

AETHER DIGITAL PLATFORMWEB APPLICATION INSTRUCTIONS

Version 4.0 / 2023.10.13

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△ Warning!

Date of the last update of this Software instruction: 2023.10.13

We highly recommend reading this document carefully before using the software

- o This document contains information about the proper and safe use of the software.
- This document is regarding Aether Digital Platform v. 1.7.0 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

Clinicians certified by Aether Biomedical can connect with the Zeus prosthetic hand by opening the Zeus Configurator application through the Aether Digital Platform. If you are testing/evaluating the Zeus hand and are a demo user, use the application available under the url: https://www.zeus-configurator.com/. Do not use any third party software to connect with the Zeus hand.

igl(riangle igl) Warning!

Only certified clinicians can use Aether Digital Platform to make changes in the Zeus prosthesis settings.

1. GENERAL INFORMATION

 Aether Digital Platform software is only compatible with the Zeus bionic 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 119 or higher) or Microsoft Edge web browser (version 119 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 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]).

Another functionality of the Aether Digital Platform is to collect usage data of the Zeus hand and enable clinicians to adjust 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

- o 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 with permissions determined by their care team.
- o The software provided by Aether Biomedical is designed exclusively for the Zeus hand.
- The Aether Digital Platform is intended to be used to remotely configure the Zeus hand and customize it for the user by collecting their user data. Additionally, the software also provides the required tools to service and repair the Zeus hand.

Contraindication

The Aether Digital Platform is not recommended for those not authorized by Aether Biomedical.



Avoid moving the hand when data is being sent, connecting to the platform and during firmware update.

3. BASICS

With the Aether Digital Platform, it is possible to change the control settings - Input options, Input sites,
 Control strategy, Grip switching modes, Soft-grip settings, Ignore EMG spikes settings and as well as communicate with the patient remotely and create user profiles assigned to specific devices.

- There are three Zeus sessions that can be utilized within the program. These sessions will allow the clinician to make parameter changes to the Zeus hand and send these changes to the hand either locally, asynchronously/offilne or remotely.
- The clinician can view the user's muscle contractions in real-time graphs and adjust the activation levels/ thresholds.
- REMEMBER: Changes should be made to optimize use for the patient; previous settings can be restored simply by loading previously saved configurations from the database.

4. BLE CONNECTION

- o The Zeus hand uses BLE (Bluetooth Low Energy) to communicate with the Zeus Configurator.
- o To start configuring the Zeus, it is necessary to turn on the Bluetooth on your computer.
- o 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.

5. STRUCTURE OF THE AETHER DIGITAL PLATFORM

The software is structured as follows:

- Aether Biomedical is the administrator of the software.
- Clinic Admin is the administrator at the clinic level. Clinic Admin can create clinicians, patients and Allied Health within company.
- o Clinicians are the users
- o Allied Health are users with specific permissions granted by clinic admin or clinicians.

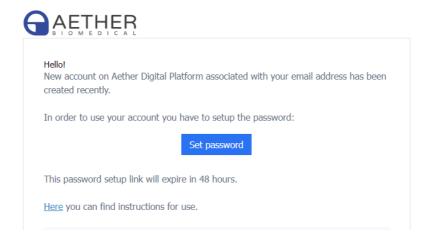
6. STARTING THE PROGRAM

- To run the program, it is necessary to open a Google Chrome or Microsoft Edge web browser. The program is compatible with systems running Windows (version 11 or higher) or Mac OS (version 14 or higher). An internet connection is required.
- o If you are a clinician certified by Aether Biomedical open the Aether Digital Platform at the following URL in the chosen web browser: https://panel.aetherdigitalplatform.com

7. LOGIN FOR USERS

7.1 REGISTER YOUR ACCOUNT

An automated email will appear in your inbox once your clinician account has been set up by Aether Biomedical. Register your account by clicking on "Set password" to be directed to the ADP web software.



7.2 REGISTER YOUR ACCOUNT

Create password and re-enter.

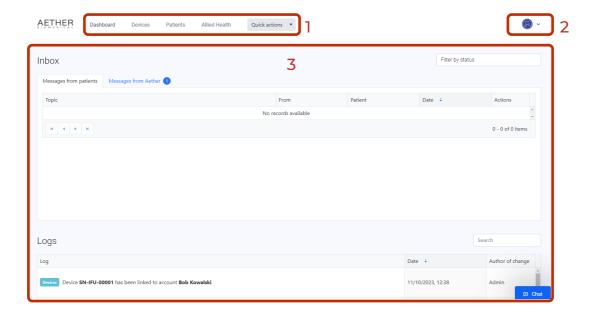


After you set up the password you will be prompted to enter your email address and password that you just created.





o If you forget your password at any time, please click "Forgotten password" and an email will be auto generated to your email inbox with instructions on how to reset your password.



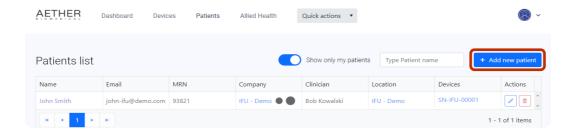
o After launching the program, the main screen of the Aether Digital Platform will show up.

- o This main screen is divided into 3 parts:
 - 1. Main Menu
 - 2. Profile Settings Area
 - 3. Main Area
- o In the Main Menu you can select different tabs which will allow you to access information on the current Zeus hand and patient allocation. These tabs are described below.
- o In the Profile Settings Area you can change your user/profile settings and information that is visible on the platform.
- o The content of the main screen is dependent on which selection tab in the main menu is chosen.

8. CREATING A NEW USERS ACCOUNT

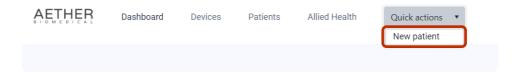
8.1 Creating new patient account (as clinician or a clinic admin)

- Navigate to Patients tab
- Click "Add new patient" button
- Medical record number: The Medical Record Number (MRN) is a unique identifier that hospitals and medical practices use to keep track of individual patient records.

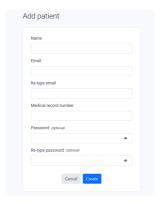


Now fill in the appropriate fields. You can also set a password for the patient, but it is recommended to leave this field blank, then the patient will receive an email asking them to set a new password to the account.

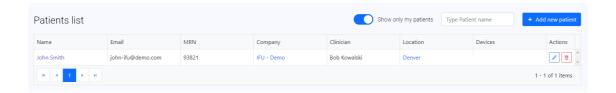
You can also add a new patient from Quick actions "New patient" from the tab panel.



Complete the form with or without the Password field completed.



The new patient "John Smith" has now been added to the patient list.



8.2 Creating new clinician account as a Clinic Admin

- Navigate to Clinicians tab
- Click "Add new clinician" button



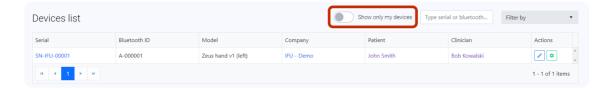
8.3 Creating new Allied Health as a Clinic Admin

- Navigate to Clinicians tab
- Click "Add new clinician" button
 - Choose patient
 - -Choose permissions



9. DEVICES

Under the Devices tab the Devices List will appear and show all the devices at the clinic level. Disable "show only my devices" to see all devices assigned to the clinic. Select "show only my devices" to see devices assigned to you.

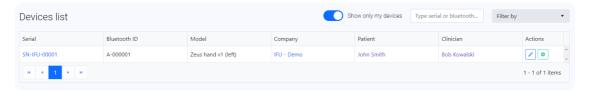


The next step is to assign a device to this patient as the "Devices" column is blank for John Smith

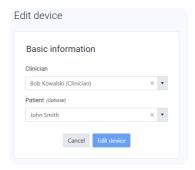


Edit device (as a clinician or a clinic admin)

If you want to assign a device to a newly created patient, you have to edit the device. To do this, click the edit button under the Devices tab, then select the edit button (highlighted blue) in Actions column for the hand that needs to be assigned to John Smith.



From the Patient dropdown choose John Smith and select Edit device



The device list now shows John Smith assigned to L100 hand. A patient can only have 2 devices assigned to them.



To change the clinician assigned to a patient and their device: under the Devices menu select the edit icon on the device to edit and change clinician from the drop-down.





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

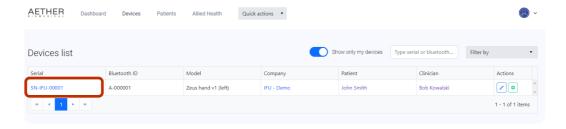


The hand can only be assigned to one patient at a time.

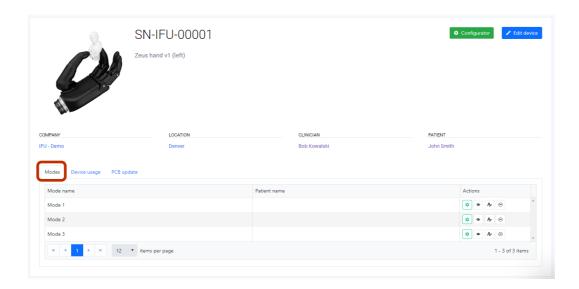


Device details:

Select the device you would like to access through the Device list window under the column Serial.



Here you will have access to the profile of the device as well as the history of changes, modes and device usage. This is also where you can access the Zeus Configurator to make changes to the hand.



o Modes represent different configurations saved in the device. See 'Modes' section of IFU

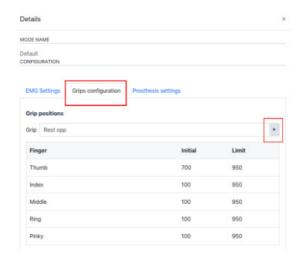
Actions provides the ability to configure , see details , edit name , enable

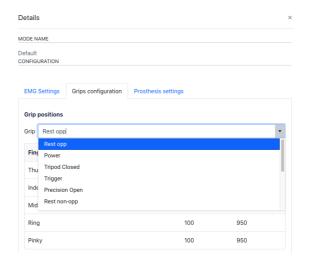


o Details provides details of hand configuration, such as EMG Settings, Grips configuration, Prosthesis settings

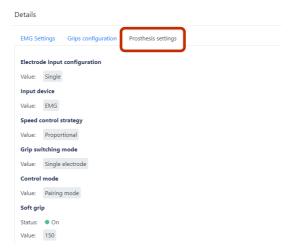
Details	
MODE NAME	
Default CONFIGURATION	
EMG Settings	
Emg spike Status: • Off	
Value: 300 ms EMG gains	
Extension: 100%	
Flexion: 100%	
EMG thresholds	
CS extension thresholds: 35	
CS flexion thresholds: 35	
Threshold control open value: 15	
Proportional control open second value: 40	

o Grips configuration has a drop down menu to show each grip mode and the associated finger and thumb setting





o Prosthesis settings allow the clinician to see control setting parameters of the hand.

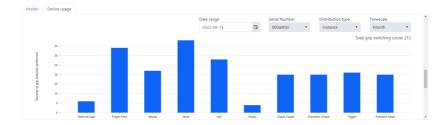


o Edit h to change the name of the mode.



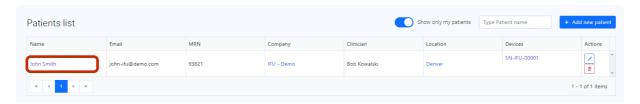
o Enable allows you to disable and enable modes of the hand. To disable, press the icon and it will turn red. To reinstate the mode, click the icon again and it will turn white.

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.

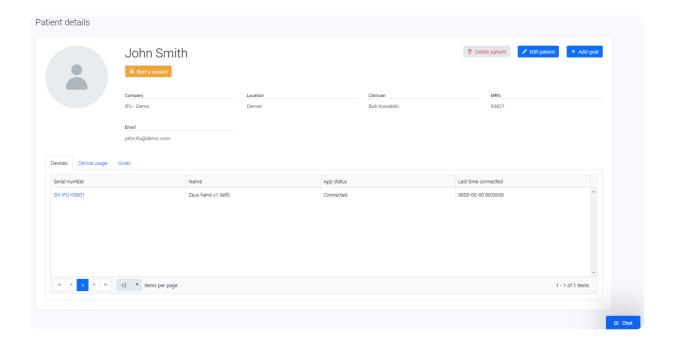


10. PATIENTS

- The Patients tab shows a list of patients using the Zeus hand in your company.
- o To see patient information click on the name in the Patients list



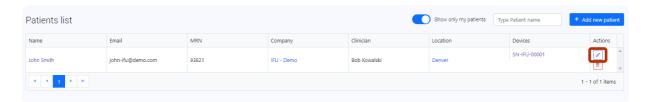
o The patient details window opens up, providing company details associated with patients and hands that are linked to patients. This is also where you can access a remote session to communicate with a patient. See the chapter on "Remote Session" for further details.



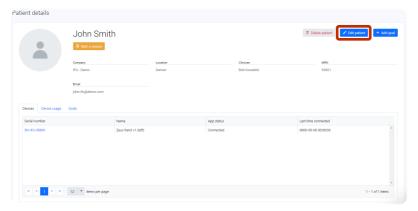
- o The edits available at the clinic level are patient name and email.
 - Other edits such as Company and or Location can only be done at the admin level. Please contact Aether Biomedical for further assistance.



o To edit the name and email address of the patient select the edit icon on the right under the Actions column



o Or from the Patient details window





- o To change the clinician assigned to a patient and their device:
- Under the Devices menu, select the edit icon for the device to be edited and change the clinician from the drop down menu.

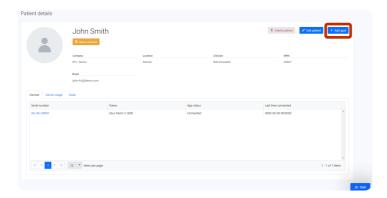




• From same Edit device menu you can also change the patient assigned to device and clinician



11. ADD GOAL



When "Add goal" is choosed you will go directly to the form where you can set up the goals for the patient.

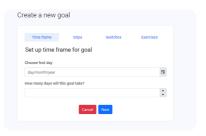
Step 1:

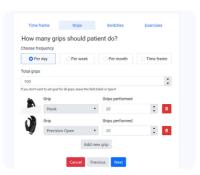
In step one, choose how long this goal will last. Set the date of the first day (it cannot be "today") and indicate how many days it should last.

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).

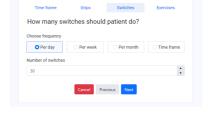
You can choose the grip details whether the patient is to perform a total number of grips or a certain number of grips. You can set both of these goals at the same time. The sum of the specific grips cannot be greater than the goal for the "Total grips" count.





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:

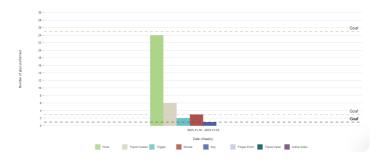
In the last step, you can choose which exercises the patient should perform. You can set the number of repetitions and frequency for each exercise separately. If you would like to add some exercises please write to us.



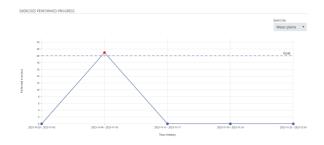
Under the Goals tab, you can find information about the history of goals set and completed. By clicking on the plus icon you can see the full information. Clicking on the eye icon takes you to the settings preview. The trash icon removes the goal from the history.

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.

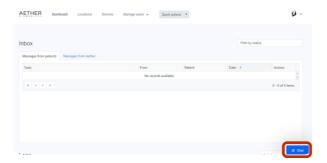






12. CHAT

You can see the chat label in the right bottom corner of ADP. When you click on it it will open a modal with a list of active chat. There is one chat for each patient. The clinician can be a participant of the chat as a Primary Clinician (can remove other users from chat) or invited by other Clinicians to chat.



When you click on chat with patients you will see an option to send a text message to all participants. In the upper part of the chat you can see the list of participants and you can filter messages only about new tickets.



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



Add users to chat:



Chat messages:



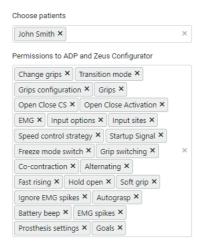
Any user that send message can delete it and it won't be visible to other from this point.

Delete messages:



13. ALLIED HEALTH PERMISSION

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



Device details:

The device list from Allied Health view is able to see the patient device when they have received access from clinician or clinic admin. Allied Health is not able to see options to edit the devices, but can go to the configuration from Device list

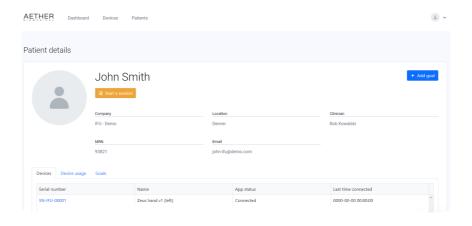


Patient list:

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



The full view of the patient's information is available by clicking the patient's name in the list. Allied Health does not have rights to edit or delete patients. To do this, report to the Clinic Admin or Clinician.



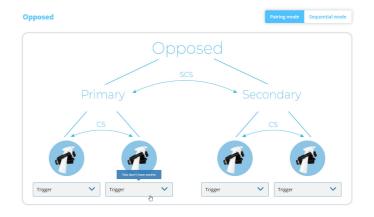
Profile Settings:

Please check "Section 14 Profile Settings".

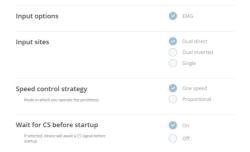
Zeus Configurator

Allied Health is granted access to Zeus Configurator functionality in accordance with the permission granted by Clinic Admin. More on this in section: ACCESSING THE ZEUS CONFIGURATOR FROM THE AETHER DIGITAL PLATFORM

Detailed description of their functionalities is located in section ACCESSING THE ZEUS CONFIGURATOR FROM THE AETHER DIGITAL PLATFORM and the next following section. Functionalities can be blocked if you did get the access to them.



Prosthesis settings

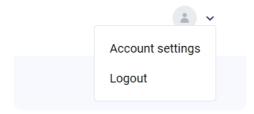


Other common resources

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/Offline session, Config template, Modes, Goals, History log.

14. PROFILE SETTINGS

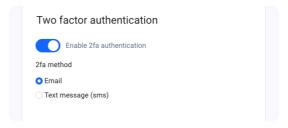
To go to the account settings, click on the avatar in the upper right corner, and then select the "Account settings" option



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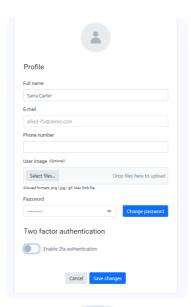
After clicking, you will be redirected to your account settings page where you can:

- o 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
- o Change the avatar image
- 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 and after its verification. The principle of operation remains the same as for the option with email



15. ACCESSING THE ZEUS CONFIGURATOR FROM THE PATIENT MANAGEMENT PANEL

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. The Local, Asynchronous/Offline and Remote Session. 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, at office configuration, where the clinician connects to the device via Bluetooth without the need of a patient to use the mobile app.
- Asynchronous/Offline Session remote configuration, during which a clinician can propose changes to the device in the patient's absence, generating an email 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 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. After closing a remote session the patient will receive a notification on their mobile app. where they are able to save the changes from the session permanently or dismiss them.

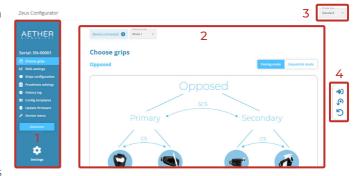
Log in and learn about the Zeus configurator

- Login to ADP. See Chapter "Login for Users"
- Once logged in, navigate to devices tab
- Find the device that you want to configure, and click on the green cog icon on the right, from where you will be redirected to the Zeus configurator



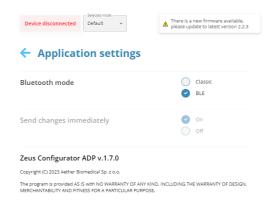
• After launching the program, the main screen of the Zeus Configurator will show up.

- This main screen is divided into 4 parts:
 - 1. Main Menu
 - 2. Settings Area
 - 3. Top Bar
 - 4. Side buttons
- In the Main Menu you can select different tabs which will change the settings displayed on the Settings Area. These tabs are described below. You can also enable the connection process with the prosthesis.



- 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.
- Application settings In the Application Settings you can see Bluetooth Module and Send Changes to the hand settings.

Application settings :
 In the Application Settings you can see Bluetooth Module and Send Changes to the hand settings.

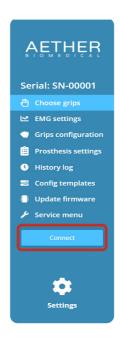


- o On every page there is also the Top Bar. On the Top Bar, the view of the display can be changed between Standard, Minimal and Minimal + EMG
- Side Buttons enable you to save settings to the prosthesis, restore most recent versions of the settings, and undo the last change in the settings.

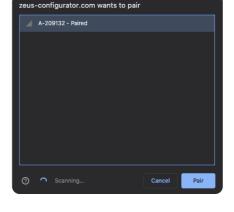
16. CONNECTING THE HAND TO THE SOFTWARE

If you are a clinician certified by Aether Biomedical, open the Zeus Configurator application through the Aether Digital Platform and follow the steps below:

- o Turn on the battery of the prosthesis.
- o Click on the connect button in the Zeus Configurator.



- A pop up should appear with only one device listed in it
- The process of scanning for the hand will begin.
 Your device should show up on the popup screen.
 The scanning process might take up to several seconds. If your device does not appear on the list, make sure that the battery of the prosthesis is turned on.
- Select the device and click on the Pair button.



 A bluetooth connection request will pop up (if you are on an Apple Macintosh system). Select Connect. If you are on Windows PC this pop up will not occur



The application should now connect with the Zeus hand. It will retrieve the hand settings and display them on the screen. If you cannot connect to the prosthesis, check if you selected the correct prosthesis and turn its battery off and on.

o To see your hand serial number select the information icon next to Device connected. The hand serial number will also show up at the top of the main menu. Example below shows Serial: SN-00001

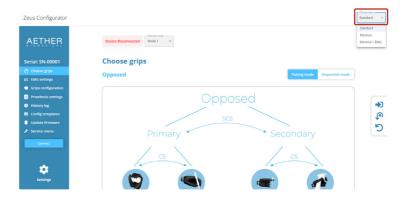


 A pop up will appear with the hand serial number and firmware version



Serial number: SN-00001 Firmware version: 2.2.3

Choose view:



Standard:

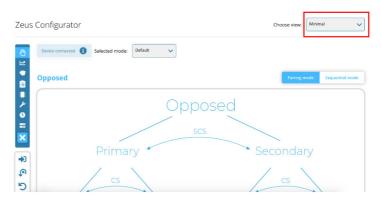
Standard view is the default one of the application. It is the most detailed and accessible. Has all navigation elements described. Recommende to use if screen size allows for it.

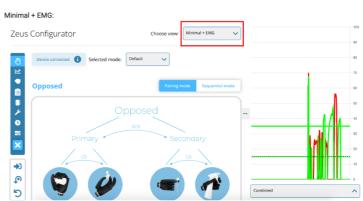
Minimal:

Minimal removes the text from the Main Menu screen and just shows the icons. It also moves the Side buttons to the left side of the screen. Brings the Settings Area into larger view. Ideal for use with a small screen.

Minimal + EMG:

Minimal + EMG has a similar view to Minimal. However, it reduces the Settings Area size and includes an adjustable window on the right to view the EMG signals. Use when you want to make changes and also look at EMG signals simultaneously.

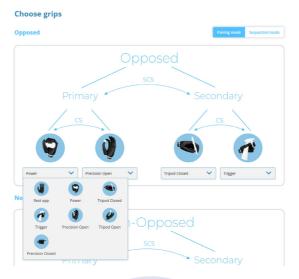




17. CHOOSE GRIPS TAB

• 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.

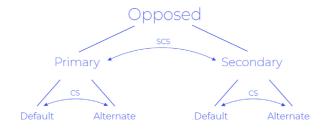
o Choosing the control mode changes the displayed graphics in the Settings Area. There you can select the order in which the grips will be accessed in each of the control modes.

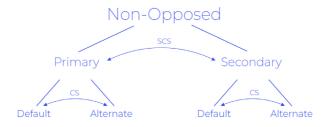


• The Zeus has 12 grip patterns. The clinician can choose the grips that are the most useful in the patient's daily life.

Pairing Mode

- o 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 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.
- o To switch between the default grip and the alternate grip, provide a Change Signal.
- o 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.





CS - Change Signal SCS - Secondary Change Signal

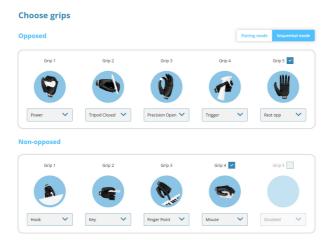
The table below shows what type of signal is treated as a Primary Change Signal and Secondary Change Signal in different grip switching modes.

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 elctrode alternating	Open open	Open open open
Single electrode slope	Hold open	Long hold open

Sequential mode

o In the 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.



o 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 grayed out. You can re-activate the grip by checking the box over it.

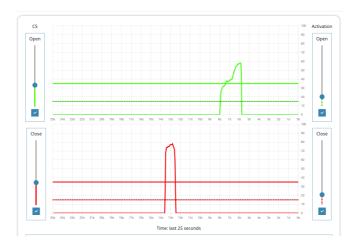
18. EMG SETTINGS TAB

- o In the EMG Setting tab you can see the graph depicting the signals and their strength acquired from the patient's muscles.
- To accommodate for 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.
- o 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.
- o 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 slider at the bottom of Settings Area.
- o 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.

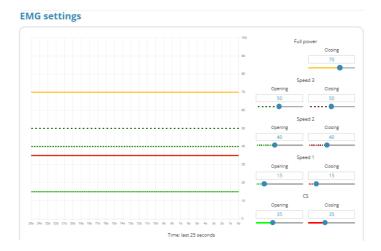
o Combined - in this option, both muscle signals (Flexion and Extension) are shown on the same graph



o Separate - in this option, both muscle signals (Flexion and Extension) are shown on the separate graphs



o 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 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.

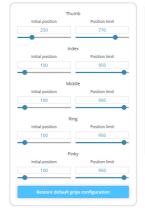
o If the patient has problems controlling the hand, the threshold bar can be adjusted.

Adjustment	Effect	Consequence
Raising	Patient needs a higher sig- nal 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 inadver- tent operation / accidental opening

19. GRIPS CONFIGURATION TAB

- o 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.
- o 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.

Grips configuration





△ Warning!

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.

20. PROSTHESIS SETTINGS TAB

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

Input Options

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

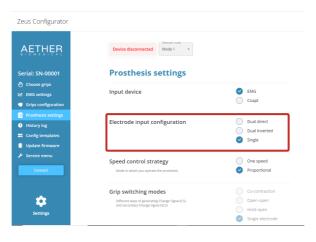


- EMG control the prosthesis using single or dual channel EMG electrodes, or any other device with analog output from 0 to 5V
- Coapt control the prosthesis using Coapt pattern recognition system which detects the intended grip pattern that the user wants to achieve.

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.

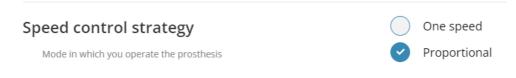
- Dual Direct
- Dual Inverted
- Single
- These options mean the patient can use one electrode or two in direct or inverted mode to control the prosthesis.
- Dual direct mode is the default option, with signals from two electrodes being used to control the prosthesis. Dual inverted mode simply swaps the electrode inputs. The electrode that would close the prosthesis' fingers in the direct mode will open them in the inverted mode.
- o Single electrode mode is designed for patients that cannot use dual modes because of difficulty in producing two differentiable, strong signals. When selected, the application will automatically choose "single electrode" grip switching mode.



Speed Control Strategy

- In this section, there are 2 options for the speed of the hand:
 - One speed
 - Proportional
- 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.

o 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.



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, user needs to hold opening signal, while the fingers are fully open.

Grip switching modes	Co-contraction
Different ways of generating Change Signal (CS)	Open-open
and Secondary Change Signal (SCS)	Hold-open
	Single electrode

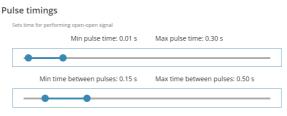
Grip switching settings

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 and single electrode slope - hold-open timings. In these settings there are two sliders used for specifying the time for primary change signal and secondary change signal.



Soft-Grip

o 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.



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



Ignore EMG spikes

o 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.

△ Warning!

Keep in mind that this function will create a delay in the prosthesis response time, as the initial part of the signal is ignored.

△ Warning!

With this selected, the timing parameters of open-open may need to be adjusted to allow for intentional grip switching.



Wait for Change Signal before startup

When the option is turn on the fingers will not move at all until CS is given

Wait for CS before startup

On

If selected, device will await a CS signal before startup



Off

EMG freeze mode

When the option is turn on the fingers will not move at all until CS is given

EMG freeze mode switch



On





Off

Low battery beep mode

Low battery beep

Sets low battery checker alarm voltage level and state of activation.



Emergency mode

Emergency mode

Turning this off might lead to a situation where the patient cannot open the hand while holding an object when the battery was fully depleted.



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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.

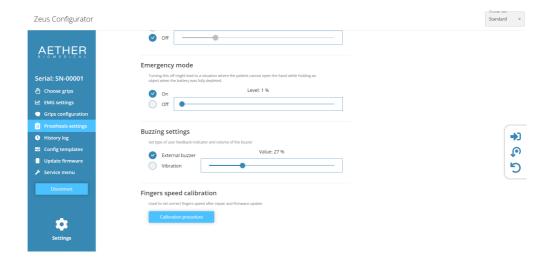
If the hand has firmware version prior to 2.1 the finger calibration will not be displayed.

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





In remote and local sessions:



o During calibration:



After calibration:



• 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.

 Emergency Mode: If the emergency mode is activated, an signal will be emitted and the hand will only be able to open. Turning this off might lead to a situation where the patient cannot open the hand while holding an object when the battery was fully depleted.



- 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.



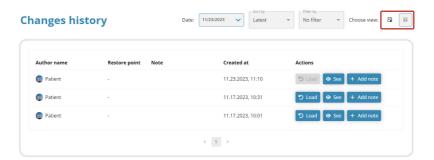
21. HISTORY LOG

- History log allows the clinician to track every change made to the device.
- o It consists of two views:
 - Calendar changes are displayed in calendar, grouped and assigned to each day based on date of creation, when pressing on specific entries in calendar, detailed popup will appear





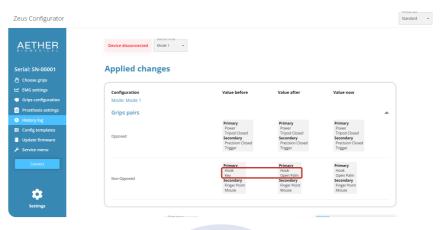
• Log - changes are displayed in a list, they can be sorted by date, or filtered based on restore point status



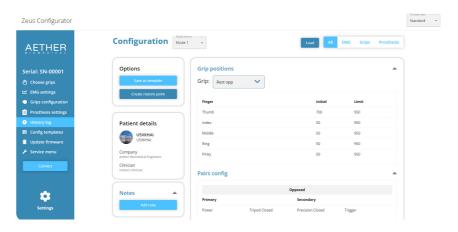
Actions available for every entry:

- Restore used to restore saved configuration and send to prosthesis.
- See opens detailed view of entry, where applied changes and configuration summary are displayed. Includes information about which mode was changed. This view also supports adding notes to an entry, and creating a template from it.
- Add note allows the clinician to write a short description regarding the configuration.
- o Differences between the configurations will show up in the Before and After Values. Changes that are made are under "Applied changes". Everything else under Configuration.

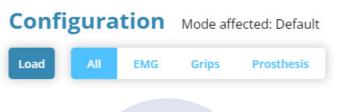
In example below. The grip pattern was changed between "Key" and "Open palm".



o Scroll down and under Configuration you are able to see all the particular settings of the hand.



o In order to apply a previous configuration setting you must press the restore button. The restore button loads the values of the selected configuration..



Click Yes, send



• Add note - allows adding short descriptions to entry



△ Warning!

When restoring configuration in async mode, the device configuration and database configuration will be different until the prosthesis is connected either to mobile or web app and synchronized.

△ Warning!

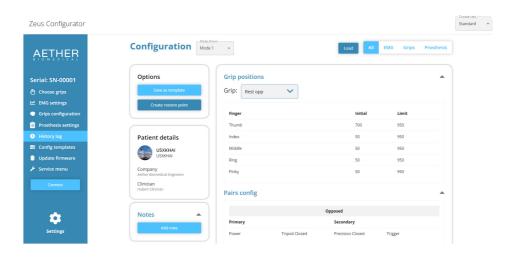
When restoring the configuration during the session, the patient will have to accept the changes to the hand prior to the changes being saved in the database.

22. CONFIG TEMPLATE

- o Templates are a way of saving certain configurations as presets for later use.
- A template can be owned either by a clinician directly, a company or Aether Biomedical.
 - Clinician templates saved with clinician ownership, will be visible only to the user that created them
 - Company company templates are visible to every clinician in that company
 - Aether Biomedical global templates, visible to every clinician using ADP platform
- o Templates main view, the only filtering available is based on ownership.



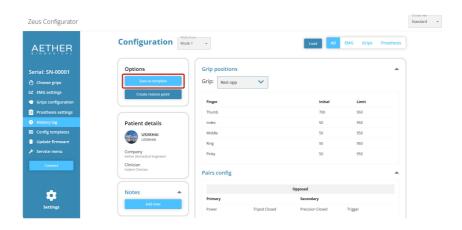
- o Actions available for every entry:
 - Import used to apply a template to specified mode
 - See opens detailed view of template



Add note - allows adding short descriptions to template

Creating new template:

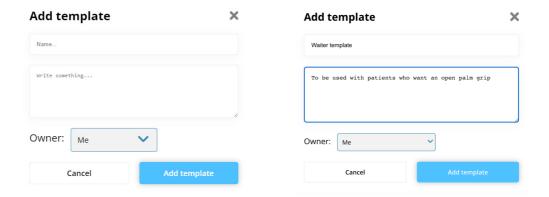
- Go to History log tab
- Choose history log entry either in calendar or log view and go into detailed view
- Press "Save as template" button. Under "Options" Select "Save as template" to save template of current configuration to be used with future patients.



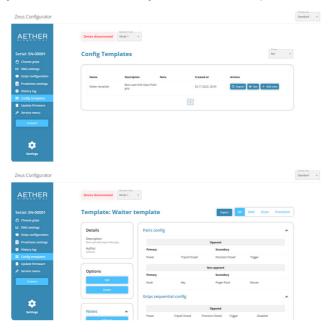
Restore point adds a marker to the configuration for easy filtration in the history.



o Fill in the name and choose ownership. Give the template a name and add a note. From the dropdown you can choose the owner, whether it be the clinician or the company. When you select "Me" only you have access; choosing "Company" all will have access to the template.



o Under Config templates on the left toolbar you can see the templates that have been saved by either you or saved to the company. Select "See" will allow you to see the template and edit.



△ Warning!

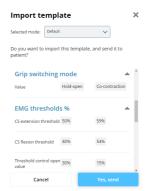
"Common" (described in modes section) part of history log entry configuration will not be saved to the template.

 Once saved, template can be imported to specific mode in the device Importing template:

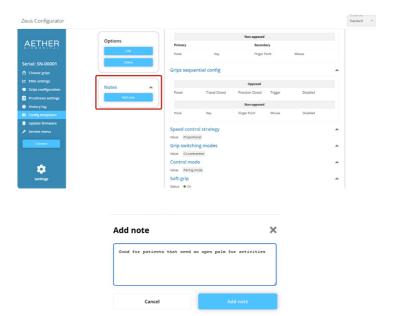
- Navigate to Config templates from Navbar
- Press "Import" button on a chosen template, popup with comparison between current, and imported configuration should appear
- Select to which mode the template should be imported and press "Yes, send".



Click Yes, Send.



o Notes can be added here about the template.

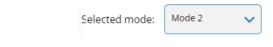


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23. MODES

o 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.

• Modes represent different configurations saved in the device. They can be switched using the dropdown visible in the upper-center part of the screen.



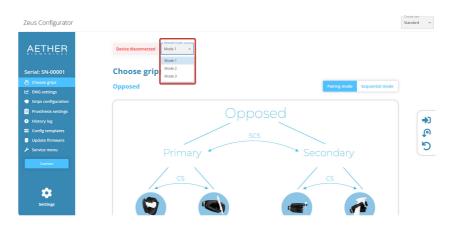
Switching between modes, removes all unsaved changes.

- 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

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

- Grips fingers position
- Input sites
- 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
 or asynchronously



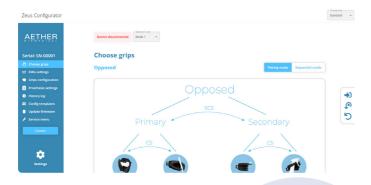


24. LOCAL SESSION

- Login to ADP. See Chapter "Login for Users".
- o Once logged in, navigate to devices tab.
- Find the device that you want to configure. Clicking on the green cog icon will redirect you to the Zeus configurator.



o In local mode click Connect and select device to pair.





• A Bluetooth connection request will pop up (if you are on an Apple Macintosh system). Select Connect. If you are on Windows PC this pop up will not occur.



Standard:



o Minimal:

Minimal removes the text from the Main Menu screen and just shows the icons. It also moves the Side buttons to the left side of the screen and brings the Settings Area into larger view.

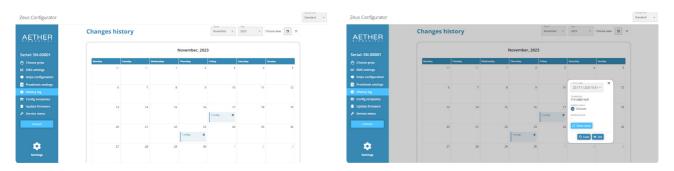
o Minimal + EMG:

Minimal + EMG has a similar view to Minimal. However, it reduces the Settings Area size and includes an adjustable window on the right to view the EMG signals.





• History log allows you to track the different configurations that have existed within a hand.



To access the configurations in the history log, select the date and time of the log you want to access and click the "See" button.



The first time you connect the hand to the configurator you will see every change as an Applied Change, because the configurator updates itself by taking the values from the hand for the first time. Scroll down to see all the settings of the hand.



 Configurations after the initial configuration will show a before and after change value. Changes that are made are under "Applied Changes". Everything else under Configuration.

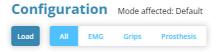
In example below. The grip pattern was changed from "Key" to "Open Palm"



 Scroll down and under Configuration you are able to see all the particular settings of the hand.



 In order for the configuration to be sent to the Zeus hand you must click "Load". This will take the Applied changes and send to the Zeus hand for use.



o Click Yes, send.



Avoid moving the hand while sending data to the user.



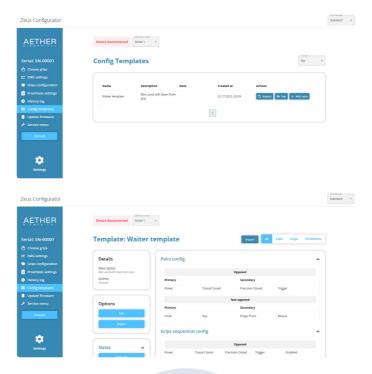
• Select "Save as template" to save template of current configuration to be used with future patients.



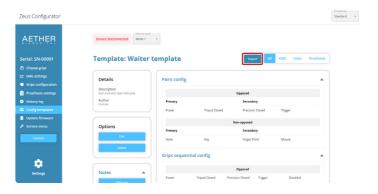
o Give template a name and add a note. From dropdown you can choose the owner, whether it be the clinician or the the company. When selecting "Me" only you have access; for: Choosing "Company" all will have access to the template.



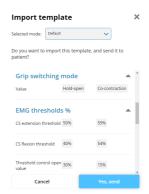
• Under Config templates on left toolbar you can see the templates that have been saved by either you or saved to the company. Selecting "See" will allow you to see the template and edit.



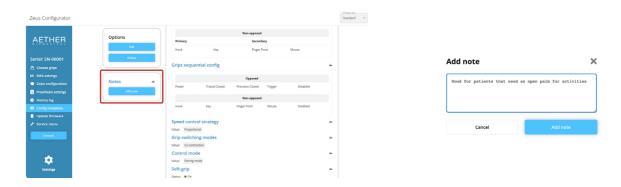
 Select "import" to import the template to a patient.



o Click Yes, Send.



o Notes can be added here about the template.



THERE ARE THREE WAYS TO SEND THE CHANGES TO THE HAND WITH LOCAL CONFIGURATION:

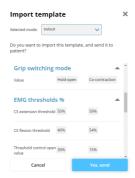
1. Send current changes to hand by using the "Send to prosthesis" button



2. Send the configuration to the hand by loading a previous template and hitting the "Load" button.



3. Import configuration template and send to hand.



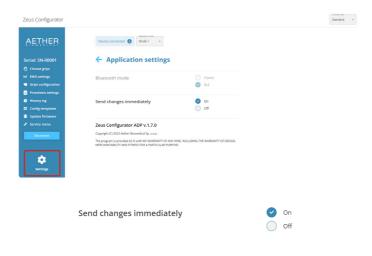
• At the end of the session, you will be asked if any parts are needed for replacement. If so, you will be redirected to a special form where you will select the appropriate parts and place an order for them.



IMMEDIATE SENDING MODE

Immediate sending can be turned on only during local session. When turned on, all changes made will be sent to the device immediately, allowing the patient to test them right away.

However, in order to save changes permanently clinician still has to press "Send to prosthesis" button located on the far right of the screen. It can be toggled in "Settings' view" accessed by clicking the cog icon on the bottom of the sidebar.



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25. ASYNCHRONOUS/OFFLINE SESSION

To start async configuration:

- Login to ADP. See Chapter "Login for Users"
- o Navigate to devices tab
- Find the device that you want to configure. Clicking on the green cog icon will redirect you to the Zeus configurator.



 During Async Session, the Zeus Configurator is not connected to the device. The clinician can go ahead and make parameter changes to the Zeus hand. These changes will take affect once the patient accepts the new configuration from their mobile device.

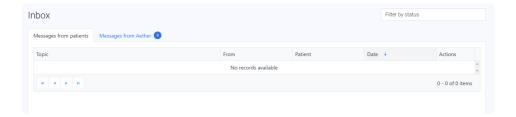
INBOX TICKETS

The Asynchronous/Offline session allows the clinician to respond to patient messages directly from the ADP to the patient's mobile application where they will get a notification in their inbox.

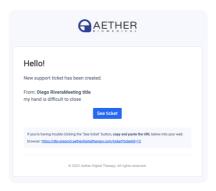


Because of bad internet connection or interrupted internet connection to user can get notifications with delay or not get at all.

o Under the Tickets window of the ADP homepage you will see messages to you from patients.



o The clinician will also be notified in their email inbox that a ticket has come through via the ADP.

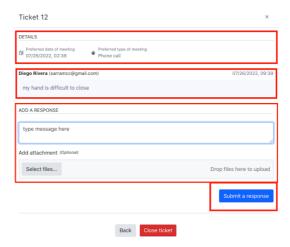


o Click on the message in the Ticket window.



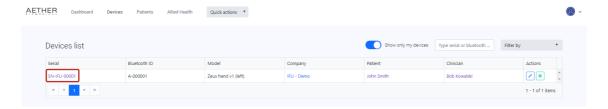
This window has 4 areas you will see:

- 1 Details
- 2. Patient message window
- 3. Add a response window
- 4. Submit a response
- The Details window provides type of communication request from the patient and the date.
- The patient message window shows patient name, email, date and time that the message was sent from the patient and the message text.
- You can reply to the patient in the response window and it will show up in their mobile app inbox.
- Once you finish typing a message click "Submit a response".
- Select Close ticket once all communication on this topic is complete.

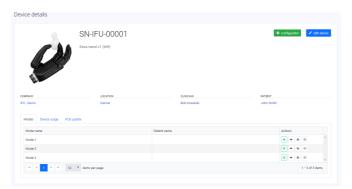


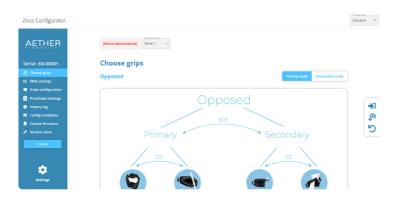
o To make changes to the hand in Async Session click on the Devices tab at top of page

• Select the hand associated with the patient



- o Device details will open up.
- o Click on Configurator.

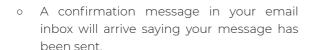


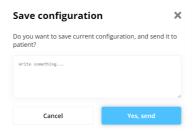


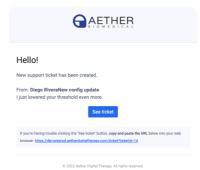
• Zeus Configurator will open up. DO NOT CLICK CONNECT. The device disconnected notification is correct and will remain while making parameter adjustments. Since the hand is with the patient and not in your office you will be making setting changes to the hand asynchronous/Offline (without the hand being in your office). Make the necessary parameter changes and then select the "Send to prosthesis" button.



Similarly to the local session, changes made during the asynchronous/Offline session must be saved using the "Send to prosthesis" button on the right side of the screen. When used in Asynchronous/Offline Session, a pop-up asking for confirmation will appear. The clinician may also add a short description of changes made using it. Write a message and hit "Yes, send" button.



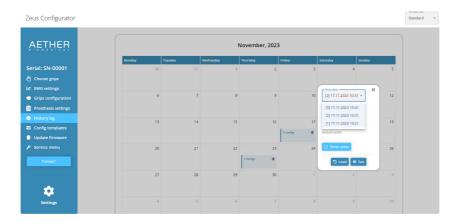




• When using this method of configuration, the patient needs accept the changes in the mobile app for them to take effect. See patient app user instruction manual.

Keep in mind that changing settings of the prosthesis impacts its functionality, which may lead to unintended behavior of the prosthesis. Inform a patient to be careful when holding objects while testing out the new settings.

Once a patient has uploaded any changes made to their hand via the mobile app you will see this appear in the History log. Select the date and time of the configuration ticket that you sent to the patient.



The Applied changes section shows the changes applied to the patient's hand.



REPLAY FEATURE

The patient can select the options for reporting problems in the mobile application and activate the recording. The current configuration will be downloaded from the hand and all EMG signals will be saved. Then the patient can send it in the form of a ticket to clinician. You will receive a message from which you can run the configurator and play the recorded signals, and check the hand configuration.



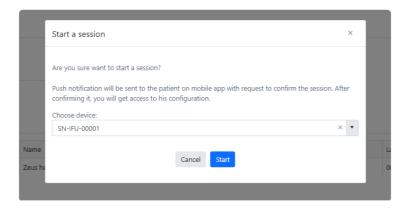
26. REMOTE SESSION

To start a a Remote Session:

- Login to ADP. See "Login for Users"
- To start working in Remote Session mode, go to the Patients tab, then select the patient with whom you want to conduct a remote session. After selecting the patient, go to their details and from there click the "Start a session" button. If the patient has the device assigned to them, you will be able to start a remote session. The patient will have to have the hand connected to the mobile app to be part of the remote session.

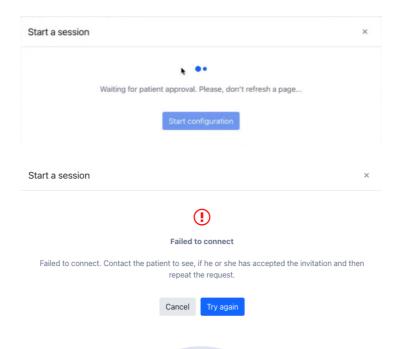


After clicking the button, a short notice appears along with the possibility of selecting the device with which the patient will work. After making your selections, click Start

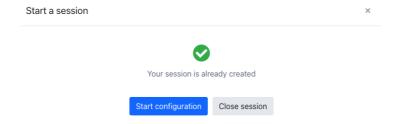


- o After clicking the button, two scenarios are possible:
- Starting a new session at this point, the popup will be displayed with a short text message and the option to select the device with which the patient will be working at the moment.

The patient now has the option of either rejecting or accepting the session. In the event of no response from the patient, the clinician gets feedback. At this point, they can send a re-notification using the "Try again" button or completely abandon the connection attempt by clicking "Cancel"



Joining an existing session - if the session is not closed, you can join it again. In this case, the system will automatically detect an open session and display such information in the pop up window. If the patient confirms they want to join the existing session by clicking "Start configuration", notifications will be automatically sent to the patient that they can join the session, and clinician will be automatically redirected to the configurator.

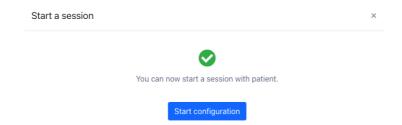


The patient rejects the call. What's next?

o If the patient was notified but decided not to use the remote session, the clinician will be notified that the connection was rejected. At this point, you can try to connect again or completely decline the session.

The patient accepts the invitation. What's next?

- o If the patient accepts the invitation, information about it will be displayed in the same pop up window in which the session was started.
- o After clicking "Start Configuration" you will be redirected to the Configurator

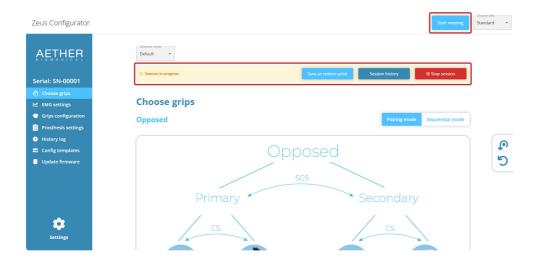


 The patient's hand is now connected remotely to the configurator. The clinician is able to see the EMG signals and make changes in real time that directly get sent to the hand. There is no "send to prosthesis button".

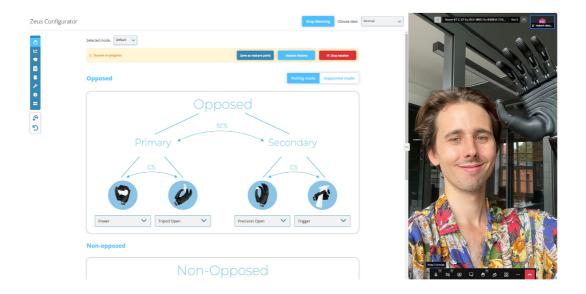
After switching to a new page, a new bar will appear with information about the started session. There are three options on the bar:

- Save as restore point saves the current state of the hand configuration. The saved point can be restored later from the Session history tab
- Session history here you will find all the changes that were made during the session. Each of these changes will have an option to undo
- Stop session permanently stops the current session with the patient. After clicking, you will receive information about the end of the session and a question if you want to keep the current configuration created during the session.

o To start a session with video click "Start meeting". You will be able to communicate with your patient via audio and video (if enabled by both parties). The patient will appear on the ADP screen.

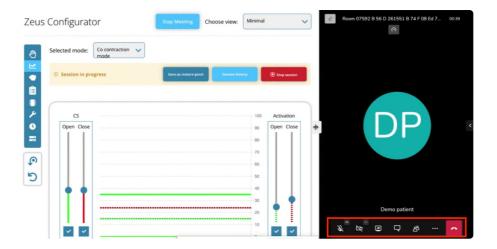


o Example of remote session with the patient video enabled.

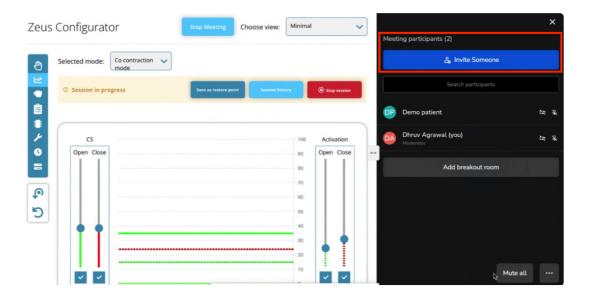


• At the control panel on the bottom of the video screen you have the option to (left to right):

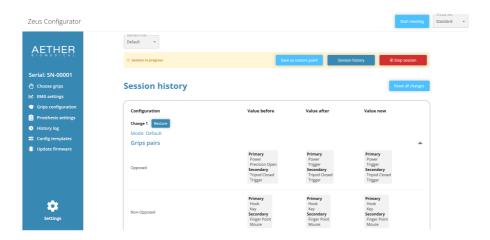
- 1. Turn off microphone
- 2. Turn off video
- 3. Share screen
- 4. Chat
- 5. Add participants to the meeting
- 6. Additional settings
- 7. Hang up (red phone icon)



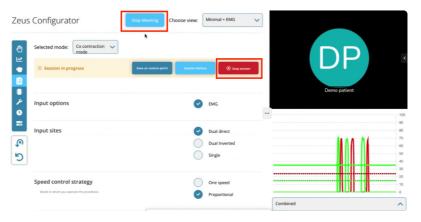
• When selecting the icon for adding participants to the meeting a window will appear where additional people can be added to the session.



- o In the session history tab, we have the following general options:
 - Reload Configuration this option allows you to load a previous setting from your patient history.
 - Reset all changes restores all settings to the starting point.
- o In addition to the above-mentioned elements, there are also options for individual entry
 - Undo undoes a specific change to value before.



• When you are done making changes, select "Stop Meeting" to remove the video/audio and "Stop session" to stop the remote session.



• A window will open up asking if you want to send a message to the patient regarding the meeting. Click close session.

e you sure want to stop	session? Every unsent con	figuration will be lost.	
Write something	I		
	Cancel	Close session	

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27. AUDIO AND VIBRATION SIGNAL GUIDE

This section would serve as a comprehensive guide, providing detailed explanations of each audio and vibration signal. It would include information on the circumstances under which each signal is activated, its duration, frequency.

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 / deac- tivate	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 (ISOOms - 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

28. FIRMWARE UPDATE

 Firmware update should be performed when the following warning is shown:



Current device firmware 1.8.2 is not fully compatible with this software version, please update to latest firmware 2.2.3

• Firmware update may be performed, but is not critical for ADP to work properly:

Update firmware

 \times

Device version: 1.8.2 Newest version: 2.2.3

Update

 An indication that a new firmware update is available can mean that some features of the Zeus configurator will not work properly until the firmware is updated.

- O Updating firmware:
 - Navigate to Firmware from navigation bar
 - Press Update



29. REMOVING SOFTWARE FROM USE

Please contact Aether Biomedical to delete your account.

30. TROUBLESHOOTING

Device -ADP firmware version mismatch:

Firmware version of the device is different from the one stored in ADP, contact support.

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.

Configuration not found:



Device config could not be retrieved, connect the device and send config

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.

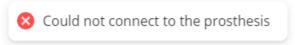
Upgrade needed:



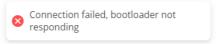
This device is not fully compatible with ▲ software version 1.0.0. Please contact support to upgrade it

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.

- o In the case of any issues with the software:
 - Check if the hand is turned ON
 - Check if the battery is charged
- o If a problem initiating Bluetooth connection occurs, the following error will be displayed. In such a case try refreshing the page, check device's battery level, turn it off and on again, and try connecting once more.



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



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o 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 sucesfully in such 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.
- o The bluetooth ID not detected? Reopen your browser and connect with the hand.

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

WIFI Connection:

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 and Turn OFF and then Turn ON once again.

31. COMPATIBILITY

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

32. REPORTING

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

33. SECURITY

- Application should be operated from a secure device. It should have the firewall enabled and have anti-malware software installed.
- o It is recommended to check the certificate of the web page before logging in.
- o It is recommended to close the application when you are not using it or you are away from the computer.

34. 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.

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.

Definitions

User: Clinician, Clinic Admin, Allied Health

ADP: Aether Digital Platform



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