EGZOTech

User Manual

Stella BIO

Electromyography Biofeedback and Electrical Stimulation Device

CE 2274

Gliwice, 2024

We are here for you!

Thank you for ordering your Stella BIO and welcome to our family!

At **EGZO**Tech, we truly believe that **great user experience isn't just about great products, but reliable support, constant development, and understanding the needs of people using our products** - patients and therapists. We truly believe that together, we can change the future of healthcare and physiotherapy!

The next steps will **empower your therapy with Stella BIO!**

To learn more about Stella BIO, visit the following:

Our YouTube page for videos and tutorials!

https://youtube.com/**EGZO**Tech

If you have experienced an unexpected event, device malfunction, medical incident, or any trouble with your Stella BIO, please contact us under the following:

Our Service Desk page

https://service.egzotech.com

Other direct contact information

support@egzotech.com
https://egzotech.com
+48 32 750 49 45
EGZOTech Sp. z o.o.
ul. Romualda Traugutta 6H
44-100 Gliwice, Poland

Why is this manual important?

1. Danger warning

Remember, **Stella BIO can be dangerous if used incorrectly!**
Do not start using Stella BIO before reading this manual, especially the **2. Warnings and basic safety** chapter.

2. Who is Stella BIO for?

Stella BIO is intended for two primary user groups:

PATIENTS - especially suffering from the conditions listed in the **4.2. Indications for use**. This device is for you, to help you achieve the benefits of the combination of electromyography and electrical stimulation under your clinician's supervision, as well as, by yourself at home and at home healthcare environment. Feel free to use electromyography biofeedback functionalities, as they are considered safe to use in most cases. Remember however to still be careful while working with Stella BIO (read the safety instructions!). You need training and consultation from a healthcare professional on how to use electrical stimulation safely, before you start using it yourself.

We do expect patients using Stella BIO themselves to be adults (at least 18 years old) with at least primary education. You have to be conscious, aware and understand the risks and safety regarding the use of Stella BIO. If you have any doubts about whether you understand this manual and especially the **2. Warnings and basic safety** chapter, please ask your clinician for assistance with Stella BIO.

MEDICAL PROFESSIONALS - healthcare service providers of one of the following specialities: a physical therapist, an occupational therapist, a rehabilitation doctor, a neurologist, a sexologist, a nurse or nurse practitioner, an orthopaedic doctor and other general practitioners - Stella BIO is definitely a tool for you, to use in daily clinical practice (both in-patient and out-patient care), as well as to support your patients through telerehabilitation. If you're a medical professional, you will be in charge of prescribing treatment procedures, including electrical stimulation parameters for your patients. Feel free to use this manual and the resources gathered here to expand your knowledge and find a quick guide on how to proceed with your patients.

We do expect medical professionals to have graduated with a higher education degree of at least bachelors and are adults (at least 18 years old). Please make sure that you fully understand the contents of this User Manual and the principles of electromyography and electrical stimulation, before you start working with your patients with Stella BIO. If you have any doubts, especially regarding the **2. Warnings and basic safety** chapter, feel free to reach out to **EGZO**Tech directly and we will do our best to help you.

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1. Definitions

1.1. Glossary of Terms

Kiosk - Operation Mode of the application for Stella BIO on a device configured by the **EGZO**Tech team

EMG - electromyography

EMS - electrostimulation

TENS - transcutaneous electrical nerve stimulation

NMES - neuromuscular electrical stimulation

Product specialist - **EGZO**Tech representant

F - frequency

FM - frequency modulation

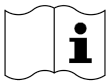
AM - amplitude modulation

ch - channel

1.2. Symbols

Stella BIO labels are located on the bottom of the device and on the connector of the EMG/EMS cable.

Stella BIO uses safety symbols on the device itself, as well as inside the software application and on packages with accessories. Below is an explanation of all the symbols you'll encounter while using Stella BIO.

Symbol	What it means	Symbol	What it means
	Indicates the medical devices manufacturer		Indicates the date when the medical device was manufactured
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences		Indicates the manufacturer's serial number so that a specific medical device can be identified
	Applied part type BF, used for electrical connections to and from the patient. Part isolated from all other parts of the device		CE marking indicates that a product complies with applicable European Union regulations. No 2274 is a no of Notification Body
	DC current		Ingress Protection
	Indicates the need for the user to consult the instructions for use		Refer to User Manual
	Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005		N-Mark to point NFC technology tag
	FCC mark		Indicates the item is a medical device

Symbol	What it means	Symbol	What it means
	The device generates radio frequency energy during operation		Indicates the temperature limits to which the medical device can be safely exposed
	Indicates the range of humidity to which the medical device can be safely exposed		Indicates a medical device that needs to be protected from moisture
	This way up		Indicates a medical device that can be broken or damaged if not handled carefully
	Do not stack		Do not roll

1.3. Additional symbols on accessories

Symbol	What it means	Symbol	What it means
	Indicates the manufacturer's catalogue number so that the medical devices can be identified		Indicates the manufacturer's batch code so that the batch or lot can be identified
	Indicates the date after which the medial device is not to be used		Indicates a medical device that is intended for one single use only
	Indicates that a medical device that should not be used if the package has been damaged or opened and that the users should consult the instruction for use for additional information		Latex free
	PVC free		Indicates a medical device that needs protection from light sources
	Ag/AgCl Sensor		

2. Warnings and basic safety

Stella BIO is an electrical medical device incorporating direct electrical connection with the patient's body with the intent of measuring electromyography and providing physiological currents through electrical stimulation. As such, **Stella BIO can be dangerous if used incorrectly**. Please **read the safety information below and follow the guidelines provided in this manual**.

2.1. General safety considerations and precautions

Stella BIO has been created for specific physiotherapy treatments and exercises. **Do not use Stella BIO for any other purpose not included in this manual or training videos provided by EGZO**Tech.

Before treating each patient or operating Stella BIO, you should review the information regarding the intended treatment, contraindications, and safety precautions.

You should never operate Stella BIO on yourself, if your motor skills are insufficient to fully operate the device, such as stopping it in case of disconnection or reacting to any adverse situations. In such cases, seek professional care or assistance.

Keep caution while using Stella BIO if you notice any changes in its performance. If you do, please contact **EGZO**Tech through one of the channels provided at the end of this manual. Please refrain from using Stella BIO if you experience any performance changes.

Use Stella BIO only with EGZO Tech **authorised accessories!** That includes all the package contents listed in subchapter **4.5 Accessories**.

Use only the power adapter supplied. **Do not plug third party sensors, electrodes or other accessories!**

Stella BIO's measurement functions, including electromyography, are susceptible to electromagnetic disturbances. As such, please be aware of other electromagnetic devices or installations that can affect measurements. Stella BIO meets the electromagnetic compatibility requirements, including immunity to electromagnetic disturbances, providing basic safety. If you encounter any signal artefacts or noise, discard the measurements and don't consider them diagnostically relevant.

Stella BIO is not intended to be used with needle electrodes.

Persistent use of the device in the presence of skin irritation may be harmful, and improper use may result in electrode burns.

Remove the battery if the device is to be out of service for one month because a leakage from the battery could cause an unacceptable risk.

Do not use Stella BIO while driving, operating machinery, cycling or during activity in which electrical stimulation can put you at risk of injury.

Do not use Stella BIO while sleeping.

Do not use Stella BIO outside of its operating environment, including temperature, humidity or atmospheric pressure, specified in the Technical Specification in this manual.

Use of Stella BIO by a child only under the supervision of an adult.

The device should be kept out of the reach of children and pets.

Warning: Use of the device with visible damages is forbidden and can lead to injury. In case of any noticeable damages on the device, **stop using the device and please contact the service.**

2.2. Clinical safety

The patient should consult their clinician if there is any change in an existing condition or if any new condition develops.

Any medical incident related to Stella BIO needs to be reported to **EGZO**Tech and the competent authority of the country in which the user and/or patient is based.

Using the device on patients with demand-type cardiac pacemakers may pose a hazard.

When pregnant or menstruating, when applying electrostimulation do not place electrodes directly over the uterus or connect pairs of electrodes across the abdomen or use the pelvic floor electrodes for electrostimulation.

Stella BIO produces results that are informative, not diagnostic. The results must be interpreted by qualified individuals.

Keep caution while using Stella BIO on patients with suspected or diagnosed heart problems.

Keep caution while using Stella BIO on patients with suspected or diagnosed epilepsy.

Keep caution while using Stella BIO for patients with body-worn electromechanical medical devices, i.e. insulin pump, electronic medical devices attached to the body and other medical devices e.i. cochlear implant, electrical or skeletal implants.

Keep caution while using Stella BIO with patients with serious arterial circulation problems in lower limbs.

Exercise caution when using Stella BIO on patients with extra-urethral incontinence (fistula, ectopic urethra) and overflow incontinence caused by evacuation disorders, especially when using pelvic floor probes.

Keep caution in the following situations:

- when there is a tendency to haemorrhage following acute trauma or fracture,
- after recent surgical procedures, when muscle contraction may disrupt the healing process,
- when using pelvic floor electrodes for EMG evaluation, while pregnant or menstruation
- over areas of the skin that lack normal sensation.

Patients should consult their physicians before using Stella BIO if they have any of the following:

- muscle atrophy,
- persistent pain,
- after trauma or a recent operation, (less than 6 months prior),
- need for muscle rehabilitation.

Do not use Stella BIO with patients or if you're diminished mental capacity or physical competence limiting the use of the device.

Use of Stella BIO should be immediately terminated upon any sign of treatment-related distress or discomfort.

2.3. Electrical safety and electromagnetic compatibility

Stella BIO has met the requirements of IEC 60601-1-2 for electromagnetic compatibility, including immunity, however, **while running Stella BIO near high frequency/power medical devices, follow the safety manuals of those devices.** Incorrect use of other devices, and non-compliant devices may influence the parameters of Stella BIO.

Do not connect leads or electrodes to other objects.

Do not use Stella BIO if you are connected to a high-frequency surgical instrument as this could cause skin irritations or burns under the electrodes.

Simultaneous connection of the patient to a high-frequency surgical device and to an electromyograph or to a device for recording burst biopotentials, can cause burns at the site of application of the electrical stimulator electrodes or electrodes of the input part for biopotentials and possible damage to the electrical stimulator or biological amplifiers.

Do not use the Stella BIO unit within 1.5 metres of shortwave or microwave devices as this could alter the output generated by the stimulator. If you have any doubts when using the stimulator in close proximity to another medical device, please contact the device manufacturer or your doctor.

Keep caution to avoid accidental contacts between Stella BIO's patient lead wires and/ or electrodes with other equipment with conductive parts, including parts connected to the ground.

If you witness any wear and tear problems or damage regarding cables, chassis, or any safety elements, take extra caution and contact **EGZO**Tech.

Use of accessories, transducers and cables other than those specified or provided by **EGZO**Tech of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Stella BIO, including cables. Otherwise, degradation of the performance of this equipment could result.

Use of this equipment adjacent to or stacked with other equipment should be avoided, because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The electrostimulation treatment needs to be stopped before disconnecting the electrodes.

2.4. Electrical stimulation safety (including TENS)

Electrical stimulation should **only be used after receiving training from a healthcare professional**. Always consult your physician before using electrical stimulation to ensure the correct output parameters and program are selected for you.

Never touch electrodes directly during electrical stimulation.

In distress or unexpected operations of Stella BIO, pull rapidly on the cables.

Always check the impedance, distance between the electrodes, and their wear and tear between uses. Using worn or torn electrodes may cause severe burns.

Do not use electrical stimulation wearing clothes lined with, made with or including conductive (especially metal) materials. Metals on the body and in worn clothing can conduct electricity during electrical stimulation, causing severe burns. Metal can also impact electromyography measurements.

The long-term effects of chronic electrical stimulation are unknown.

Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

Stimulation should not be applied transthoracically, as introducing electrical current into the heart may cause cardiac arrhythmias.

Stimulation should not be applied transcerebrally.

Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

Stimulation should not be applied over or in proximity to cancerous lesions.

Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.

Stimulation should not be applied in proximity to abdominal or inguinal hernia because high tension in the abdomen and pelvic floor may worsen this condition.

Stimulation should not be applied in proximity of the abdominal and back for the patients with intestinal clamps.

Do not apply stimulation near metal. Remove jewellery, body piercings, belt buckles or any other removable metallic product or device in the area of stimulation.

During a stimulation session, do not disconnect electrodes when stimulation is running. Stop the stimulation first.

For output exceeding 10 mA or 10 V, please make sure to use electrodes meeting those output requirements.

Safety of TENS devices or powered muscle stimulators for use during pregnancy or delivery has not been established.

TENS is a symptomatic treatment and as such may suppress the sensation of pain that would otherwise serve as a protective mechanism on the outcome of a clinical process.

Electrode placement and stimulation settings should be based on the guidance of the prescribing medical practitioner.

The special attention of the operator is required when current density exceeds 2 mA/cm^2. A hazard could exist if excessive current densities are present. Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.

Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators. If skin irritation occurs, discontinue use and consult your physician.

If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

TENS is not effective for pain of central origin, as compared to pain of peripheral origin.

TENS is of no known curative value.

The treatment outcome will be influenced by the patient's psychological state and use of drugs.

TENS should be used only under the medical supervision of a physician or under the supervision of a qualified medical practitioner to whom the patient is referred by a physician.

Do not use electrical stimulation with cardiac demand pacemakers, implanted defibrillators or other implanted electronic devices, unless specialist medical opinion has first been obtained.

While using electrical stimulation electrodes, make sure that the impedance displayed is correct in the software. The adhesive properties of electrodes do not transfer to good conductivity.

2.5. Mechanical safety

Do not step, sit or stand on any part of Stella BIO.

Keep small children away and keep caution not to get entangled in the patient's lead wires. Strangulation and asphyxiation are possible! Consider shorter cables (available on request).

Always use cables with the least amount of channels, as needed for the training, to limit unnecessary risk.

Keep small children away and ensure they do not inhale or swallow small parts, as there is a choking hazard.

2.6. Multiple use precautions and consumables

Stella BIO has been tested to be reliable for multiple use and cleaning with the disinfection products described in the **12.6. Cleaning instructions**. The use of different cleaning products can have varying results and can lead to contamination, surface deterioration, loss of biocompatibility and malfunction.

Caution should be used for the disposal of Stella BIO. Stella BIO shouldn't be thrown out, or improperly utilised due to electronic components. Consult your product specialist on how to act best to utilise Stella BIO that won't negatively impact the environment.

Surface electromyography electrodes are designed for single-use. **Using the same electrodes multiple times will lead to signal degradation and possible misuse and misdiagnosis**.

Pelvic floor probes are designed to be used by a single person. **Sharing pelvic floor electrodes between patients is forbidden and poses a major health risk**. Pelvic floor electrodes have to be cleaned accordingly. Please consult the Cleaning instructions and accompanying documents.

Electrical stimulation electrodes are designed for single person use only and reusable up to 20 times. Note: The lifetime of the electrode varies depending on skin conditions, skin preparation, type of stimulation, storage and climate.

Stella BIO accessories and the device itself will experience normal wear and tear over time. Possible degradation of performance over time is possible, especially in electrical connections between the cables and electrodes, the belt and multi-use pelvic floor and electrical stimulation electrodes themselves.

2.7. Biological safety

Never use Stella BIO **with compromised or wounded skin**.

Stella BIO (the device with the use of the surface electrodes) is intended for surface contact only - **skin contact only. Avoid contact with mucosal membranes and breached or compromised surface**, or in any case inside your body. The internal probes for vaginal and rectal use can be used accordingly with their intent.

Stella BIO has been analysed for biocompatibility that includes cytotoxicity, sensitization, and irritation or intracutaneous reactivity, however **if you or your patient experience an allergic reaction, irritation, or signs of toxicity, whether from Stella BIO or any other source, cease all training** until the underlying cause has been dealt with.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.

Caution should be exercised when using pelvic floor electrodes on patients with allergic reaction, particularly in case of nickel sensitivity.

The user or the medical service provider must contact its local authorities to determine the proper method of disposal of potentially biohazardous materials, including but not limited to: surface and pelvic electrodes, belts or other Stella BIO accessories etc.

2.8. Environmental safety

Do not perform service, maintenance and modifications of Stella BIO yourself! Use only service providers authorised by **EGZO**Tech.

Always use and store Stella BIO, the accessories, electrodes and probes according to their storage instructions. Please consult the accompanying documents for electrode and probe storage instructions.

Do not use Stella BIO in an oxygen-rich atmosphere.

Do not use Stella BIO in a dangerous environment (including explosion risk, gas risk, etc.).

Stella BIO is intended for usage in a moisture-free environment. Keep away from water, including generated by other devices, e.g. kettles, nebulisers, showers etc.

Stella BIO is intended to be used in the operating temperature, humidity and air pressure specified in **4.4. Technical specification**.

Stella BIO is intended to be used in a home environment, a home healthcare environment (e.g. retirement homes) and a healthcare environment (e.g. hospital, clinic).

Stella BIO should be used in well lighted rooms.

Dust, water, lint or other pollutants can interfere with electronics, especially if they are located near the cable or battery connectors. Please clean Stella BIO periodically, according to the **12.6. Cleaning instructions**.

Due to Stella BIO's sensitivity and risk of damage during improper handling, please keep away from kids, pets and pests.

Stella BIO's Ingress Protection code (IP) is specified in the **4.4. Technical specification**. The rating is IP32, therefore:

- It is rated 3 for solid particle protection of objects larger than 2.5 mm (0.098 in). This means that the enclosure provides protection against hazardous parts, especially electrical conductors and the ingress of solid foreign objects of the mentioned size.
- It is rated 2 for liquid ingress protection of dripping water when tilted at 15°. This means that the enclosure provides protection against harmful ingress of water, to the extent of vertically dripping water when the device is tilted at an angle of 15° from its normal position.

Do not immerse Stella BIO in water or any other liquid substance, including water vapour.

2.9. Periodical checkup and maintenance

Do not perform service, maintenance and modifications of Stella BIO yourself! Use only service providers authorised by **EGZO**Tech.

Do not open Stella BIO or perform any service and maintenance activities while the Stella BIO is in use.

Keep Stella BIO and accessories clean. Follow the **12.6. Cleaning instructions** provided.

2.10. Software safety and cybersecurity

Do not use different applications while using Stella BIO App or EGZOClinic, as it can disturb normal operations.

Stella BIO can be delivered by **EGZO**Tech with a preconfigured 3rd party ICT device (tablet, phone, laptop) with restricted access. In such cases, do not install any unapproved applications. **Untested software can interfere with Stella BIO's normal operations!**

2.11. Risk and Benefits

As a medical device, Stella BIO was developed for therapeutic application and diagnostic indications. Stella BIO is indicated for the treatment of stress, urge or mixed urinary incontinence, fecal incontinence, constipation - pelvic floor dyssynergia, and sexual dysfunction and also for biofeedback, muscle relaxation, and muscle reeducation purposes.

Stella BIO has safety features to provide complex treatment based on electromyography biofeedback and electrical stimulation for surface and pelvic floor muscles. The positive treatment results were confirmed and a concept of the device is well described in literature, based on the clinical trials. Relying on the clinical literature research, clinical evaluation and the similar devices introduced on the market the effectiveness of the treatment concept is confirmed.

Available information for similar devices and risk analysis conducted by manufacturer indicated that likelihood and severity of risk for Stella BIO is low. Stella BIO fulfils safety requirements included in standards.

Based on the clinical evaluation and the risk analysis it was found that the benefits of the device to be high with the low level of risk.

The manufacturer provides appropriate warnings and labelling which limits the possible risk.

2.12. Benefits

Outcomes therapy using Stella BIO depends on treatment mode. Typical outcomes include:

- Improve urinary and faecal control,
- Strengthening muscles,
- Improve sexual dysfunction,
- Therapeutic activities,
- Muscle relaxation,
- Prevention or retardation of disuse atrophy,
- Increasing local blood circulation,
- Muscle reeducation,
- Immediate post-surgical stimulation to prevent venous thrombosis,
- Maintaining or increasing range of motion,
- Relief and management of pain,
- Relearning voluntary motor functions of extremities.

Using the Stella BIO provides objective measures to assess the severity of pathological human movement conditions and gauge any subsequent improvement offered by therapy, training or design changes.

Patients can also expect:

- The exercises can be tiring. If necessary, reduce their intensity and take appropriate rest breaks.
- If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

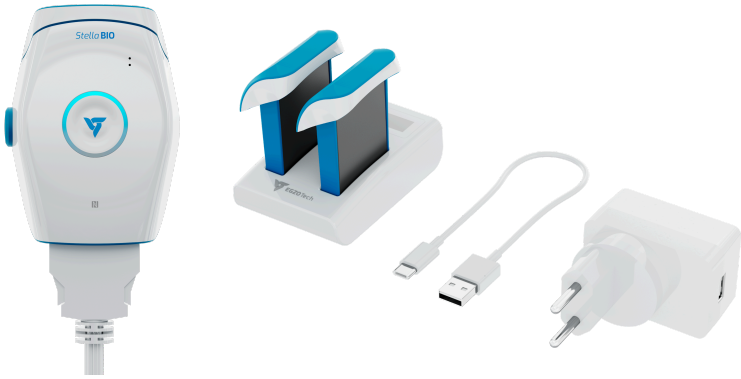
3. Quickstart guide

As such, **Stella BIO can be dangerous if used incorrectly**. Please **read the safety information below and follow the guidelines provided in this manual**.

If you encounter any problems, check out the **12. Handling, maintenance and troubleshooting** chapter of this manual.

3.1. Unboxing

Stella BIO is delivered with all ordered accessories in a package as shown below and (optionally) with the device containing software in the form of kiosk. On initial delivery, **please check the contents to confirm that everything you've ordered has been properly delivered.**

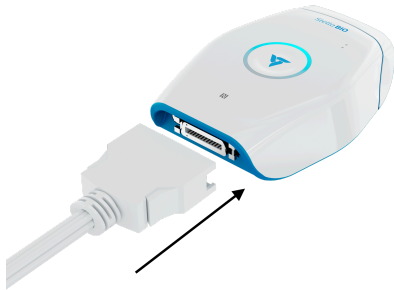


Before you start working with your Stella BIO, let it warm up (or cool down) to its operating temperature (0 - 35 °C).

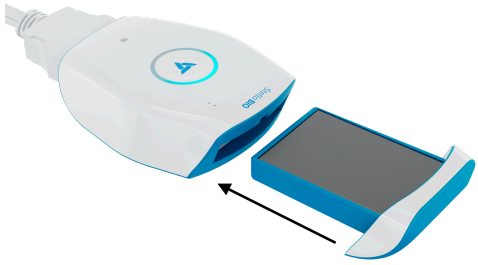
3.2. Starting up your Stella BIO

Step 1: Connect the Patient cable you're planning on using with Stella BIO.

Consider how many channels you will need and whether you will be working with surface or pelvic muscles, as their connective elements are different (snaps vs pigtail plugs).



Step 2: Plug in the battery to Stella BIO.
The shape of the batteries' chassis should align with Stella BIO's chassis, as presented below.



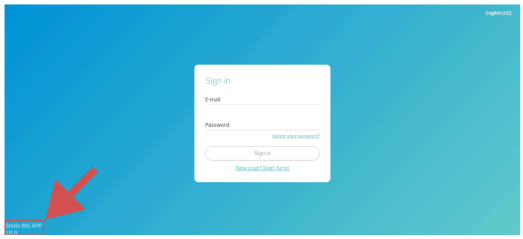
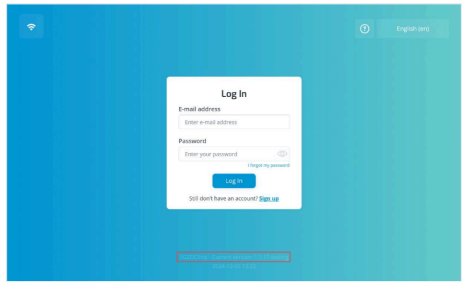
Step 3: After the battery will be connected to the Stella BIO **the LED ring will light up white which means the unit is starting up.** However, if nothing happens the batteries are not sufficiently charged.

Step 4: A white bar rotating counterclockwise indicates the process of connecting to the Wi-Fi network. The Wi-Fi setup process is described in **3.4. Connecting the Stella BIO to Wi-Fi** chapter. **Once connected to the Wi-Fi network, the LED ring will fill with white light.**

Step 5: When Stella BIO will connect to the app, the LED ring will turn **dark blue and start pulsing.**

3.3. Registering your account

To distinguish what software you are working with, please check the version on the bottom of the login page.

Stella BIO App	EGZOClinic
	

3.3.1. Stella BIO App account

Step 1: Make sure you have a device compliant with the **12.1. Hardware and software requirements** chapter, and have a stable Internet connection available and connected on that device.

Step 2: Visit the main page of the application and choose the 'Create a new account' option.

Step 3: Follow the instructions in setting up your **Stella BIO App** account, presented on the website above. Remember your **email address and password** to sign into your account later.

3.3.2. EGZOClinic account

Step 1: Make sure you have a device compliant with the **12.1. Hardware and software requirements** chapter.

Step 2: Visit the main page of the application and click the 'Sign up' link.

Step 3: Follow the instructions in setting up your account, presented on the screen. Remember your **email address and password** to sign into your account later.

3.4. Connecting Stella BIO to application

3.4.1. Stella BIO App

3.4.1.1. Using the application in Kiosk mode

Launch Stella BIO on your Kiosk device configured by **EGZO**Tech. The application in Kiosk mode will start automatically. Stella BIO will connect to the Kiosk's Wi-Fi network and you can immediately start working on it. In this case no additional configuration is required.

3.4.1.2. Using the Web browser and Bluetooth

Below, we will consider “your device” as a phone, computer, tablet etc. that you’re going to be using with the Stella BIO device. Before you start, make sure that you’ve

followed all the steps in **3.2. Starting up your Stella BIO** and the Led Ring is shining in yellow.

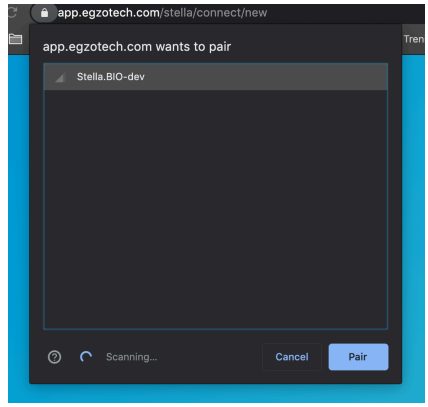
Step 1: Turn the Bluetooth on on your device and make sure that the network you want to connect your Stell BIO with is on.

Step 2: Log into your account and select your clinic and then the patient. A window will appear asking you to connect the device.

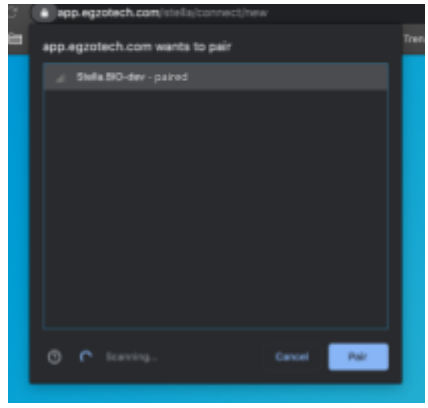
Step 3: Select "configure new Stella BIO".

Step 4: Make sure all the steps from "Setup checklist" are done correctly and click "Continue".

Step 5: A browser pop-up will appear at the top of the screen with a list of found Bluetooth devices.



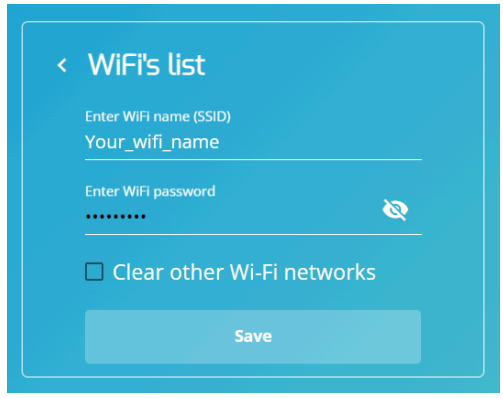
Step 6: Select the Stella BIO which was found and press "Pair".



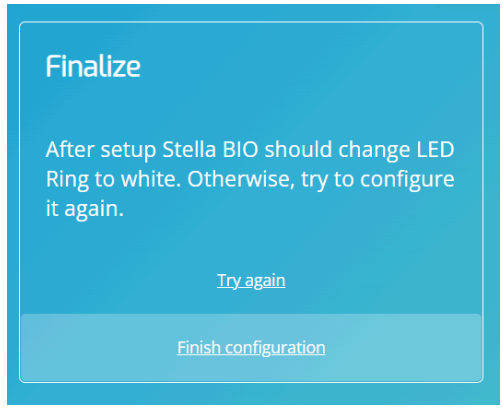
Step 7:
(a) **Select your Wi-Fi SSID** (network name) or
(b) **press "Connect to another network", if your SSID is not visible**

Step 7a: If you've selected 6a, type in your Wi-Fi password and press "Save".

Step 7b: If you've selected 6b, type in your Wi-Fi SSID and Wi-Fi password and press "Save".



Step 8: Press the "Finish Configuration" button.



Step 9: If your SSID and password are correct, Stella BIO will connect to that network. A Serial Number and battery level of connected Stella BIO will appear in the top right corner.

3.4.2. EGZOClinic

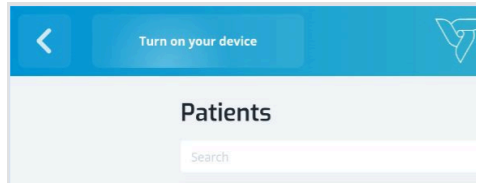
Launch Stella BIO on your Kiosk device configured by **EGZO**Tech. The application in Kiosk mode will start automatically. If there is a singular Stella BIO near you, after accessing the application you will see a tile with the Stella BIO's serial number on the top left corner of the screen. After clicking the tile Stella BIO will connect to the application's network and you can start working with it.

The number of available devices will be presented in the device tile, when more than one Stella BIO is turned on near the tablet. you may click the tile on the top left of the screen to access the list of all available Stella BIOs near you. After selecting any device from the list, that device will connect to the application on your tablet.

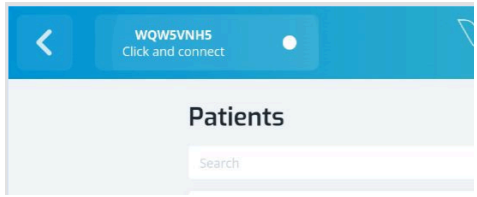
Only one Stella BIO device can be connected to the app at a time, even if multiple devices are available nearby.

If there is "Turn on your device" information displayed in the tile on the top left corner of the screen, that means there are no Stella BIOs turned on near the tablet.

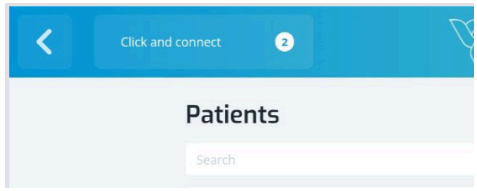
Please, turn on your Stella BIO. In case of any troubles refer to chapter **3.2. Starting up your Stella BIO**.



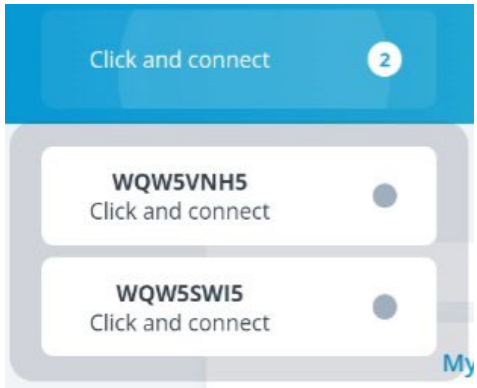
After successfully turning on the Stella BIO, its serial number should be visible. **You may click the tile to connect the tablet with the Stella BIO.**



If there are more available devices that the tablet could possibly connect to, the number of them will be displayed in the tile.

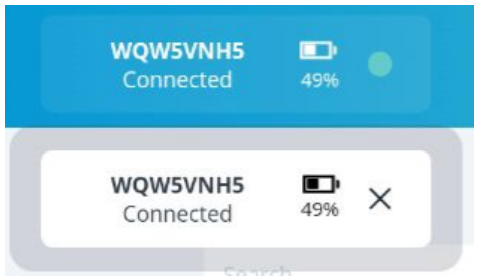


After clicking the tile, a list of all available to connect Stell BIOs appears.



After establishing a connection with designated Stella BIO its **Serial Number will appear in the tile with the information about connectivity status below and the battery level.**

You can click the tile and disconnect the Stella BIO by clicking the cross button.



3.5. Accessing the Application

3.5.1. Stella BIO App Application

Step 1: Before you use Stella BIO, you need to turn on your Kiosk devices or access the application website on your private device like a tablet, a smartphone or a computer. The application should take you directly to the sign-in page.

Step 2: Sign-in with your Stella BIO App account credentials, if you already have an account, or register a new one. For help with Stella BIO App account registration please refer to chapter **3.3. Registering your account** or **5.1.2 Registration**.

Step 3: Make sure your Stella BIO is visible in the application. If any problems occur check out the **3.4 Connecting Stella BIO to application** chapter.

3.5.2. EGZOClinic Application

Step 1: Before you use Stella BIO, you need to turn on your Kiosk device.

Step 2: Sign-in with your EGZOClinic account credentials, if you already have an account, or register a new one. For help with EGZOClinic account registration please refer to chapter **3.3. Registering your account** or **5.2.2 Registration**.

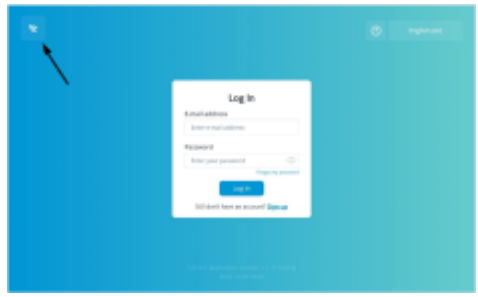
Step 3: Make sure your Stella BIO is visible in the application. If any problems occur check out the **3.4 Connecting Stella BIO to application** chapter.

3.6. Updating the EGZOClinic Application

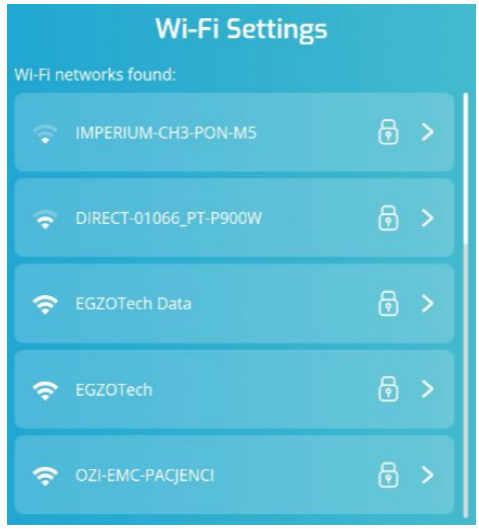
To update the application to the latest version the tablet needs to have an Internet connection.

To connect the tablet to the Internet follow the below steps.

Step 1: After opening the application, you will not be connected to any Wi-Fi network. To do so enter the network screen by clicking the Wi-Fi icon on the top left corner of the screen.



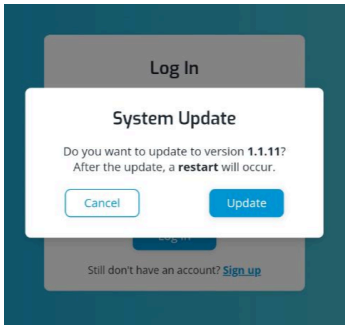
Step 2: Select the Wi-Fi network you would like to connect to and provide the password if needed.
After successfully connecting to the Internet, you may return to the login screen.



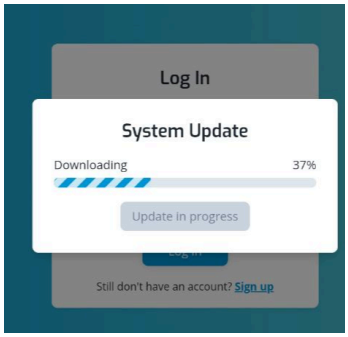
To update the application follow the below steps:

Step 3: After successfully establishing the Internet connectivity, if an update is available an update notification will appear on the bottom left corner of the screen.

Step 4: After clicking the notification, a window will appear, informing the user what the newest version is. The user can proceed to updating or return to the login screen without updating the application.



Step 5: If the Update button has been pressed, the update process will start. After finishing, the application has to be restarted.



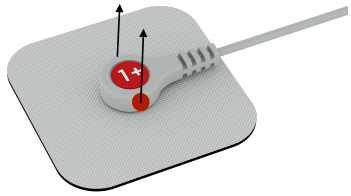
3.7. Finishing your work with Stella BIO

Step 1: Disable electrical stimulation and end programs within the Application first. Stella BIO should be shining in white at this time.

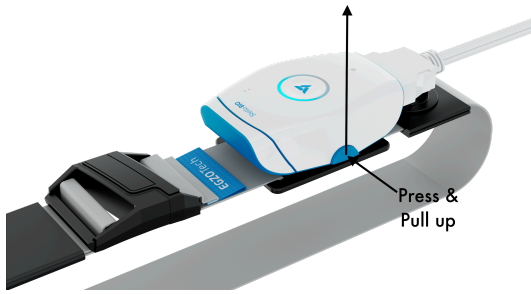
Never grab electrodes during electrical stimulation. Always make sure that the stimulation is disabled first.

Step 2: Disconnect the battery from Stella BIO by grabbing the battery housing (marked in red) from both sides and pulling the battery from the device.

Step 3: Disconnect all the electrodes and cables from the patient's body. Grab by fingers cable snap (red mark located on the right and left side) and pull-off from the electrode by giving some force to detach it.



Step 4: If you were using one of the belts, disconnect Stella BIO from the belt. Grab the device with your hand and push in the side latch-button by your finger (marked in blue). It will release the latch and allow you to disconnect Stella BIO from the belt.



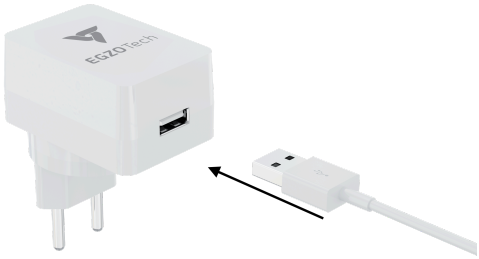
Step 5: Disconnect the patient lead wire cable by pressing the side latches (marked red) of the connector and pulling it out of Stella BIO.

Step 6: **Store everything in the transportation box.**

3.8. Charging the batteries

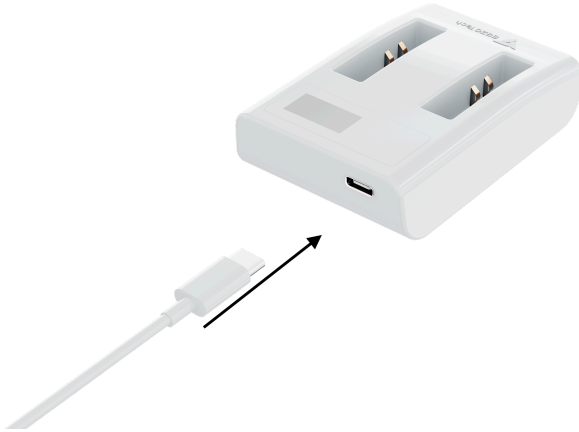
Charger station is a dual battery slot device ready to charge 1 or 2 batteries at the same time. To start this process - prepare parts as shown below.

Step 1: Make sure that the power supply is not connected to the AC source. Install USB cable plug into power supply.

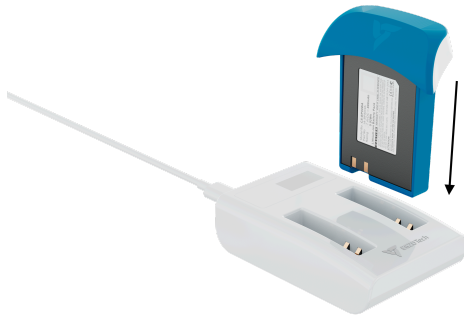


Step 2: Put the power supply to the AC socket.

Step 3: Connect micro-USB plug into charger.

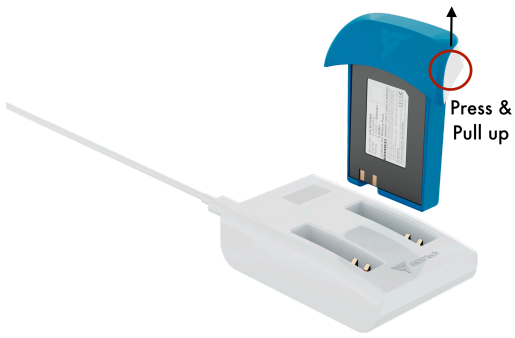


Step 4: Put battery into charger slot - charger's LCD display presents the battery charge status.



Step 5: Once the battery reaches 100%, it will stop the charging process and you can detach the battery from the charger. **To detach the battery from the charger,**

grab the battery by the red mark located on the right and left side and pull out the battery from the charger.



3.9. Connecting the belts

Stella BIO can be used with belts to allow transit-operation as a body-worn device (e.g. to evaluate proper walking patterns of patients). To connect Stella BIO to a mobile belt, follow the steps below.

Step 1: Place Stella BIO on the belt provided near the belt connector.

Step 2: Push the belt's connector into Stella BIO's bottom side until you hear the latch click. You can use any orientation out of 4 available depending on your training needs.

4. What is Stella BIO?

4.1. Device description

Stella BIO is an electromyography biofeedback and electrical stimulation device. It can be used in (essential performance) :

- EMG biofeedback pelvic floor muscle,
- Electrical stimulation pelvic floor muscle,
- EMG biofeedback neurorehabilitation,
- Neuromuscular electrical stimulation neurorehabilitation,
- EMG-triggered electrical stimulation neurorehabilitation,
- Transcutaneous electrical neuromuscular stimulation (TENS) for pain therapy,
- Assessing muscle activity through EMG signals.

As an **electromyography biofeedback device**, Stella BIO is used for electromyography studies of muscles, including: **surface and pelvic floor muscles**. It is intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles. The indications for use are neuromuscular re-education, strengthening and relaxation of muscles, muscle coordination and EMG biofeedback.

As an **electrical muscle stimulator**, Stella BIO is used for the treatment and the contraction of muscles (including surface and pelvic). It is a non-implanted electrical stimulator for urinary and faecal incontinence.

Stella BIO is intended to re-train the urinary and fecal continence mechanisms in the pelvic muscles, including the anal and urethral sphincters, through electrical stimulation or EMG biofeedback applied to the pelvic floor musculature and surrounding structures. The device is indicated for the treatment of patients with stress incontinence, urge incontinence or mixed incontinence, fecal incontinence, constipation - pelvic floor dyssynergia and sexual dysfunction.

Stella BIO combines the functionalities of electromyography measurements and biofeedback with electrical muscle stimulation, allowing **electromyography triggered functional muscle stimulation** (EMG-triggered FES).

Stella BIO can also use other integrated sensors alone or in combination for triggering electrical stimulation, including inertial measurement sensors.

4.2. Indications for use

Stella BIO is indicated for assessing electromyography signals from the pelvic floor and surface muscles and for providing EMG signals to use as biofeedback. Stella

BIO is indicated for the treatment of pelvic floor disorders, is also a transcutaneous electrical nerve stimulator and external functional neuromuscular stimulator.

Stella BIO indication for use are:

- Improve urinary and faecal control,
- Strengthening muscles,
- Improve sexual dysfunction,
- Therapeutic activities,
- Muscle relaxation,
- Prevention or retardation of disuse atrophy,
- Increasing local blood circulation,
- Muscle reeducation,
- Immediate post-surgical stimulation to prevent venous thrombosis,
- Maintaining or increasing range of motion,
- Relief and management of pain,
- Relearning voluntary motor functions of extremities.

That means that Stella BIO is especially useful with the following patients:

- Pelvic floor disorders (urinary or fecal incontinence, constipation - pelvic floor dyssynergia, sexual dysfunction),
- Stroke (cerebral haemorrhage, ischaemic damage),
- Traumatic brain injury (TBI),
- Spinal cord injuries,
- Parkinson's disease,
- Chronic illnesses such as multiple sclerosis (MS),
- Cerebral palsy (CP),
- Motor neuron diseases, e.g. amyotrophic lateral sclerosis (ALS),
- Meningitis, encephalitis,
- Duchenne's, Spinal muscular atrophy,
- Recovery from surgical interventions,
- Muscle weakness due to lack of mobility,
- After limb amputation,
- Muscle disease,
- Neuropathies (e.g. Guillain Barré syndrome),
- Foot Drop Syndrome.

This list is not meant to be exhaustive.

Treatment with Stella BIO for improving sexual dysfunction needs to be supervised by a healthcare professional (e.g. a sexologist, clinical sexologist or psychosexologist). Stella BIO is not intended as a monotherapy for improving sexual dysfunction.

Stella BIO should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The patient shouldn't use electrical stimulation on other individuals. The device is suitable for **home use.**

4.3. Contraindications

You should always adhere to the provided **2.1. General safety considerations and precautions** chapter of this manual to address contraindications.

When **not to use Stella BIO** (contraindications):

- Cardiac demand pacemaker or any implanted defibrillator (Electrical stimulation),
- No stimulation in the proximity of metal implants,
- Pregnancy (electrical stimulation over uterus or with the usage of pelvic floor electrodes),
- Feverish or infectious diseases,
- Skin disorders subject to inflammation, as well as thrombosis or phlebitis,
- Extra-urethral incontinence (fistula, ectopic urethra),
- Overflow incontinence caused by evacuation disorders,
- Total peripheral denervation of the pelvic floor,
- Body-worn electro mechanical medical devices, i.e. insulin pump,
- Cardiac arrhythmia (do not use on chest),
- Symptomatic local pain relief unless aetiology is established or pain syndrome has been diagnosed,
- Serious arterial circulation problems in lower limbs,
- Abdominal or inguinal hernia,
- Patients with electronic life support equipment, such as respirators,
- Patients with electronic medical devices attached to the body, such as electrocardiographs,
- Patients with other electronic medical devices (device may cause erroneous operation of those devices.),

When **not to use pelvic floor electrodes** (contraindications):

- Bladder or vagina infection,
- Cervical cancer,
- If you have or have had epilepsy,
- Pregnancy (for electrostimulation, Stella BIO is safe for EMG evaluation),
- Patients with intestinal clamps.

Warnings while using Stella BIO:

- No transcerebral applications,
- No stimulation in the vicinity of the carotid artery or carotid gland,

- No contralateral stimulation (i.e. plus and minus pole of the same channel on opposite sides of the body),
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias,
- This device should not be used, when cancerous lesions are present in the treatment area.

4.4. Technical specifications

ESTABLISHED AND TRADE NAME :
Stella BIO

DIMENSIONS & WEIGHT (WITHOUT ACCESSORIES):
Total length: 9.15 cm (3.60 in)
Total width: 6.84 cm (2.70 in)
Total height: 2.40 cm (0.95 in)
Total weight (without battery):
112 g (0.25 lbs)

ENVIRONMENT:
Operating temperature: 0 °C to 35 °C
Operating humidity: 10 % to 90 % RH, not-condensing
Maximum operating altitude:
3 000 m a.s.l.
Cooling: convectional
Liquid ingress and solid particle protection: IP32
Mobility: Transit-operable, hand-held, body-worn under the operating environmental conditions listed above.
Operation type: Continuous, software controlled

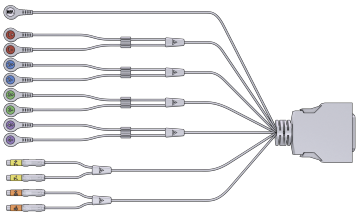
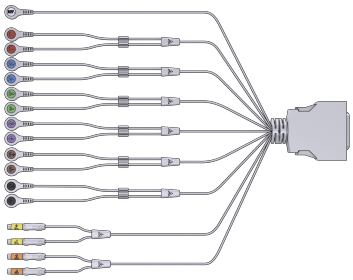
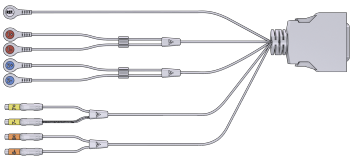
OTHERS:
Power supply:
Battery powered Lithium-Ion 7.4 V / 800 mAh / 5.92 Wh
Applied part type: BF
Communication:
Wireless: Wi-Fi and Bluetooth Low Energy

ELECTROMYOGRAPHY:
Electromyography measurement channels:
Up to 8, simultaneous sampling
Electromyography accuracy:
± 0.5 % full scale
Baseline noise: < 0.5 µV RMS
Measurement resolution:
± 6 000 µV: 0.1µV
Sampling frequency:
Up to 4000 samples per second per channel
Internal sampling: 24-bit
Impedance measurement accuracy: ± 0.5 kΩ
Input impedance: > 100 MΩ

ELECTRICAL STIMULATION:
Electrical stimulation channels:
Up to 8, sequential
Waveforms and types:
Low-frequency, dual-phase, and direct current free rectangular, triangular, and trapezoidal pulses, electromyography-triggered
Maximum output voltage and current:
50 V / 100 mA at 500 Ω
Waveform generation accuracy:
± 0.5 % full scale
Output Resolution: 16-bit
Sampling frequency: Up to 1 000 000 samples per second
Load impedance: 500 - 2000 Ω

4.5. Accessories

4.5.1. Cables

What does it look like?	Description
	Stella BIO EMG/EMS Cable 4 + 2 channels *4 channels (8 snaps) to connect the surface electrodes (EMS/EMG)* *+ 2 channels (4 pigtails)* *to connect the vaginal/anal electrodes (yellow and orange)* *+* *1 Reference lead wire (white snap with the REF sign)*
	Stella BIO EMG/EMS Cable 6 + 2 channels *6 channels (12 snaps) to connect the surface electrodes (EMS/EMG)* *+ 2 channels (4 pigtails)* *to connect the vaginal/anal electrodes (yellow and orange)* *+* *1 Reference lead wire (white snap with the REF sign)*
	Stella BIO EMG/EMS Cable 2 + 2 channels *2 channels (4 snaps)* *to connect the surface electrodes (EMS/EMG) only* *+2 channels (4 pigtails)* *to connect the vaginal/anal electrodes (yellow and orange)* *+* *1 Reference lead wire (white snap with the REF sign)*

Length of each cable is 130 cm and is optional. Shorter cable lengths available on request.

Availability of other cables should be verified by contacting the **EGZO**Tech sales department sales.poland@egzotech.com.

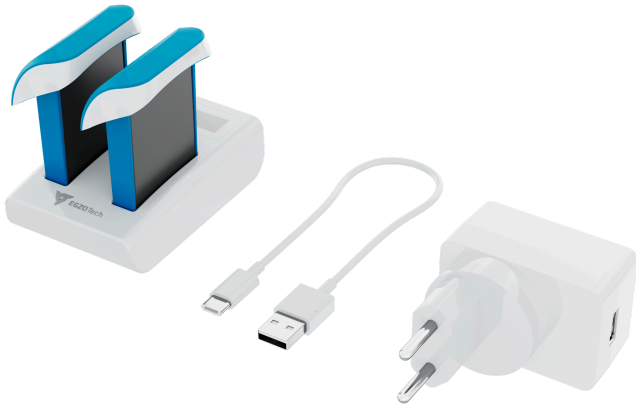
4.5.2. Rechargeable Battery

SPECIFICATION:

Product Category: Lithium-Ion Rechargeable Battery Pack (Dual Cell Battery)

Manufacturer:	Cameron Sino	**Rated Capacity:**	800 mAh / 5.92 Wh
Model:	CS-BP80WA	**Nominal Voltage:**	7.4 V

4.5.3. Battery Charger



SPECIFICATION:

Input Power:	10 W	**Input:**	⎓ 5 V / 2 A Max
Overheat protection:	Yes	**Output:**	⎓ 8.4 V / 0.6 A
Surges protection:	Yes	**Certificates:**	CE

4.5.4. Fastening belts

A fastening belt enables patients to perform dynamic assessment or exercise. It can be used at the waist, leg or arm according to the test and patient's preferences.

To mount the device on the belt, simply put it on the plastic belt slot. When properly installed, you should hear a characteristic sound. Blue Quick Release Button permits to disconnect the device from the belt.

4.5.5. Electrodes for surface electromyography - EMG Biofeedback

The table below presents the electrodes that are approved and safe for use with surface electromyography using Stella BIO. However the type and quantity of electrodes provided with the device depend on the order specifications and may vary.

What does it look like?	Description
	ECG surface electrode **EGZO**Tech **EE S5540 FWG** Area intended to contact the surface of the skin: 22 cm^2 55 x 40 mm 50 psc/case
	ECG surface electrode **EGZO**Tech **EE S5540 FWG1** Area intended to contact the surface of the skin: 15.4 cm^2 44 x 35 mm 50 psc/case

Stella BIO is compliant with any surface ECG/EMG electrodes that meet IEC 60601-1 requirements. The device is designed for use with snap electrodes; using other types of electrodes requires an adapter.

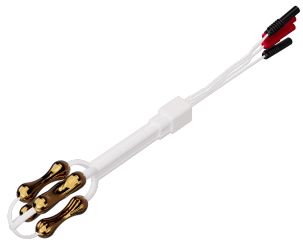
Before use, always check and follow the information provided by the electrode manufacturer.

Always **confirm the use of electrodes** not listed above **with the manufacturer or the local distributor**. The use of electrodes not listed in the table above or not confirmed by the manufacturer or local distributor may result in device malfunction, failure to operate, or **pose a burn risk to the patient**.

4.5.6. Probes for pelvic floor muscle therapy

The table below presents the probes that are approved and safe for use with Stella BIO. However the type and quantity of probes provided with the device depend on the order specifications and may vary.

What does it look like?	Description
	Adult 2 lead **vaginal** electrode **Everyway PR-02A** Area intended to contact the surface of the skin: 7.65 cm^2 x 2 Length: 76 mm, Diameter: 28 mm Pcs or set Manufactured by: Everyway Medical Instruments Co., Ltd. 3Fl. No.5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan
	Small 2 lead **vaginal** electrode **Everyway PR-14A** Area intended to contact the surface of the skin: 9.05 cm^2 x 2 Length: 53 mm, Diameter: 20 mm Pcs or set Manufactured by: Everyway Medical Instruments Co., Ltd. 3Fl. No.5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan
	Adult 2 lead **anal** electrode **Everyway PR-09A** Area intended to contact the surface of the skin: 2,025 cm^2 x 2 Pcs or set Manufactured by: Everyway Medical Instruments Co., Ltd. 3Fl. No.5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan

What does it look like?	Description
	Adult 2 lead **anal** electrode **Neen Anuform** Area intended to contact the surface of the skin: 3 cm^2 x 2 Length: 69 mm, Width: 19.2 mm Pcs or set Manufactured by: Performance Health International LTD Nunn Brook Rd, Huthwaite, Sutton-in-Ashfield, Nottinghamshire, NG172HU, United Kingdom
	Adult 2 lead **anal** electrode **Everyway PR-06A** Area intended to contact the surface of the skin: 1.93 cm^2 x 2 Length: 83 mm, Diameter: 14 mm Pcs or set Manufactured by: Everyway Medical Instruments Co., Ltd. 3Fl. No.5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan
	Adult 2 lead **anal** electrode **Everyway PR-13A** Area intended to contact the surface of the skin: 3.74 cm^2 x 2 Length: 108 mm, Diameter: 19.6 mm Pcs or set Manufactured by: Everyway Medical Instruments Co., Ltd. 3Fl. No.5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan
	2 channels **vaginal** electrode **Perisphera - H** Area intended to contact the surface of the skin: 3.2 cm^2 x 4 Pcs or set ***For EU only*** Manufactured by: BEACMED s.r.l. Via Monte Bianco 12 27040 Portalbera (PV) Italy

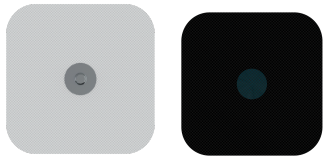
What does it look like?	Description
	2 channels **vaginal** electrode **Perisphera - U** Area intended to contact the surface of the skin: lateral 3.5 cm^2 x 2, lower 4.7 cm^2 x 2 Pcs or set ***For EU only*** Manufactured by: BEACMED s.r.l. Via Monte Bianco 12 27040 Portalbera (PV) Italy
	2 channels **anal** electrode **Perisphera - A** Area intended to contact the surface of the skin: 1.6 cm^2/electrode x 4 Pcs or set ***For EU only*** Manufactured by: BEACMED s.r.l. Via Monte Bianco 12 27040 Portalbera (PV) Italy

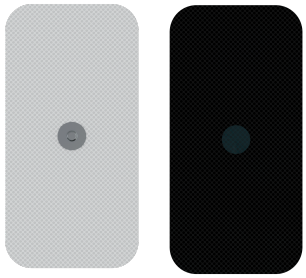
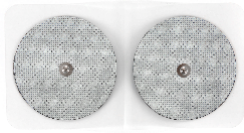
Before use, always check and follow the information provided by the electrode manufacturer.

Always **confirm the use of electrodes** not listed above **with the manufacturer or the local distributor**. The use of electrodes not listed in the table above or not confirmed by the manufacturer or local distributor may result in device malfunction, failure to operate, or **pose a burn risk to the patient**.

4.5.7. Electrodes for electrical stimulation

The table below presents the electrodes that are approved and safe for use with electrostimulation using Stella BIO. However the type and quantity of electrodes provided with the device depend on the order specifications and may vary.

What does it look like?	Description
	Small electrical stimulation electrode **UltraStim Snap SN2020** Area intended to contact the surface of the skin: 25 cm^2 50 x 50 mm 4 psc/case Manufactured by: Axelgaard Manufacturing Co., Ltd. 520 Industrial Way Fallbrook, CA 92028, USA

	Large electrical stimulation electrode **UltraStim Snap SN2040** Area intended to contact the surface of the skin: 50 cm^2 50 x 100 mm 4 psc/case Manufactured by: Axelgaard Manufacturing Co., Ltd. 520 Industrial Way Fallbrook, Axelgaard 92028, USA
	Small electrical stimulation electrode **HRTC32BP** Area intended to contact the surface of the skin: 8 cm^2 Diameter: 32 mm 4 pcs/pack Manufactured by: HUREV Co., Ltd. 107-3 Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea

Stella BIO is compliant with any surface self-adhesive EMS electrodes that meet IEC 60601-1 requirements (carbon electrodes are not recommended). **Using electrodes smaller than 32 mm in diameter (with a surface area less than 8 cm^2)** may lead to burns due to the concentration of current over a smaller area. The device is designed for use with snap electrodes; using other types of electrodes requires an adapter.

Before use, always check and follow the information provided by the electrode manufacturer, paying particular attention to the maximum allowable current for electrical stimulation.

Always **confirm the use of electrodes** not listed above **with the manufacturer or the local distributor**. The use of electrodes not listed in the table above or not confirmed by the manufacturer or local distributor may result in device malfunction, failure to operate, or **pose a burn risk to the patient**.

4.5.8. Tablet

4.5.8.1. Tablet for Stella BIO App

Product Category: Tablet

Manufacturer: Lenovo

RAM: 6 GB

Model: Tab P11 5G

CPU: Snapdragon 750G

4.5.8.2. Tablet for EGZOClinic

Product Category: Tablet

Manufacturer: Zebra

RAM: 4 GB RAM / 64 GB SSD

Model: ET40-AB

CPU: Qualcomm Snapdragon SM6375 Octa-Core: 2.2 GHz (2) and 1.8 GHz (6)

4.5.8.2.1. Accessories for EGZOClinic Tablet

- **Single Slot Charging Cradle**

A charging station allows charging the tablet in a comfortable standing position.

Product Category: Zebra tablet accessory

Manufacturer: Zebra

Model: CRD-ET4X-1SCG1-01 ET40/ET45

- **Workstation Cradle**

A workstation with HDMI ports. It allows connecting an external monitor to your tablet while also charging it in a comfortable standing position

Product Category: Zebra tablet accessory

Manufacturer: Zebra **Model:** EVM CRD-ET4X-1SNWS-01

- **Zebra keyboard**

A keyboard case that turns your tablet into a laptop.

Product Category: Zebra tablet accessory

Manufacturer: Zebra **Model:** ET40/45 10" 2in1 Keyboard

- **HealthCare Handstrap**

A rubber case for the tablet providing a secure hand grip with the hand strap.

Product Category: Zebra tablet accessory

Manufacturer: Zebra **Model:** SG-ET4X-HCHNDSTR1-01 ET40/ET45

4.5.9 Laptop

4.5.9.1. Laptop for Stella BIO App

Product Category: Laptop

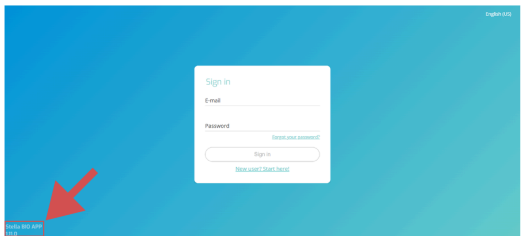
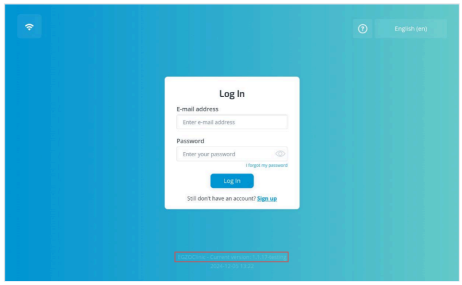
Manufacturer: ASUS **RAM:** 4GB DDR4 2666 MHz

Model: VivoBook R R564JA **CPU:** Intel Core i3-1005G1 1.20 GHz up to 3.40 GHz

5. Software

Stella BIO is designated for use in clinical and home healthcare environments. While in a clinical environment it can be used with either Stella BIO App and EGZOClinic, **the home-use patients can only use Stella BIO App software with their Stella BIO**.

To distinguish what software you are working with, please check the version on the bottom of the login page.

Stella BIO App	EGZOClinic
	

5.1. Stella BIO App

5.1.1. How to launch the application?

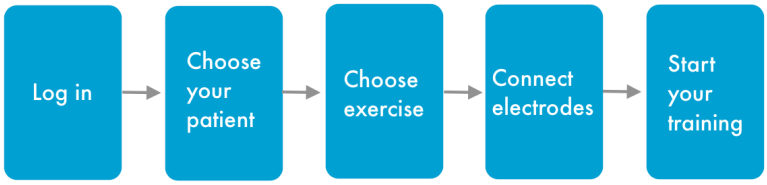
5.1.1.1. Application in the Kiosk mode

If you have a device configured by **EGZO**Tech with the application in Kiosk mode, launching the application requires you to start the device. The application will automatically load without any additional steps and be ready to use. Once launched, a login window will appear and if you already have an account, you can immediately log in and start using the application.

5.1.1.2. Web Application

The training on Stella BIO is created for patients based on exercises. Use e.g. Google Chrome web browser to launch the Stella BIO application and go to the website address provided by the product specialist.

Follow the simple steps below to easily set up your first training program.



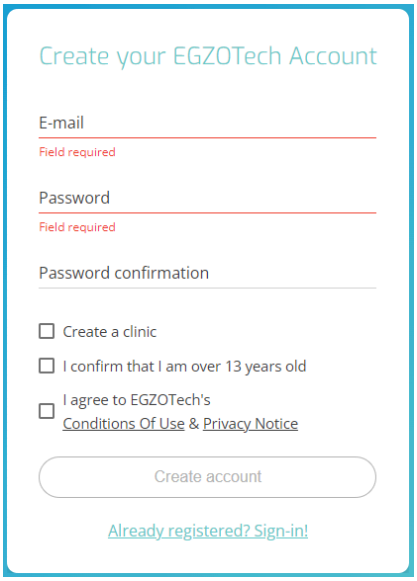
5.1.1.3. NFC - quick access to the application

The Stella BIO application can be accessed using the NFC (Near Field Communication) system, which allows communication over a short distance between compatible devices.

- Check with your device provider whether your device (phone, tablet, etc.) supports NFC and how to enable NFC on your device.
- With NFC enabled, simply place your device near the "**N**" sign on the front of your Stella BIO device and you will be automatically redirected to the Stella BIO App.

Align your device with the N on Stella BIO to quickly access the Stella BIO App. Only available for NFC - enabled devices.

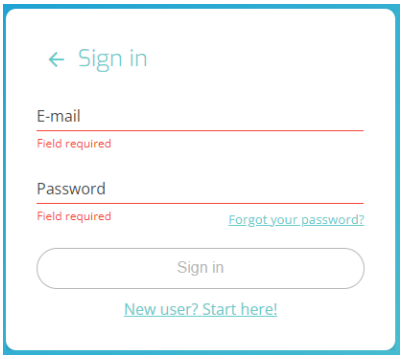
5.1.2. Registration



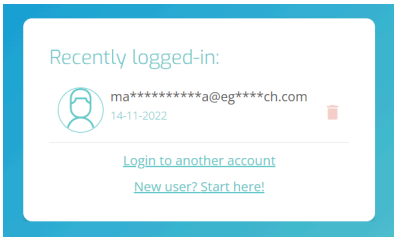
To use Stella BIO, you will need a Stella BIO App account.

To register, please, visit the homepage of the website and click on the "**Create a new account**" link.
If you've purchased Stella BIO directly from **EGZO**Tech, you should already have this created.

5.1.3. Signing in

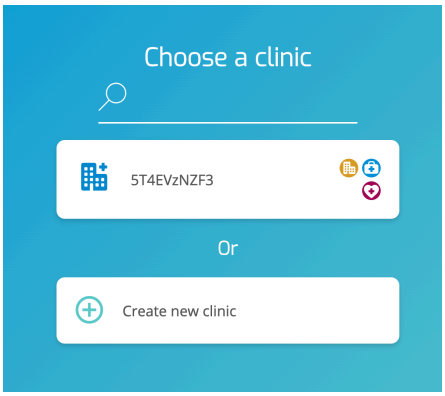


Once the application has started, the login screen will appear. Enter your e-mail address and password, then confirm with the "**Sign in**" button or the Enter key.



After logging into the app, a screen of recently logged in accounts will appear, select your account with a click and then enter your password and log in.

5.1.4. Clinics and roles in the application



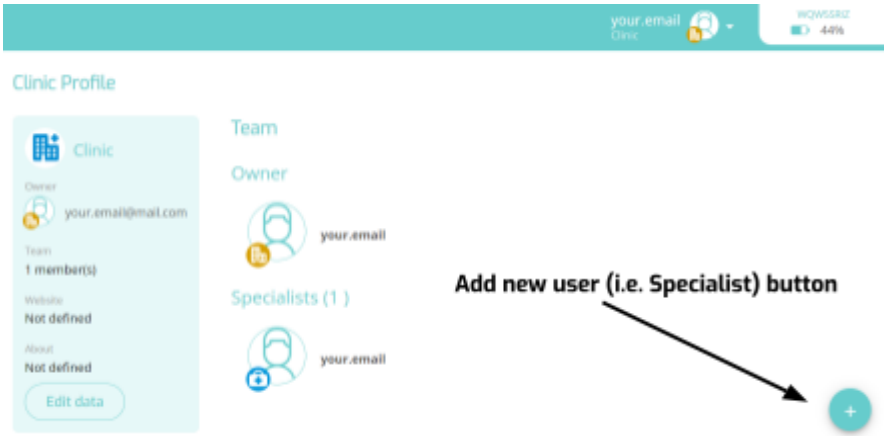
You can create a new Clinic by clicking the **"Create new clinic"** button.

After you enter your Clinic, you will have to choose your role in the program. You can choose an Owner, Specialist or Patient account.

As an **Owner** in a healthcare clinic, you can:

- Invite new user or specialist to the application,
- Delete user or specialist from your clinic,
- Edit users roles in your clinic,
- Edit information about your clinic.

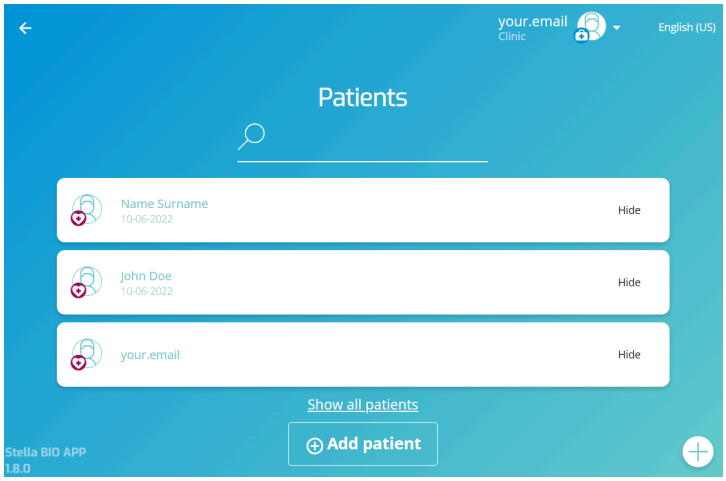
Owner's screen:

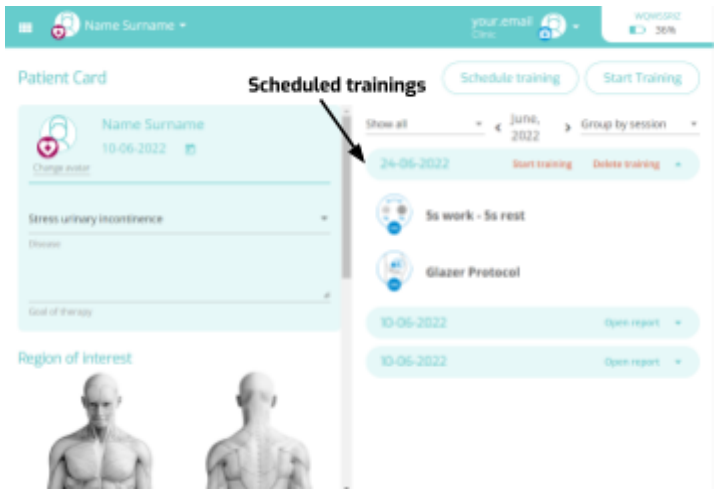


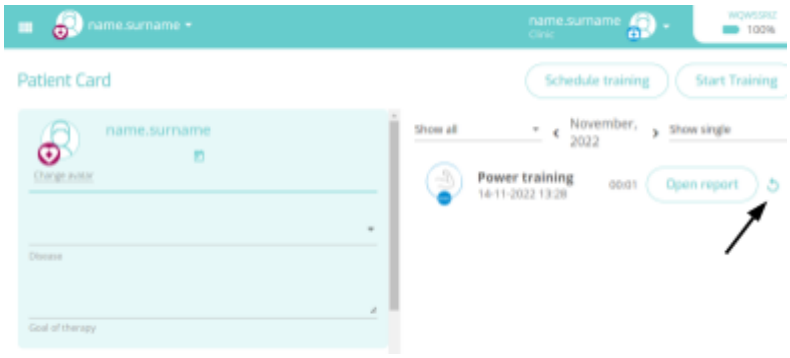
As a **Specialist** (physician or physical therapist), you can:

- Add or invite new patient to the application and your clinic,
- Invite new specialist to your clinic,
- Have access to personal and medical data of patients in your clinic,
- Edit personal and medical data of patients in your clinic,
- Schedule appointments and trainings for patient in your clinic,
- Create template of evaluation, training and exercises,
- Perform training with patients,
- Repeat the training conducted with the patient previously,
- Have an overview of the patient's chart.

Specialist's screen:



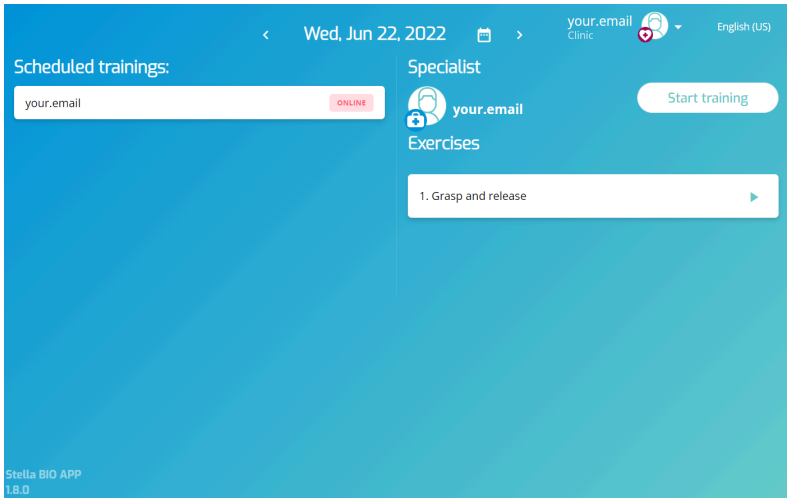




As a **Patient** you can:

- Have access to your personal and medical data in the clinic,
- Schedule an appointment with a specialist,
- Perform training prescribed by your medical provider,

Patient's screen:

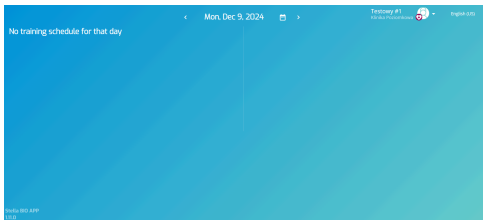
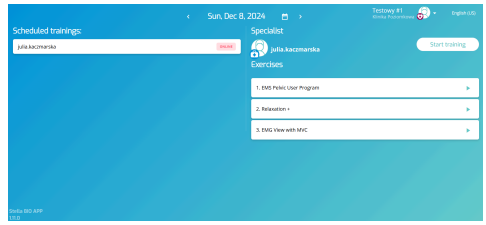


5.1.5. Home use

To use your Stella BIO as a patient in a home environment, you need to access the application in a web browser on any device like a laptop, a tablet or a phone. To do so please refer to chapter **5.1.1.2. Web Application**.

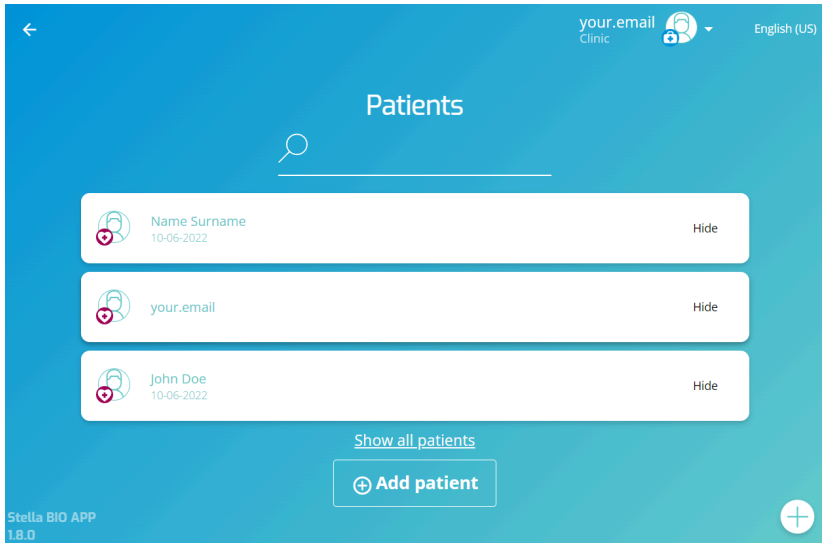
After signing in your account you should see your dashboard screen. From this view you will be able to access trainings that your specialist has prescribed you for that specific day.

You will be able to perform the trainings on your own, in the home environment by clicking on them and following the instructions on the screen.

Empty dashboard page	Dashboard page with prepared trainings
	

5.1.6. Managing patients

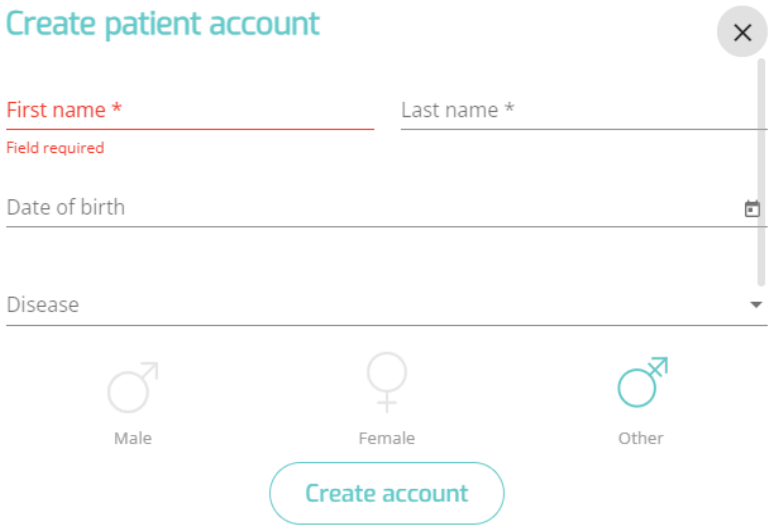
On the main page of the Specialist account, you will see the list of your patients, sorted by last visit date.



In order to add a new patient, click the "**+ Add Patient**" button at the end of your patient's list.

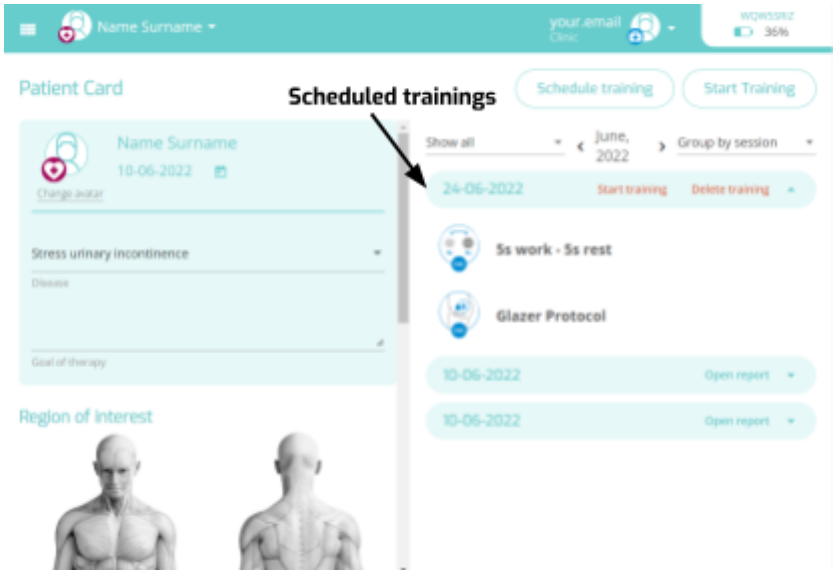
To **create a new patient's account**, simply enter the patient's name and select gender. An e-mail address (optionally in the option supporting the telemedical pathway) allows you to log in to the service and view the results.

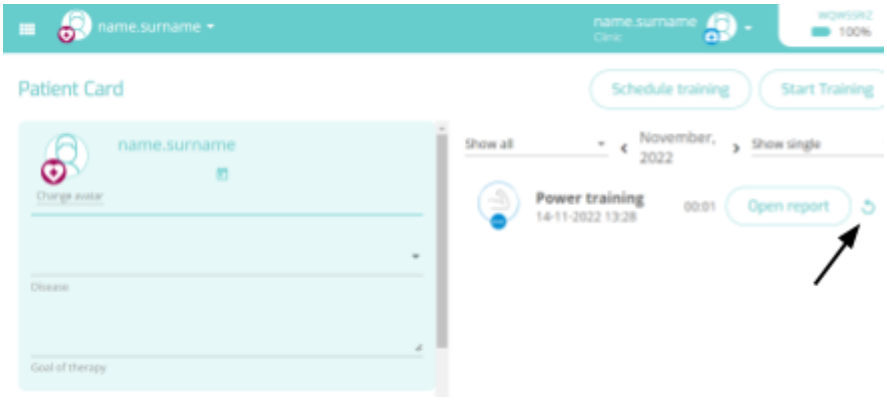
Once the form is completed (the mandatory fields are marked with an asterisk) click "**Create account**" button.



5.1.7. Patient's card

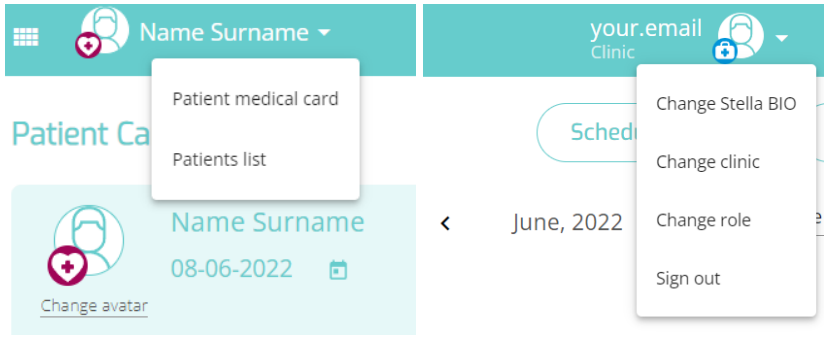
After logging in and selecting a patient, you will see the patient card with all the information about their current and past health status, therapy goal, training sessions performed and recommended. You can also repeat a previously completed training session using the 'repeat' button on the completed training entry.





5.1.8. Top bar and side menu

The top bar menu on the patient card allows you to search for patients, view the current status of the Stella BIO device and access advanced functions or log out.
If you click on the patient's name or the therapist name in the top bar, a drop-down menu with special functions for your role will appear.



5.1.9. Battery state and remaining energy

In the top left corner of the patient card, you will find information about the status of the Stella BIO device, including the wireless connection and battery charge status. The remaining battery energy is displayed via the battery percentage indicator, as shown on the pictures below.

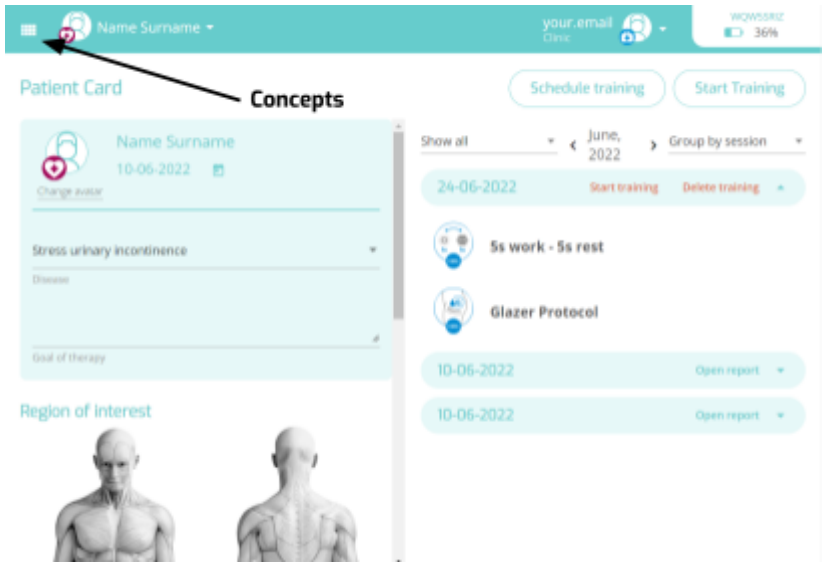
Stella BIO connected, 70% battery left

Stella BIO not connected

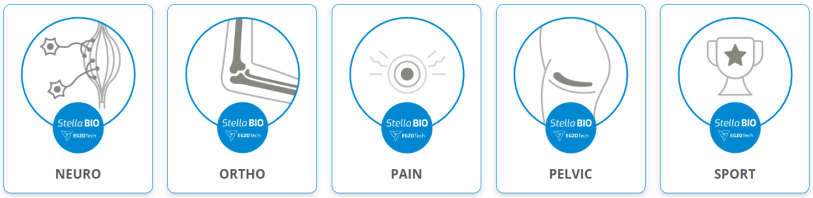
5.1.10. Concepts

Stella BIO offers Electrical Stimulation programs (EMS), FES programs, EMG-triggered EMS/FES programs, TENS programs and EMG Biofeedback programs for the superficial and pelvic floor muscles.
All programs are divided into specific thematic groups called **"Concepts"**, allowing quick access to the desired exercises depending on the treatment goal or indication.

By clicking on the icon in the top left corner you will access the list of Concepts.



You can find the following Concepts:



Neuro - combines all neurology-related programs. Useful for biofeedback, muscle relaxation and muscles re-education, helpful to relearn voluntary muscle contractions and maintaining or increasing range of motion.

Ortho - combines all programs related to orthopaedics. Useful for preventing muscle atrophy, improving blood circulation and muscle relaxation.

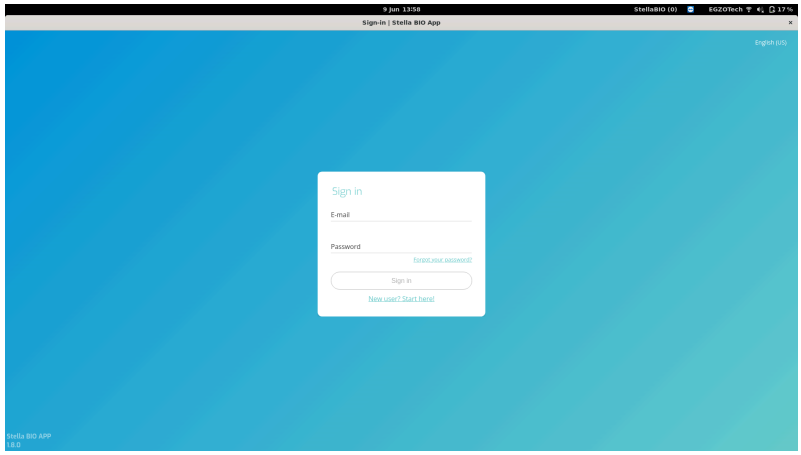
Pain - combines all TENS programs for pain relief (chronic and acute).

Pelvic - combines all programs for pelvic floor treatment. Helpful for stress, urgency and mixed urinary and/or faecal incontinence.

Sport - combines all sports-related programs. Helps in stimulating healthy muscles to improve and facilitate muscle function.

5.1.11. Operating the application in Kiosk mode on laptop

The laptop configured by **EGZO**Tech with the application in Kiosk mode has several additional functionalities that do not directly relate to the application. The information below will enable you to familiarise yourself with and efficiently use such a device.



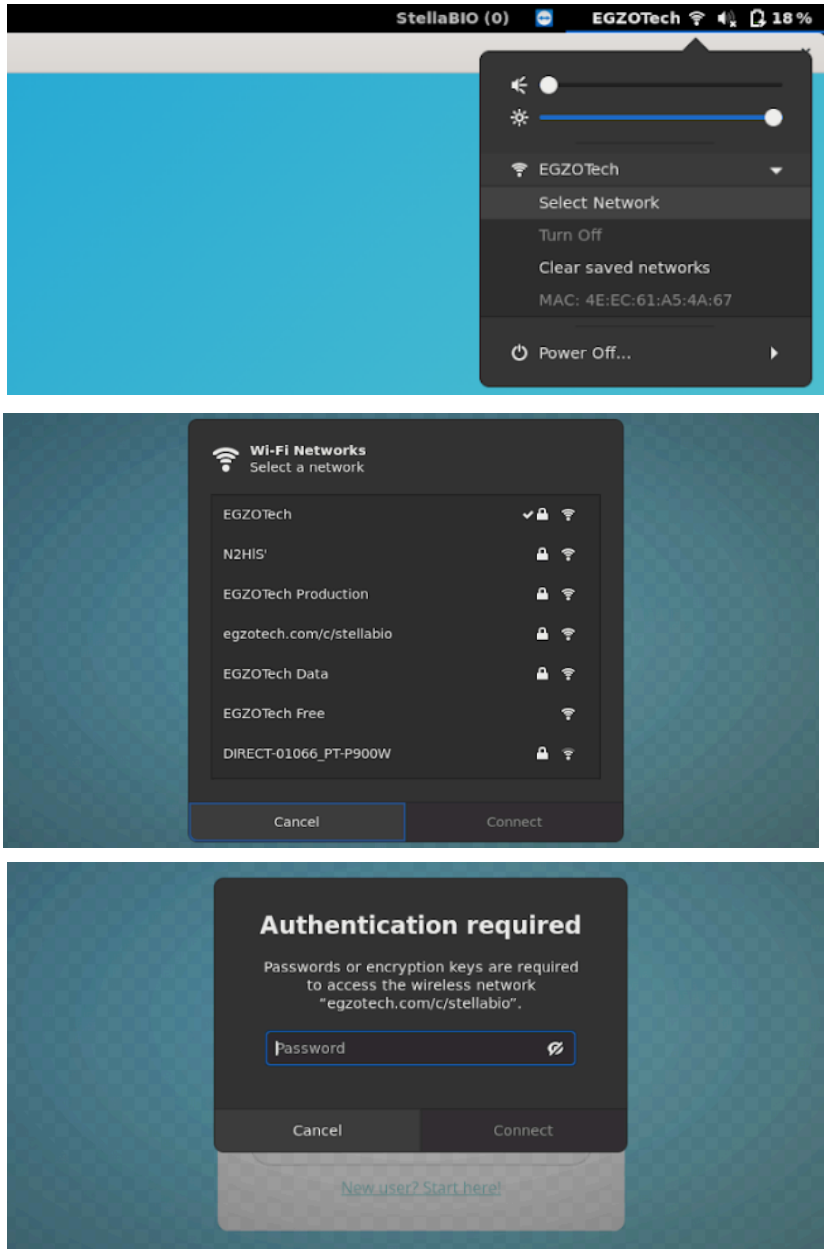
5.1.11.1. Sound and screen brightness

The sound and brightness settings for your laptop are located in the menu at the top right of the screen. You need to click on them to open. When the menu appears, you will initially see two sliders, the first is responsible for the volume level of the device and the second for the brightness of the screen. You can adjust the levels of these sliders to suit your own needs.

5.1.11.2. Connecting to a Wi-Fi network

Under the sound and brightness settings, you will find a list of Wi-Fi networks. Depending on the version of the device, two networks may be shown in the list at once, as one of them is used to connect to the Stella BIO device. To connect the device to Wi-Fi, press on one of the networks and see if the "**Select network**" button is shown active. If the button is inactive, press on the other of the network. Then click on the "**Select network**" button and then a window will appear with the

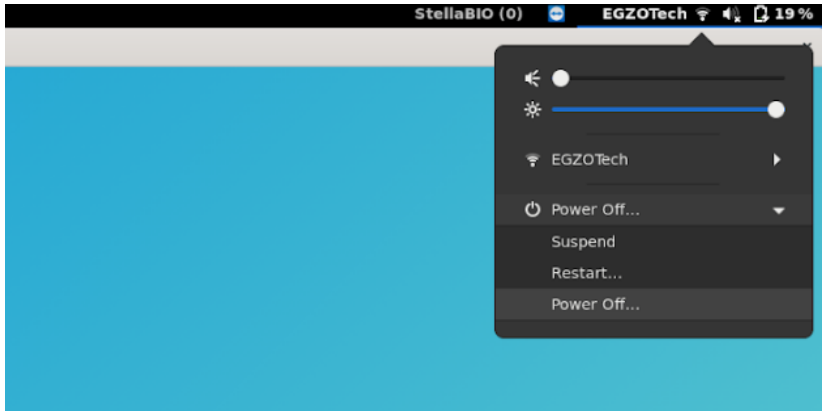
possibility of selecting a Wi-Fi network. After selecting the network in this window, the device will ask you to enter the network password if necessary. In the case of hidden Wi-Fi networks, a service request should be made (a service request form is available at: https://service.egzotech.com).



5.1.11.3. Shutdown, Sleep and Reboot

The last option in the menu in the top right corner is "**Power off computer**". If you press it, a list with possible actions will unfold. The available actions are:

- "**Power Off...**" - the device shuts down completely.
- "**Suspend**" - the device goes into sleep mode, where it consumes much less power and is also very quickly ready to go when any key on the keyboard is pressed. The main difference between power off and sleep is the amount of time that must elapse before the device is ready for use. In sleep mode, the device is still drawing power from the battery and can run down if it is not connected to a charger.
- "**Restart...**" - the device switches off and then on again.



5.1.12. Operating the application in Kiosk mode on tablet

The tablet configured by **EGZO**Tech with the application in Kiosk mode has several additional functionalities that do not directly relate to the application. The information below will enable you to familiarize yourself with and efficiently use such a device.

5.1.12.1. Sound

The sound settings for the tablet can be changed using the physical buttons located on the top left side of the tablet. The button located further to the left increases the volume and the button on the right decreases it.

5.1.12.2. SIM card installation

A working SIM card must be inserted into the device in order for it to use the Internet correctly via mobile data. Using the SIM card key, pull out the tray located on the left side of the device. Place the SIM card in the tray and then insert it back into the device. After a moment, the tablet will ask for the SIM card's PIN number (if the card requires one), and then automatically find the network and start mobile data.

5.1.12.3. Wi-Fi network connection

Connecting the tablet to the Wi-Fi network requires service authorization, so it is best to contact the service centre by e-mail at serwis@egzotech.com.

5.1.12.4. Screen lock

The tablet has the ability to lock the screen. Locking the screen blankens the screen and reduces battery consumption. To lock the screen, press and release the button located on the left side of the device. Another press will wake up the device and allow you to unlock the screen and continue working with the application.

5.1.12.5. Shutting down and restarting

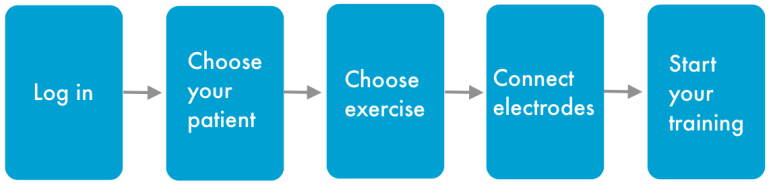
To turn off or restart the tablet, press and hold the button on the left side of the device until the window with the action selection appears. Then select the action "**Power off**" or "**Restart**" depending on the expected behavior. Once the tablet is switched off, it can be restarted by pressing and holding the same button.

5.2. EGZOClinic

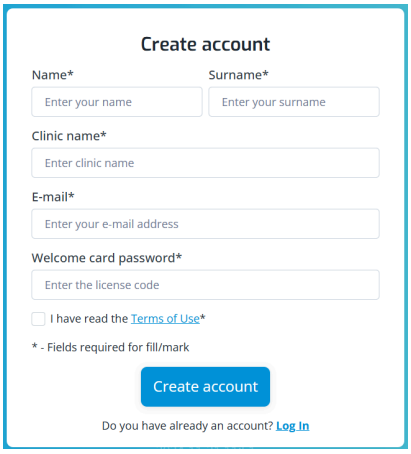
5.2.1. How to launch the application on the tablet?

If you have a device configured by **EGZO**Tech with the application in Kiosk mode then launching the application involves starting the device. The application will load automatically without any further action and will be ready to use. After launching a login window will appear and if you already have an account you can immediately log in and start using the application.

Follow the simple steps below to easily configure your first training program.



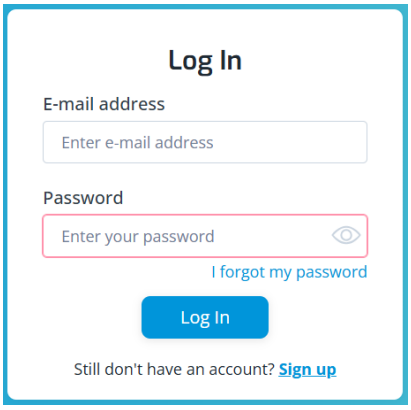
5.2.2. Registration



To use Stella BIO with EGZOClinic application, you will need to create a clinic account.

To register, please, visit the homepage of the application and click on the "**Sign up**" link.

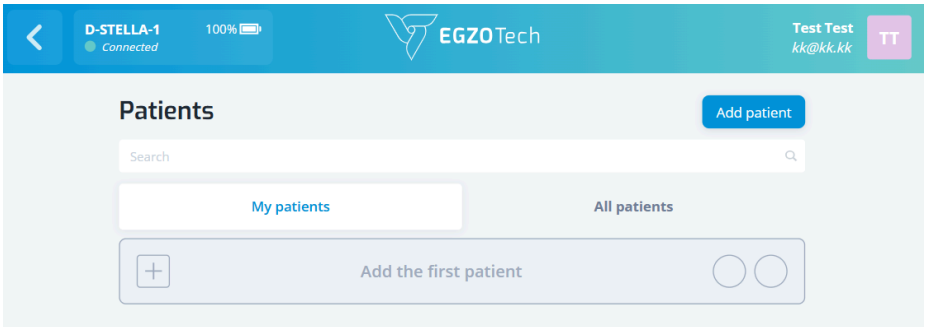
5.2.3. Signing in



After launching the app, you will be greeted by a login screen. If you already have an account, type your email address and password and confirm with the "**Log in**" button.
If you do not have an account yet, follow the instructions provided in the previous paragraph.

5.2.4. Managing patients

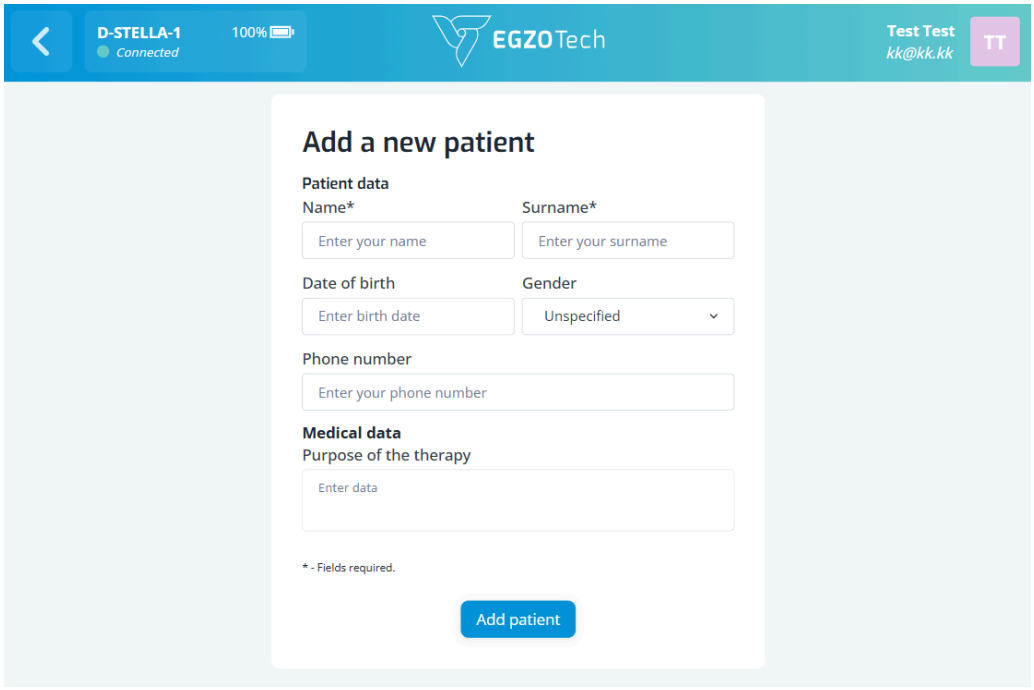
On the main page after you have logged in, you will see the list of your patients, sorted by last visit date.



To create a new patient, click the **Add Patient** button above your patient's list, or the empty slot directly on the list.

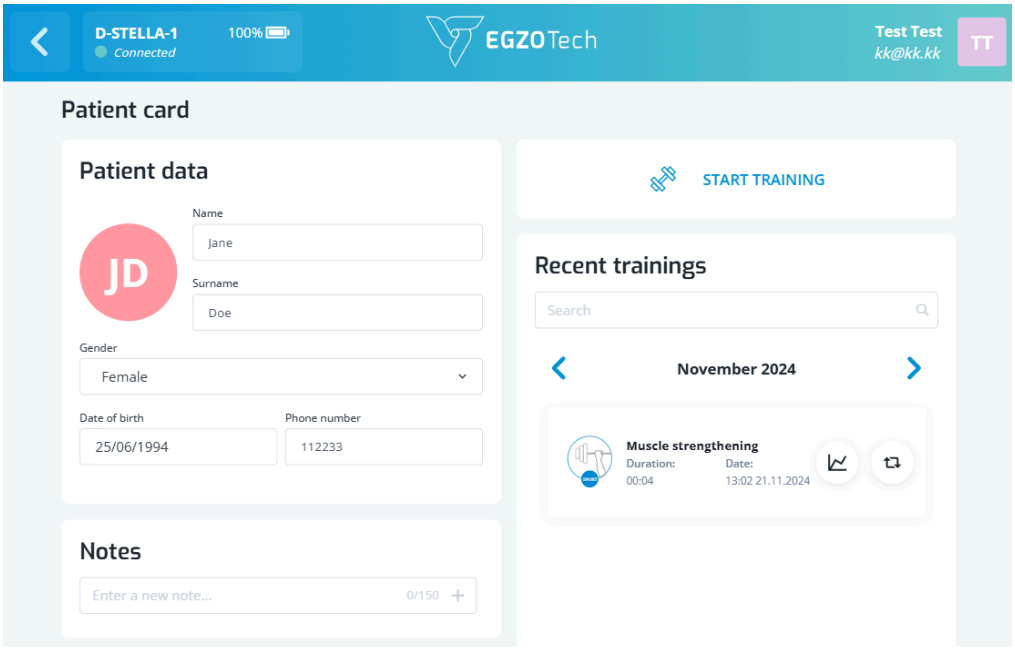
To **create a new patient's account**, just type the patient's first and last name. You can also provide the date of birth, their gender, phone number and type in any note regarding the therapy and its purpose. After that you may click the "**Add patient"** button at the bottom.

After adding a patient, you will be redirected to their **Patient card**.



5.2.5. Patient card

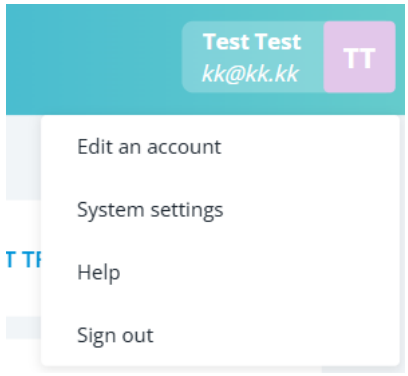
After logging in and selecting a patient, you will see the patient card with all the information provided in the Patient data, purpose of the therapy sections, and also the exercises they have finished. You can also open the exercises' reports , and repeat an exercise they have done before by using the "**Repeat training"** button next to it.



5.2.6. Top bar

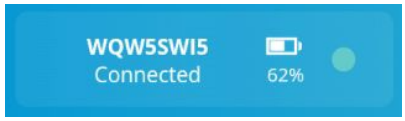
The top bar menu enables you to visit other useful sites, such as Account editing site, system settings, Help page, and also it provides the Sign out link.

To unfold the top bar menu click on the therapist name in the top bar, then the drop-down menu with special functions will appear.

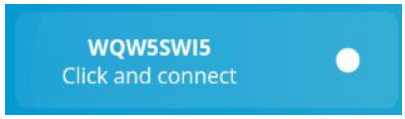


5.2.7. Battery state and remaining energy

In the top left corner of the screen you will find the Information on Stella BIO's state, including wireless connection and remaining battery energy. The remaining battery energy is displayed via the battery percentage indicator, as shown in the screens below.



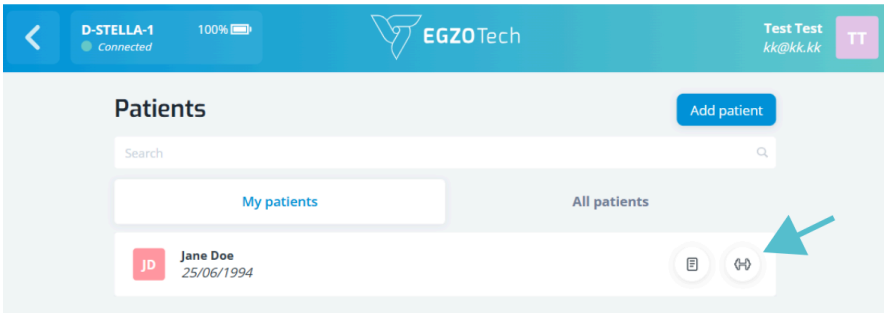
Stella BIO connected, 70% battery left



Stella BIO not connected

5.2.8. Exercise list

Stella BIO offers Electrical Stimulation programs (EMS), FES programs, EMG-triggered EMS/FES programs, TENS programs and EMG Biofeedback programs for the superficial and pelvic floor muscles.
You can access the list of exercises by clicking the "**Start training button**" in the Patient card or the "**Training button**" situated on the right side of the patient tile.



You can find the Concepts mentioned in chapter **5.1.9. Concepts** in the filter by patient type search engine.

Neuro - combines all neuro-related programs. Useful for biofeedback, muscle relaxation and re-education, helpful for functional electrostimulation, maintaining or increasing range of motion.

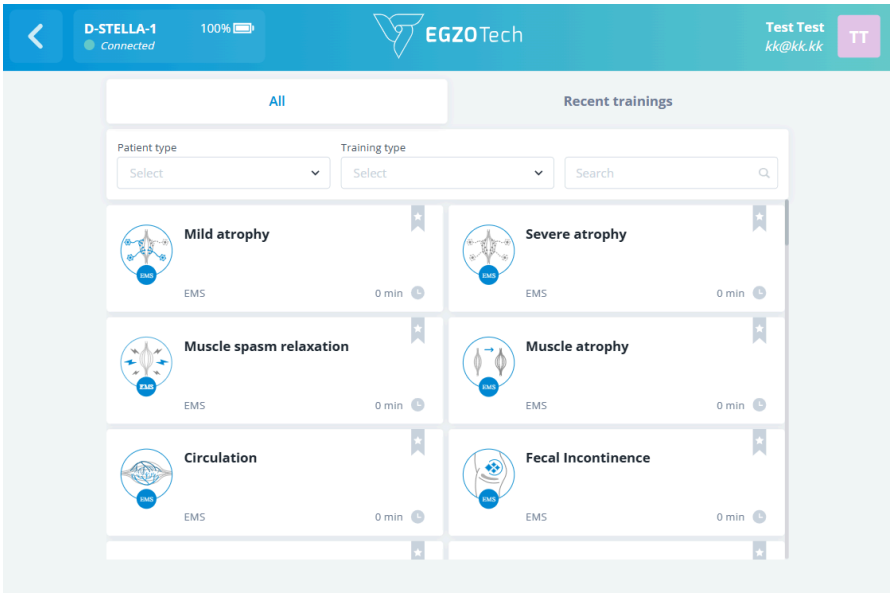
Ortho - combines all programs related to orthopaedics. Useful for preventing muscle atrophy, improving blood circulation and muscle relaxation.

Pain - combines all TENS programs for pain relief (chronic and acute).

Pelvic - combines all programs for pelvic floor treatment. Helpful for stress, urgency and mixed urinary and/or faecal incontinence.

Sport - combines all sports-related programs. Helps in stimulating healthy muscles to improve and facilitate muscle performance.

You start the Basing part of the exercise directly after choosing an exercise from the list.



5.2.9. Operating the application in Kiosk mode on a tablet

The tablet configured by **EGZO**Tech with the application in Kiosk mode has several additional functionalities that do not directly relate to the application. The information below will enable you to familiarize yourself with and efficiently use such a device.

5.2.9.1 Sound

The sound settings for the tablet can be changed using the physical buttons located on the top left side of the tablet. The button on the top increases the volume and the button on the bottom decreases it.

5.2.9.2. Screen lock

The tablet has the ability to lock the screen. Locking the screen blankens the screen and reduces battery consumption. To lock the screen, press and release the button located on the top right side of the device. Another press will wake up the device and allow you to continue working with the application.

5.2.9.3 Shutting down and restarting

To turn off or restart the tablet, press and hold the button on the top right side of the device until the window with the action selection appears. Then select the action "**Power off**" or "**Restart**" depending on the expected behavior. Once the tablet is switched off, it can be restarted by pressing and holding the same button.

6. Programs Overview

The information presented in this section applies to both the Stella BIO App and the EGZOClinic unless otherwise specified.

6.1. NEURO Concept

EMS programs:

- Muscle spasm relaxation
- EMS User Program - custom settings

EMS programs for denervated muscles (peripheral paralysis):

- Mild Atrophy
- Severe Atrophy

FES programs for incomplete central paralysis and to reduce muscle tone in spastic muscles:

- Grasp and release - gripping exercise
- Open and close - gripping exercise
- Hand to mouth - helpful to reeducate eating and drinking ADL's
- Arm extension/support - helpful to reeducate supported sitting and sit-->stand transfer

EMG-triggered FES programs :

- EMG-triggered Grasp and release
- EMG-triggered Open and close
- EMG-triggered Hand to mouth
- EMG-triggered Arm Extension/support
- Reactive EMG - EMS (1 channel)
- Reactive EMG - EMS (2 channels)

All EMG Biofeedback programs and games except the Glazer Protocol, lower back test and Sorensen test.

6.2. ORTHO Concept

EMS Programs:

- EMS User Program - custom settings
- Circulation improvement
- Atrophy

All EMG Biofeedback programs and games except the Glazer Protocol.

6.3. PAIN Concept

TENS programs:

- Conventional TENS
- Modulated TENS
- Acupuncture TENS
- TENS Burst
- TENS User Program - custom settings

6.4. PELVIC Concept

EMS Incontinence programs :

- Urge Incontinence
- Stress Incontinence
- Mixed Incontinence
- Faecal Incontinence
- Relaxation
- Relaxation +
- EMS Pelvic User Program

EMS-EMG - EMG-triggered electrical stimulation

- EMG - triggered EMS (1 channel) in urinary incontinence
- EMG - triggered EMS (1 channel) in incontinence

All EMG Biofeedback programs and games except the lower back test and Sorensen test.

6.5. SPORT Concept

EMS programs:

- Exercise Prep
- Active Recovery
- Endurance training
- Power training
- Strength training
- Agonist/Antagonist program
- Massage

All EMG Biofeedback programs and games except the Glazer protocol, lower back test and Sorensen test.

6.6. EMG Biofeedback Concepts (in Ortho, Neuro and Pelvic concepts)

Muscle activity assessment programs

- Glazer protocol (helpful in assessing pelvic floor muscle activity) *
- EMG View (helpful in assessing EMG activity of superficial muscles)
- Relaxation analysis (helpful in assessing the level of resting tension of the superficial muscles)
- Lower back pain test **
- Sorensen test ***

EMG Biofeedback exercises

- 5 s. Work - 5 s rest
- 10 s. Work - 10 s rest
- EMG Endurance training (30 s hold)
- Quick flicks (less than 5 s contraction)
- EMG Biofeedback (custom settings for contraction / relaxation time)

EMG Games (available on Stella BIO App only)

- Burger Mania
- Brick Pirates
- Slice and DIce

EMG Games (available on EGZOClinic only)

- Cosmic Mission

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* For the **Glazer** - the patient will have to perform 5 activities on voice commands:
    1. 60-second rest (pre-baseline).
    2. Five, 2-second (flick) contractions with a 2-second rest in-between.
    3. Five 10-second tonic contractions with a 10-second rest in-between.
    4. One 60-second endurance contraction.
    5. One 60-second rest (post-baseline).

The voice commands in the program will guide the patient through the exercise.

Lower Back Pain Test - Description:

1. The patient stands upright with arms along the torso.
2. At the sound signal, bend your body. At the next audible signal, return to the starting position.
3. The patient repeats the exercise 5 times.

***Sorensen Test** - Description:

1. The patient lies in a forward lying position with the torso lowered off the couch.
2. At an audible signal, the patient raises the trunk to a horizontal position with the hands interlocked behind the head.
3. The patient holds the position for 2 minutes or as long as they are able.

6.7. Typical use cases

Basic schemes of device use were defined on the basis of a device usability analysis.

1. The operator turns on the device by pressing the Multifunctional Button on its cover.
2. After logging in to the application on the control tablet (Specialist account), the operator creates a patient account or selects the patient from the patients available in the database.
3. The operator chooses an exercise or evaluation program for the patient.
4. The operator connects electrodes to the patient.
5. The patient performs the exercises.
6. The operator can generate a training report after finishing the training.

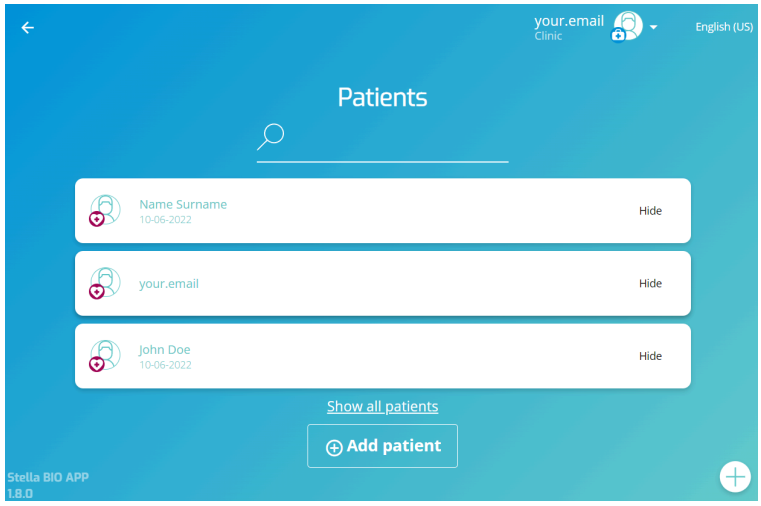
7. The operator unfastens the patient from the device.
8. After finishing the training, the operator turns off the device and cleans it.

7. How to perform trainings

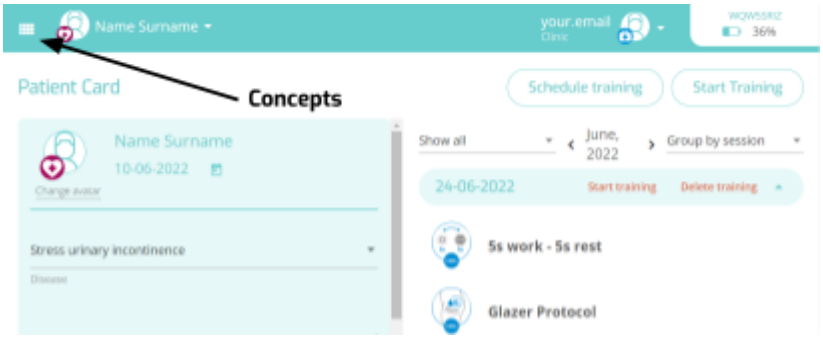
7.1. Stella BIO App

For each exercise the software will guide you through the program setup.

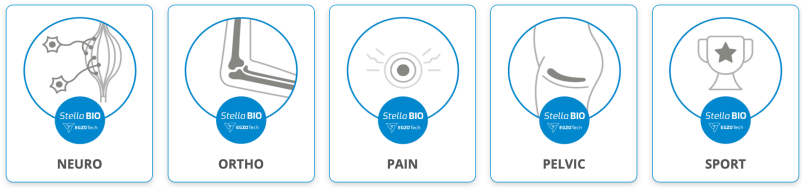
Step 1: On the Specialist account, select the patient from the list of your patients.



Step 2: In the Patient's chart, click on the  icon in the top left corner to go to the Concepts - exercise groups menu.

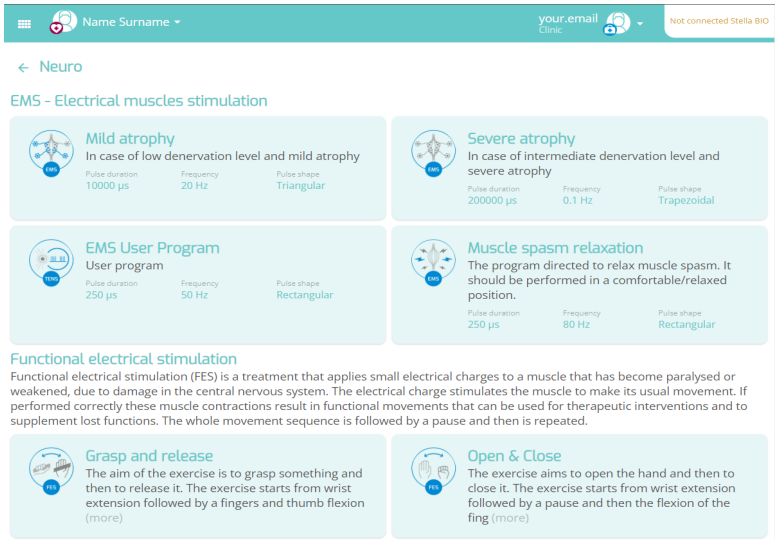


Step 3: Choose the Concept based on the goal of your treatment.



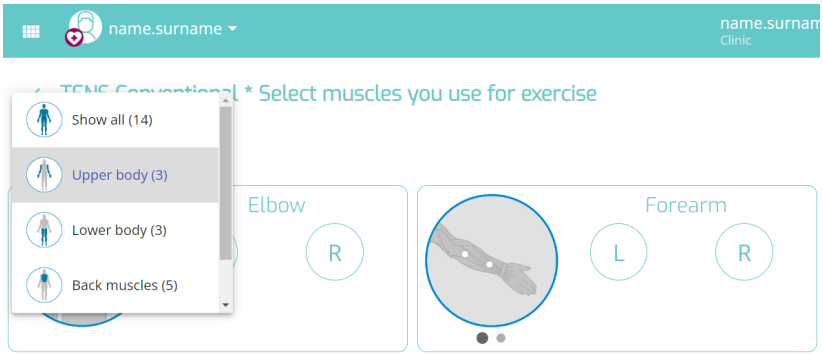
Step 4: Choose an exercise you want to perform.

See **6. Programs Overview** for the list of all available exercises. In each Concept the exercises will be organised in the groups: EMS, FES, TENS, EMG-triggered, EMG Biofeedback and/or EMG Games. You will find the description of each group and each exercise in the software.



Step 5: Select the muscle or body part you want to work on.

You can scroll down through the list of all available muscles or use Body parts filter to find the muscle group from the specific body part.

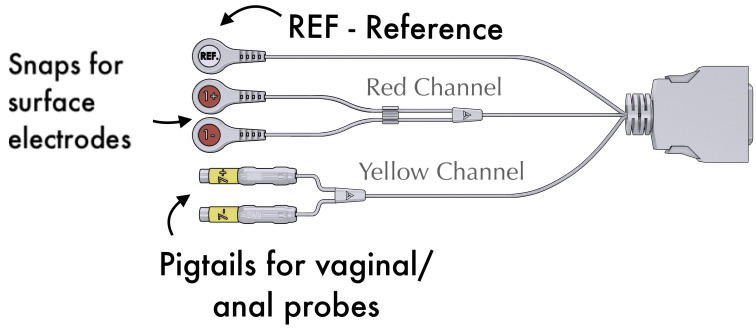


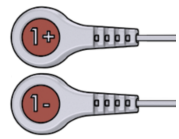
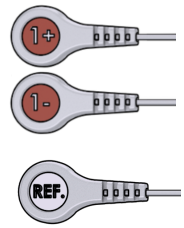
Step 6: Connect the electrodes to the lead wire channels.

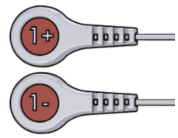
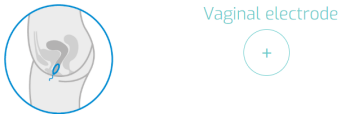
Next to an illustration of a particular body part is its name and two buttons indicating the side of the body (L for left, R for right), select the ones that correspond to the actual connection of the electrodes.

Following the illustration in the picture, attach the electrodes to the wires and then place them on the skin. Apply the Electrodes based on Electrode placement for the selected muscle or body part, displayed in the software. If the exercise allows it, you can work on multiple channels. Remember to connect one muscle to one channel. When the exercise requires it, use a reference electrode in your training.

Channel colours in the software correspond to the lead wire colours.



Icons used in the exercise	Instructions	Minimum number of channels
 Eg. for EMS exercises	Place the EMS Electrodes connected to the snaps with a "+" and "-" sign in the appropriate place as shown on the icon.	
 Eg. for EMG exercises	Place the EMG Electrodes connected to the snaps in the appropriate place as shown on the icon. You should connect the Reference electrode to the	

Icons used in the exercise	Instructions	Minimum number of channels
	white single lead wire with the REF sign if there is a grey electrode on the software icon.	
 Eg. for TENS exercises	Place Electrodes connected to the snaps in the appropriate place as shown on the icon. Black dots indicating one channel and white ones indicating the other channel.	
 Eg. for Pelvic exercises	Insert the appropriate probe and connect the probe's pigtail with the electrode cable numbered 7 and/or 8. Connect the plus pigtail with the plus pigtail plug, and the minus pigtail with the minus pigtail plug.	

For EMG Biofeedback programs and EMG Games use **EMG electrodes**. For EMS programs use **EMS electrodes**, and for Pelvic programs use **Probes**.

Use only electrodes authorised by **EGZO**Tech described in chapter **4.5. Accessories**. **Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns**. Electrode properties like dimensions, conductivity, impedance and connector types can greatly influence safety. **Never use ECG/EMG electrodes for the purpose of electrical stimulation.**

For more detailed instructions on electrode choice and electrodes placement see chapter **8.4. EMS Electrode placement and configurations** and chapter **9.4. EMG Electrode placement and configurations**.

Step 7: Confirm your choice.

After applying the electrodes, Confirm your choice by clicking the **"Confirm"** button in the top right corner.

Attention! In case of connection problems, the following message will appear in the top right corner "Electrodes are not connected properly. Check if cables are properly connected to electrodes or replace electrodes with new ones, because current ones can be dry."

Step 8: Setup parameters.

Adjust parameters during Calibration. The window with parameters setup will pop out.

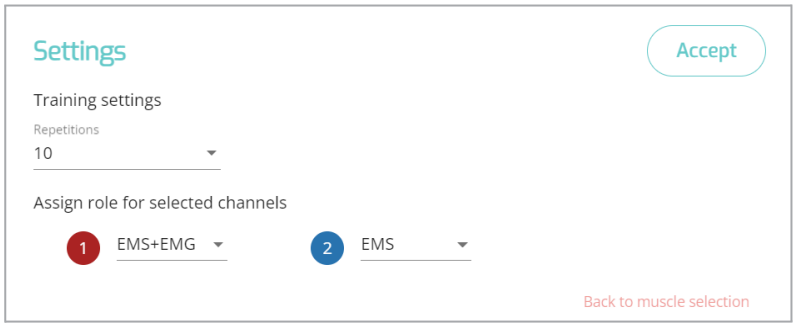
User settings for each program vary. See Chapter **11. Programs settings** to see what parameters you can adjust for each exercise.

In the EMG-triggered electrostimulation programs it is possible to change the channel that will act as an electrostimulation trigger. In the EMG-triggered exercise settings window a list of previously selected channels appears, along with information about the channel's behaviour during the exercise:

- EMS - the channel will be used for electrostimulation only,
- EMG - the channel will be used only to trigger electrostimulation (EMG measurement),

- EMS+EMG - the channel will be used to trigger electrostimulation (EMG measurement) and to perform electrostimulation,

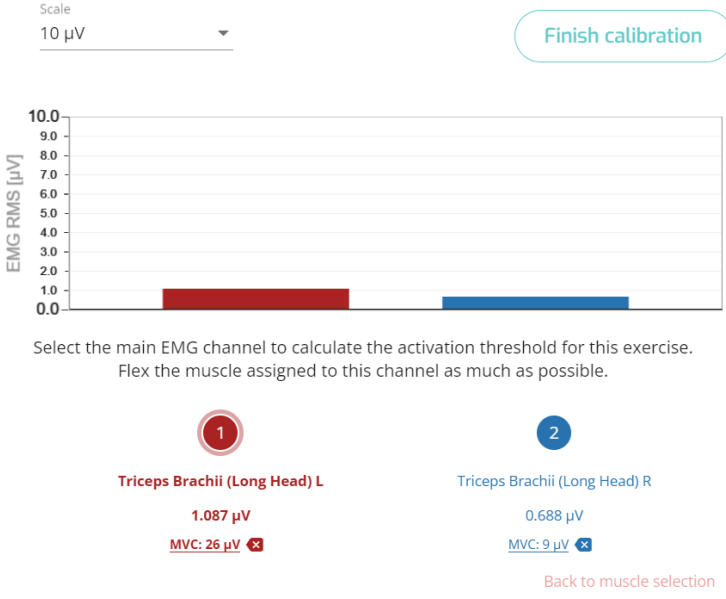
The EMG-triggered electrostimulation exercises must always have at least one electrostimulation trigger channel indicated.



Step 9: Device calibration.

Step 9a: In the EMG-triggered electrostimulation programs, EMG Biofeedback programs, EMG View with MVC and EMG Games, after setting the exercise parameters, it is necessary to calibrate the measurement range. In order to do this, generate a Maximal Voluntary Contraction (MVC) with the muscle(s) on which the electrodes are located.

If multiple channels are used in the exercise, the main EMG channel should be selected.

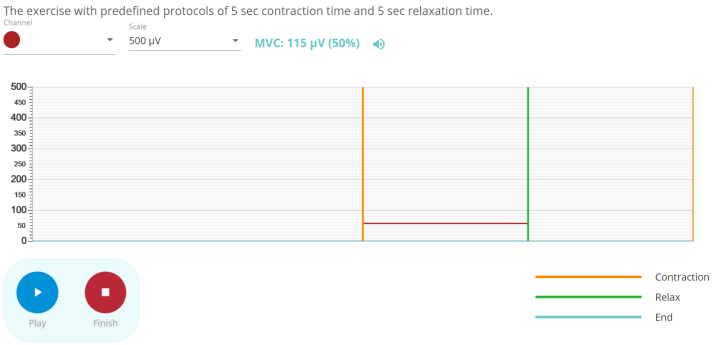


Step 9b: In programs that use electrostimulation, it is also necessary to calibrate the intensity of the flowing current according to the individual patient's feelings before starting the workout. Press +1 to increase the intensity and -1 to decrease the intensity by 1 mA.

Once the setup is done, press the "**Finish Calibration**" button.

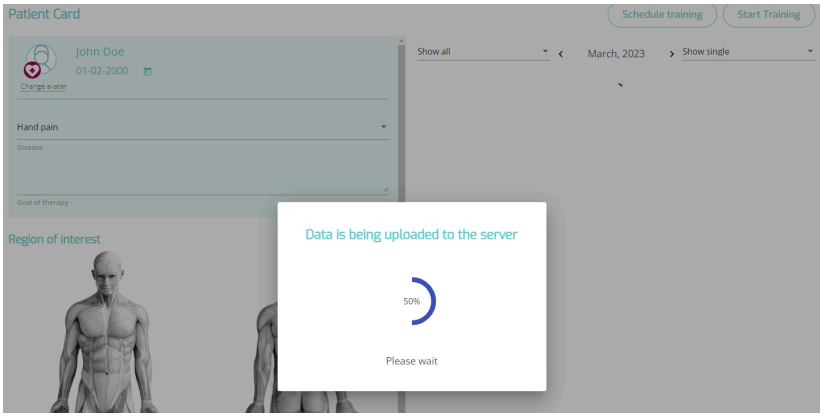
Step 10: Perform the training.

Press the "**Play**" button to begin your training. Treatment display views vary for the exercises. If you want to see the training windows for different programs, go to chapter **8.2. EMS Treatment windows** or **9.2. EMG Biofeedback and EMG Games treatment windows** for more detailed information.



Step 11: After training is done, disconnect the electrodes.

After the training, disconnect the electrodes and wait for the training report to load on the data server.



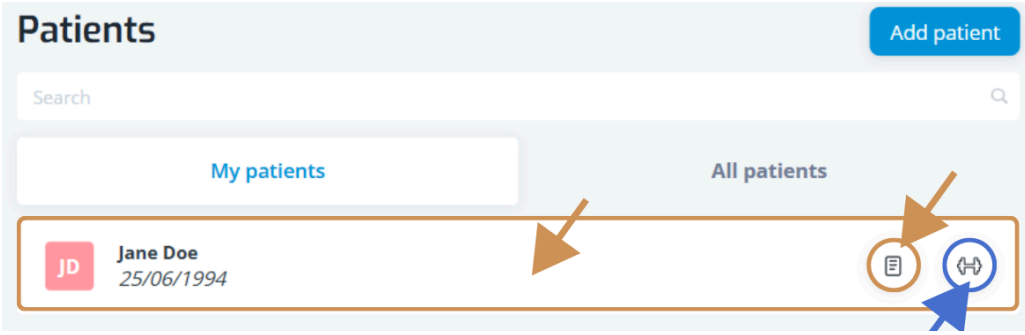
Step 12: Turn off the device and clean it.

See chapter **3.7. Finishing your work with Stella BIO** and chapter **12.6. Cleaning instructions.**

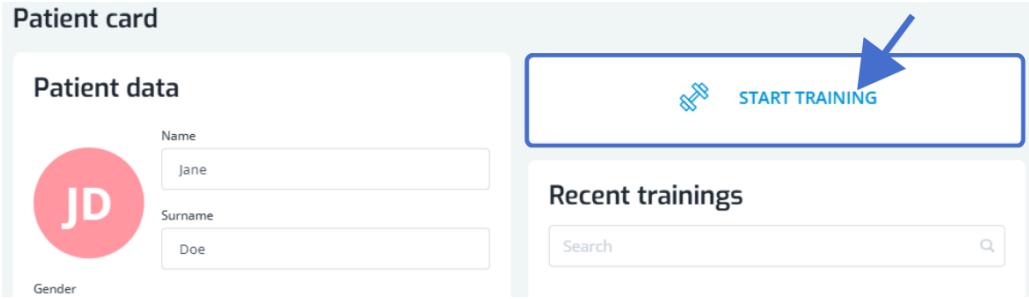
7.2. EGZOClinic

For each exercise the software will guide you through the program setup.

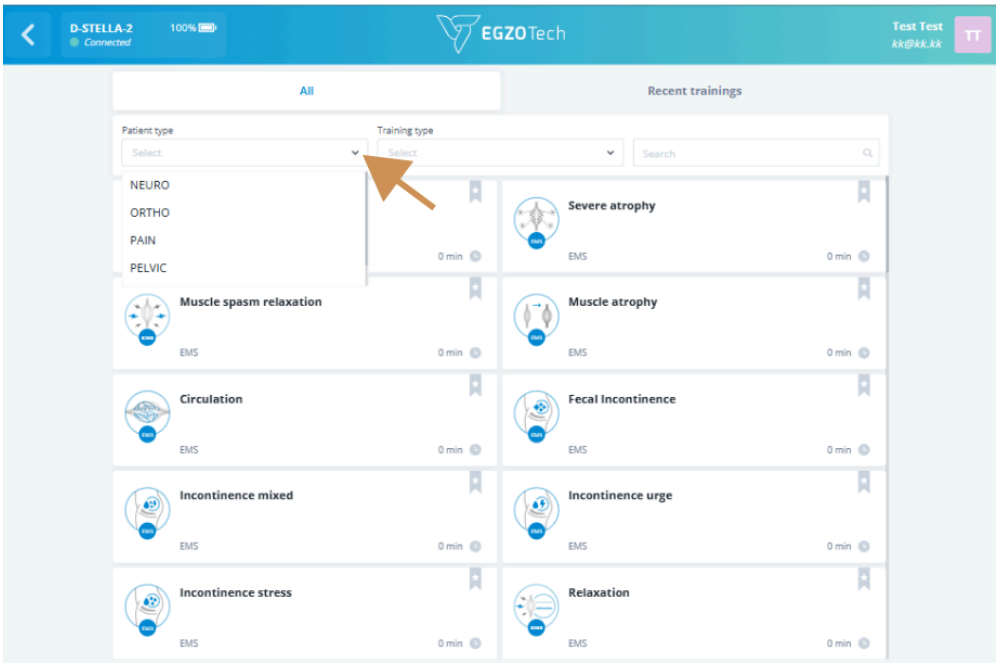
Step 1: The list of exercises can be accessed from the patient list by clicking the dumbbell icon in the tile with the chosen patient name.



You may also enter the chosen patient card by clicking on the tile or the note icon first, then click the "**Start training**" button.

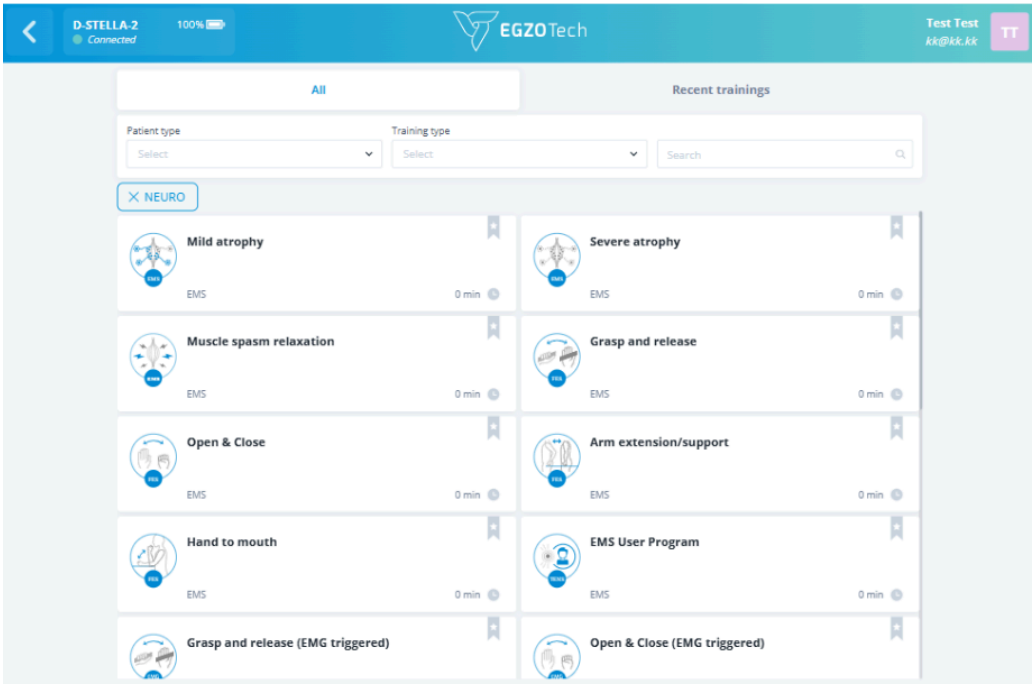


Step 2: You may filter the exercises by selecting the Concept for easier navigation or type the name of the exercise you are interested in in the search engine.

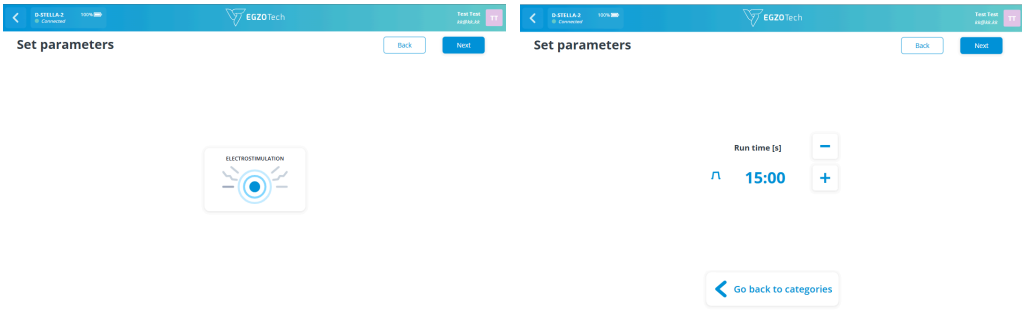


Step 3: Choose an exercise you would like to perform based on the goal of your treatment.

See **6. Programs Overview** for the list of all available exercises. Every exercise tile has its type written on the bottom: EMS, EMG+EMS, EMG and/or EMG Game.



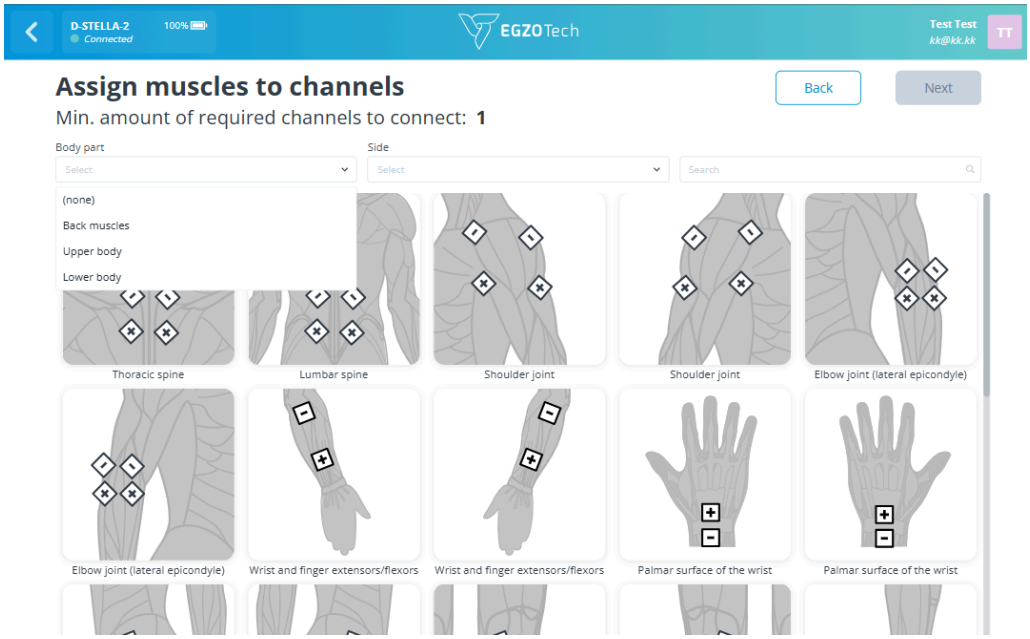
Step 4: After selecting the exercise, set up the available parameters.



Step 5: Select the muscle or body part you want to work on.

You can scroll down through the list of all available muscles or use Body parts filter to find the muscle group from the specific body part.

After selecting a muscle, the electrodes on the icon will light up with a specific channel's color.

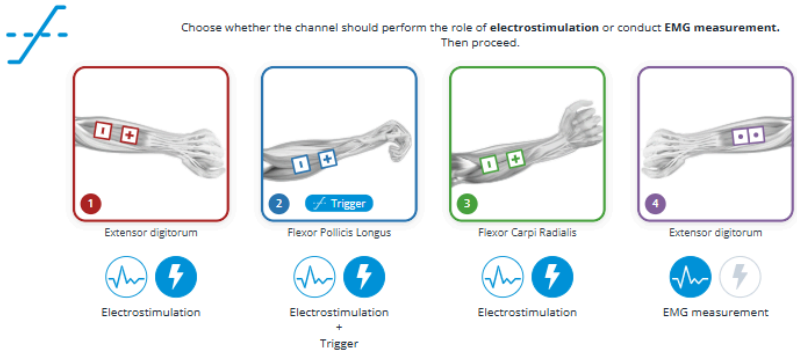


Step 6: Choose the channels functions and triggering channel.

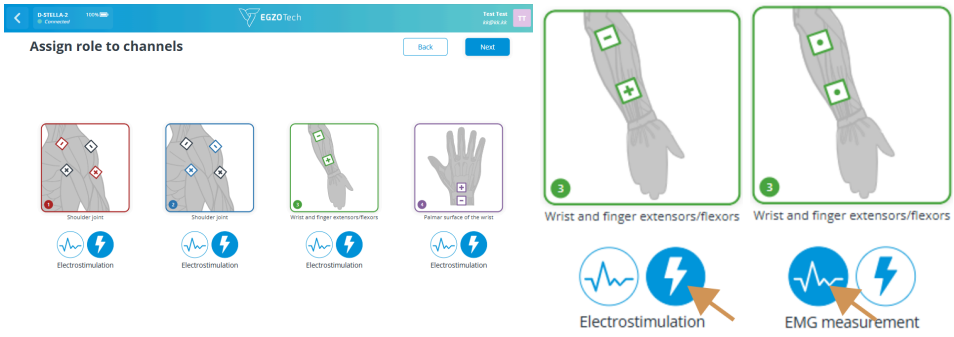
Step 6a: Triggering channel

If you have chosen an EMG+EMS exercise you will need to decide which channel will be the triggering one. You can leave it to be channel 1, but also you can change it by clicking on the other channels.

If needed the next channel provides the information which channel is the triggering one. You can always go back and change the triggering channel.



Step 6b: If you have selected an EMS or EMG+EMS exercise, you may choose the channels' function. Each channel can have an electrostimulation or EMG measurement function. You can change it by clicking the icons on the bottom.



There are exercises that let you set every channel to EMS function, and others that have a specific number of channels set to EMS function after entering this view.

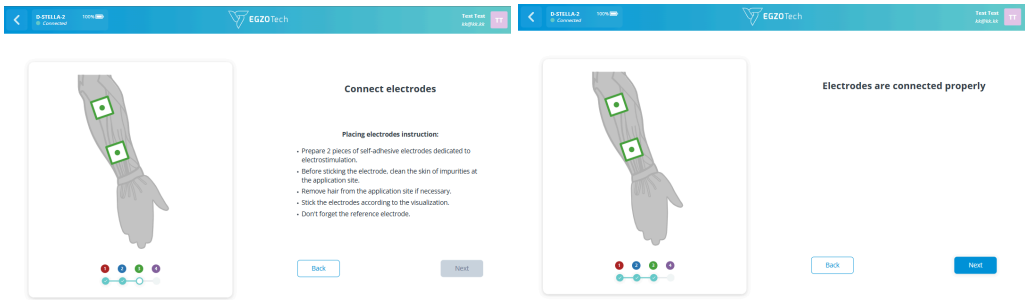
You can change the configuration of functions each channel has, but to proceed further, the number of channels set to EMS function needs to be the same as at the start.

The following configurations may occur:

Function icons	Description
 Electrostimulation	The channel will be used to perform electrostimulation.
 EMG measurement  EMG measurement	The channel will be used for EMG measurements only.
 Electrostimulation + Trigger	The channel will be used to trigger electrostimulation (EMG measurement) and to perform electrostimulation.
 EMG measurement + Trigger	The channel will be used to trigger electrostimulation and for EMG measurements.

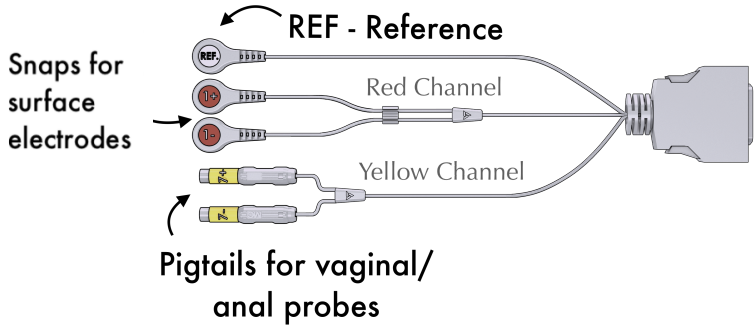
Step 7: Connect the electrodes to the lead wire channels.

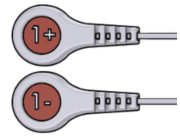
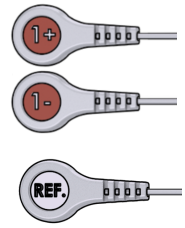
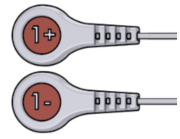
Following the illustration in the picture, attach the electrodes to the wires and then place them on the skin. Remember to connect one muscle to one channel. When the exercise requires it, use a reference electrode in your training.

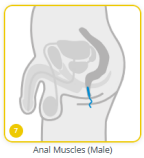


Next to an illustration of a particular body part is an instruction on how to connect the electrodes, or how to better the connection, if the signal is weak.

Channel colours in the software correspond to the lead wire colours.



Icons used in the exercise	Instructions	Minimum number of channels
 Eg. for EMS exercises	Place the EMS Electrodes connected to the snaps with a "+" and "-" sign in the appropriate place as shown on the icon.	
 Eg. for EMG exercises	Place the EMG Electrodes connected to the snaps in the appropriate place as shown on the icon. You should connect the Reference electrode to the white single lead wire with the REF sign if there is a grey electrode on the software icon.	
 Eg. for TENS exercises	Place Electrodes connected to the snaps in the appropriate place as shown on the icon. Black dots indicating one channel and white ones indicating the other channel.	

Icons used in the exercise	Instructions	Minimum number of channels
 Eg. for Pelvic exercises	Insert the appropriate probe and connect the probe's pigtails with the electrode cable numbered 7 and/or 8. Connect the plus pigtail with the plus pigtail plug, and the minus pigtail with the minus pigtail plug.	

For EMG Biofeedback programs and EMG Games use **EMG electrodes**. For EMS programs use **EMS electrodes**, and for Pelvic programs use **Probes**.

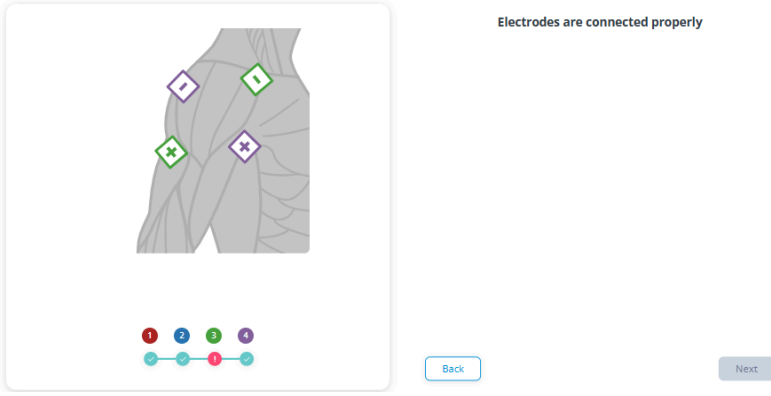
Use only electrodes authorised by **EGZO**Tech described in chapter **4.5. Accessories. Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.** Electrode properties like dimensions, conductivity, impedance and connector types can greatly influence safety. **Never use ECG/EMG electrodes for the purpose of electrical stimulation.**

For more detailed instructions on electrode choice and electrodes placement see chapter **8.4. EMS Electrode placement and configurations** and chapter **9.4. EMG Electrode placement and configurations.**

Step 8: Proceeding further.

After you have placed the electrodes and all of them have good connection, you may proceed further by clicking the "**Next**" button.

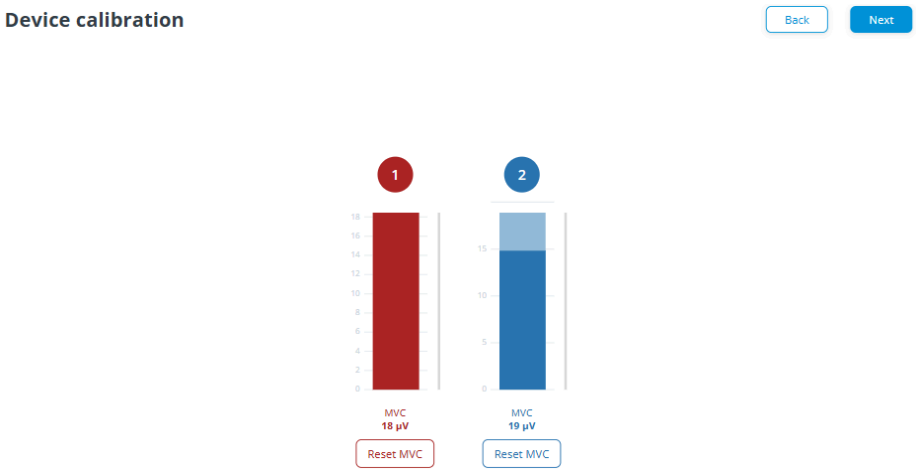
If any electrode disconnects during this or next steps, you will be returned to Step 7.



Step 9: Device calibration.

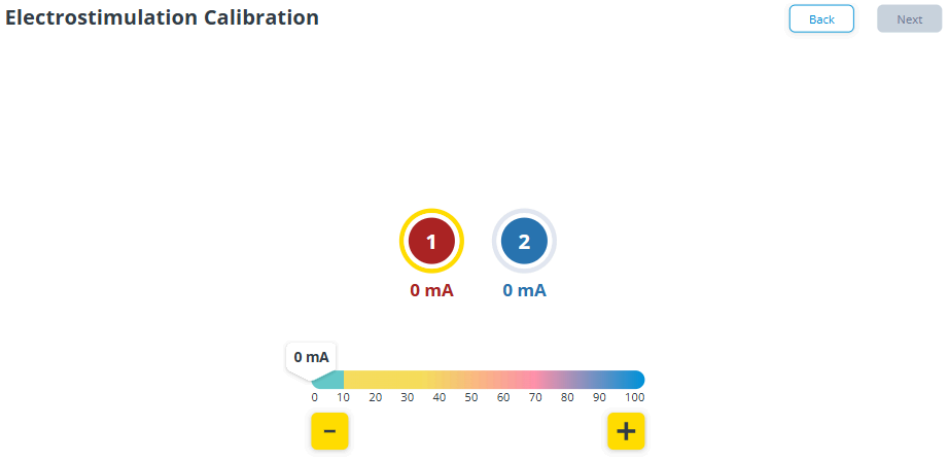
Step 9a: EMG Calibration.

In every exercise EMG+EMS and EMG type (excluding the EMG view exercise), it is necessary to calibrate the measurement range. In order to do this, generate a Maximal Voluntary Contraction (MVC) with the muscle(s) on which the electrodes are located.



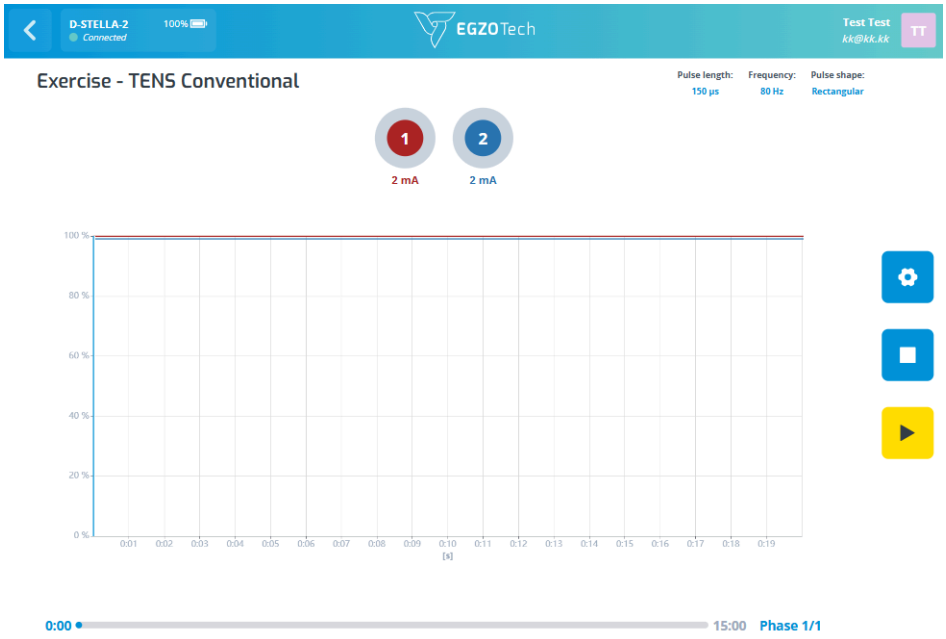
Step 9b: EMS Calibration.

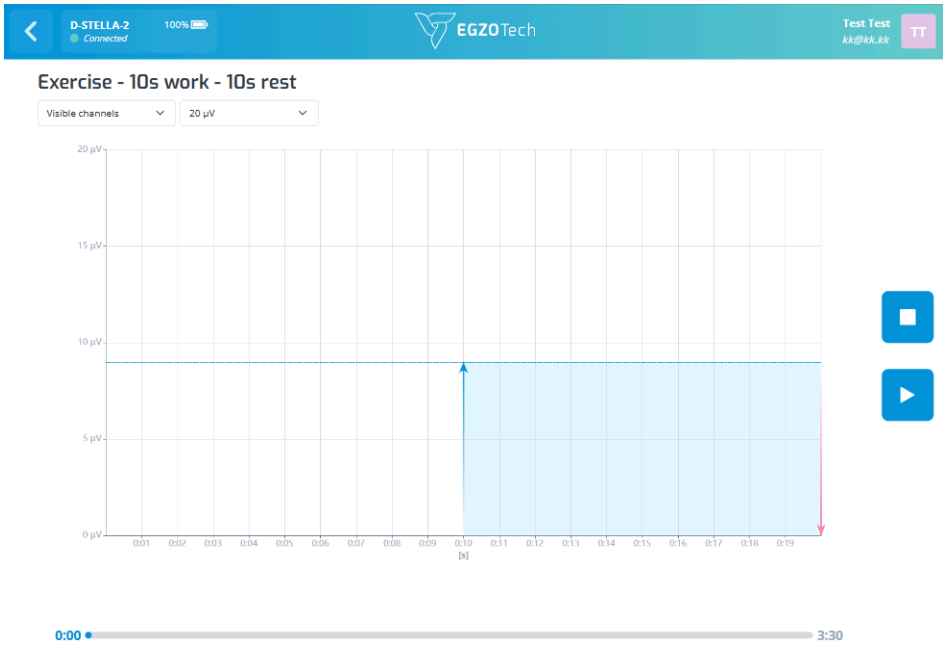
In programs that use electrostimulation, it is also necessary to calibrate the intensity of the flowing current according to the individual patient's feelings before starting the workout. Press +1 to increase the intensity and -1 to decrease the intensity by 1 mA.



Step 10: Perform the training.

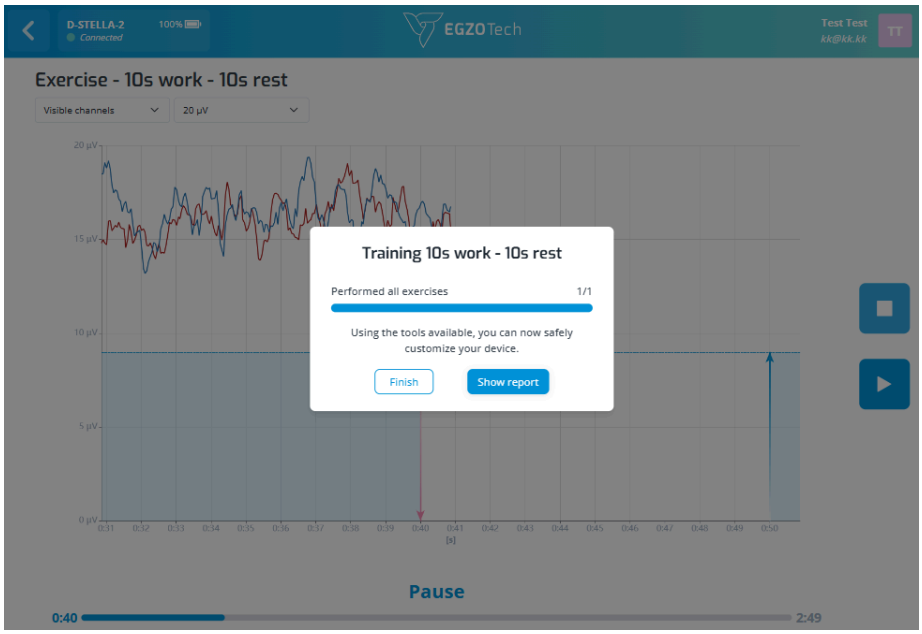
Press the "**Play**" button to begin your training. Treatment display views vary for the exercises. If you want to see the training windows for different programs, go to chapter **8.2. EMS Treatment windows** or **9.2. EMG Biofeedback and EMG Games treatment windows** for more detailed information.





Step 11: After training is done, disconnect the electrodes.

After you finish the training, wait for the closing window to appear and disconnect the electrodes. You may now open the report or return to the patient card.



Step 12: Turn off the device and clean it.

See chapter **3.7. Finishing your work with Stella BIO** and chapter **12.6. Cleaning instructions.**

8. Electrical Stimulation

8.1. Basics of electrical stimulation

Electrical stimulation should **only be used after training from a healthcare professional. Always consult your physician** before using electrical stimulation, to choose the right output parameters and program for you.

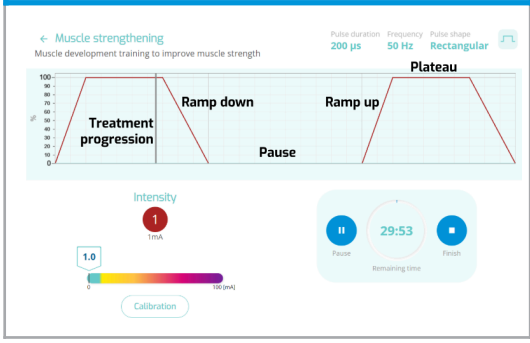
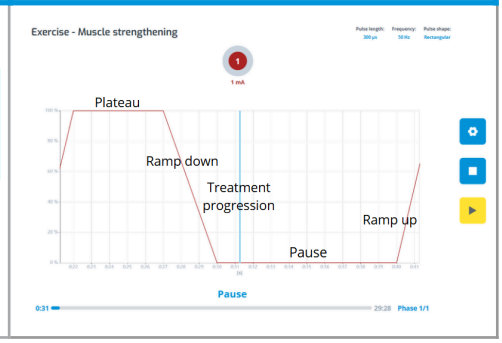
Electrical stimulation uses electrical pulses to mimic the action of signals coming from the nervous system.

Electrical stimulation programs in Stella BIO are:

- **EMS programs** in **Ortho, Neuro, Pelvic and Sport Concepts** - EMS programs enable electrical stimulation of the motor neurons and muscles.
- **FES programs** in the **Neuro** Concepts - enable functional muscle stimulation based on preset programs to facilitate Activities of Daily Living.
- **EMG-triggered EMS** and **EMG-triggered FES programs** - in **Neuro Concepts** involve initiating a voluntary contraction for a specific movement until the muscle activity reaches a pre-set threshold level, and then an assisting electrical stimulus begins.
- **EMS and EMG- triggered EMS Incontinence programs** - in **Pelvic Concepts** - enables electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence and/or faecal incontinence.
- **EMS Relaxation and Relaxation +** - in **Pelvic Concepts** category - enables electrical stimulation to relax excessively tense pelvic floor muscles.
- **TENS programs** - in **Pain Concepts** - Transcutaneous Electrical Nerve Stimulation programs (TENS) enable the sensory muscles stimulation to modify pain perception of the patient.

8.2. EMS Treatment windows

EMS, TENS and EMS Incontinence Programs treatment window

Stella BIO App	EGZOClinic
	

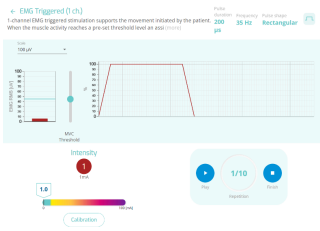
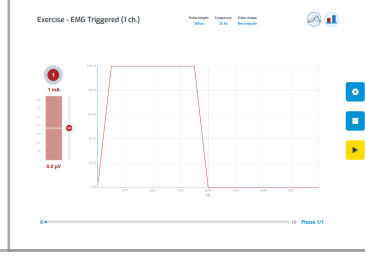
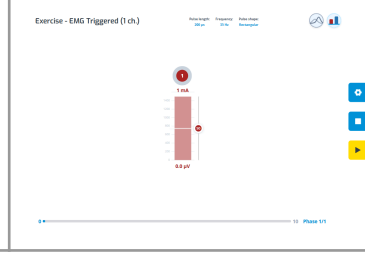
You will see the line chart with exercise phases (ramp up, down and plateau time) and pulse settings. The line with exercise progression will move during treatment to allow you to see where you are. You will be able to adjust intensity, pause or stop the program.

FES programs treatment window

Stella BIO App	EGZOClinic
	

You will see a line chart that will guide you when stimulation begins for each muscle in a sequential manner to facilitate functional tasks such as for example wrist extension followed by fingers flexion to promote object gripping.

EMG-triggered Programs treatment window

Stella BIO App	EGZOClinic - default view	EGZOClinic - simplified view
		

In addition to muscle stimulation parameters you will see your muscle activity on the EMG bar chart. Once you reach the set MVC (Maximal Voluntary Contraction) threshold, the electrical stimulation will begin.

8.3. Lead wires and channels for EMS

For electrical stimulation you should use two outputs from one channel - positive "+" and negative "-" corresponding to 2 lead wire snaps of the same colour.

8.4. EMS Electrode placement and configurations

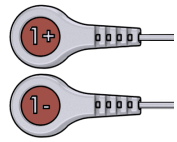
Electrical stimulation provides muscle contraction by conducting an electric current through the muscle fibres of the targeted muscle. In Stella BIO, a two-electrode electrical stimulation is used. The method involves placing two, equal-size electrodes on the skin in places corresponding to the transition of the muscle to the tendon. This method is usually used in the case of electrostimulation of denervated muscles. The two-electrode electro stimulation method can also be used with good results in stimulating healthy or slightly damaged muscles to contract.

Use only electrodes authorised by **EGZO**Tech described in chapter **4.5. Accessories**. **Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.** Electrode properties like dimensions, conductivity, impedance and connector types can greatly influence safety. **Never use ECG/EMG electrodes for the purpose of electrical stimulation.**

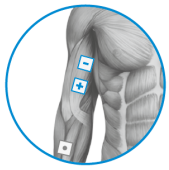
Bipolar electrode placement, two stimulation electrodes are placed to affect the target area. In this way, the current flow through tissue is more limited to the excitable tissue of interest. **Do not exceed an intensity of 0.1 W/cm^2. Follow these steps to maximise reliability, safety and accuracy of output parameters for your electrical stimulation.**

8.4.1. EMS Programs - Electrode Arrangement:

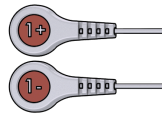
1. Make sure the electrical stimulation is off and Stella BIO LEDs do not indicate any abnormalities or program operation. before proceeding.
2. Select an electrical stimulation electrode size according to the width of the stimulated muscle. Use larger electrodes for wider muscles and smaller electrodes for thinner muscles.
3. Connect the self-adhesive electrodes to the lead wires snaps of the same colour.
4. Remove the protective liner from the electrode. Save the liner.
5. Skin must always be clean, dry and free from lotion. Do not apply to injured skin.
6. Place the negative (-) electrode on the proximal end of the muscle. Apply the electrode securely to the skin. Apply centre first, then smooth down to electrode edges.
7. Place the positive (+) electrode on the distal end of the same muscle. The distance between the electrodes should be minimum 1 cm.



8.4.2. EMG - Electrode Arrangement for EMG-triggered EMS Programs



Follow **8.4.1. EMS Programs - Electrode Arrangement** to connect surface EMS electrodes (marked blue) to one channel.

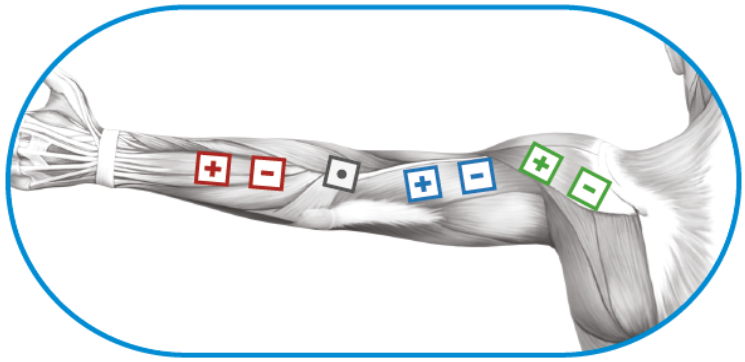


Place third, Reference EMS electrode (marked grey) connected to the white lead wire snap with REF sign. The reference electrode must also be attached to the extremity that is the object of therapy, near the bony landmark.

8.4.3. FES Programs - Electrode Arrangement

1. For FES you will need more than one channel. One muscle group should be connected to one channel. Electrodes marked in different colours will guide you on what channel to connect to the given muscle group. Grey electrode is for the Reference electrode used only in the EMG-triggered FES programs. Use the white lead wire with the REF sign to connect the Reference electrode if presented on the icon.

2. Follow the EMS electrodes application guidelines from **8.4.1. EMS Programs - Electrode Arrangement** to connect 2 surface EMS electrodes (marked in different colours) to one channel.



8.4.4. EMS Incontinence Programs - Probe Arrangement

For the **Stress, Urge and Mixed incontinence, Relaxation /Relaxation + Programs** apply the vaginal electrodes for Female and rectal electrodes for Male. For the **Faecal Incontinence Program** apply Anal electrode.

Vaginal probe

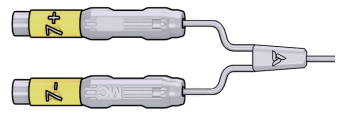
Anal probe

(Female)

Anal probe

(Male)

1. Connect the probes to the lead wire with a straight, pigtail ending (yellow or orange channel).
2. Apply the probe into the vagina or anus (depending on the exercise) with a small amount of lubricant.

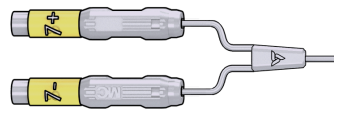


3. Always use **EGZO**Tech approved probes listed in the **4.5. Accessories**. **Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.**

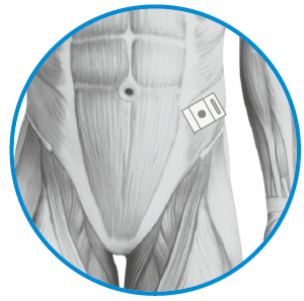
8.4.5. EMG-triggered EMS Incontinence Programs - Probe Arrangement

- **Incontinence (EMG-triggered)**
- **Faecal incontinence (EMG-triggered)**

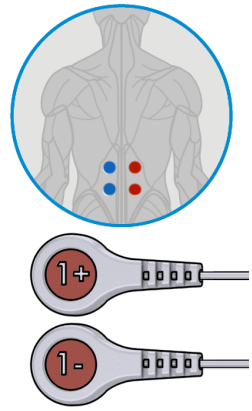
1. For the EMG-triggered EMS incontinence programs in order to apply either vaginal or anal probe follow the application instructions described in Chapter **8.4.4. EMS Incontinence Programs - Probe Arrangement**.



2. Apply third EMG surface electrode - Reference Electrode connected to the white snap of the wire with the REF mark near the nearest bony point (e.g., anterior superior iliac spike).



8.4.6. TENS Programs - Electrode Arrangement



1. Make sure the electrical stimulation is off and Stella BIO LEDs do not indicate any abnormalities or program operation before proceeding.
2. Select an electrical stimulation electrode size according to the area of pain. Use larger electrodes for wider body parts.
3. Remove the protective liner from the electrode. Secure the liner.
4. Connect the self-adhesive electrodes to the snap lead wires of the same colour for 1 channel.
5. Connect the electrical stimulation surface electrodes to the lead wires before you connect them to the patient's skin.
6. Skin must always be clean, dry and free from lotion. Do not apply to injured skin.
7. Place Self-adhesive electrodes on the skin near the area of pain.

8.5. Electrical stimulation modes

This type of mode enables electrical stimulation based on preset programs.

Parameter	Description	Clinical relevance
Type of current	Direct current is at most basic level continuous and flows in only one direction. Alternating is a current that passes in one direction and then another. Pulse current is the current (direct or alternating) in which there is a gap between successive pulses.	Direct current is used for iontophoresis. The alternating current is used mainly for innervated muscle contraction and sensory stimulation, and the pulses are joined and continuous. However from the point of view of nerve excitation, the direct/alternating current is irrelevant. The pulse current is distinguished from the alternating current because the pulses are separated. This means less energy may be delivered to the tissue when using this type of current.
Current amplitude	Magnitude of current with reference to the zero-current baseline at any one moment. It can be referred to as the intensity of stimulation.	Increasing current amplitude will increase the amount of one delivered to the tissues under the electrode. It contributes to the sensory or motor response the electrical current produces. The current amplitude is one of the determinants of torque production when using neuromuscular electrical stimulation. Increasing the current amplitude increases the percentage of muscle activated; increasing the current amplitude results in a proportional increase in the torque produced and the size of the activated cross-sectional area of stimulated muscle.
Current polarity	Monophasic pulse: the charged particles move in only one direction. Biphasic pulse: charged particles move in one direction and then in the opposite direction.	If the current is polar, physiological effects will include alterations in the cell membrane permeability, causing different responses under positive (anode) and negative (cathode) electrodes. For example, a marked hyperemia is usually expected under the cathode and a decreased nerve excitability is expected under the anode.
Pulse duration	The elapsed time between the beginning and end of all phases in a single pulse; on a clinical stimulator is often incorrectly labelled "pulse width".	The greater the pulse duration, the greater the skin impedance and the greater the patient's discomfort. Increasing pulse duration has been shown to increase the charge of the pulse and motor unit recruitment. Alternating the pulse duration is dependent on the patient's comfort and desired therapeutic effect. However, pulses with too short duration are inefficient.
Pulse frequency (F)	The number of pulse cycles generated per unit of time for pulse current.	Frequency of the pulses has been studied extensively because of its important role in determining the torque development and controlling muscle fatigue. Increasing frequency results in a sigmoidal increase in torque production but concurrently accelerates muscle fatigue.
Waveform shape (shape	Geometric shape of the pulse as it appears on the graph of current (or voltage) versus time	Little clinical research has examined the clinical effect of using different pulse shapes. Previous studies showed that there were individual

Parameter	Description	Clinical relevance
rectangular, square, triangular, sawtooth or spike)		differences in preferences for three different waveforms of sinusoidal, sawtooth and square symmetric biphasic waveform and no particular waveform that was either the least or most comfortable to the patient during neuromuscular electrical stimulation.
Stimulation mode (when more than one channel)	Reciprocal, asynchronous or sequential	Channels operate in a simultaneous or alternating fashion, per set duty cycle. In sequential stimulation, multiple stimulation channels are used (usually, to separately activate multiple synergist muscles), thereby allowing motor units to rest when the corresponding stimulation channel is not active. Asynchronous stimulation also uses multiple stimulation channels. However, the stimulus pulses are delivered in an interleaved manner so that lower stimulation frequencies are achieved at each stimulation frequency is achieved at each stimulation channel while retaining a high composite stimulation frequency.

Medium-frequency alternating current parameters		
Carrier frequency	Frequency of underlying alternating current waveform in the burst	Medium frequencies are used to diminish the impedance offered by the skin and subcutaneous tissues, turning the current more comfortable to the patient. Thus, by diminishing skin impedance, the discomfort normally incurred by traditional low-frequency current is reduced.
Burst	The generation of 2 or more consecutive pulse or cycles separated (by burst interval) from the next series of consecutive pulse or cycles	The burst duration has a role in torque production, discomfort and fatigue.
Burst frequency or modulation	Frequency at which bursts are generated.	This parameter focuses on the fatigue possibilities of muscles if the frequency is high (> 50 or 60 Hz). In low frequencies we have good recruitment of nervous fibres (between 20 and 50 Hz), and in very low frequencies (2-10 Hz) the nervous fibre relaxes the muscle fibres.
Burst duty cycle	Burst duty cycle of medium-frequency alternating current, expressed as a percentage, can be defined as the ratio of the burst duration to the total time of the cycle.	Burst duty cycle, similarly to burst duration, has an impact on torque production, discomfort, and fatigue.

9. Electromyography and EMG Biofeedback

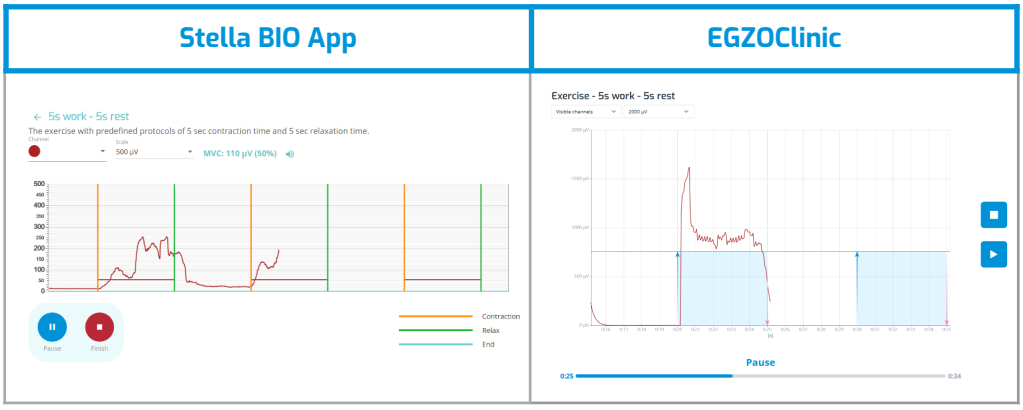
9.1. Basics of electromyography

Electromyography is an electrodiagnostic medicine technique for evaluating and recording the electrical activity produced by skeletal muscles. The signal originates from the depolarisation of the motor units and muscle fibres by the action potentials (signals generated in our motor cortex, going through the spinal cord and into skeletal muscles). The more motor units get activated simultaneously during muscle contraction, the higher the amplitude of EMG RMS signal.

9.2. EMG Biofeedback and EMG Games treatment windows

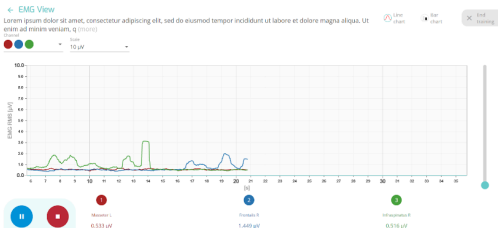
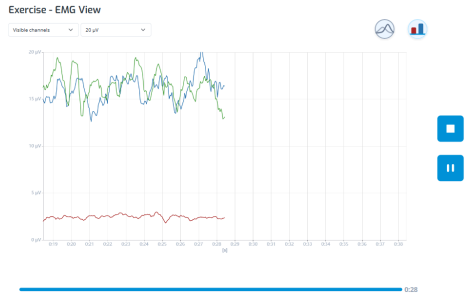
EMG Biofeedback - treatment window

The View for 5:5, 10:10, Quick flicks, Endurance, EMG Biofeedback, Glazer Protocol. Contract the muscle, when you hear “Contract” and relax your muscle when you hear “Relax”.



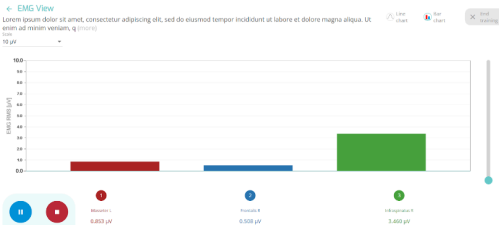
EMG View, EMG View with MVC, Relaxation Analysis - treatment window

When the start button is pressed, an EMG readout is started, which can be paused at any time with the pause button; this way of conducting the training gives the opportunity to take measurements only from the moments of interest of the therapist.

Stella BIO App	EGZOClinic
	

Appearance of the treatment window in the variant with a line chart for EMG Preview, Relaxation Analysis exercises

You can also convert the graphical preview into a bar chart using the button in the top right corner of the screen.

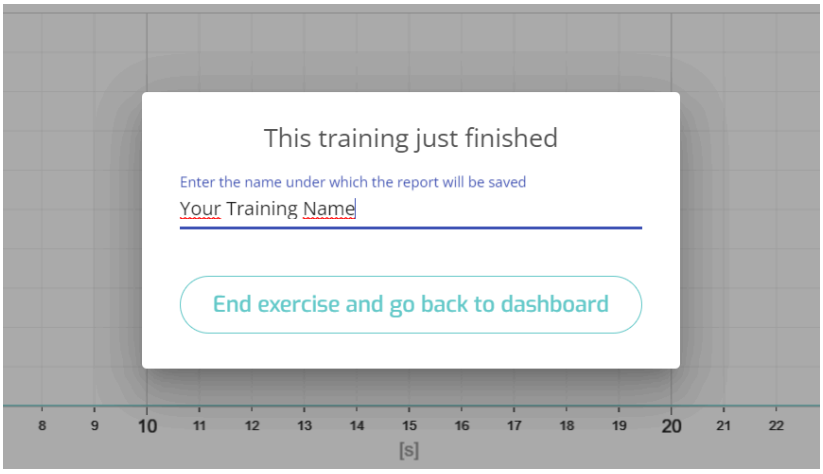
Stella BIO App	EGZOClinic
	

Appearance of the treatment window in the bar chart variant for EMG Preview, Relaxation Analysis exercises

In the case of the EMG View with MVC exercise, additionally you can change the scale of the graph between the unit in µV and the unit % MVC showing the current % of the MVC value determined in the calibration process described in **7. How to perform trainings** step 10a.

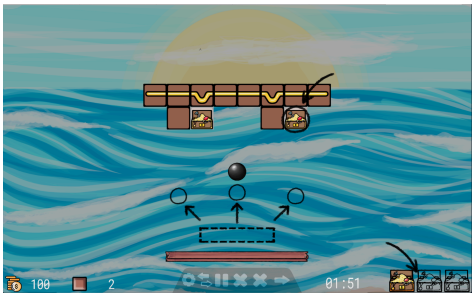
For the EMG View with MVC exercise, you can also change the plot unit

In Stella BIO App software, once you have completed your training, a window will appear in which you can name it.



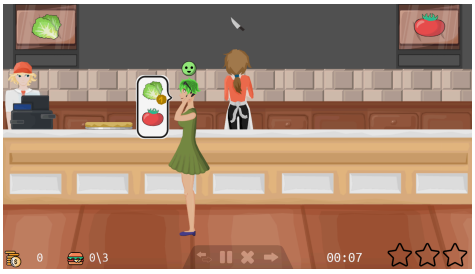
EMG Games - treatment window

Brick Pirates - Exclusive for Stella BIO App



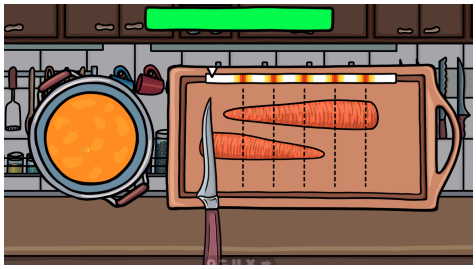
Brick Pirates Game - Contract your Pelvic Floor Muscles to move the ball bat to the right, relax to move it to the left and try to launch the ball in the direction of the bricks. The Goal is to break the bricks and collect gold.

Burger Mania - Exclusive for Stella BIO App



Burger Mania - contract your pelvic floor muscles to keep the avatar in one place and grab the ingredients needed to fry the hamburgers. The goal of the game is to make as many burgers as possible in the shortest possible time.

Slice and Dice - Exclusive for Stella BIO App



Slice and Dice - control the movement of the knife by contracting and relaxing the pelvic floor muscles. The muscles have to stay relaxed on dash-dotted lines and maximally contracted in cutting mode. The goal of the game is to cut as many vegetables as possible in the shortest possible time to prepare a soup.

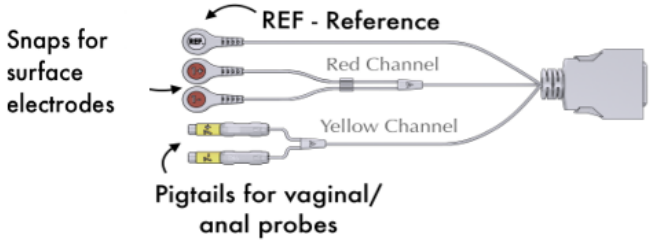
Cosmic Mission - Exclusive for EGZOClinic

Cosmic Mission - control the movement of the spaceship by contracting and relaxing the muscle. Contraction of the muscle makes the ship fly higher, while relaxing leads it lower. Maneuver the flight trajectory to stay on the line and avoid the asteroids. The alien opponents can be turned on and off, depending on how difficult you want the level to be. The goal of the game is to get as many points as possible by staying on the line.

9.3. Lead wires and channels for EMG

For Electromyography it's essential to connect both positive and negative inputs of one channel to the same muscle.

For each EMG program (whether diagnostic or therapeutic) you will need at least 3 connected electrodes (2 of the same colour, connected to one channel and one white Reference electrode).



The reference electrode can be connected to any part of the skin surface that is not under diagnosis or is not a part of the training routine, near the bony landmark. The closer the reference electrode will be to the measured channel, the less electromagnetic interference there will be.

Electromyography and electromyography biofeedback can be safely used by any user - patient or therapist alike.

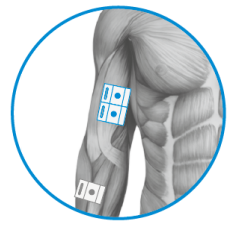
9.4. EMG Electrode arrangement and configurations

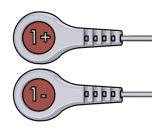
Because electromyography is connected to motor unit action potentials and the depolarisation of muscle fibres, there are multiple factors that influence the reliability of the EMG signal acquisition, including:

- Electrode specific factors:
  - Area and shape of the electrode detection surfaces, which in turn determines the number of active motor units and innervated muscle fibres – same type of electrodes should be used to compare different results,
  - Distance between the electrodes that determines the bandwidth of the differential electrode configuration – should be constant for each measurement,
- Location of the electrode with respect to the motor points determines the amplitude and frequency characteristics as well as comparability between a series of measurements. The further from the motor point, the more the amplitude decreases,
- Crosstalk with other muscles due to close proximity of the electrode positions – electrodes should be placed in the middle of the belly and away from the lateral edge. With smaller muscles, crosstalk should be taken into consideration during result interpretation,
- Orientation of the bipolar configuration of the electrodes with respect to the muscle fibres – affecting measured conduction velocity, amplitude and frequency of action potentials (depolarisation of muscles).

Follow these steps to maximise reliability, sensitivity and accuracy of your electromyography measurements.

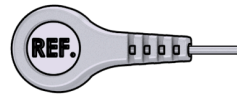
9.4.1. EMG Biofeedback and EMG Games - Electrodes Arrangement for the Surface muscles:





1. Remove hair from the patient's skin in the application area, when necessary.
   Clean with appropriate cleaning and disinfecting agents.
2. Always use **EGZO**Tech approved electrodes, listed in this User Manual, as electrode properties like gel type, conductivity, snap dimensions can greatly influence measurements.

3. Connect the EMG/ECG surface electrodes to the lead wires **before** you connect them to the patient's skin.
4. Select a muscle you want to measure according to the electrode placement demonstrated in the software for the selected exercise.
5. Place the first electrode on the centre of the muscle - muscle belly (neuromuscular junctions are located in the centre of the belly).
6. Place the second electrode adjacent to the first electrode, along the muscle fibres, so that the distance between the electrodes can be repeated.
7. Place **Reference Electrode (marked grey)** with the White lead wire ending and REF sign to the skin that is not under diagnosis.



8. Place electrodes on to dry and cleaned skin, according to the muscle placement and muscle atlas presented in the following chapters.
9. Don't use electrical stimulation (EMS) electrodes for electromyography (EMG), as the results will vary.

9.4.2. EMG Biofeedback and EMG Games - Probes Arrangement for the Pelvic Floor muscles:

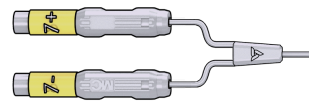
For the EMG Biofeedback Programs and EMG Games you will need the vaginal or anal probe and Surface EMG Reference electrode.

Vaginal probe

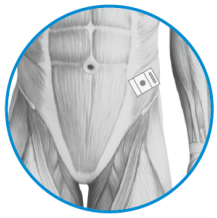
Aanal probe (Female)

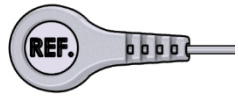
Anal probe (Male)

1. Connect the probes to the lead wire (use yellow or orange lead wire colours to connect the probes)
2. Apply the probe into the vagina or anus (depending depending on the exercise) with a small amount of lubricant.



3. Always use **EGZO**Tech approved probes described in **4.5. Accessories**. **Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.**



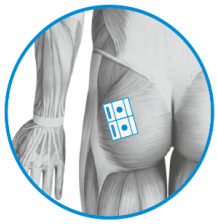


4. Apply third EMG surface electrode - Reference Electrode connected to the white snap of the wire with the REF mark near the nearest bony point (e.g., anterior superior iliac spike).

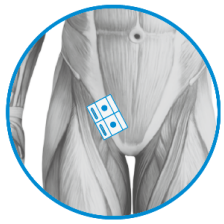
Additional EMG electrodes placement - Additional muscles

To evaluate if your patient is correctly using the accessory, abdominal muscles (i.e. Transverse Abdominal) during pelvic floor muscle contraction and is not compensating the pelvic floor muscles with the glutes or adductors, use Glazer protocol training.

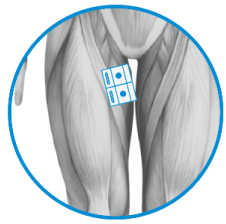
Connect EMG not only to the pelvic floor muscles as demonstrated above (vaginal probe and reference electrode near the ASIS) but also to the accessory muscles. Apply EMG electrodes next to each other as shown on the pictures below.



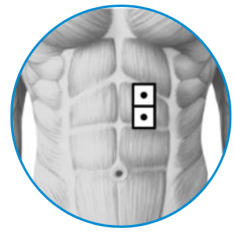
Gluteus Maximus



Transverse Abdominal



Adductors

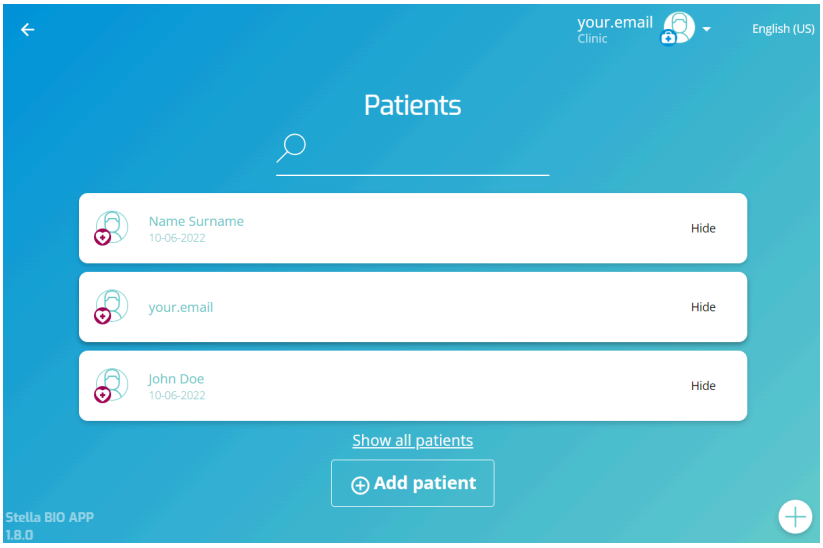


Rectus Abdominis*

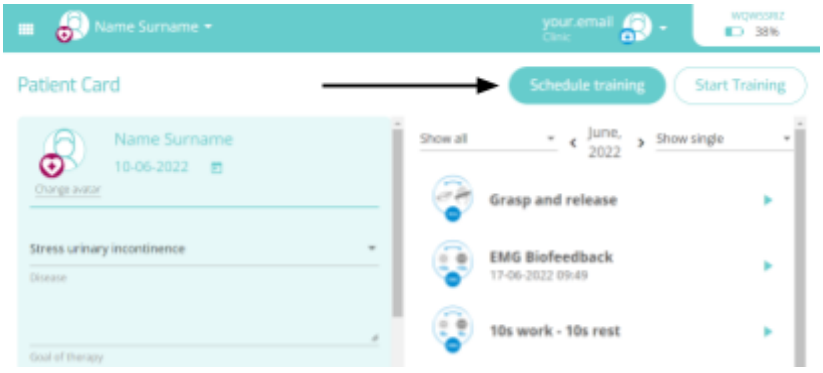
** Available only in EGZOClinic application*

10. How to prescribe exercises to patients on Stella BIO App

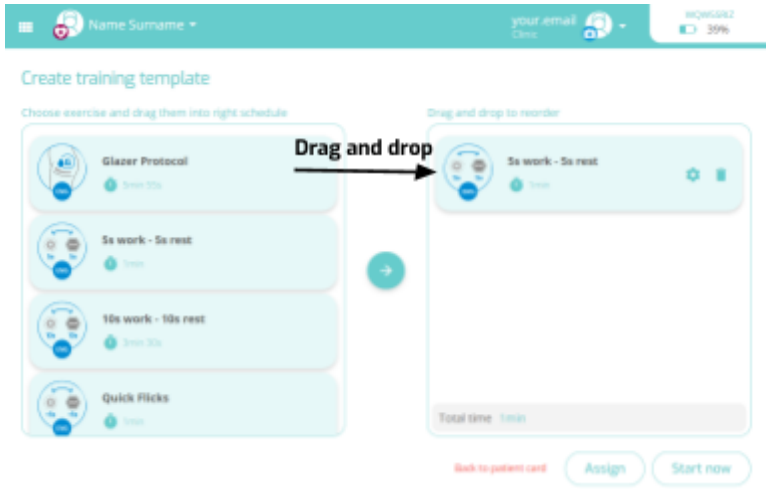
Step 1: From the list of patients, choose a patient you want to prescribe your exercise to.



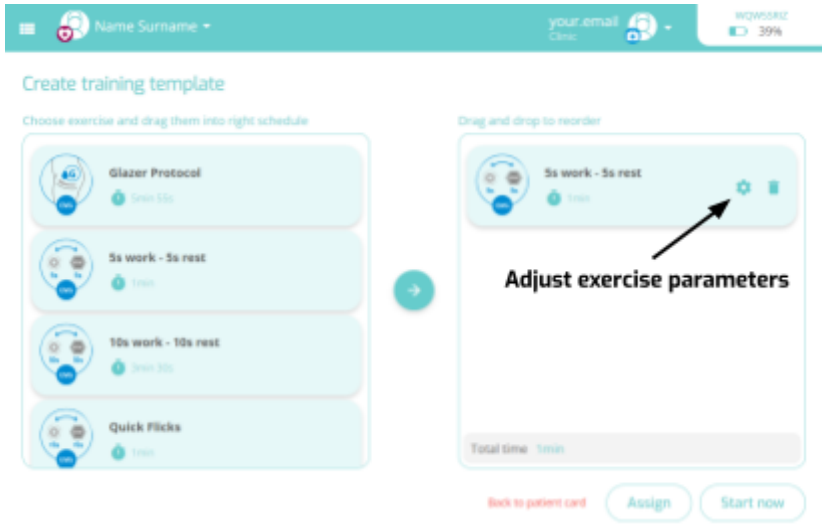
Step 2: To schedule training for your patient, press the "**Schedule Training**" button in the top right corner of the selected Patient card.



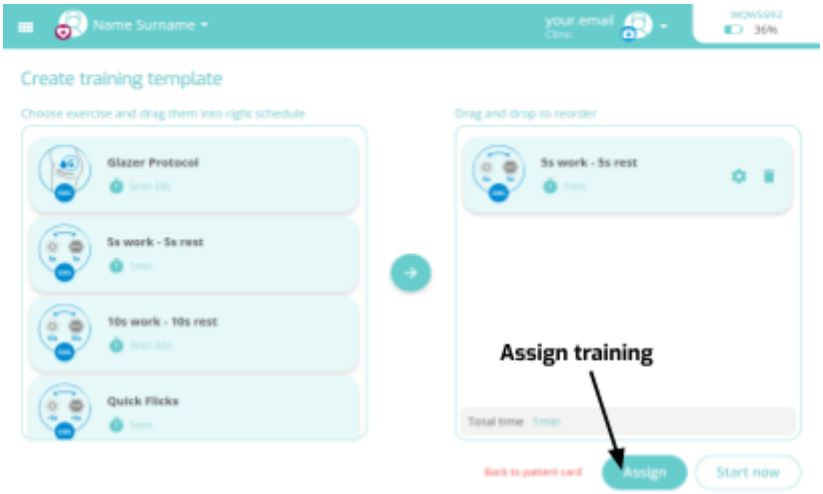
Step 3: From the list on the left side choose the exercise you want to schedule for your patient, grab it and drag to the right column.



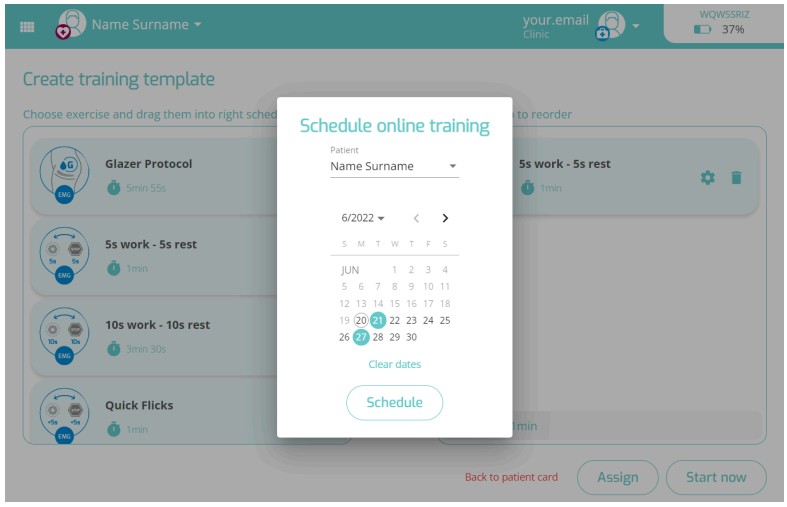
Step 4: Choose the body part you want to work on and adjust parameters for your patient by clicking on the settings sign next to the prescribed exercise.



Step 5: Press "**Assign**" to schedule the date when the patient is supposed to perform the exercise.

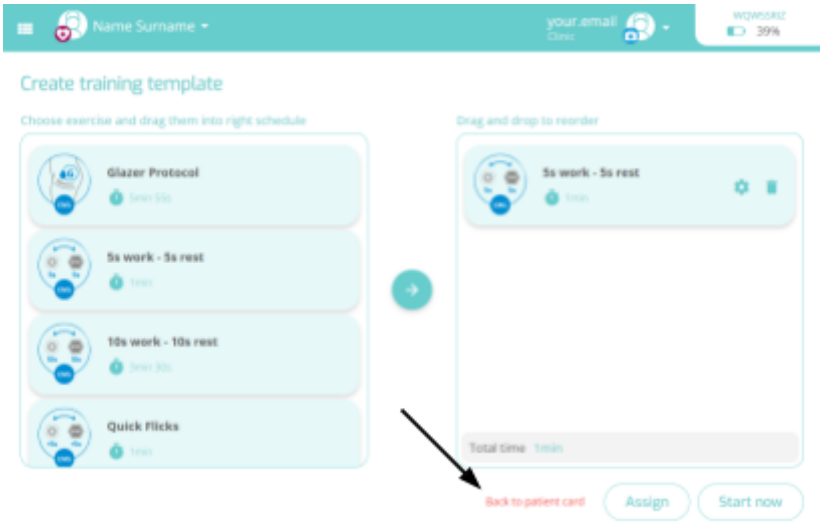


Once you press the "**Assign**" button, the calendar will appear that will allow you to schedule the training.
The chosen date will turn green. Note that you can pick more than one date.



After selecting days on the calendar, press the "**Schedule**" button to assign exercises to the patient.

Step 6: Press "**Back to patient chart**" to return to the patient card.



You're all set! Scheduled training will appear in the patient's chart.

11. Programs settings

In the following subchapters you will find possible settings for typical electrostimulation procedures. They are valid for the load impedances specified in section **4.4. Technical specifications.**

11.1. Typical settings for EMS Programs

11.1.1. EMS User Program - Neuro and Ortho Concept

Type of current: Biphasic symmetric
Shape: Rectangular

Treatment duration (min)	Pulse duration (µs)	Ramp up/down (s)	Plateau time (s)	Rest time (s)	Frequency (Hz)
5 - 60	50 - 500	0 - 4	1 - 20	1 - 20	5 - 100

11.1.2. EMS User Program - Pelvic Concept

Type of current: Biphasic symmetric
Shape: Rectangular

Treatment duration (min)	Pulse duration (µs)	Ramp up/down (s)	Plateau time (s)	Rest time (s)	Frequency (Hz)
5 - 60	50 - 1000	0 - 4	1 - 20	1 - 20	1 - 50

11.1.3. Muscle spasm relaxation program - Neuro Concept

Type of current: Biphasic symmetric
Shape: Rectangular

Treatment duration (min)	Phases	Pulse duration (µs)	Ramp up/down (s)	Plateau time (s)	Rest time (s)	Frequency (Hz)
20	1	250	2/2	8	4	80

User settings	Intensity	0 - 100 mA

11.1.4. Circulation improvement program - Ortho Concept

Type of current: Biphasic symmetric
Shape: Rectangular
Therapy recommendations: Several times daily

Treatment duration (min)	Phases	Pulse duration (µs)	Frequency (Hz)
10	1	300	8

Circulation program User settings	
Intensity (mA)	0 - 100
Pulse duration (us)	50 / 100 / 150 ... 450 / 500

11.1.5. Muscle Atrophy program - Ortho Concept

Type of current	Biphasic symmetric			
Shape	Rectangular			
Phases	1	2	3	4
Phase duration (min)	5	15	15	5
Frequency (Hz)	10	40	60	3
Pulse duration (µs)/phase	300	300	300	300
Ramp up (s)	-	2	2	-
Plateau time (s)	-	8	8	-
Ramp down (s)	-	1	1	-
Therapy recommendations	2 - 3 x per week and muscle group			

Atrophy program User settings	
Intensity (mA)	0 - 100
Pulse duration (µs)	50 / 100 / 150 ... 450 / 500

11.1.6. Denervated muscles programs - Neuro Concept

Indications	Mild Atrophy	Severe Atrophy
Phases	1	1

Indications	Mild Atrophy	Severe Atrophy
Treatment duration (min)	20	15
Frequency (Hz)	20	0.1
Pulse duration (ms)/phase	10	200
Plateau/pause (s)	3 / 6	-
Shape	Triangular	Trapezoidal
Max. number of channels	4	4
Therapy recommendations	1 - 2 x per day	2 x per day

Denervated muscles programs User settings	
Treatment duration	5 / 10 / 15 / ... / 55 / 60
Frequency (Hz)	Mild atrophy: 1 / 2 / 5 / 10 / 20 Severe atrophy: 0.1 / 0.2 / 0.5
Pulse duration (ms)/phase	Mild atrophy: 1 - 20 Severe atrophy: 50 - 300
Intensity (mA)	0 - 80

11.2. Typical settings for EMG-triggered EMS programs - Neuro Concept

EMG channels	1 channel	2 channels *
Treatment goal	Coupling voluntary muscle innervation with EMG-triggered stimulation, which results in visible, noticeable muscle contractions/muscle movements.	
Repetitions	10	10
Frequency (Hz)	35	35
Pulse width (µs)	300	300
Ramp up (s)	0.5	0.5
Plateau time (s)	3	3
Pause time (s)	6	6

EMG channels	1 channel	2 channels *
Ramp down (s)	0.5	0.5
Automatic threshold adjustment	NO	NO
Training recommendations	2 - 3 x per day and muscle group	2 - 3 x per day and muscle group

EMG-triggered EMS programs - User settings	
Number of repetitions	5 / 10 / 15 / ... / 25 / 30
Pulse duration (µs)	50 / 100 / 150 ... 450 / 500
Ramp up (s)	0 / 0.5 / 1 / 2 / 3 / 4
Ramp down (s)	0 / 0.5 / 1 / 2 / 3 / 4
Plateau time (s)	1 / 2 / 3 / 4 ... 18 / 19 / 20
Rest time (s)	1 / 2 / 3 / 4 ... 28 / 29 / 30
Intensity (mA)	0 - 100

* When 2 channels are connected during Reactive EMS, to induce a muscle contraction from channel 1, the muscle connected to the second EMG channel must be relaxed so that the graph of muscle activity from the second channel remains below the set MVC threshold.

11.3. Typical settings for Functional Electrical Stimulation / FES program - Neuro Concept

Important note regarding the use of FES programs:
In order to avoid overtraining the muscles, the value for pause time + delay time should be at least equal to the value for plateau time (**pause time + delay time >= plateau time**).

All FES Programs can be used with EMG-triggered stimulation. **For EMG-triggered FES programs, the reference electrode must be also attached to the extremity that is the object of therapy.**

11.3.1. Grasp and Release Program and EMG triggered Grasp Release Program - Neuro Concept

Indications	Hand grip exercise.		
Channels	1	2	3
Muscles	Wrist extensor	Finger flexors	Thumb flexor
Plateau time [s]	10	7	4
Delay [s]	0	3	6
Treatment duration [min] - FES program	20		
Number of repetitions (EMG triggered FES only)	10		
Frequency [Hz]	35		
Pulse duration [µs] /phase	200		
Ramp up [s]	1		
Ramp down [s]	1		
Pause [s]	10		
Therapy recommendations	2 - 3 x per day		

Grasp and Release User settings	
Treatment duration (**FES only**) [min]	10 / 15 / 20 / 25 ... 55 / 60
Number of repetitions (**EMG-triggered FES only**)	5 / 10 / 15 / 20 / 25 / 30
Pulse duration [µs]	50 / 100 / 150 ... 450 / 500
Rest time [s]	1 / 2 / 3 / 4 ... 28 / 29 / 30
Intensity [mA]	0 - 100

11.3.2. Open and Close Program and EMG - triggered Open and Close Program - Neuro Concept

Indications	Hand grip exercise.		
Channels	1	2	3
Muscles	Thumb and finger joint extensors	Finger flexors	Thumb flexor
Plateau time [s]	6	8	6
Delay [s]	0	8	10
Pause - FES only [s]	20	10	10
Treatment duration (FES only) [min]	20		
Number of repetitions (EMG triggered FES only)	10		
Frequency [Hz]	35		
Pulse duration / phase [µs]	200		
Ramp up [s]	1		
Ramp down [s]	1		
Therapy recommendations	2 - 3 x per day		

Open and Close User settings	
Treatment duration (**FES only**) [min]	10 / 15 / 20 / 25 ... 55 / 60
Number of repetitions (**EMG-triggered FES only**)	5 / 10 / 15 / 20 / 25 / 30
Pulse duration [µs]	50 / 100 / 150 ... 450 / 500
Rest time [s]	1 / 2 / 3 / 4 ... 28 / 29 / 30
Intensity [mA]	0 - 100

11.3.3. Hand to mouth Program and EMG- triggered Hand to mouth Program - Neuro Concept

Indications	Promote eating and drinking activities of daily living.			
Channels	1	2	3	4
Muscles	Wrist extensors	Elbow flexors	Deltoid	Forearm inverters
Plateau time (s)	7	5	5	5
Delay (s)	0	1	1	1
Pause (s)	9	10	10	10
Treatment duration (FES only) (min)	20			
Number of repetitions (EMG triggered FES only)	10			
Frequency (Hz)	35			
Pulse duration (µs) /phase	200			
Ramp up (s)	1			
Ramp down (s)	1			
Therapy recommendations	2 -3 x per day			

Hand to mouth User settings	
Treatment duration (**FES only**) (min)	10 / 15 / 20 / 25 ... 55 / 60
Number of repetitions (**EMG triggered FES only**)	5 / 10 / 15 / 20 / 25 / 30
Pulse duration (µs)	50 / 100 / 150 ... 450 / 500
Rest time (s)	1 / 2 / 3 / 4 ... 28 / 29 / 30
Intensity (mA)	0 - 100

11.3.4. Arm extension/support Program and EMG - triggered Arm extension/support Program - Neuro Concept

Indications	Allows to re-learn voluntary movement contractions to improve sit-up support and transfer from sit-up to stand-up.		
Channels	1	2	3
Muscles	Wrist extensors	Elbow extensors	Spinal section of the deltoid
Plateau time (s)	7	5	4
Delay (s)	0	1	2
Pause (s)	9	10	10
Treatment duration (FES only) (min)	20		
Number of repetitions (EMG triggered FES only)	10		
Frequency (Hz)	35		
Pulse duration (µs) /phase	200		
Ramp up (s)	1		
Ramp down (s)	1		
Therapy recommendations	2 - 3 x per day		

Arm extension/support User settings	
Treatment duration (**FES only**) (min)	10 / 15 / 20 / 25 ... 55 / 60
Number of repetitions (**EMG triggered FES only**)	5 / 10 / 15 / 20 / 25 / 30
Pulse duration (µs)	50 / 100 / 150 ... 450 / 500
Rest time (s)	1 / 2 / 3 / 4 ... 28 / 29 / 30
Intensity (mA)	0 - 100

11.4. Typical settings for EMS Programs - Sport Concept

Programs	Ramp up / Ramp down (s)	Plateau (s)	Break (s)	Frequency (Hz)
Exercise Prep	2/1	-	-	10
Strength training	2/3	5	10	50

Program	Power Training			
Phases	1	2	3	4
Phase duration	5	10	10	5
Frequency (Hz)	10	60	90	3
Ramp up (s)	-	2	2	-
Ramp down (s)	-	1	1	-
Plateau time (s)	-	10	7	-
Pulse duration (µs)	300			

Program	Endurance Training		
Phases	1	2	3
Phase duration	5	20	5
Frequency (Hz)	10	40	3
Ramp up (s)	-	2	-
Ramp down (s)	-	1	-
Plateau time (s)	-	8	-
Pulse duration (µs)	300		

Program	Massage				
Phases	1	2	3	4	5
Phase duration (s)	20	20	20	20	20
Frequency (Hz)	80	75	10	70	65
Pulse width (µs)	250				

Sport Programs User settings	
Intensity [mA] All EMS programs	0 - 100

11.4.1. Agonist/Antagonist program - Sport Concept

Type of current	Biphasic symmetric					
Shape	Rectangular					
Phases	1	2	2	3	3	4
Channel	1-4	1 + 3	2 + 4	1 + 3	2 + 4	1-4
Phase duration[min]	5	15	15	15	15	5
F [Hz]	10	40	40	60	60	3
Ramp up [s]	-	2	2	2	2	-
Plateau time [s]	-	8	8	8	8	-
Pause time [s]	-	16	3	16	3	-
Ramp down [s]	-	1	1	1	1	-
Pulse duration [µs]/phase	300					
Therapy recommendations	3 x per week					

Agonist/Antagonist User settings	
Intensity [mA]	0 - 100

11.5. Typical settings for Incontinence Programs - Pelvic Concept

Pulse width for all programs except user program and Relaxation / Relaxation +: 200 [µs].

Pulse width for User Program: 150 - 250 [µs].

Pulse width for program Relaxation: 50 - 400 (default 150) [µs].

Pulse width for program Relaxation +: 200 - 250 (default 220) [µs]

Program	Treatment duration [min]	Phase[s]	Frequency [Hz]	Ramp up / Ramp down [s]	Plateau [s]	Break [s]
Urge Incontinence	15	1	10	1/1	5	10
Stress Incontinence	20	1	50	1/1	5	10
Mixed Incontinence	20 total (10 min each phase)	1	10	2/2	5	10
		2	50	2/2	5	10
Relaxation	20	1	2	continuous signal		
Relaxation +	20	1	2	1/1	6	10
EMG- triggered (1 channel) Incontinence EMS	10	1	35	1/1	4	6
EMG- triggered (2CH) Incontinence EMS	10 reps	1	35	1/1	4	6
Faecal Incontinence	20	1	35	1/1	5	5
EMG-triggered Faecal Incontinence EMS	10 reps	1	35	1/1	5	5

Incontinence Programs User settings	
Treatment duration (**FES only**) [min]	5 / 10 / 15 / 20 ... 55 / 60
Number of repetitions (**EMG triggered FES only**)	5 / 10 / 15 / 20 / 25 / 30
Pulse duration [µs]	50 / 100 / 150 ... 450 / 500
Rest time [s]	1 / 2 / 3 / 4 ... 28 / 29 / 30
Intensity [mA]	0 - 100

11.6. Typical settings for TENS Programs

Pulse type: Rectangular, symmetric biphasic

Program	Phases	Treatment duration [min]	Frequency [Hz]	Plateau time [s]	Pulse width [µs]/phase
TENS Conventional	1	15	80		150
TENS Frequency Modulated	1	15	2	5	200
	2		30	1	
	3		70	1	
	4		100	1	
	5		70	1	
	6		30	1	
TENS Burst	1	15	80	0.4	200
TENS Acupuncture	1	15	4		200
TENS User Program	1	5 - 60	5 - 100		50 - 500

TENS Programs User settings	
Duration (min)	5 / 10 / 15 ... 55 / 60
Intensywność (mA)	0 - 100

12. Handling, maintenance and troubleshooting

12.1. Hardware and software requirements

You can connect to Stella BIO using a device compliant with the hardware and software requirements listed below.

Operating system	IOS	Android	PC/Notebook
Speed and memory requirements	min. SoC A9 (1.85 GHz dual-core Apple Twister/ 2GB RAM)	min. Qualcomm Snapdragon 42 / 2 GB RAM	min. Intel Core i3 1.5 GHz or similar / 2 GB RAM
Operating system	min. iOS 10.3	min. Android 5.0 Lollipop	min. Windows / Linux / OS X
Display specification	min. 4,7" for mobile, Recommended tablets min. 7,9" or larger		min. FHD
Flash memory	min. 8 GB		
Speaker	audio output / speaker		
Wi-Fi	2.4 GHz Frequency		

Chrome browser version min. 100 Required.

Other Requirements

- for IOS: in order to run exercise, go to settings. Choose "***Display & Brightness***", go to "***Auto-Lock***" set "***Never***"
- Bluetooth Low Energy
- Only mobile devices: Wi-Fi Hotspot

12.2. Behaviour of Stella BIO

During usage of Stella BIO, it is important to monitor the activity of the device based on LED Ring communication, located around the multifunction button with the **EGZO**Tech company logo.

Description	Operators Activity	Status
The LED ring lights up slowly in white, then flashes slightly	After inserting the battery or pressing the multifunction button if the device was turned off.	**Turning on**
White LED ring rotates counterclockwise	-	**Connecting to Wi-Fi/BLE**

Description	Operators Activity	Status
The white LED ring rotates counterclockwise. The background flashes yellow.	Check the Wi-Fi signal quality. Try restarting the router. Check in the application - in the Stella BIO information section, the Wi-Fi password you entered	**Trouble with Wi-Fi/BLE connection**
The white LED ring pulses slowly in white.	-	**Standby mode, correctly connected to Wi-Fi**
The entire LED ring flashes blue slowly	-	**Connecting to application**
Occasional flashing of the LED ring in yellow.	Change or charge up the battery	**Battery running out**
The LED ring performs a flow animation in the direction from the battery to the connected cable.	-	**Electrical Stimulation or EMG**
The LED ring flashes slightly and then slowly begins to dim until it stops glowing.	After switching off Stella BIO via the app or by holding down the multifunction button	**Turning off**
The whole LED ring flashes yellow	Check the alert notification in the app and follow the instructions in the app. e.g. check the cable connection	**Warning**
The whole LED ring flashes red	Check the error notifications in the application and follow the instructions in the app. If there is a problem, a service request form is available at: https://service.egzotech.com	**Error**
LED ring fill from black, to fully purple. The fill level indicates the current update progress.	Wait for the circle to fill to the end. The device will update and reset automatically.	**Firmware update**

12.3. Typical problems

Anyone who attempts to repair and/or modify the Stella BIO and/or its accessories risks damaging the Stella BIO and/or accessories. Therefore, any steps not

described in the troubleshooting guide are prohibited. Improper use voids all warranty claims.

Problem	Possible Cause	Solution
Stella BIO doesn't connect to Wi-Fi.	There is a problem with Wi-Fi. The Wi-Fi password is incorrect.	Check the quality of the Wi-Fi signal on the control unit. Try to restart the router. Check at application section Stella BIO info typed Wi-Fi password.
Stella BIO device doesn't display in the application.	Device doesn't turn on. Device is connected to different Wi-Fi.	Turn on the device by pressing the button on the cover. Check if the control unit is connected to the same Wi-Fi as Stella BIO.
The application displays the "Internet connection lost" message	There is a problem with the network to which the device is connected.	Make sure the access point is in sight. Check for problems with Internet access due to the provider.
Stimulation weak	Electrodes dried out or damaged. Electrode incorrect placement. Lead wires worn or damaged.	Replace and re-connect electrodes. Replace and re-connect electrodes. Replace leads.
Device doesn't turn on.	Battery is probably very low.	Change or charge your battery.
The device suddenly turns itself off during the self test or during stimulation at high intensity.	Battery is discharged.	Change or charge your battery.
Intermittent EMG signal	Electrode lead set is loose or disconnected. Electrodes dried out or damaged or were not in contact with bare skin.	Check lead set connections at both the Stella BIO and electrodes. Change the electrode to a new one.
The EMG signal cannot be controlled	Electrode cable is not connected properly. Reference cable is not connected properly. Electrode lead set is loose or disconnected. Electrodes dried out or damaged or were not in contact with bare skin.	Check and improve connection cable and reference. Check lead set connections at both the Stella BIO and electrodes. Change the electrode to a new one.
Operative time is too low	Defective battery.	Contact with product specialist or support for battery replacement.

12.4. Description of user maintenance responsibilities

The consumable items for use with your Stella BIO:

- EMG electrodes are designed for single-use.
- Pelvic floor probes are designed for single person use only.
- Electrical stimulation electrodes are designed for single person use only and reusable up to 20 times. Note: The lifetime of the electrode varies

depending on skin conditions, skin preparation, type of stimulation, storage and climate.

It is suggested to regularly restock your supply to have available products when needed.

The Stella BIO batteries are Li-Ion, the only battery maintenance required of the user is recharging described in chapter **12.5. Battery handling, maintenance and life.**

Routine user's maintenance recommended for the Stella BIO is cleaning the device's case and cable and fastening belts after each patient or periodically (see **12.6. Cleaning instructions**).

12.5. Battery handling, maintenance and life

Users can perform battery charging. **Batteries can only be charged when disconnected from Stella BIO.** Stella BIO doesn't allow simultaneous charging and operations. To enable quick battery replacement and minimum down-time of Stella BIO, please consider having multiple batteries for Stella BIO.

1. Connect the battery charger into a power strip or into the wall outlet.
2. Remove battery from Stella BIO. You don't have to press any button, just pull at the battery's attachment.
3. Insert the battery into the charger with an arrow pointing right. The display should light up blue and show animation of battery charging. If it isn't, you have to turn the battery.
4. When the display stops light up blue and shows full battery, you can disconnect the battery and charger. The battery is ready to use. Estimated charging time from fully depleted to fully charged is 2.5 hours.

The battery used in the Stella BIO is rated for a minimum of 150 charge-discharge cycles. Typical usage is 300 charge-discharge cycles. As the number declines thereby reducing run time of charge-discharge cycles increases the battery capacity slowly despite being fully charged.

If the battery has been stored without using for a prolonged period of time, you should recharge it before use. We recommend recharging the battery after you finish the training.

Battery replacement should be considered:

- If you notice damage to the battery housing.
- The battery is swollen.
- The device discharges quickly.
- Charging the battery fully discharged to full charge takes less than an hour.
- If the last time was charged 9 months after the last use.
- Discoloration around the main battery terminals has occurred.
- Frequent battery shutdowns appear.
- The battery suffered a free fall from a height of more than 1.8 m.
- The battery has been immersed in liquid.
- The temperature after use is over 50° Celsius.
- The battery nameplate has been damaged or removed.
- When connected to charging, the charger does not charge the battery.
- After connecting to the device (and before charging the battery) it does not start.
- The battery has been exposed to temperatures higher than 50° Celsius.

Please contact **EGZO**Tech for battery replacement.

12.6. Cleaning instructions

For long life and excellent quality, remember to clean Stella BIO and accessories on a regular basis - after each patient. Where are three types of materials used for Stella BIO, that have specific cleaning requirements.

Material type	How to clean it
Case and cables	Use wet cloth with non-allergic alcohol (disinfection) based detergent and wipe the surface.
Fastening belt	Hand wash.
Probes	Use cold soapy water before and after each treatment. Dry it with a paper towel after cleaning. Alcoholic solution is not suitable for cleaning this probe. The probe cannot be sterilised.

- For best cleaning experience we advise the use of a specialised medical equipment disinfection product that can handle both bacterial and viral contaminations. An example can be Amity International's Virusolve+ products, both in the form of spray and wipes.
- Do not immerse Stella BIO in any water or liquid during cleaning.

While using high level disinfectants, always follow the guidelines for safety. Always read and follow the information provided with the substance.

If Stella BIO is used for multiple patients, please:

1. Clean Stella BIO, the cables and accessories after every use and before first use that day, according to the instructions above.
2. Consider using multiple fastening belts, to limit exposure between patient-to-patient.
3. Stella BIO and its accessories should be dried before storage or re-use.
4. Store according to **12.8. Storage and transportation instructions**.

12.7. Expected product service life

Expected product service life of Stella BIO is 5 years, under normal operations and proper maintenance and handling. Stella BIO's accessories and detachable parts **will experience normal wear and tear**, which will decrease the product service life.

Rechargeable batteries used in the Stella BIO are rated for a minimum of 150 charge-discharge cycles. As the number of charge-discharge cycles increases the battery capacity slowly declines thereby reducing run time despite being fully charged. Afterwards, battery replacement should be considered. Battery handling and maintenance is described in **12.5. Battery handling, maintenance and life**.

Expected shelf life and product service life for accessories, including surface and pelvic electrodes may differ. Please refer to their associated documents and packaging for more information.

Batteries connected to Stella BIO for long periods of time and during extended storage can severely reduce product service life, as they will get drained. Please store batteries disconnected.

If you see any of Stella BIO parts declining in performance, especially the multifunctional button, the battery holder, the chassis or any of the accessories, please consider replacement.

Detectable device failures are signalised by the Led Ring and if they are unrelated to wireless connectivity - in the software.

12.8. Storage and transportation instructions

The device and accessories should be stored and transported in its case.

The device and accessories should be stored in a dry environment. Do not immerse them in water or liquid.

Storage and transportation conditions for Stella BIO should be:

- Temperature: -20 °C to 35 °C,

- Relative humidity: 10% to 90% RH, non-condensing.

Remove the battery if the device is to be out of service for one month because a leakage from the battery could cause an unacceptable risk.

Batteries need to be stored within the recommended temperature and humidity limit, in a well-ventilated area.

Do not expose Stella BIO and accessories to high temperatures, above specified. Since short circuits can cause burn hazard or gas release, do not store metal jewellery, metal covered tables, or metal belts.

Every 3 months fully charge the sensors once and then normal storage without connection to power may resume. The batteries will undergo expansion if left alone for too long.

In some countries, the operator will need an adapter and may need a converter to convert to the proper voltage for the battery charger.

The operator should check with the carrier to confirm how the device can be carried on the aeroplane.

12.9. How to safely dispose the device

Stella BIO device and Stella BIO Battery Charger contains electrical and electronic components that may contain materials which, if disposed of with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.

The pictogram wheeled bin barred means that the equipment can't be thrown with the household refuse, but that it makes the object of a selective collection.

The equipment has to be given to a suitable collection point for the treatment by this way, you contribute to the safeguarding of the natural resources and human health protection.

Rechargeable Batteries must be disposed of in accordance with your country's national laws governing the disposal of such items. Stella BIO Battery may be hazardous if disposed of incorrectly.

Electrodes should be disposed of according to their manual on the package.

12.10. Warranty

EGZOTech Sp. z o.o. provides a warranty to the original purchaser that this product will provide for a period of 1 years from the date of purchase.

Within the warranty period, the manufacturer will replace your faulty Stella BIO or accessories at no charge (except shipping & handling fees in some cases), provided that the product:

- Has been used for the intended purpose and in the manner described in this manual.
- Has not been connected to an unsuitable power source.
- Has not been subjected to misuse or neglect.
- Has not been modified or repaired.
- Has not been damaged further by shock.

Legal rights are not affected by this warranty.

13. Data protection

13.1. Compliance with GDPR. Personal data controller. Data protection officer

Software available for Stella BIO, including the device software and the online application https://app.egzotech.com, complies with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, or GDPR).

The personal data controller is **EGZO**Tech Sp. z o.o. with the registered seat in Gliwice. **EGZO**Tech Sp. z o.o. entered into the Register of Entrepreneurs, of the National Court Register, kept by the District Court in Gliwice - 10th Commercial Division of the National Court Register, under KRS number 0000475698, at the address: 44-100 Gliwice, ul. Traugutta 6h.

Data protection officer contact information:
privacy@egzotech.com, tel. + 32 750 49 45

13.2. End user licence agreement

In order to provide services by **EGZO**Tech using the Stella BIO device to collect and process personal data, each user, during registration will be asked to sign an End User Licence Agreement with **EGZO**Tech, in order to regulate legal obligations of **EGZO**Tech towards the user.

13.3. Reason for collecting and processing data. The basis for collecting and processing personal data.

EGZOTech collects your personal data to ensure correct functioning of Stella BIO as a product, and in order to correct functioning and improvement of **EGZO**Tech services and products, including https://app.egzotech.com, easier usability and user experience, creating new therapeutic and rehabilitation programs for users, better safety, providing software and firmware updates, notifying users of safety notices, product recall, service and maintenance services, and to in order to build easier access for users to remote medical services and consultations, including telerehabilitation, telemedicine.

Collecting and processing data is done by **EGZO**Tech on the explicit consent of the user for the purposes of operating Stella BIO and providing services through apps like https://app.egzotech.com, according to GDPR Article 9(a), paragraph 2 point A. The consent may be withdrawn at any time without affecting the lawfulness of data processing based on consent before its withdrawal.

Collected data is also used to ensure high standards of quality and safety of health care and of medicinal products or medical devices, according to GDPR Article 9(i).

EGZOTech follows the requirements for post-market surveillance for medical device manufacturers, especially:

- European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices,
- ISO 13485:2016 International Standard on Medical devices — Quality management systems — Requirements for regulatory purposes.

In an instance, where processing of the collected data is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional, and subject to the conditions and safeguards referred to in GDPR Article 9.3., the processing not require the user's consent, according to the Article 9, paragraph 2, point H GDPR.

Providing personal data is voluntary, but necessary to achieve the above-mentioned purposes.

13.4. What data is being collected

Required for operation: email, password (encrypted), numerical procedure data gathered by Stella BIO (electromyography inputs, electrical stimulation output, impedance, accelerometer, accessories attached, temperature), wireless networks detected, bluetooth devices detected, network credentials (SSID, password, encryption method), health condition information, affected body regions (ROIs), electrodes used, muscles electrodes were used on, date and time information of all events, information provided by http requests

Optional: address, personal national identification number (e.g. PESEL, social security number, etc.), phone number,

Service and maintenance: User actions in app (mouse clicks, keystrokes, time spent on specific pages, First-party Cookies, Advertising identifiers, IP Address).

13.5. Third parties

EGZOTech collects the data through an external cloud service provider - Google. To learn more about how Google protects your data stored on Google Cloud Platform, visit https://cloud.google.com/security/gdpr.

Collected data is likely to change as we improve our software solutions. Please refer to the most up to date end user licence agreement (EULA) at https://support.egzotech.com/terms-and-conditions.

13.6. Access to your information

Each user, registered with an **Stella BIO App** account, whose data is processed by **EGZO**Tech can enjoy all the right associated with GDPR, including:

- GDPR Article 15 - Right of access by the data subject,
- GDPR Article 16 - Right to rectification,
- GDPR Article 17 - Right to erasure ('right to be forgotten'),
- GDPR Article 18 - Right to restriction of processing,
- GDPR Article 19 - Notification obligation regarding rectification or erasure of personal data or restriction of processing,
- GDPR Article 20 - Right to data portability,
- GDPR Article 21 - Right to object.

Each user also has the right to lodge a complaint with the supervisory body (UODO, ul. Stawki 2, 00-193 Warsaw, Poland).

To exercise any of the above rights, please contact **EGZO**Tech directly under the following:

EGZOTech Sp. z o.o.
Ul. Romualda Traugutta 6H
44-100 Gliwice, POLAND
gdpr@egzotech.com
+48 32 750 49 45

13.7. Data retention

EGZOTech reserves the right to retain the collected data for the period of no less than 10 years from the cessation of manufacturing of the last Stella BIO, based on the requirements of European Council Directive 93/42/EEC.

13.8. Automated individual decision - making, including data profiling

In order to support Stella BIO, **EGZO**Tech will process user data in an automated manner (including in the form of profiling). Automated decisions will be made based on the data indicated in chapter **13.4 What data is being collected?** and the consequence of such processing will be the selection of appropriate content of information and training materials for a specific user.

13.9. Transfers of personal data to third countries.

In order to use the Stella BIO device, **EZGO**Tech processes personal data in the European Union. If it is necessary to transfer personal data to a third country, **EGZO**Tech will first make sure that the country provides an adequate level of personal data protection (equal to or higher than at the European level).

13.10. Privacy policy

Detailed rules for data processing by **EGZO**Tech for the purpose of operating Stella BIO are set out in the Privacy Policy available at: https://support.egzotech.com.

14. Declarations of conformity and compliance statements

14.1. Declaration of conformity

We hereby declare that Stella BIO, complies with the transposing European Council Directive 93/42/EEC concerning medical devices, annex II.3. Classification: Class IIa, rule 9, according to Annex IX of the European Council Directive 93/42/EEC.

This product conforms to international standards IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 60601-2-10.

14.2. Radio Regulatory Statement

FCC Statement

This device complies with part 15 of the FCC rules.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device contains an RF module with FCC ID: 2AC7Z-ESPWROOM32

14.3. Recommendations on separation distance from other devices

Recommended separation distance between portable and mobile RF communications equipment and the Stella BIO

Stella BIO is intended for use in an electromagnetic environment in which radiated RF disturbances are in reasonable ranges. To limit or prevent electromagnetic interference, maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and Stella BIO as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

14.4. Electromagnetic compatibility information

Stella BIO complies with the electromagnetic compatibility requirements for emissions and immunity, specified in the tables below. Users must adhere to the electromagnetic environment guidance and any deviations from collateral standards specified. For necessary instructions for maintaining basic safety and essential performance in relation to electromagnetic disturbances and expected service life, please refer to general warnings, described in this manual.

Accessories, including Stella BIO's battery charger compliance, are available in its documentation.

Guidance and manufacturer's declaration - electromagnetic emissions		
Phenomenon and basic EMC standard or test method	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Stella BIO uses RF energy only for its internal function and radio communications. RF emissions outside radio communication are low and are not likely to cause any interference in nearby electronic equipment. RF emissions resulting from radio communications are compliant with regulations and international standards.
RF emissions CISPR 11	Class B	The Stella BIO is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable - Stella BIO is battery powered.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable - Stella BIO is battery powered.	

Guidance and manufacturer's declaration - electromagnetic immunity			
Phenomenon and basic EMC standard or test method	**Test levels**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	-
Electrical fast transient/burst IEC 61000-4-4	A.C. Power Ports, D.C. Power Ports: ± 2 kV 100 kHz repetition frequency Signal I/O Ports: ± 1 kV 100 kHz repetition frequency	Not applicable - Stella BIO is battery powered, without external A.C., D.C. and I/O ports.	-

Surge IEC 61000-4-5	A.C. Power Ports Line-to-line ± 1 kV Line-to-ground ±2 kV D.C. Power Ports Line-to-line ± 1 kV Line-to-ground ±2 kV Signal I/O Ports Line-to-ground ±2 kV	Not applicable - Stella BIO is battery powered, without external A.C., D.C. and I/O ports.	Mains power quality should be that of a typical home, commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles Single phase: at 0°	Not applicable - Stella BIO is battery powered, without external A.C., D.C. and I/O ports.	
Voltage interruptions IEC 61000-4-11	0 % U_T: 250/300 cycle		
Electrical transient conduction along supply lines	As specified in ISO 7637-2	Not applicable - Stella BIO is battery powered.	-
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See guidance and manufacturer's declaration - immunity to RF wireless communications equipment		
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Conducted disturbances induced by RF fields IEC 61000-4-6 Radiated RF fields IEC 61000-4-3	3 Vrms 0.15 MHz - 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Not applicable - Stella BIO is battery powered, without external A.C., D.C. and I/O ports. 10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of Stella BIO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ For 80 MHz to 800 MHz: $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ For 800 MHz to 2.5 GHz: $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d in the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the (ME EQUIPMENT or ME SYSTEM) is used exceeds the applicable			

RF compliance level above, the {ME EQUIPMENT or ME SYSTEM} should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the {ME EQUIPMENT or ME SYSTEM}.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than {V_1} V/m.

Guidance and manufacturer's declaration - immunity to RF wireless communications equipment					
Test f (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Max power (W)**	**Immunity test level (V/m)**
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	27
450	430 - 470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	9
745	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	28
780					
810					
870					
930					
1 720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, IMTS	Pulse modulation 217 Hz	2	28
1 845					
1 970					
2 450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	28
5 240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	9
5 500					
5 785					
The Manufacturer is Compliant with all the above listed specifications.					
GUIDELINES:					

(a) For best performance of Stella BIO's wireless communication use Wi-Fi channels that are less populated by other Wi-Fi networks, (b) Other wireless communication may impact Stella BIO's essential performance, but not basic safety. (c) Please consider cybersecurity guidelines in this manual to prevent hacking.
NOTE: (a) For some services, only the uplink frequencies are included. (b) The carrier shall be modulated using a 50% duty cycle square wave signal (c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

15. Notes (Special instructions from the physician)

Thank You for taking Your time to read this manual!

Feel free to contact us at any time. We are here for You!

If you're having unexpected operation or events, issues, medical incidents or any trouble with your Stella BIO, please contact us under the following:

The service request form is available at:

https://service.egzotech.com

To access additional manuals and use cases, go to:

https://support.egzotech.com

Direct contact to **EGZO**Tech is available here:

EGZOTech Sp. z o.o.
Ul. Romualda Traugutta 6H
44-100 Gliwice, POLAND
office@egzotech.com
+48 32 750 49 45