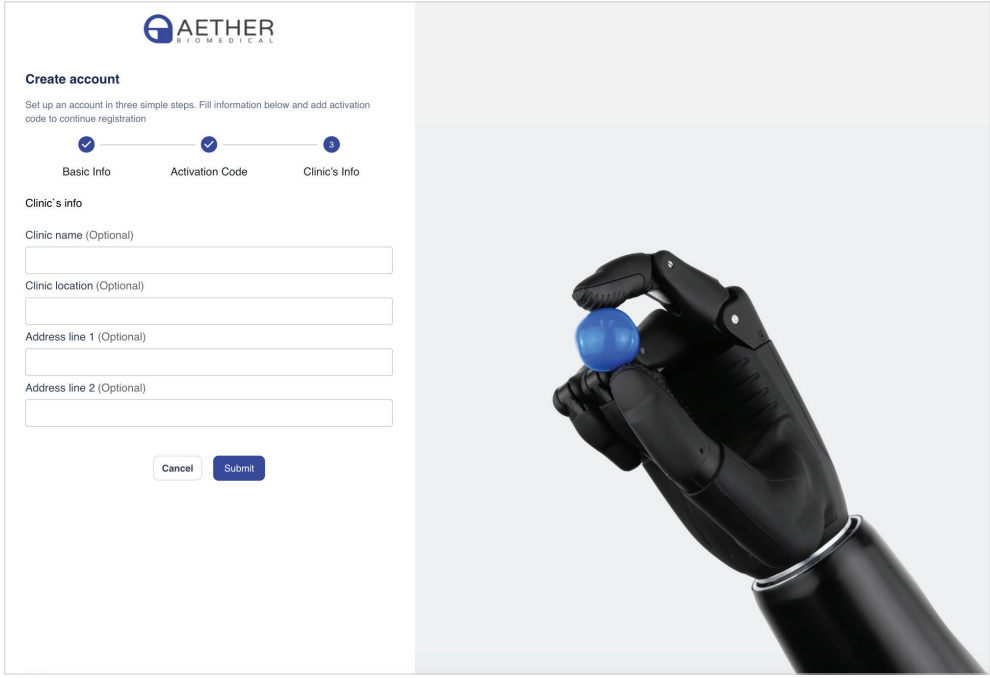


4.1.2 Create an account page



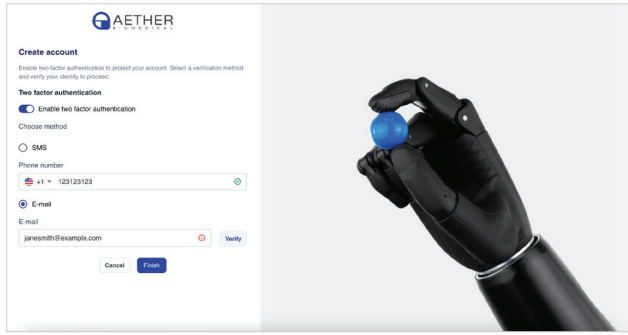
If you do not yet have an account setup, click on the “Create Account” button on the landing page and follow the process in the screens below




AETHER
BIOMEDICAL
Create account
Set up an account in three simple steps. Fill information below and add activation code to continue registration
Basic Info
Activation Code
3
Clinic's Info
Clinic`s info
Clinic name (Optional)
Clinic location (Optional)
Address line 1 (Optional)
Address line 2 (Optional)
Cancel
Submit

Note:

- Please ensure to select your region correctly, e.g. if a US clinician, select USA. Your data and that of patients under your care will be stored in the region selected.
- You will need to enter the Activation Code received with the Zeus hand. Please enter this as indicated in the image on the right hand side.



4.1.2.1 Two factor Authentication

In order to provide an additional layer of account security, we recommend you enable two factor authentication (2FA) with either email or a phone number.

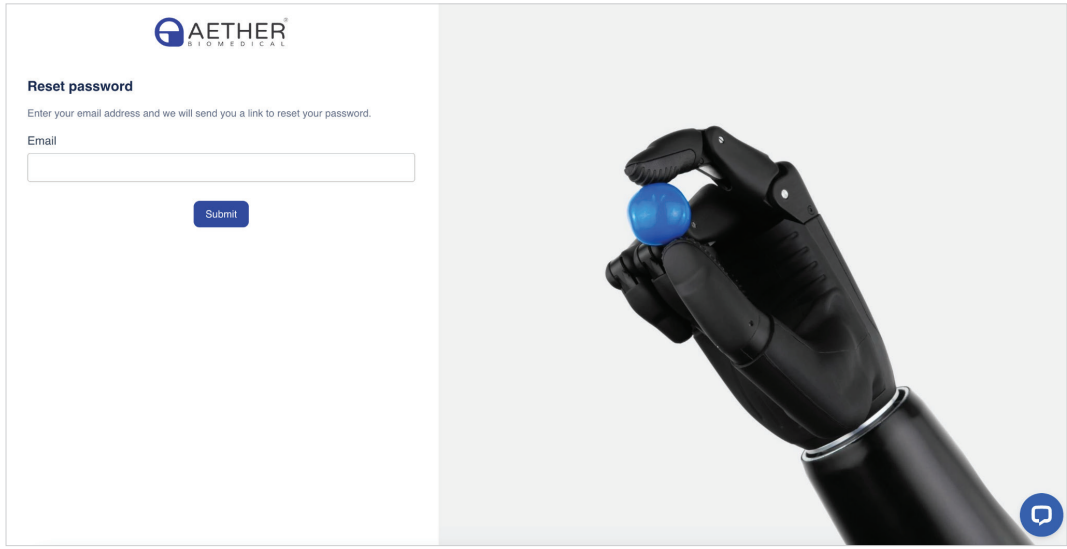
Note: Two factor authentication is enabled by default in the design

4.1.3 Clinician Account Deletion

Please contact Aether Biomedical support on support@aetherbiomedical.com to delete your account.

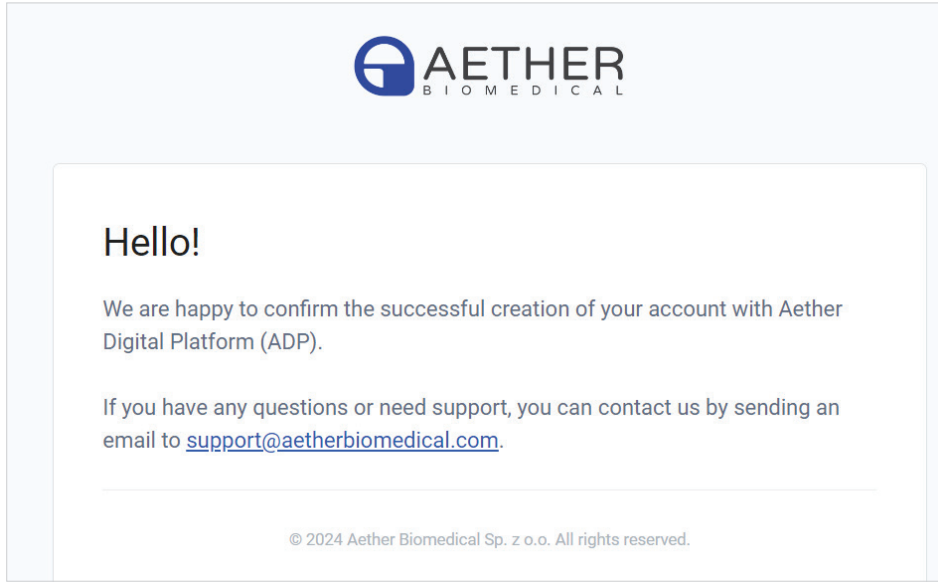
4.1.4 Reset Password

To reset your password, click the ‘Reset Password’ button to be redirected to the reset password page. Enter your email address, submit the request, and wait for an email containing the password reset link.

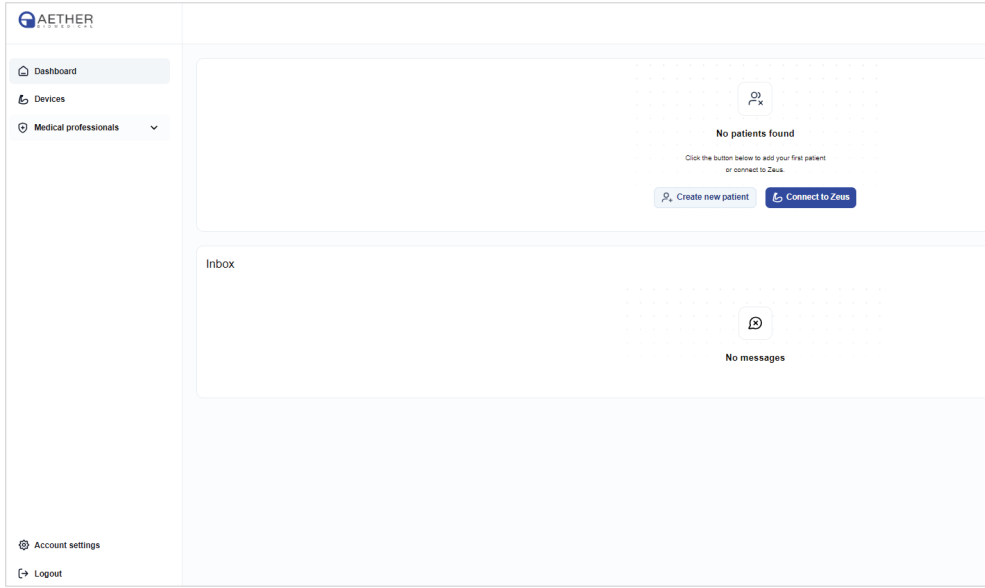


5 LANDING PAGE ONCE ACCOUNT IS SETUP

Once the account is successfully created the Clinician will receive an email with the message below.



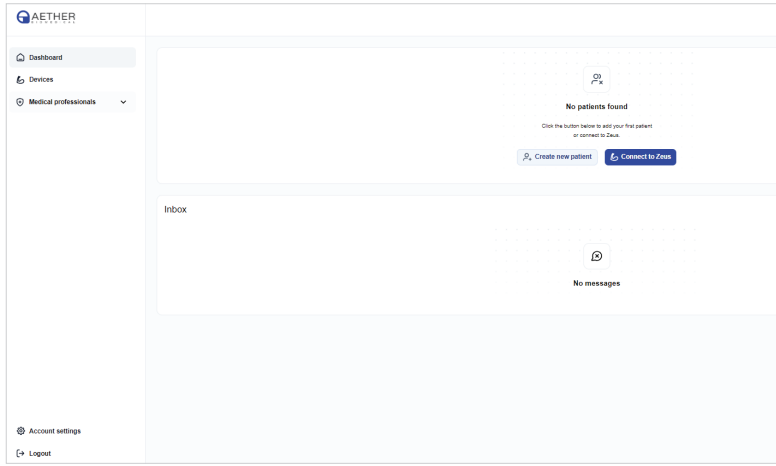
Once they login to the ADP application, the Clinician will see the screen below



From the left hand side of this main page allows the Clinician to

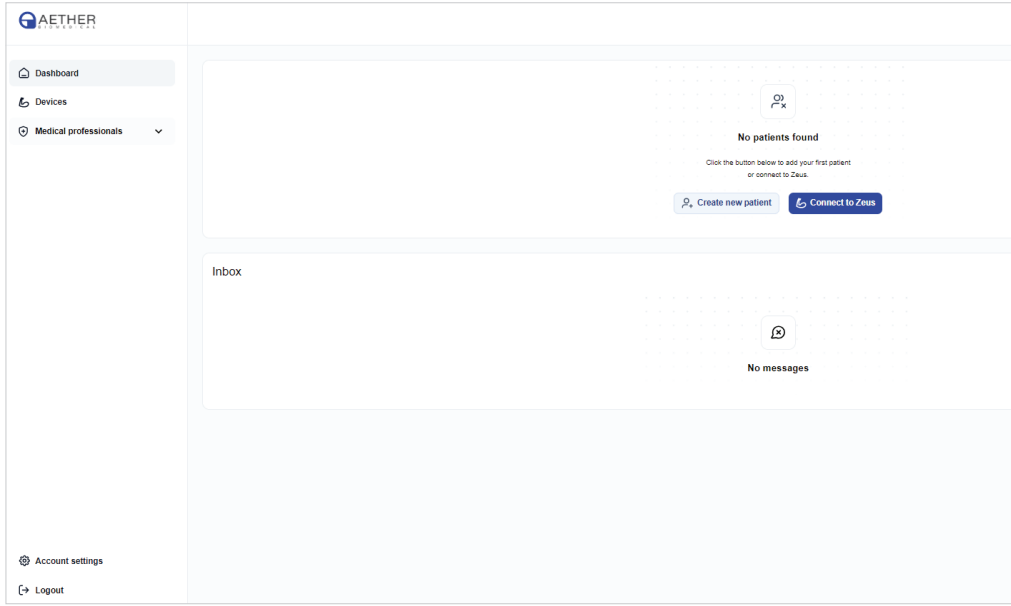
- See a patient dashboard
- See Zeus Devices
- See list of medical professionals
- Edit Account settings
- Logout from the application

From the main body of the page the Clinician can create a new patient account or connect to a Zeus Hand to begin the configuration of it.



5.1 Clinician dashboard

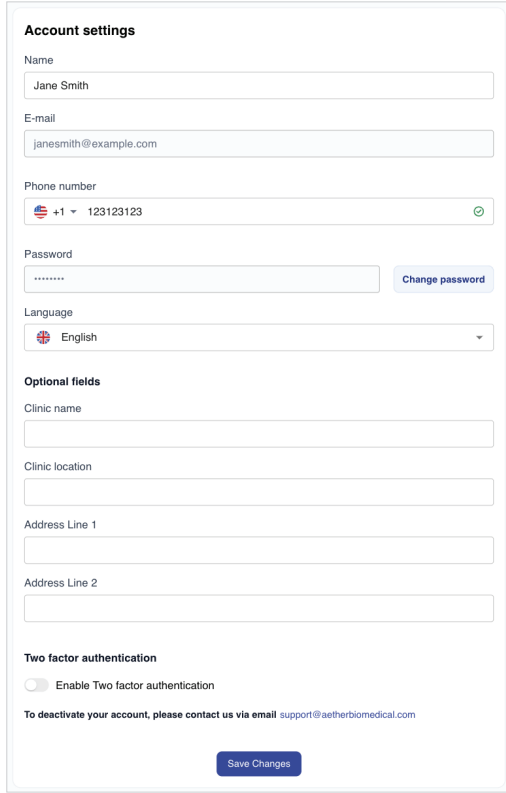
In the Clinician Dashboard, users have access to a list of patients, an inbox for messages, and a sidebar on the left for navigating through the application.



5.1.2 Account Settings

In User Settings, you can update your personal details and clinic information like:

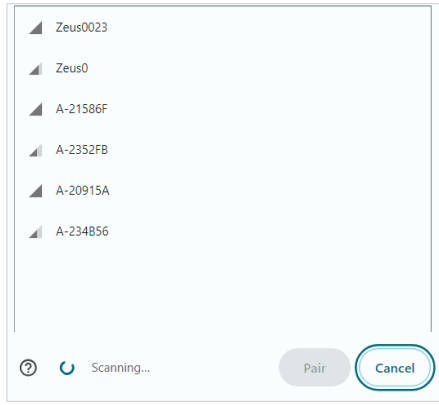
- Change the account name
- Change the email address - this action will require additional confirmation by clicking on the appropriate link that will come to the new email address
- Change the telephone number - in order to verify the new number, we will send a one-time authorization code to the provided telephone number. Enter it to confirm the operation
- Change password - the action requires entering the current password; only then is it possible to set a new password.
- Enable / Disable two factor authentication - there are two methods of providing the authorization code.
- Email method - a one-time access code will be sent to the previously verified email address, which will be valid for 15 minutes from the moment of sending. After this time, the code will be invalid and a new one would have to be generated.
- Text message method (SMS) - available only when a phone number is entered


Account settings
Name
Jane Smith
E-mail
janesmith@example.com
Phone number
+1
123123123
Password
Change password
Language
English
Optional fields
Clinic name
Clinic location
Address Line 1
Address Line 2
Two factor authentication
Enable Two factor authentication
To deactivate your account, please contact us via email support@aetherbiomedical.com
Save Changes

5.2 Connect to Zeus

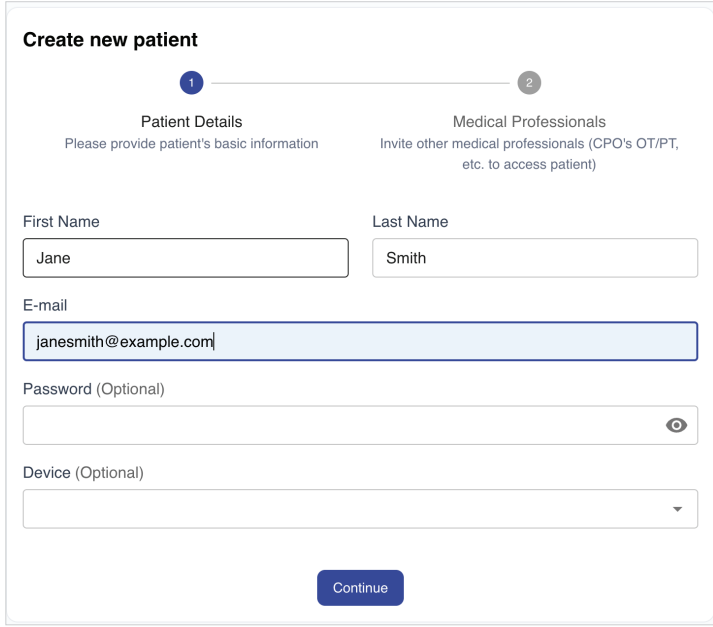
To connect Zeus Hand, click the blue button located in the top right corner.

This will open a Bluetooth pairing window displaying available devices. Select Zeus Hand from the list and click Connect to establish the connection.



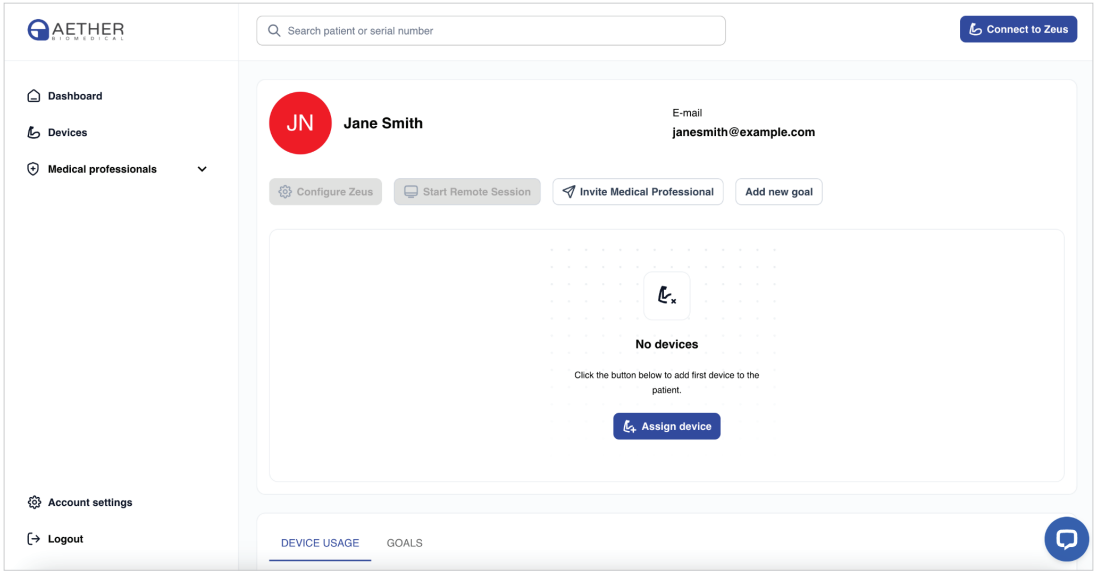
5.3 Patients

5.3.1 Create a new patient account

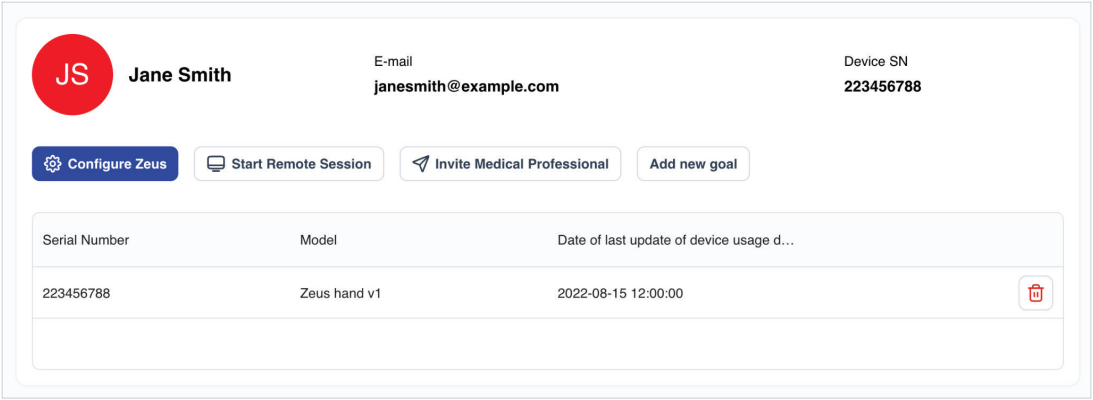


Two options exist for the clinician to create a patient account

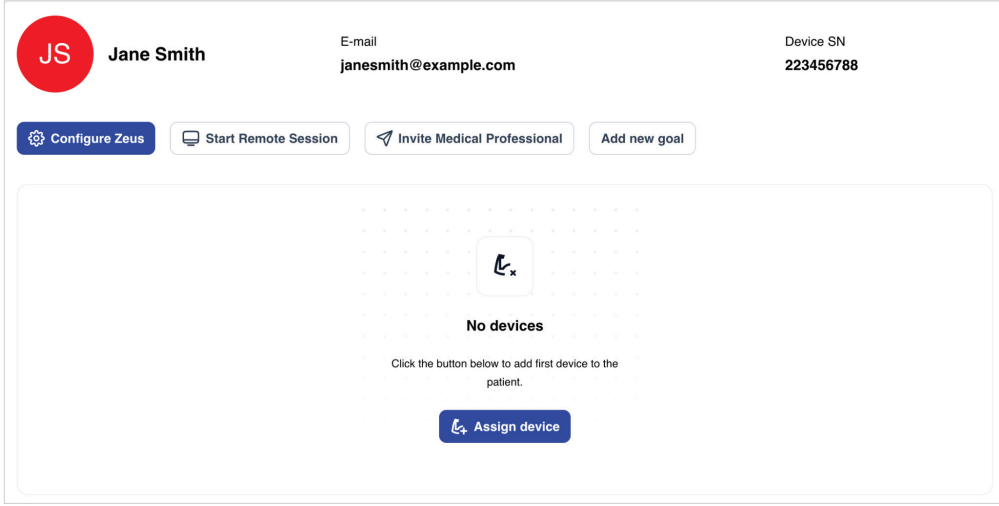
1. Creation of an account without a Zeus hand

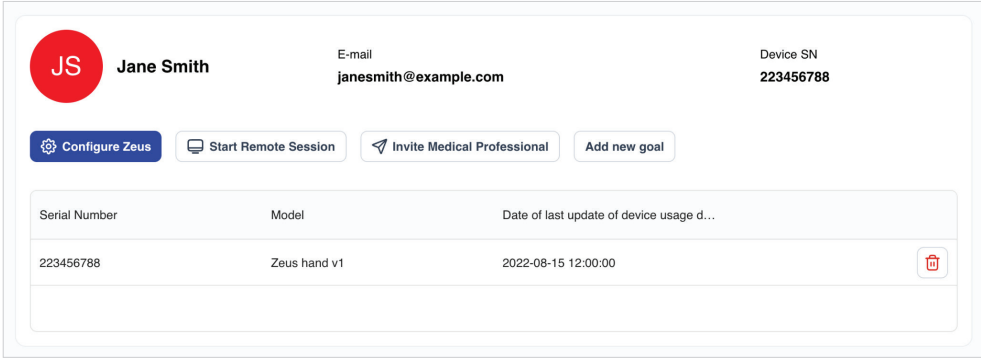


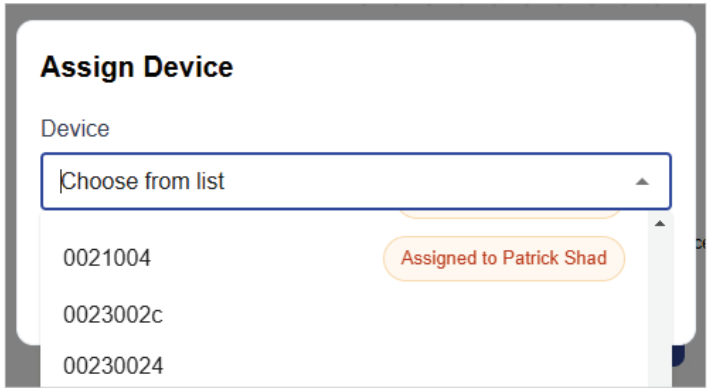
2. Creation of an account with a Zeus hand



Once a patient is selected the window shown below will appear. From this the Clinician can then configure the Zeus hand if the Patient is in their office locally, initiate a remote session with the Patient, add new goals for the Patient or invite another medical professional into the Patient's plan.




JS
Jane Smith
E-mail
janesmith@example.com
Device SN
223456788
Configure Zeus
Start Remote Session
Invite Medical Professional
Add new goal
Serial Number
Model
Date of last update of device usage d…
223456788
Zeus hand v1
2022-08-15 12:00:00


Assign Device
Device
Choose from list
0021004
Assigned to Patrick Shad
0023002c
00230024

The **My patients** tab shows a list of patients whose data and configurations the Clinician has access to, whether created by them or invited by another clinician.

To see patient information click on the Profile button under the Patient's name

From this Patient view, the Clinician can:

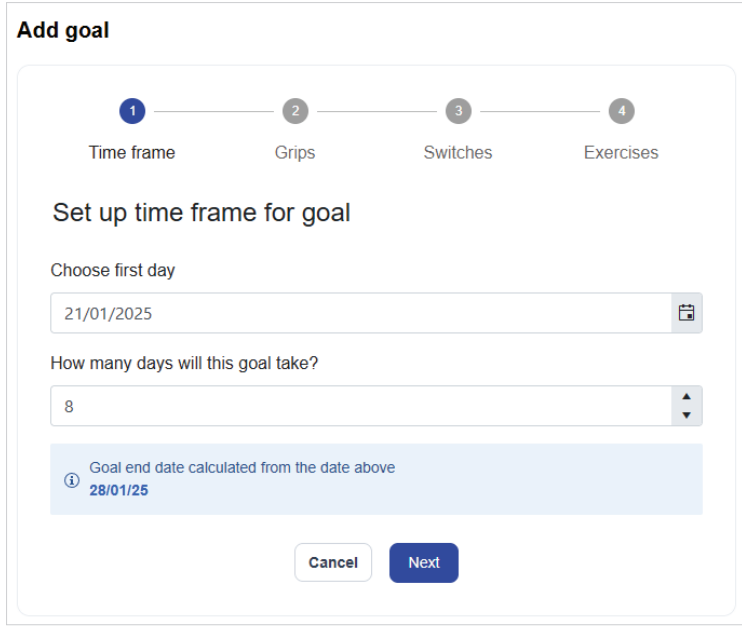
- connect to the Patients Zeus Hand in a local or asynchronous session
- start a remote session
- invite another medical professional to access this patient
- add Goals for the patient
- see the list of devices and remove the device from the patient
- check the patients Device Usage Monitoring (DUM) statistics

The patient details page opens up, providing details associated with patients and hands that are linked to patients. This is also where you can access a remote session to communicate with a patient.

Clinicians and Allied health will receive e-mail when there will be a new message to read. Patients will receive push notifications on the mobile app.

5.3.2 Goals

When “Add goal ” is chosen you will go directly to the form where you can set up the goals for the patient.



Step 1:

In step one, choose how long this goal will last. Set the date of the first day and indicate how many days it should last.

Step 2:

In this step, you can set goals for the patient regarding grips. First, choose the frequency at which you want to start counting the number of grips performed (daily, weekly, monthly, or for the entire date range selected for the goal). You can choose the grip details whether the patient is to perform a total number of grips or a certain number of grips. You can set both of these goals at the same time. The sum of the specific grips cannot be greater than the goal for the ”Total grips” count.

Step 3:

As in step 2, you indicate here the frequency and number for the grip switches. You can set a different frequency than for the grips

Step 4:

In the last step, you can choose which exercises the patient should perform. You can set the number of repetitions and frequency for each exercise separately. If you would like to add some exercises please write to us.

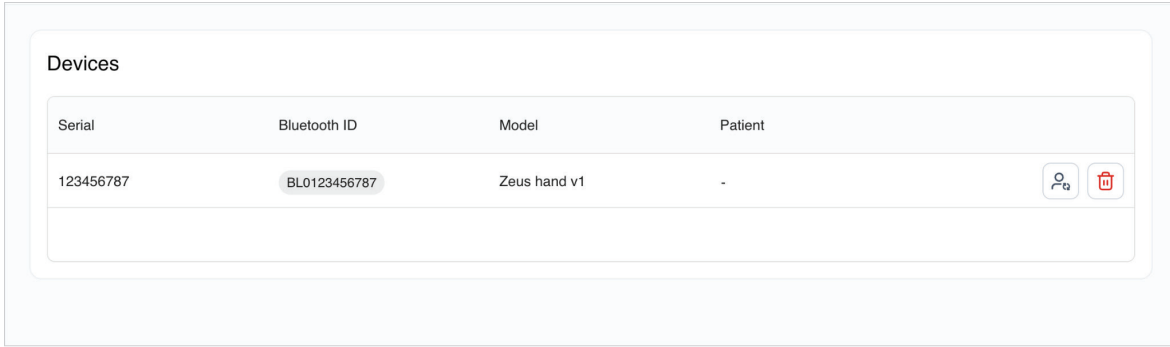
Under the Goals tab, you can find information about the history of goals set and completed. By clicking on the plus icon you can see the full information. Clicking on the eye icon takes you to the settings preview. The trash icon removes the goal from history.

There are 3 charts available in the goal history.

These charts outline the specific goals that the clinician selected for the patient, such as number of grips performed, frequency, and exercises.

5.4 Devices

Under the Devices tab, the Devices List displays all devices assigned to the clinician. Devices might already be assigned to a patient. This section also allows users to reassign devices to a different patient if needed



5.4.1 Assign a device to a Patient

The device is assigned to the patient during the account creation flow.

From the same Edit device menu you can also change the Patient assigned to the device.

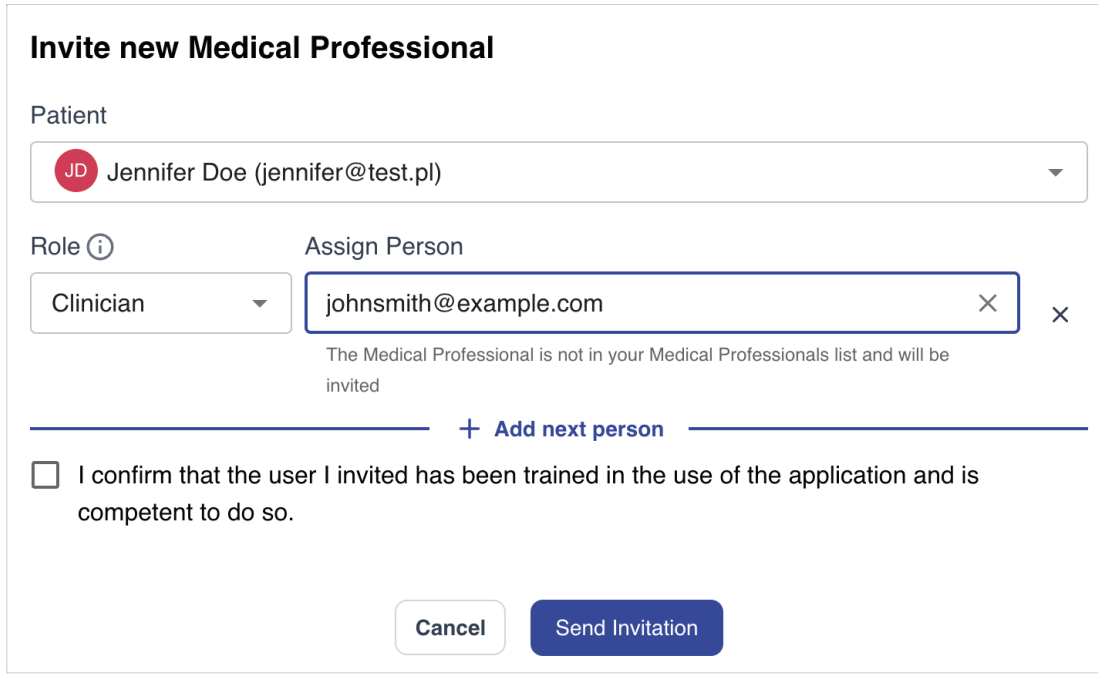
The hand can only be assigned to one patient at a time.

5.5 Medical Professionals

5.5.1 List of Medical Professionals

Under this tab, the Clinician can view the list of medical professionals in their network. This typically be a medical professional in their network who works with a common patient to both or another medical professional the Clinician wishes to bring into the medical care delivery to the Patient.

5.5.2 Invite new Medical Professional



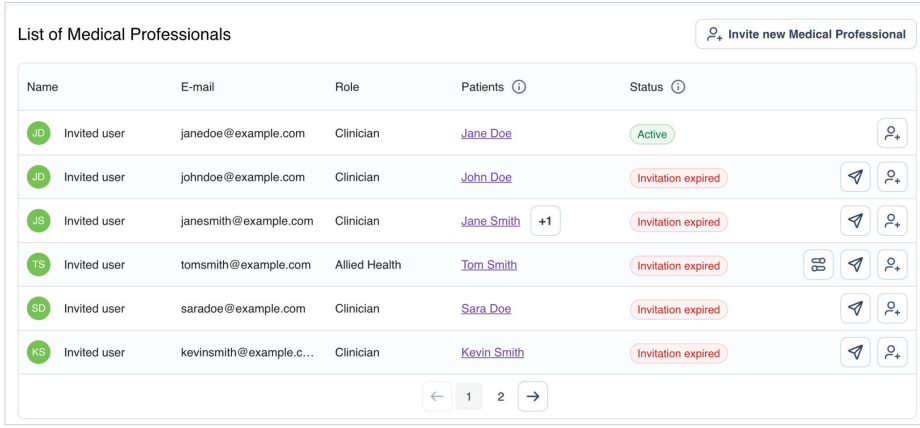
A clinician can invite another clinician or medical professional even from outside their own organisation. The process of doing this is captured below.

Once invited, the invited medical professional will be able to assist and manage the patient's account.

Note: Prior to inviting the medical professional, the invitee needs to have received training on the Zeus hand and ADP.

The ADP shall allow a clinician to invite up to a maximum of ten (10) medical professionals in one time. The invitation is valid for 24 hours, after which it must be resent.

The Clinician can view the medical professionals they have added and the status of the invite.



6 ZEUS CONFIGURATOR

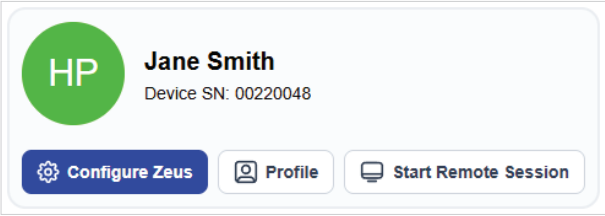
Our concept at Aether Biomedical was to create multi-functionality in communicating and accessing the Zeus hand through multiple sessions. This will allow the greatest amount of freedom and flexibility for you and your patients.

Our multi-functional communication tool has 3 perspectives aka 3 sessions.

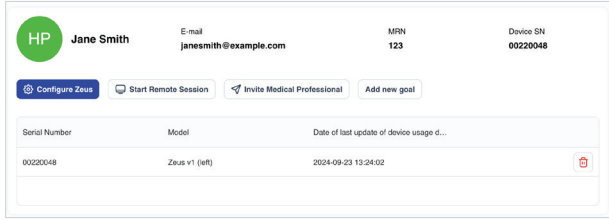
- Local,
- Asynchronous
- Remote Session.

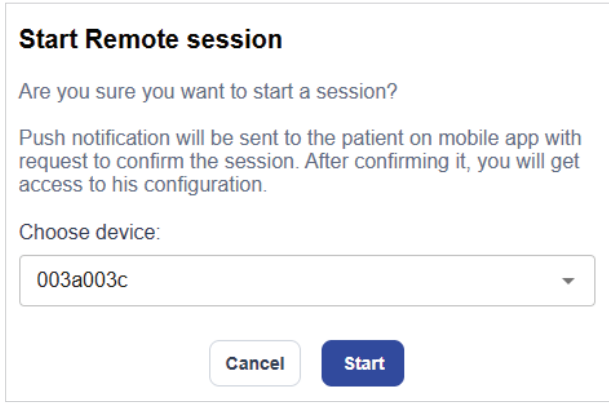
1. A Local session can be accessed using the ‚Connect to Zeus' button in the top-right corner of the dashboard.

2. An Async session can be accessed using the ‚Configure Zeus' button located in the patient card.



3. A Remote session can be accessed using the ‚Start Remote Session' button located in the patient card.



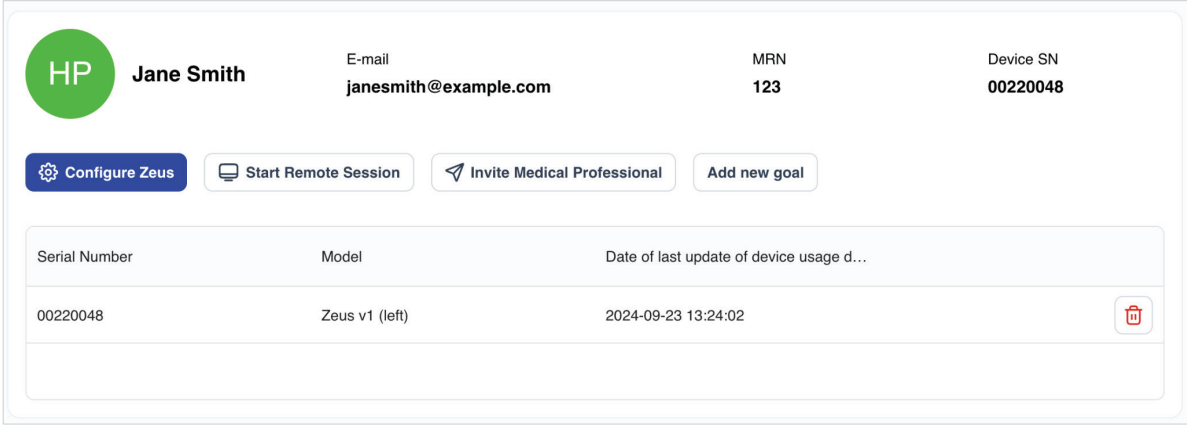


These 3 sessions give clinicians and patients flexibility and freedom to either have changes made to their Zeus hand locally (in-person at the prosthetist's clinic) or remotely.

A device registered in the ADP (Aether Digital Platform) can be configured in the following ways:

- Local Session- standard, in office configuration, where the clinician connects to the device via Bluetooth without the need of a patient to use the mobile app.
- Asynchronous Session - remote configuration, during which a clinician can propose changes to the device in the patient's absence, generating a ticket to the patient, awaiting their acceptance. For example: the patient sends the clinician a message stating that they are having difficulty with Co-contraction and wanting to change to Open-Open. The clinician will create a configuration file and send it to the patient's inbox on their mobile app. When the patient logs in to the mobile app they can then download the file to their hand.
- Remote Session - a way of simulating a face-to-face meeting with a clinician. The clinician sends an invitation to the session, to which the patient can connect via the mobile app. The built-in conferencing allows a video meeting, where the clinician can see the patient's EMG signals..
    - If the clinician closes the remote session, the changes are applied immediately. A ticket is created, and the previous settings can be restored from it.
    - If the patient closes the session, a popup appears with the question, „Do you want to save the configuration?" They can choose to save it or load the previous settings.

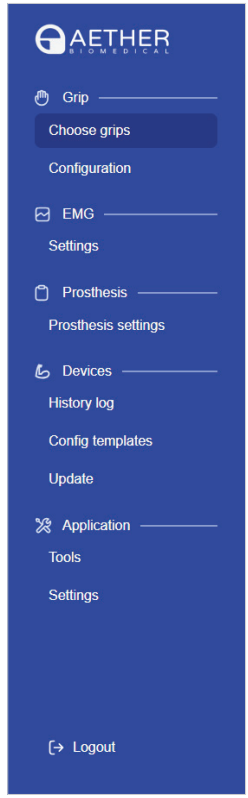
6.1 Access to Zeus Configurator



The Zeus Configurator can be launched from the Patient card, by selecting the “Configure Zeus “ Button.

Allied Health is granted access to Zeus Configurator functionality in accordance with the permission granted by the Clinician.

After launching the program, the main screen of the Zeus Configurator will show up.



This main screen is divided into a number of parts:

1. Side Bar containing the following options
    a. Grip
        i. Choose Grips
        ii. Configuration
    b. EMG
        i. Settings
    c. Prosthesis
        i. Prosthesis Settings
    d. Devices
        i. History Log
        ii. Config Templates
        iii. Update

    e. Application
        i. Tools
        ii. About
    f. Logout
2. Top Bar
    a. Device Serial Number of the connected Zeus Hand
    b. Option to “Connect to Device”
    c. Option to “Go to ADP”
3. Main page body showing Grips options in opposed and non-opposed modes

In the Settings Area you can change the settings of the Zeus hand. Its content depends on the currently chosen tab in the main menu.

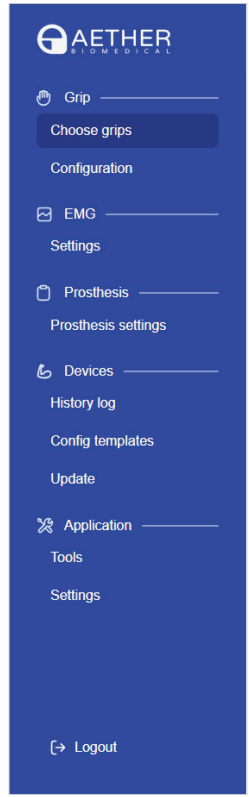
In the Application Settings, you can check the software version, view Bluetooth Module details, and send changes to the hand settings.

Side Buttons enable you to save settings to the prosthesis, restore most recent versions of the settings, and undo the last change in the settings.

6.1.1 Changing Zeus Hand Settings

Settings for the Zeus hand can be adjusted via the Zeus Configurator. By selecting Configurator, it gives access to a menu of setting options on the left hand of the screen as shown below.

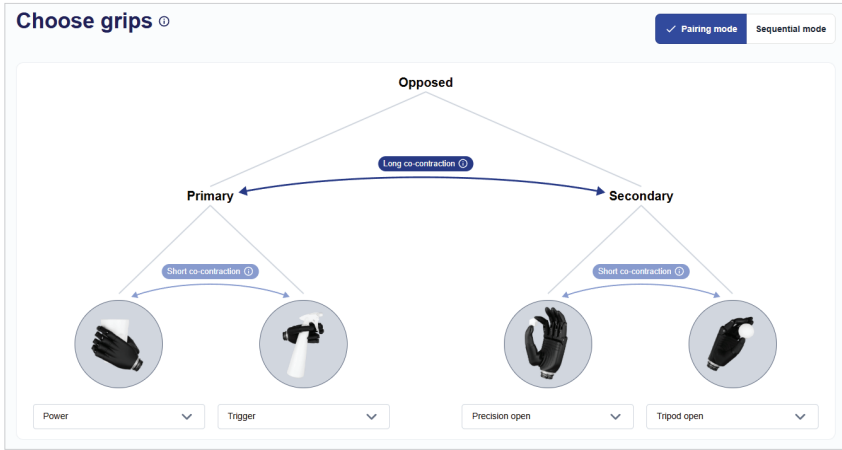
Parameters of the hand configuration which can be changed include the EMG Settings, Grips configuration, Zeus hand Prosthesis settings.



Grips Tab

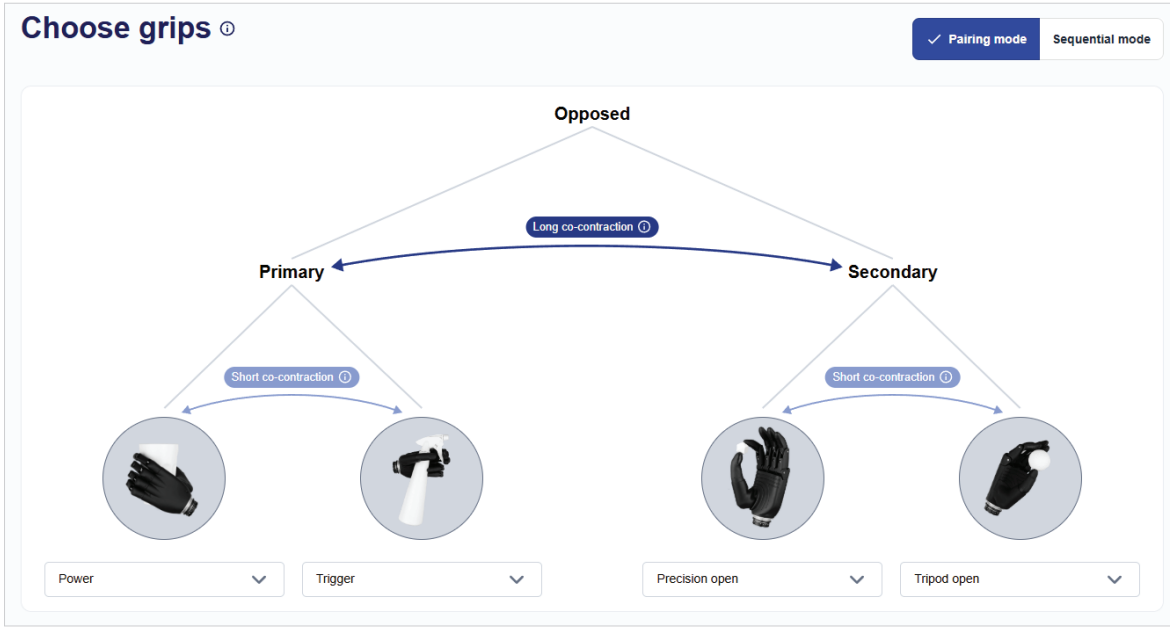
In the upper right corner of the Settings Area you will find Pairing Mode/ Sequential Mode switch. Changing this switch will select the corresponding control mode setting in the prosthesis.

- Choosing the control mode changes the displayed graphics in the Settings Area. There you can select the order in which the grips will be accessed in each of the control modes.
- The Zeus has 14 grip patterns. The clinician can choose the grips that are the most useful in the patient's daily life.




Choose grips
Pairing mode
Sequential mode
Opposed
Grip 5
Grip 1
Short co-contraction
Long co-contraction
Disabled
Power
Grip 4
Grip 2
Trigger
Tripod closed
Grip 3
Precision closed

Pairing Mode



- In 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 into the desired position and then provide a Change Signal.
- Within each group of grips, 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.
- When you change the position of the thumb, provide a Change Signal to allow the prosthesis to change between the opposed and non-opposed group of grips.

Change Signals

The table below shows what type of signal is treated as a 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	Open open	Open open open
Single electrode slope	Hold open	Long hold open

Sequential Mode

In Sequential Mode you can cycle between the grips in the loop. Using the primary grip Change Signal you go forward in the loop; using the secondary grip Change Signal, you go back. The grips are split into two groups: with the thumb opposed and non-opposed. To switch between the groups, you need to manually adjust the thumb position and generate a grip Change Signal or a secondary grip Change Signal.

The order and number of grips of each of the groups can be modified after selecting “Sequential Mode” in the Settings Area.

In Sequential Mode there can be a maximum of 5 grips in each of the groups defined by the thumb position. This number can be decreased by unchecking the last grip in the group - the unused grip will be greyed out. You can re-activate the grip by checking the box over it.

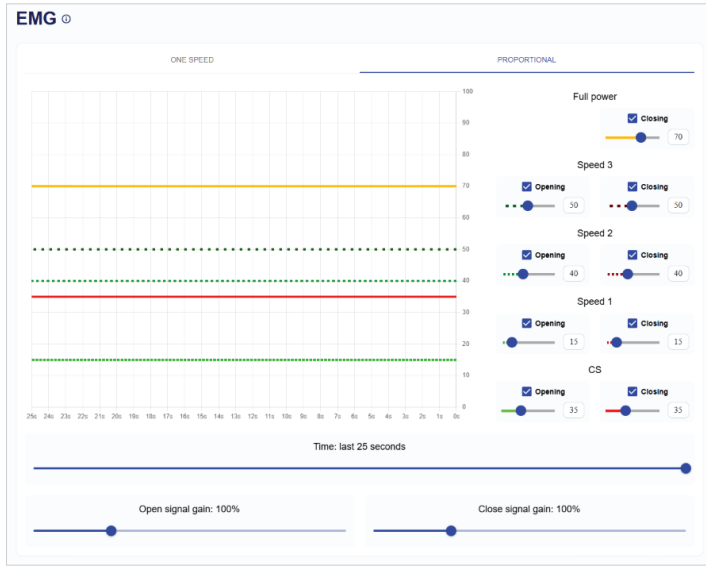

Choose grips
Pairing mode
Sequential mode
Opposed
Grip 5
Grip 1
Short co-contraction
Long co-contraction
Disabled
Power
Grip 4
Grip 2
Trigger
Tripod closed
Grip 3
Precision closed

6.2 EMG Settings

- In the EMG Setting tab you can see the graph depicting the signals and their strength acquired from the patient's muscles.
- To accommodate varying levels of signal strength and electrode sensitivity, there are special slider adjustments to change the threshold levels for the grip Change Signal and the activation levels to open and close the hand.
- On the left side of the screen there are 2 sliders with a scale. They can be easily adjusted to establish a suitable grip Change Signal threshold for each patient individually.
- On the right side of the screen there are 2 additional sliders. They can be used to adjust a suitable activation level for the open and close signal.
- You can adjust the timescale on the graph by a slider at the bottom of the Settings Area.
- You can hide or show the thresholds on the graph by toggling the checkbox beneath their sliders.
- You can set the gain on the sliders at the bottom of the screen. It is recommended that the gain is primarily set on the electrode first (when applicable), and the slider is used as an adjuster when the electrode adjustability is not available.
- There are a couple of options that affect the appearance of the graphs.

- One Speed- in this option, both muscle signals (Flexion and Extension) are shown on the same graph

- Proportional - this option enables you to change the thresholds for proportional control of the hand. Both of the signals are visible on the same screen. The thresholds are available on the right-hand side of the Settings Area. There is also a special “Full power” threshold which is used for Soft-grip functionality. If you have One speed setting selected, you won’t be able to change the threshold for ”speed 2” and ”speed 3”. Also the sliders corresponding to them will be grayed out.



- The threshold bar reflects how high each signal must reach to register as a valid signal. It verifies if the signal the patient made is strong enough to be read and for the hand to start moving.
- If the patient has problems controlling the hand, the threshold bar can be adjusted.

Adjustment	Effect	Consequence
Raising	Patient needs a higher signal in order for the hand to start moving	The user is less likely to have un intended hand movements, but the hand may seem slower as a higher signal needs to be given
Lowering	Patient needs weaker signal for the hand to start moving	It's easier to activate the prosthesis, but there is more potential for inadvertent operation / accidental opening

6.3 Grips configuration tab

- In the Grips configuration tab you can change the initial and end limit positions for each and every grip.
- The initial position of each finger is the position that is assumed after changing to the grip.
- Position limit is the maximum end position the finger can move to while closing. Both of those parameters can be adjusted for each finger individually in every grip; 1000 is fully closed, 0 fully open. This can be used for fine tuning of the grips.
- To begin, you have to select the right grip in the dropbox at the top right corner.
- You can activate the movement of the hand while configuring the grips to see what the finger positions actually look like by checking the box at the bottom right corner.
- As well as the 14 default grips in the Zeus Hand, the Clinician can configure 3 additional Custom Grips for the Patient.

Be aware of the surroundings of the hand while doing this. Try to avoid moving fingers in a way that they might hit other digits, as this may lead to damaging the fingers.

6.4 Choose grips tab

In the upper right corner of the Settings Area you will find the Pairing Mode / Sequential Mode switch.

Changing this switch will select the corresponding control mode setting in the prosthesis.

- Choosing the control mode changes the displayed graphics in the Settings Area. There you can select the order in which the grips will be accessed in each of the control modes.

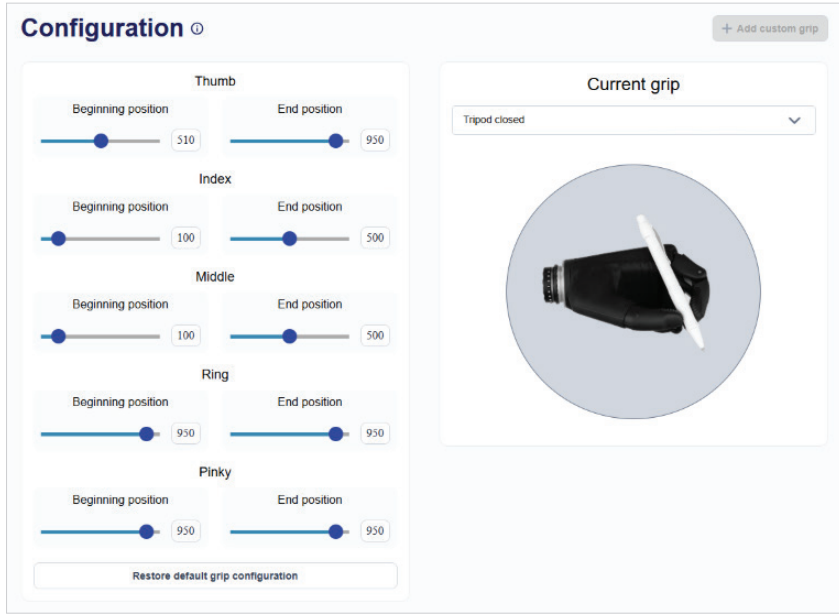
The Zeus has 14 selectable grip patterns. The clinician can choose the grips that are the most useful in the patient's daily life.

Additionally the Clinician can set 3 custom grips for the Patient.

6.4.1 Custom Grips

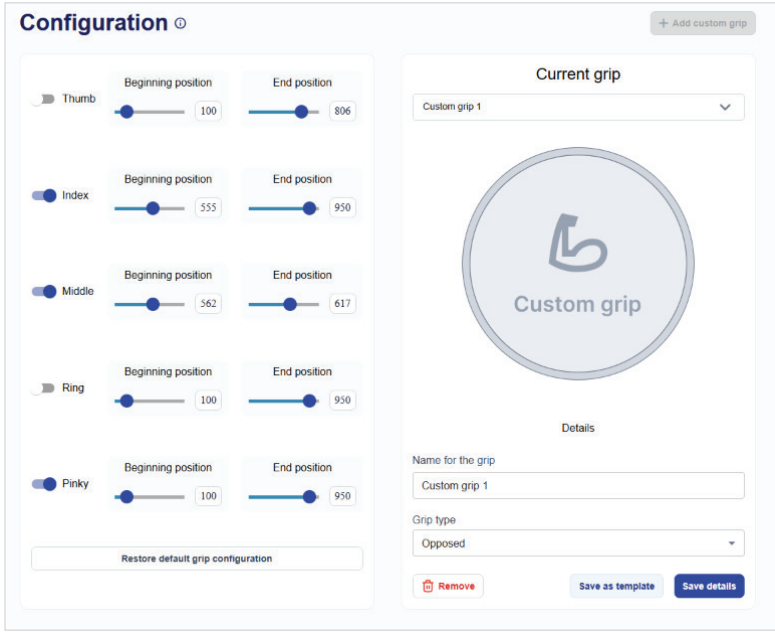
As mentioned above the Clinician can set an additional 3 custom grips for the patient.

The custom grip function is accessed via the button “Add Custom Grip” button. See image below.



This then opens a window for the Clinician to design a specific grip for the Patient. It can then be named, saved and available for the Patient.

See image below.

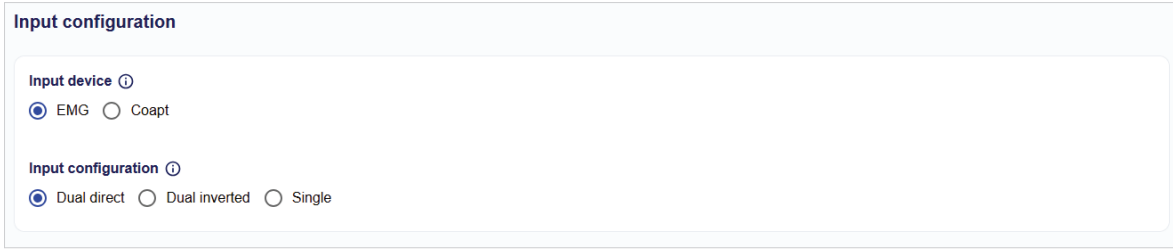


6.5 Prosthesis settings tab

In the Prosthesis settings tab you are able to configure various settings and parameters for the Zeus hand.

6.5.1 Input Options

This refers to the method by which a patient can control the prosthesis.



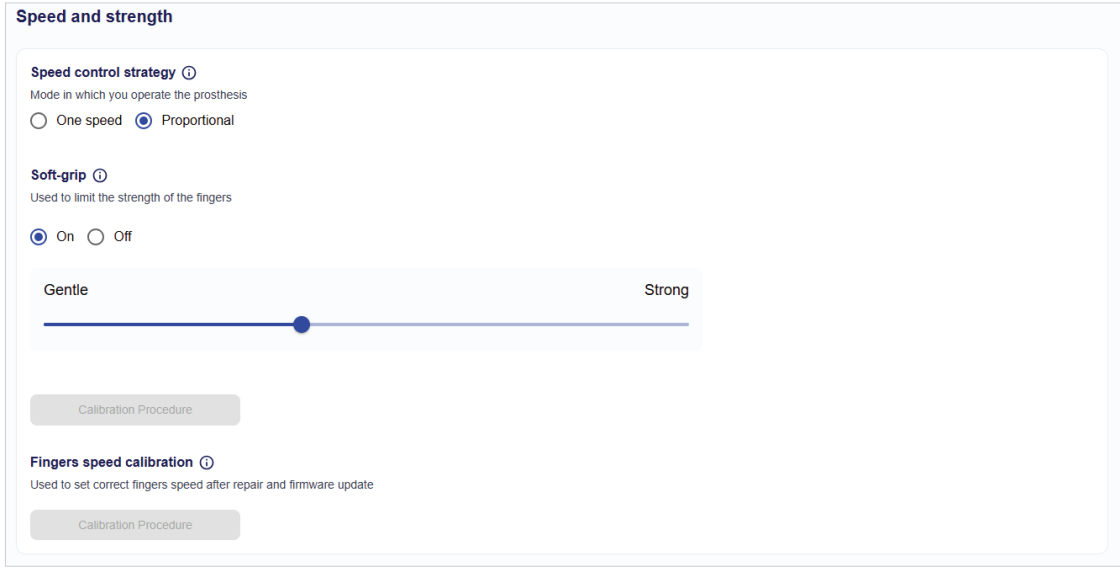
- EMG - control the prosthesis using single or dual channel EMG electrodes, or any other device with analog output from 0 to 5V.
- Pattern Recognition- control the prosthesis using a pattern recognition system which detects the intended grip pattern that the user wants to achieve.

6.5.2 Input Sites

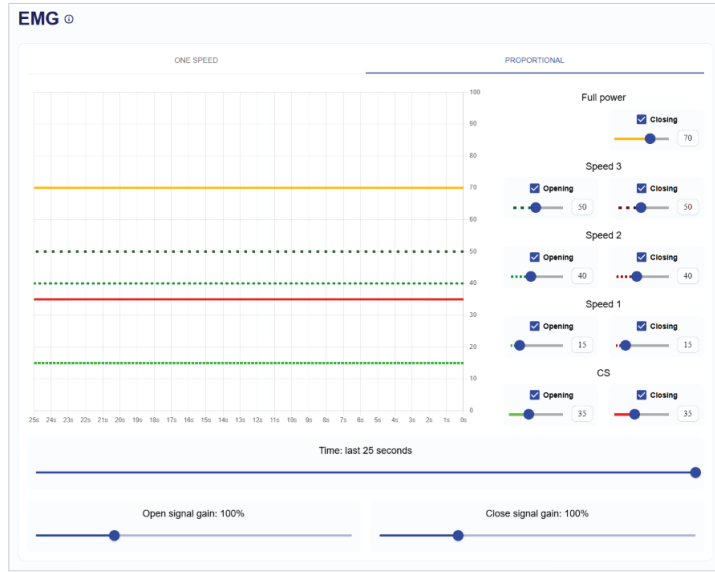
- The choice of this option depends on the patient's muscle condition, the level of the amputation and their stage in the rehabilitation process. It relates to the production and sending of good quality EMG signals.
  - Dual Direct
  - Dual Inverted
  - Single
- These options mean the patient can use one electrode or two - in direct or inverted mode - to control the prosthesis.
- Dual direct mode is the default option, with signals from two electrodes being used to control the prosthesis. Dual inverted mode simply swaps the electrode inputs. The electrode that would close the prosthesis' fingers in the direct mode will open them in the inverted mode.
- Single electrode mode is designed for patients that cannot use dual modes because of difficulty in producing two differentiable, strong signals.

6.5.3 Speed Control Strategy

In this section, there are 2 options for the speed of the hand:



- One speed: One speed control means that once the threshold has been passed, the speed of the hand is always at the same level regardless of the EMG signal strength. The threshold can be changed in the settings.



- Proportional: control means that speed of the hand is proportional to the patient's EMG signal strength. In this mode the patient has to contract his muscles stronger to move the fingers of the prosthesis faster. There are three achievable speeds; each of them is applied to the prosthesis fingers after exceeding a certain EMG strength threshold.

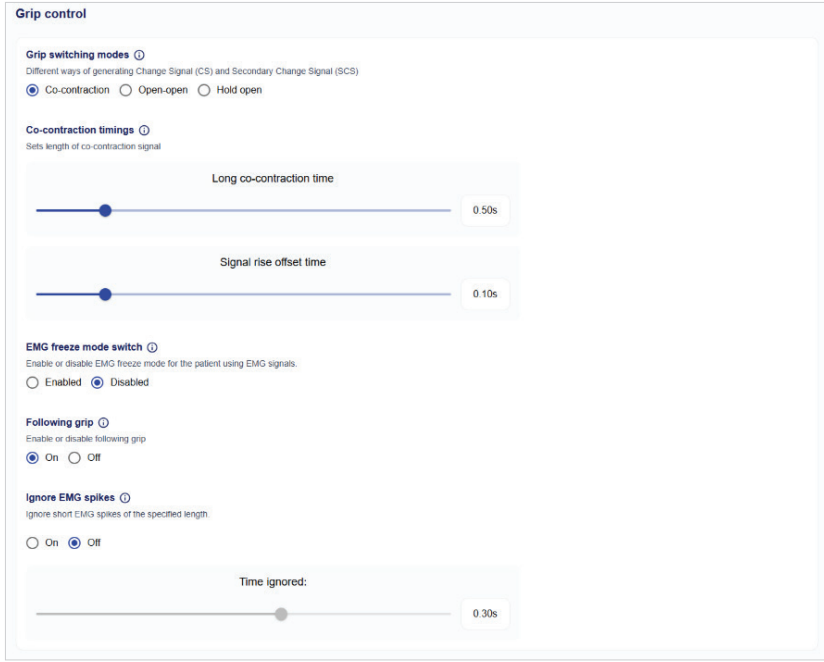
This section allows the user to select the type of signal used to change the grip. This can either be:

- Co-contraction (default) is the simultaneous contraction of both muscles used to control the prosthesis. If the co-contraction is shorter than 0.5s, then it is treated as the primary grip Change Signal. Longer co-contractions act as secondary grip Change Signals. The timing that defines the short and long co-contraction can be changed in the software.

- Open-open grip Change Signal is the sequence of two quick contractions of a muscle used to open the prosthesis. If the time between two such contractions is shorter than 0.5s, it will activate the primary grip Change Signal. To achieve a secondary grip Change Signal, the user needs to perform three muscle contractions in a sequence (open-open-open).
- In hold-open mode, the patient generates the primary grip Change Signal by keeping the open signal high while the fingers are already fully open for 1.5 seconds and they generate the secondary grip Change Signal by doing the same for 2.5 seconds. These timings can be adjusted by changing the Hold-open grip switching mode sliders.
- Single electrode grip switching mode is used when only one input / signal is possible. In this mode, the patient can choose between two ways of changing the fingers movement direction:
    - **Alternating:** the patient closes and opens the hand with the same signal. The first generation of the signal closes the fingers, the second generation of the signal opens the fingers. Double short impulse of the signal is used for a primary grip Change Signal and triple short impulses are used for a secondary grip Change Signal.
    - **Slope:** the speed at which the patient increases the signal strength defines the movement direction. Increasing the signal slowly causes the hand to close. Fast increase in signal strength causes the hand to open. To change a grip, the user needs to hold the opening signal, while the fingers are fully open.

6.5.4 Grip switching settings

These settings will appear when correct grip switching mode is selected



Co-contraction - Co-contraction timings. Long co-contraction time allows you to specify the time after which holding a co-contraction signal is treated as a secondary grip Change Signal. Signals shorter than this value are treated as the primary grip Change Signal. The signal rise offset time slider allows you to specify the maximum time between two signals crossing the CS threshold to be treated as a grip Change Signal.

Open-open and single electrode alternating - Pulse timings. Minimum and maximum pulse time slider allows you to specify which length of the signal impulses will be treated as valid. The minimum time between pulses slider allows you to specify precisely this so that noisy signals won't be treated as multiple pulses. The maximum time defines at what time the hand stops waiting for a second signal - important for daily use and remembering there may even be a third open signal.

Hold-open - hold-open timings. In these settings there are two sliders used for specifying the time for primary Change Signal and secondary Change Signal.

6.5.5 Soft-Grip

The strength of the fingers can be limited by the soft-grip functionality. It adjusts the maximum grip force applied by the hand on an object. It also enables you to specify an additional threshold for the EMG closing signal, which once exceeded, restores the full strength. By default then, the patient can have a very light touch, but likewise can squeeze and even squash an object if desired. When enabling this function, you need to calibrate the fingers by pressing the Calibration procedure button.

⚠ Warning!

Keep your hand in a safe position while calibrating as its fingers will be moving.

6.5.6 Finger speed calibration

For hands that have firmware version 2.1 or greater Finger speed calibration will calibrate all fingers to match the slowest finger speed. This should be done after a finger is replaced, or there might be visible speed difference between the fingers.

Once the Calibration procedure button is pressed the fingers will move to calibrate. Once complete, a table with information status will be displayed.

If the hand has firmware version prior to 2.1 the finger calibration will not be displayed.

Note: In asynchronous session: Finger speed calibration can't be performed during asynchronous session, because the device is not connected.

6.5.7 Ignore EMG spikes

If the patient is facing difficulty with EMG spikes - for example while exercising - you can activate the "ignore EMG spikes" function. By doing this, the prosthesis will ignore short spikes of EMG of the length specified by the adjustable slider.

Keep in mind that this function will create a delay in the prosthesis response time, as the initial part of the signal is ignored. With this selected, the timing parameters of open-open may need to be adjusted to allow for intentional grip switching.

6.5.8 EMG freeze mode

When the option is turned on the fingers will not move at all until the Change Signal (CS) is given

6.5.9 Audio & vibration signal guide

This section provides detailed explanations of each audio and vibration signal. It includes information on the circumstances under which each signal is activated, its duration and frequency.

See the table below for the detail of each parameter.

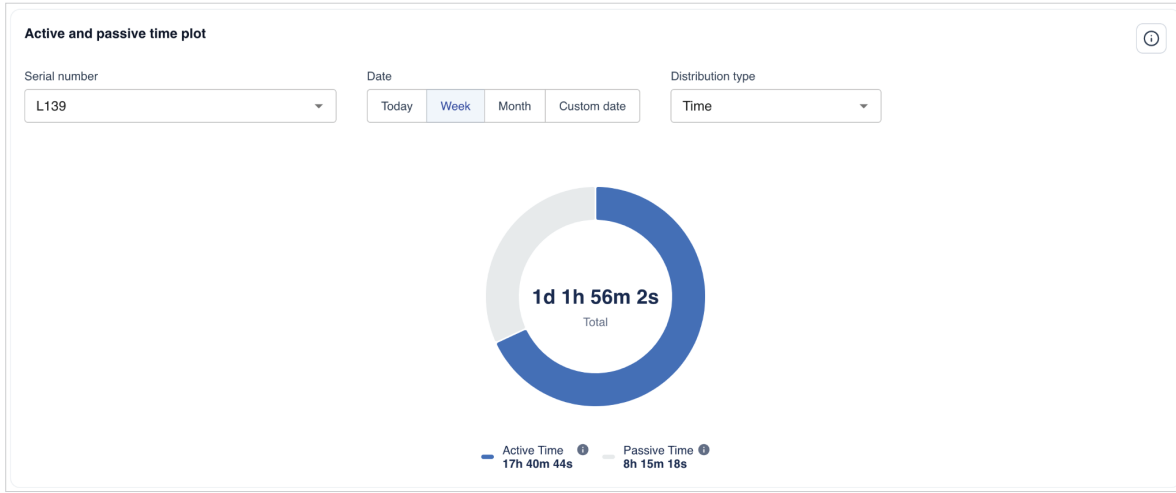
- Feedback settings: Allows the clinician to set the type of feedback the patient will get from the hand. The feedback is given on various events like passing hold-open Change Signal time, warning about low battery level etc.
  - Audio - the hand will notify the user using audible beeps. Volume of the beeps can be adjusted using the slider
  - Vibration - the hand will vibrate to notify the user. The strength of the vibrations can be adjusted using the slider. This option may not be available in some versions of the hand.

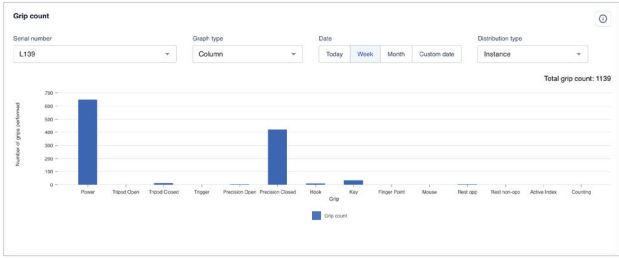
Reason	Trigger	Notification pattern	Specific settings, mode, etc.
Activate Hand	First cocontraction	Single	• Hand is power on. • Hand is initially deactivated by WaitFor-FirstCS setting.
Low battery warning	Low battery level occurred	Double - repeated every 30 seconds	• Low battery checker is enabled in settings • Current battery level is lower than low battery checker trigger level
Low battery emergency usage mode	Critical low battery level occurred	Five times - repeated every 5 seconds	• Low battery emergency usage mode is enabled in settings • Low battery emergency usage mode beep active is enabled in settings • Current battery level is lower than low battery usage mode emergency trigger
Grip change in hold open grip switching	Duration of open signal (short time passed) after full hand open	Single	• Hold open switching mode is chosen • First stage (short) of hold open time is passed
Grip change in single mode - fast open slow close (slope)	Duration of open signal (short time passed) after full hand open	Single	• Single mode switching mode is chosen • Single submode fast open slow close is chosen (slope) • First stage (short) of hold open time is passed

Direction change in single mode - alternating mode	Direction change	Single	• Single mode switching mode is chosen • Single electrode alternating mode is chosen • Single mode change direction indicator is enabled in settings (default) • Input signal is 0 during 1000ms after last move
Freeze mode activate / deactivate	Duration of open / close signal in extreme positions	Triple (First stage) Single (Second stage)	• Freeze mode is configured properly in settings • Input signal is above freeze mode thresholds and long double pattern detector threshold and the fingers are closed or blocked on an object • Input signal is longer than hold time stage 1 (1500ms - for First stage). • Input signal is longer than hold time stage 2 (1500ms - for Second stage)
Grip change feedback	Grip transition	Sequence of 4	• notify_during_grip_transition is enabled in settings
Command from external device	Communication frame	Single	• kFrameTypeTriggerFeedback frame called
Command from external device	Communication frame	Sequence of 4	• kFrameTypeTriggerFeedbackNotification frame called

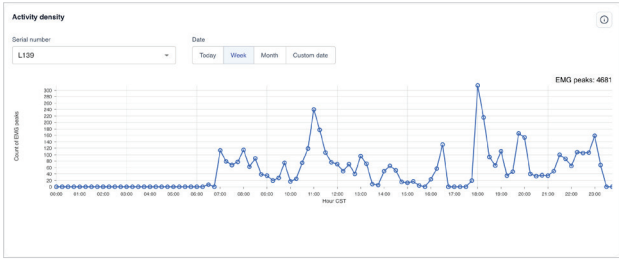
7 DEVICE USAGE MONITORING - DUM

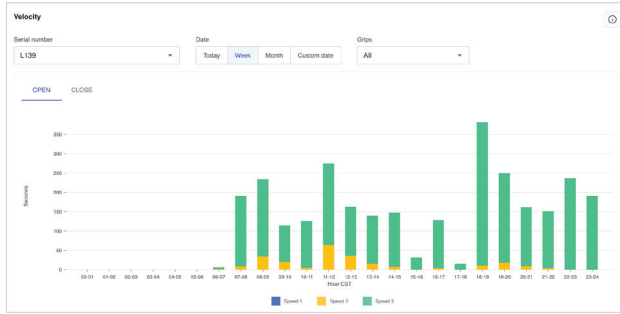
Device usage monitoring provides information regarding day-to-day use of the prosthesis by the patient. It consists of graphs that present information such as the number of performed grips and grips switches, together with hourly breakdown.



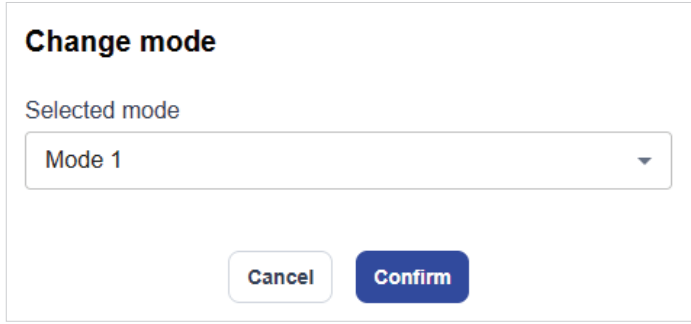

Grip count
Serial number
L139
Graph type
Column
Date
Today
Week
Month
Custom date
Distribution type
Instance
Total grip count: 1139
Number of grips performed
Power
Tripod Open
Tripod Closed
Trigger
Precision Open
Precision Closed
Hook
Key
Finger Point
Mouse
Rest opp
Rest non-opp
Active Index
Counting
Grip
Grip count


Grip count by hour
Serial number
L139
Date
Today
Week
Month
Custom date
Grips
All
Total grip count: 1139
Number of grips performed
Hour CST


Activity density
Serial number
L139
Date
Today
Week
Month
Custom date
EMG peaks: 4681
Count of EMG peaks
Hour CST


Velocity
Serial number
L139
Date
Today
Week
Month
Custom date
Grips
All
OPEN
CLOSE
Seconds
Hour CST
Speed 1
Speed 2
Speed 3

8 MODES



Modes represent different configurations saved in the device. Use this feature to create different setting modes for patients. This can be used for sports, vocation, recreational activities, etc. This can be done using modes. After the clinician creates mode profiles, they are sent to the patient's hand for use. The patient will be able to switch between modes on their mobile app. They can be switched using the dropdown visible in the upper-center part of the screen.

Modes allow you to set different hand configurations, which the patient can switch with one click from the mobile app. All mode settings are separate, e.g. Mode 1 can have different grip settings than Mode 2. There are a maximum of 3 modes per device. In the panel on the right in Configurator you can choose which mode you are currently editing.

Each mode holds the following parts of configuration:

- Grips pairs/grips sequence
- EMG settings
- Speed control strategy
- Grip switching mode
- Co-contraction/pulse/hold-open timings
- Ignore EMG spikes settings
- Soft-Grip settings

The remaining configuration elements are not stored in the mode and as such are common for all modes

- Grips fingers position

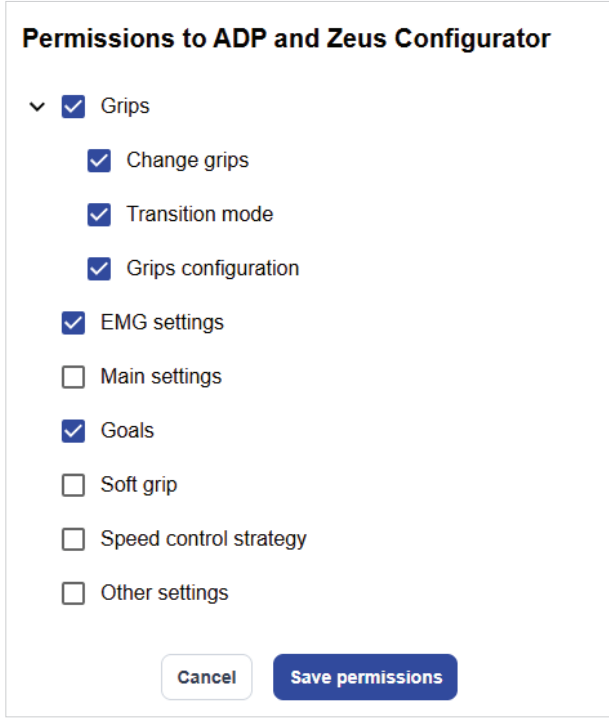
Select a mode that you would like to use and make a change to the hand configuration that will be stored in the new mode. Once the change is made, hit the send to prosthesis button. This can be done locally, asynchronously or during remote sessions.

9 ALLIED HEALTH

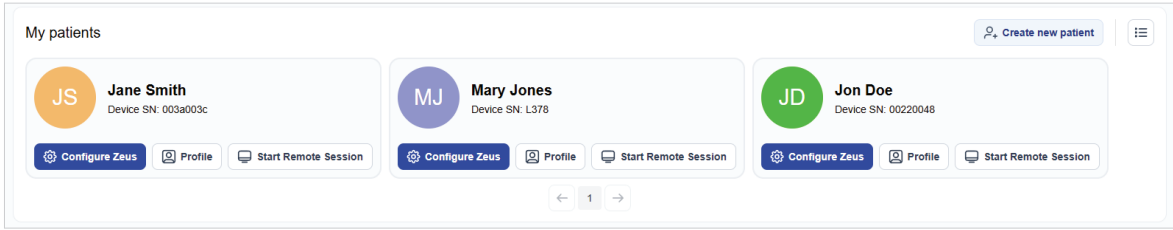
Allied Health can use other functionalities on the same rules as Clinicians after granted access.the description of the functionalities you can find under section: Remote session, Local Session, Asynchronous session, Config template, Modes, Goals, History log.

9.1 Allied Health permissions

Allied Health in the application has specific access to selected patients and functionality depending on the permission granted by the Clinician.

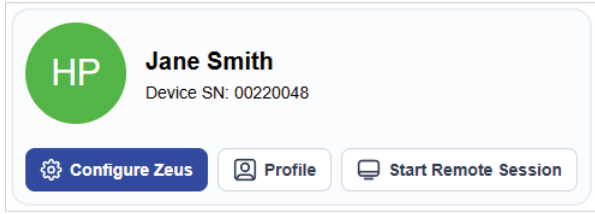


9.2 Allied Health – My patients



This view shows a list of patients for whom access has been granted by the Clinician.

The full view of the patient's information is available by clicking the button "Profile" on the Patient Card.



10 TECHNICAL SUPPORT

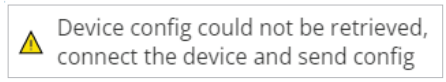
10.1 Troubleshooting

Device -ADP firmware version mismatch

Mismatch happens when the device's firmware version is different from the one ADP expects. It might mean that the device was updated outside of the ADP.

10.1.1 Configuration not found:

Shown when the device has not been connected yet, either to the web or mobile application. Without configuration initiated, session and async configuration modes stay disabled.



10.1.2 Upgrade needed:

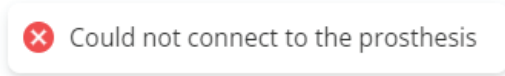
The device's firmware is not updated to the latest version so that features may not work correctly. In specific situations, the clinician may be locked out of all configurator features until firmware is updated.

In the case of any issues with the software:

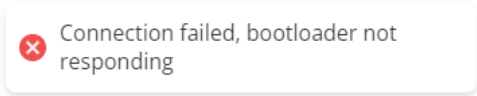
Check if the hand is turned ON

Check if the battery is charged

If a problem initiating Bluetooth connection occurs, the following error will be displayed. In such a case try refreshing the page, check the device's battery level, turn it off and on again, and try connecting once more.



Another error that might occur during Bluetooth connection is when the device's firmware is not responding. Try refreshing the page, check the device's battery level, turn it off and on again, and try connecting once more. If the problem still persists, contact Aether Biomedical.



If the firmware will become unresponsive, during initial connection a popup will appear asking you to update the device. Configuration can't be changed locally until firmware update is installed successfully in such a case. In the event of firmware update failing repeatedly please contact Aether support.

In the email message the user should specify a question or a problem that has occurred, preferably describing what led to it, what is happening and what a desired outcome would be.

- The bluetooth ID is not detected? Reopen your browser and connect with the hand.

Screenshots as attachments can be included to increase the speed in resolving a problem.

10.1.3 Firmware Update

The Clinician may update the firmware on the Patients Zeus Hand via the ADP. To access this feature, navigate to Patients profile and:

- Start a Remote Session with Patient or
- Start a Local Session with Patient

During Session (Remote or Local) in the Configurator please go to Firmware update tab and follow information on screen below.

10.1.4 WIFI

IOS can turn off wifi by itself in some cases if not used for a long time or to save battery. Due to that there is a possibility that notification will be delayed or not received at all. Please check if WIFi connection is present and Turn OFF and then Turn ON once again.

10.2 Compatability

The Aether Digital Platform is compatible with Zeus V1 hands A-01-L/R; A-01-L/R-T; A-01-L/R-TS-S.

10.3 Reporting

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

10.4 Security

Application should be operated from a secure device. It should have the firewall enabled and have anti-malware software installed.

It is recommended to check the certificate of the web page before logging in.

It is recommended to close the application when you are not using it or you are away from the computer.

11 OTHER INFORMATION

- Aether Biomedical declares that they meet appropriate European standards for design, manufacture and supply of prosthetic products and user software under CE mark. Continued compliance with the standard is monitored by a program of internal and external audits.
- All individual products are marked indicating that they comply with the requirements of the Medical Device Regulation 2017/745.

11.1 Symbols

This CE mark indicates the product conforms with the essential requirements and provisions of Medical Device Regulation 2017/745.

Refer to operating instructions

This mark indicates the user should read the operating instructions before use.

This indicates www.aetherbiomedical.com.

Definitions

User: Clinician, Clinic Admin, Allied Health

ADP: Aether Digital Platform

AETHER
BIOMEDICAL

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