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WARNING! Date of the last update of this Software instruction: 2022-07-12

- » 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 Zeus Configurator v. 1.0.3 web software application.
- » 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 <u>www.aetherbiomedical.com</u>

WARNING: Clinicians certified by Aether Biomedical can connect with the Zeus prosthetic hand by opening the Zeus Configurator application through the Patient Management panel. 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.

WARNING: Only certified clinicians can use Zeus Configurator to make changes in the Zeus prosthesis settings.



1. GENERAL INFORMATION

- » Aether Biomedical's software is only compatible with the Zeus bionic hand. All required functions are available in the Zeus Configurator application. There is no requirement to download anything from a website to launch the program.
- » The Zeus Configurator must be accessed via Google Chrome web browser (version 56 or higher) or Microsoft Edge web browser (version 90 or higher) from the device using system Windows (version 10 or higher) or Mac OS (version 11 or higher).
- » Zeus configurator allows clinicians to adjust various settings and parameters of the Zeus hand, allowing clinicians to customize the device for their patients.

2. INTENDED USE

- » The Zeus Configurator is designed to be used solely by clinicians certified by Aether Biomedical. Patients, as the users of the prosthesis, are not allowed to make any changes to it via this software.
- » The software provided by Aether Biomedical is designed exclusively for the Zeus hand configuration.
- » The Zeus Configurator is intended to be used to configure the Zeus hand and customize it for the user. Additionally, the software also provides the required tools to service and repair the Zeus hand.

3. CONTROL OPTIONS

- » The Zeus hand comes out of the box in its primary configuration the resting non-opposed grip.
- » Zeus typically utilizes two sensors that detect and amplify raw EMG signals from the skin that come from muscle movements. To create those signals, the patient has to contract their muscles.
- » Depending on the different levels of amputation, there are specific types of signals to change the grips. Co-contraction can be made by the majority of the users and provides a very reliable control of the prosthesis. Therefore it was chosen as the default option.

4. BASICS

- » With the Zeus Configurator, 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 Autograsp settings.
- » There are a number of grips which the user can choose. Co-contraction (default option) allows the user to switch between grips.
- » 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.

5.BLF CONNECTION

- » The Zeus hand uses BLE (Bluetooth Low Energy) to communicate with the Zeus Configurator.
- » To start configuring the Zeus, it is necessary to turn on the Bluetooth on your computer device.
- » If your device does not come with a Bluetooth modem inbuilt, you can use a BLE dongle. You will need to install its drivers according to the provider's instructions.

6. STARTING THE PROGRAM

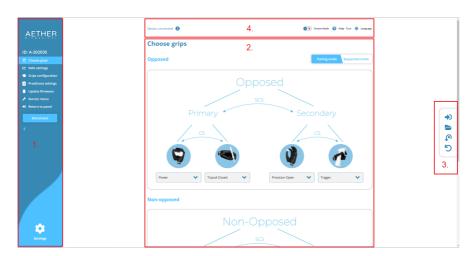
- » To run the program, it is necessary to open a Google Chrome web browser or Microsoft Edge web browser.
- » If you are a clinician certified by Aether Biomedical open the Zeus Configurator application by going through the Patient Management panel. If you are testing/evaluating the Zeus hand and are a demo user, follow the next steps.
 - ▷ Open the following url in the chosen web browser: https://www.zeus-configurator.com/



» To log in as a clinician (and have access to all settings of the prosthesis) you need to provide the following password: Zeus2021 and click the Next button.



7. NAVIGATION



- » After launching the programme, 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. Side Buttons
 - 4. Top Bar
- » 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 or return to the patient management panel.
- » 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.
- » Side Buttons enable you to save settings to the prosthesis, load saved versions of the settings, return to the default settings and undo the last change in the settings. They are described in detail in the section titled 'Side Buttons'.
- » On every page there is also the Top Bar. On the Top Bar, information is displayed about the currently connected device and the processes it's going through. There is also a Help button and language option button.



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8. CONNECTING THE HAND PROSTHESIS WITH THE APPLICATION

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

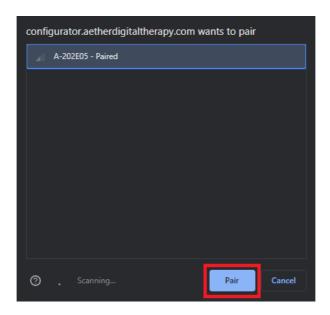
On the top of the Main Menu, the chosen device is displayed.



- Turn on the battery of the prosthesis.
- To connect to this device, press the Connect button.



» The process of scanning for the prosthetic devices 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.
- » The application should now connect with the Zeus hand. It will retrieve its 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.

If you are testing/evaluating the Zeus hand and are a demo user open Zeus Configurator application and follow the steps below:

- » Turn on the battery of the prosthesis.
- » To connect to this device, press the Connect button.





» The process of scanning for the prosthetic devices 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.



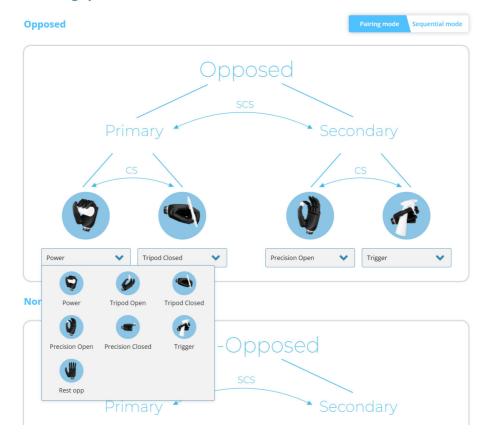
- » Select the device that you want to connect to and click on the Pair button.
- » The application should now connect with the Zeus hand. It will retrieve its settings and display them on the screen. If you cannot connect to the prosthesis check if you selected the correct prosthesis and turn its battery off and on.

9. CHOOSE GRIPS TAB

» In the upper right corner of the Settings Area you will find the Pairing mode / Sequential mode toggle. Changing this toggle 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.

Choose grips





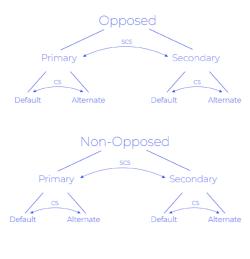


The Zeus has 12 grip patterns. The clinician can choose the grips that are the most useful in the patient's daily life.

Pairing mode

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

- » To switch between the opposed group of grips and the non-opposed group of grips, the user has to move the thumb in the desired position and then provide a Change Signal.
- Within each group of grip, there are two subgroups the primary group and the secondary group. Each subgroup has two grips within it, the default grip and the alternate grip.
- » To switch between the default grip and the alternate grip, provide a Change Signal.
- » To switch between the subgroups, primary group and the secondary group, provide a Secondary Change Signal.
- 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.
- » REMEMBER This works only with Control Modes Pairing Mode.

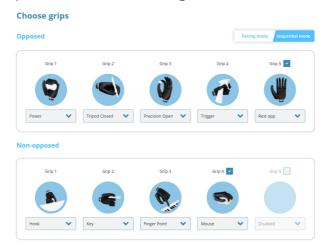


CS - Change Signal SCS - Secondary Change Signal

Sequential mode

In the sequential mode you can cycle between the grips in the loop. Using the Change Signal (CS) you go forward in the loop; using the Secondary Change Signal (SCS), 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 a Change Signal or a Secondary 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 grayed out. You can re-activate the grip by checking the box over it.

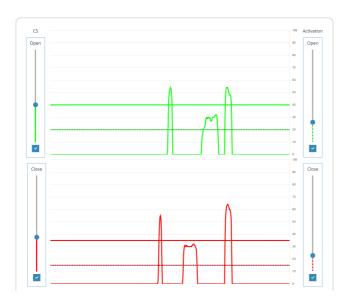
10. FMG SETTINGS TAB

- » In the EMG settings tab have a real-time graph showing 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 slider at the bottom of Settings Area.
- » You can hide or show the thresholds on the graph by toggling the checkbox beneath their sliders.
- » You can adjust the gain of the electrodes to change the strength of the signals by moving the sliders on the bottom of the screen. It is recommended to change the gains on the electrodes first, and adjust the software gains for fine-tuning.
- » There are a couple of options that affect the appearance of the graphs.
 - Combined in this option, both muscle signals (Flexion and Extension) are shown on the same graph

EMG settings



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





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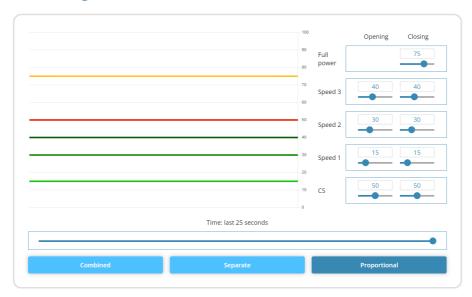
Proportional - this option enables you to change the thresholds for proportional control of the hand. Both of the signals are visible on the same screen. The thresholds are available on the right-hand side of the Settings Area. There is also a special "Full power" threshold which is used for Soft-grip functionality.



» 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 sig- nal in order for the hand to start moving	The user is less likely to have unintended 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

EMG Settings

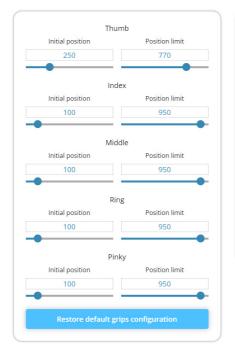


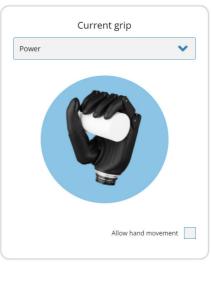




11. GRIPS CONFIGURATION TAB

Grips configuration





- » In the Grips configuration tab you can change the initial positions and position limits in any grip.
- » The initial position of each finger is the position that is assumed after changing to the grip. Position limit is the maximum 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.

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.

12. PROSTHESIS SETTINGS TAB

» 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, namely via EMG electrodes that are accepted with the Zeus hand.

Input options



EMG

» 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 Inversed
- Single

These options mean the patient can use one electrode or two - in direct or inversed 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. When selected, the application will automatically choose "single electrode" grip switching mode.

Input sites



Dual direct



Dual Inverted



Single

» 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 the relevant EMG strength threshold.

One speed control means that once the single 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.

Speed control strategy

One speed

Mode in which you operate the prosthesis

Proportional

» Grip switching modes

This section allows the user to select the type of the 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. By default, if the co-contraction is shorter than 0.5s, then it is treated as the primary **Change Signal**. Longer co-contractions act as **Secondary Change Signal**. 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. By default, if the time between two such contractions is shorter than 0.5s, it will activate the Change Signal. To achieve a Secondary Change Signal, the user needs to perform three muscle contractions in a sequence (open-open-open).
- In hold-open mode, the patient generates the Secondary Change Signal by keeping the open signal high while the fingers are already fully open for 1.5 seconds and he generates the Secondary 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 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 Change Signal and triple short impulses are used for a Secondary Change Signal.

Grip switching modes

Different ways of generating Change Signal (CS) and Secondary Change Signal (SCS)

•	Co-contraction
	Open-open
	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. A signal shorter than this value is 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 Change Signal (CS) threshold to be treated as a grip change signal.

Co-contraction timings

Sets length of co-contraction signal

Long co-contraction time: 0.50 s



Signal rise offset time: 0.10 s



• Open-open and single electrode - Pulse timings. The first slider allows you to specify the valid length of the signal impulses. The second slider allows you to specify the time that needs to pass between two pulses (which is important as the prosthesis awlays waits for a potential third impulse).

Pulse timings

Sets time for performing open-open signal

Min pulse time: 0.01 s Max pulse time: 0.30 s

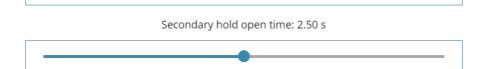
Min time between pulses: 0.15 s Max time between pulses: 0.50 s

■ 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.

Hold-open timings

Sets the short and long hold open times for grip switching

Primary hold open time: 1.50 s



» 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.

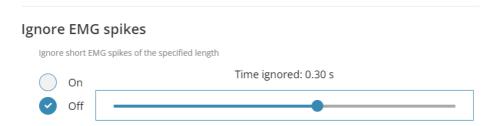
WARNING: Keep hand in a safe position while calibrating as its fingers will be moving.

Soft-grip	
Used to limit the strength of the fingers	
On Gentle	Strong
✓ Off	
Calibration procedure	

» Ignore EMG spikes

If the patient is facing a 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.



Auto-grasp

Auto-grasp is a function for preventing slippage of the object being held. Once the fingers close around an object, it is detected and a constant small force is applied to prevent dropping it. If the object starts slipping from the hand, the fingers will close to prevent it falling. The force of the fingers can be adjusted by changing the Force slider.

WARNING: Keep in mind that using this function increases the battery drain drastically.

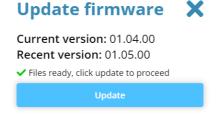


13. UPDATE FIRMWARE

» To update firmware of the Zeus hand you need to press the Update firmware button. A window should pop up showing you the version of the firmware which is currently on the prosthesis and the most recent version. You need to press the Start button to begin the update.

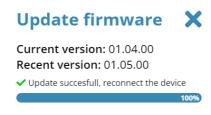


» It will download the newest firmware and wait for you to press the Update button.



» You will be informed when the update process is finished.

WARNING: Do not turn off the hand and do not close Zeus-configurator, until the update process finishes. Doing so may render the hand non-functional.



14. SERVICE MENU



- » In the Service Menu, you can open and close every finger to check the movement of the digits and also get better access to the screws and pins of the fingers
- » Pressing the Service Position button of any finger will move that finger to the best position to start the repair process of this digit.

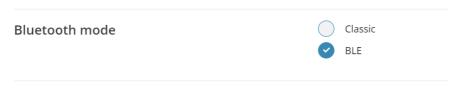




15. APPLICATION SETTINGS TAB

» The last tab is the Settings tab. Here you can get information about the version of the software and if you are dealing with the version of the Zeus prosthesis hand with Bluetooth classic connection, you can change the Bluetooth mode of the application. The default bluetooth module in the Zeus hand is the BLE module. Do not change this unless explicitly specified by the manufacturer.





Zeus Configurator v. 1.0.3

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The program is provided AS IS with NO WARRANTY OF ANY KIND, INCLUDING THE WARRANTY OF DESIGN, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

16. SIDE BUTTONS

Side buttons should appear on every tab. They are used to send settings to the prosthesis; save and load versions of chosen settings; restore settings to the default values; undo last action.

⊳ Send to prosthesis - Sends the current configuration of the settings to the prosthesis. to the prosthesis.

REMEMBER: After sending settings, if you want to undo some actions you have to send them to the prosthesis once again.



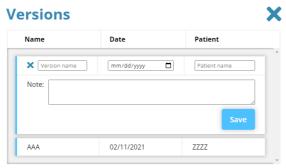
▶ Versions - this button opens the versions menu.



In the version menu you can add the version of all defined settings to the cache by pressing the Add current button.



After you press it, you can add the version name, date and insert the patient's name. Also you can add any important notes. When you are done, press the Save button.



If you want to load previously saved settings click on their name. This will expand this version options. Here you can press the Import button to load the settings to the software. **REMEMBER** that this will load the settings to the software, but you will still need to send them to the prosthesis. In this menu you can also modify the notes and other information or delete this version of settings.





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Restore Defaults - if there is any trouble with the Zeus' functionality, with changed settings or if the user is not satisfied with the current configuration, it is possible to restore the default settings.



Undo - pressing this button undoes the last change in the software. **REMEMBER** it does not modify the changes on the prosthesis device. You still need to send the settings to the prosthetic device.



17. TOP BAR

- Top Bar appears on every tab. Information about processes that are currently running, like sending settings to the prosthesis, appear here.
- You can check the Hand details by clicking on the Information icon. A new window will pop up showing the serial number of the prosthesis and its firmware version



By clicking on Help - Tour button you can activate the tutorial of the currently selected tab. It contains useful information and help regarding the settings.



» Language button enables you to change the chosen language of the application.



18. CLOSING THE SOFTWARE

- » If you want to get back to the patient management panel press the button on the Main Menu
- » To close the software please close the web browser's tab or close the web browser completely.

19. TROUBLESHOOTING

- » In case of any issues with the software:
 - check if the correct prosthetic device is selected
 - check if the hand is turned ON
 - ▷ check if the battery is charged
- If the software cannot find the device because of a connection problem, the message below should appear on the screen. If this message appears, check if the hand is turned on and try to connect to the prosthesis once again.

Could not connect to prosthesis

If the connection with the hand is lost this error message will be shown on the screen. If this message appears, check that the hand has not lost power; if so, turn the hand back on (you may need to charge it) and connect the device to the application once again.

Device disconnected



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When there is a problem with the connection this special error message will be shown on the screen. If this message appears it means that there is a problem with the communication between the Zeus hand and the application. Restart the Bluetooth module in your computer and also restart the power of the Zeus hand. After that try connecting the prosthesis to the application once again.

Connection is corrupted, restart the prosthesis and try connecting again

When there is a problem with reading the prosthesis settings this special error message will be shown on the screen. If this message appears it means that there was a problem with interpreting the settings currently stored on the prosthesis. Try connecting the prosthesis once again.

Initial config could not be loaded, try again

» If there are still problems with the program, please contact the Aether Biomedical team by filling in the form on the website www.aetherbio-medical.com or reaching out to us at info@aetherbiomedical.com

20. 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.
- » If you need to reset the hand to the factory settings you have to:
 - Connect to the hand via application
 - Click the restore defaults button

The factory settings will be restored on the prosthesis hand.

21. OTHER INFORMATION

» Aether Biomedical declares that they meet appropriate European standards for design, manufacture and supply of prosthetic products and user software. Continued compliance with the standard is monitored by a programme of internal and external audits.

- » All individual products are marked indicating that they comply with the requirements of the Medical Device Regulation 2017/745.
- » The mark may be on the packaging, accompanying literature or an enclosure, rather than the product itself.

SYMBOLS

CF mark



This 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.



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