PAJUNK®

Stim2Go

User Manual

Neurology

English

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1 General Information

This user manual contains information and instructions on how to use the Stim2Go device. Further information, warnings and technical specifications for the device can be found in the Instructions for use delivered with the device or online.

eifu-mdr.stim2go.com

PAJUNK® GmbH Medizintechnologie, Karl-Hall-Straße 1, 78187 Geisingen, Germany.

In case technical assistance is needed, please contact the manufacturer as stated above.

1.1 Symbols Used

LOT Batch code

SN Serial number

REF Item number

Date of manufacture

Manufacturer

UDI Unique device identification

MD Medical device

NON STERILE Non-sterile

Consult instructions for use

Consult instructions for use (ISO 7010-M002)

Rx only Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)

Do not use if package is damaged

LIPO Built in rechargeable LiPo battery

Caution

Keep away from sunlight

Keep dry

Protection against electric shock, type BF

-5°C 30°C Temperature limit

20% 80% Humidity limitation

Pressure range

Do not dispose of with domestic waste

CE 0124 "CE conformity marking" or "CE marking" = this marking shows that a device is in conformity with the applicable requirements as set out in the Medical Device Regulation or other European Union legislation on its affixing.

IPN,N$_2$ IP protection class NN

c UL us CLASSIFIED UL (Underwriters Laboratories) certification

2 Device Description

Stim2Go is a portable, hand-held or body-worn electrical stimulation device that generates electrical pulses, on up to 5 channels, applied via non-invasive neurostimulation electrodes. Stim2Go is primarily controlled by a smart device (either a smart phone or a tablet) – the App is available free of charge in the App Store / Google Play and allows users to execute a variety of therapy programs, as well as to control parameters on a very detailed level. Alternatively, the device can be temporarily operated via the stimulator's membrane keypad to perform basic functions.

The components to be delivered:

- 1 pc. stimulator Stim2Go
- 1 set stimulation cables (1 pc. 2-channel, 1 pc. 5-channel, 1 pc. adapter cable 1:2)
- 1 pc. charging cable
- 1 pc. power supply with 3 adapters (EU, US, UK)
- 1 pc. quick start guide and instructions for use
- 1 pc. case
- 1 set strap and strap holder

⚠ The power supply is part of the product and must not be replaced with a different type.

The Stim2Go App, to operate the stimulator is freely available on Apple App Store / Google Play Store. It requires an iOS smart device supporting ≥ iOS14.4 or ≥iPadOS 14.4 or an Android smart device supporting Android ≥ 10.

2.1 Electrode Cables

Stim2Go will be delivered with a 2-channel and 5-channel stimulation cable. All stimulation cables are colorcoded – each twin cable corresponds to one stimulation channel and has a dedicated color which will be reflected in the App and on the stimulator keypad. The cable will be wired to the electrodes with a standard 2 mm pin connector. For certain applications the polarity may be relevant – therefore the anode is marked with a red plug, the cathode with a black plug.

The channels are color-coded the following way:

- CH1: white
- CH2: anthracite
- CH3: yellow
- CH4: blue
- CH5: green

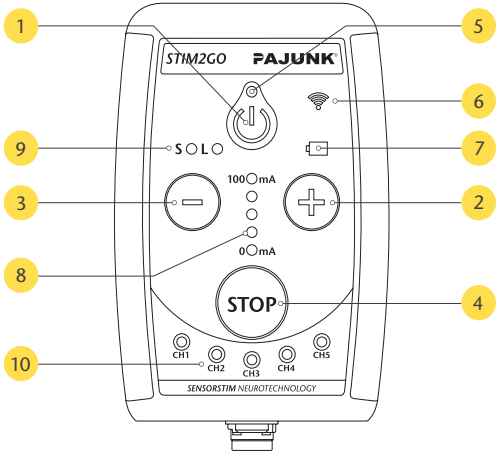
These colors will be displayed wherever the user interface is supposed to distinguish between channels – the stimulator keypad, the cables itself and the App. All cables are connected to the stimulator device with a simple pull-lock-release connector. The connector is user friendly with molded-in grooves to prevent hand slippage, permanent colored alignment indicators, and multiple polarizing keys to protect from misalignment or insertion of the wrong connector. Additionally, an adapter cable 1:2 is provided to connect two electrodes to one electrode plug of a stimulation cable.

You should visually inspect each cable before use - if a cable is damaged, it must be replaced immediately with an original spare part. The product should only be used with original and unmodified equipment and accessories.

⚠ Users affected by complete or partial color blindness shall ask for assistance when using the 5-channel stimulation cable.

2.2 The Stimulator

2.2.1 Membrane Keypad



2.2.2 Buttons

The ① POWER button will switch the device ON and OFF.

The ② PLUS[2] button will start the stimulation or increase the intensity.

The ③ MINUS[3] button will decrease the intensity.

The ④ STOP button will force an immediate stop of any output and reset of the current program.

[2,3] Is effective if the active program has only one channel or if at least one channel is bundled or if the stimulator operates in the Solo mode.

2.2.3 Status LEDs

Close to the POWER button the ⑤ power LED indicates:

- Green → device is switched on

Top Right the ⑥ connection LED indicates:

- Blue flashing → stimulator is advertising
- Blue permanent → stimulator is connected to a smart device

Above PLUS button the ⑦ battery LED indicates:

- Red → battery capacity ≤ 10%
- Yellow → battery capacity >10% … ≤ 20%
- Green → battery capacity >20%
- Green blinking → battery is charging (when fully charged permanent green)

Between MINUS and PLUS button ⑧ 5 status LEDs indicate:

- Each LED represents 20 mA intensity.
- All LEDs on: This means 81 to 100 mA of the possible intensity is applied, oneLED lighting up indicates an intensity between 1 and 20 mA.

Above the MINUS button in the string ⑨ SOLO LEDs indicate:

- The stimulator is in “Solo mode”. That means a simple application is uploaded from the App to the stimulator and the user can operate the stimulator with the membrane keypad and an App control is not required.

Below the “STOP” button ⑩ 5 status LEDs indicate for each channel:

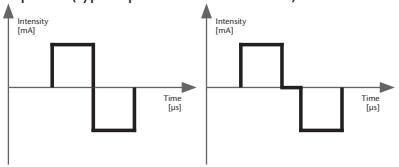
- Yellow light → stimulation activity
- Red light → electrode error

2.2.4 Technical Specification

Size and Weight	
Length	120 mm (4.72")
Width	80 mm (3.15")
Height	30 mm (1.18")
Weight	185 g (6.53 oz)

Power supply	
Power source(s)	Operation mode charging with AC Operation mode stimulation with rechargeable battery
Method of line current isolation	TR 30M090 according to EN60601-1 Battery usage: Li-Ion, IEC 62133-2
Power connection	100-240 VAC, 47-63 Hz while charging
Power input	max. 10 W

Stimulator/Controller (1)	
Display/Interface	Membrane keypad (stimulator), App on Smart Device
Communications	BT LE 4.2 (Bluetooth low energy) Receiving: • Frequency between 2.36 to 2.5 GHz • Modulation GFKS at 1 Mbps • Sensitivity -96 dbm • Integrated PCB antenna (-1 dBi max gain) Transmission: • Frequency between 2.36 to 2.5 GHz • Modulation GFKS at 1 Mbps • Transmission power +8 dBm Compliant to (RED) 2014/53/EU and FCC
Inertial Sensor	3D accelerometer (acceleration range of ± 16 g), 3D gyroscope (angular rate range of ± 2000 degrees per second)
Operation system	Special software

Stimulator/Controller (2)	
Maximum output voltage	230 Vpp (at load impedance of 1 kΩ)
Maximum phase charge	100 µC (1000 µs pulse width, 100 mA voltage)
Maximum output current	100 mA across 500 Ω/ 1 kΩ; 5 mA open circuited load condition
Maximum number of channels	5
Current output per channel	0-100 mA in steps of 1 % max. current output (at load impedance of 1 kΩ[1])
Waveform	Biphasic (typical pulse forms see below) 
Duration of stimulation impulses (pulse width)	30 µs - 1000 µs in steps of 10 µs (using up to 4 channels) 30 µs - 800 µs in steps of 10 µs (using 5 channels)
Stimulation frequency	1 - 100 Hz (1,2,3,4,5,10,16,20,25,33,50 and 100 Hz)
Range of atmospheric pressure	800 to 1060 hPa
Operation time	Typical operation time up to 5 hours
Humidity	15 % rH to 93 % rH (not condensing)
Range of altitude	Up to 2.000 m / 6.561 ft
IP classification	IP 22
Protection class	II
Application part	Type BF
Medical device according to EU regulation MDR 2017/745	IIa

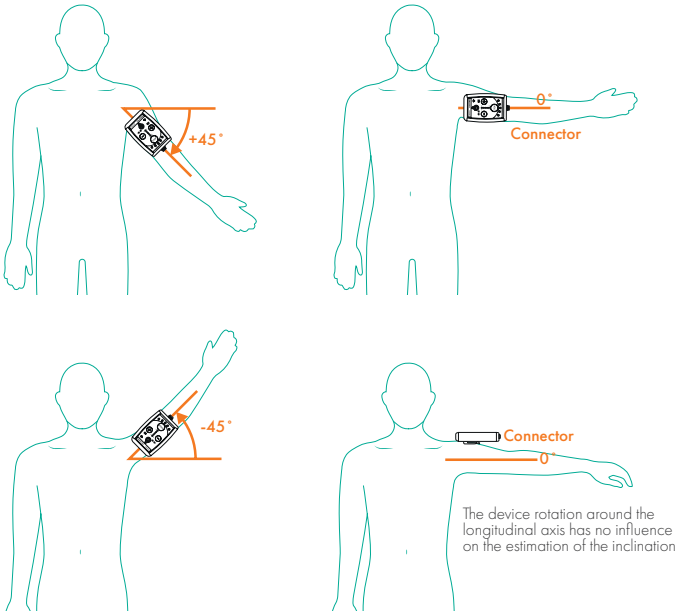
[1] Load impedances > 1 kΩ may result in maximum current of 100 mA not being reached.

Standard programs	
FES	Intensity: 0 mA ... 100 mA Frequency: 25 Hz ... 50 Hz / extendable to 100 Hz by therapists only Pulse width: 30 µs ... 500 µs / extendable to 1000 µs by therapists only Mode: auto repeat, manually triggered, motion triggered
NMES	Intensity: 0 mA ... 100 mA Frequency: 3 Hz ... 50 Hz / extendable to 100 Hz by therapists only Pulse width: 30 µs ... 500 µs / extendable to 1000 µs by therapists only Mode: auto repeat
TENS	Intensity: 0 mA ... 100 mA Frequency: 2 Hz ... 100 Hz Pulse width: 200 µs / extendable to 1000 µs by therapists only Mode: auto repeat
tSCS	Intensity: 0 mA ... 100 mA Frequency: 10 Hz ... 100 Hz Pulse width: 800 µs ... 1000 µs Mode: auto repeat

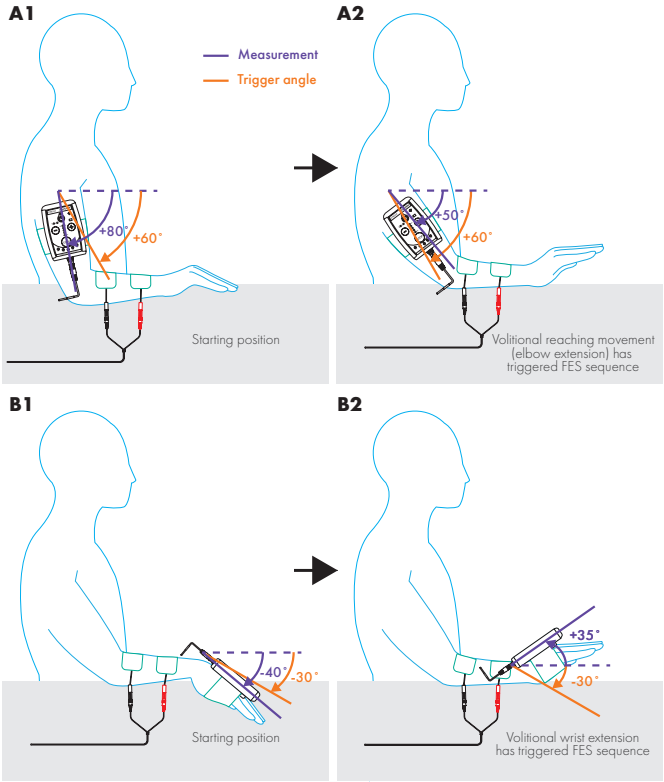
2.2.5 Built-In Sensor

The stimulator has a built-in inertial sensor (movement sensor). When the stimulator is attached at specific positions on the upper or lower limbs, the patient's movements can be captured and amplified by triggering functional electrical stimulation patterns. This mode is for patients with an active range of motion (ROM) of at least 10 degrees. Before using the device, the patient's remaining motor abilities must be assessed. The patient-individual threshold for triggering the stimulation is manually set by the therapist or patient. When attaching the stimulator, it should be aligned with the limb. The inclination angle is defined as shown in Sketch 1 (please consider the position of the connector). Rotating the device around its long axis doesn't affect how the angle is measured. The stimulator and limb must be aligned. Typical applications of motion-triggered functional electrical stimulation are the restoration of movement patterns like “Hand-to-Mouth”, “Grasp-and Release”, “Forward-Reaching-Movement”, and “Cyclic Movements”.

Sketch 2 shows two examples of a sensor-based therapy setup, where the stimulator is attached to the patient's upper limbs. The sensor detects any slight movement in the desired direction as a change in the angle of inclination. This can be used to trigger a pre-defined stimulation pattern. The stimulation starts as soon as the inclination angle exceeds or falls below a preset trigger angle threshold. In case A, a volitionally induced forward reaching movement triggers wrist extension and hand opening. In case B, a residual volitional wrist extension triggers electrical stimulation support of the same.



Sketch 1: How inclination angles are defined. Any rotation around the longitudinal axis of the stimulation device will not affect how the inclination angle is calculated.



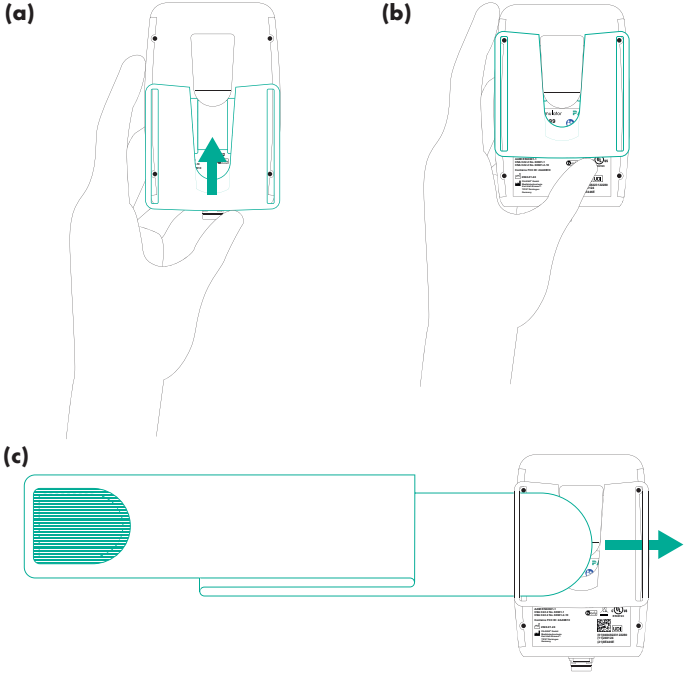
Sketch 2: Sample setup when using the internal sensor (A: Volitionally induced forward reaching movement triggers FES assisted hand opening and wrist extension; B: residual volitional wrist extension triggers FES support of the same and hand opening).

For cyclic limb movements, as during cranking with the arms or legs, the measured inclination can be used to determine the cycle percentage. A cyclic muscle stimulation can then be defined with respect to this cycle percentage to support such movements. Stim2Go continuously determines the maximal and minimal limb (stimulator) inclination during such movement to obtain the cycle percentage. The cycle percentage is defined as follows:

- 0 to 50% – limb changes from the maximal inclination to the minimal inclination and
- 50 to 100% – limb changes from the minimal inclination to the maximal inclination.

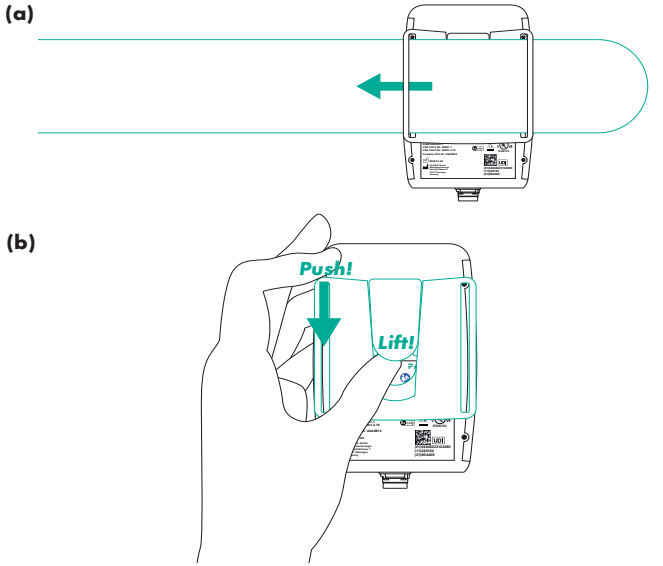
2.2.6 Strap and Strap Holder

If the stimulator is to be worn on the body, for example for motion triggered stimulation, it can be attached to the body with the strap. Sketch 3 shows how the strap holder is attached to the stimulator and how the strap is then clipped into the strap holder.



Sketch 3: Attachment of the strap holder and strap to the stimulator. (a-b) Push the strap holder below the belt clip until it snaps in. (c) Inserting the strap through the long cut-outs of the strap holder. The side with the hook patch should be facing towards you.

Sketch 4 shows how to remove the strap holder and strap from the stimulator.



Sketch 4: Detachment of the strap holder and strap to the stimulator. (a) Pull out the strap from the strap holder. (b) Lift the belt clip slightly up while pushing the strap holder with index finger to detach it.

2.2.7 Electrode Placement and Removal

The Stim2Go App will guide you with a wizard through the process of electrode selection and placement. Follow the instructions carefully, especially concerning the size, location and wiring of the electrodes. It is recommended to consult a physician or therapist to find the optimal setting for the best possible effect of Stim2Go.

To achieve the desired success of a stimulation application, electrodes must be carefully placed. The placement may include skin preparation procedures and the use of a conductive gel according to the electrode manufacturer's instructions for use. The size of the electrodes depends on the treatment.

The greater the distance between a pair of electrodes, the greater will be the volume of tissue (area and depth) being stimulated. For a greater volume of tissue an increased intensity of pulse might be necessary. The most reasonable distance is 5-15 cm.

It is not advisable to apply any enriching creams or ointments to the skin before applying the electrodes. It

might lead to unpleasant current spikes and will change the functional behavior of the electrodes.

⚠ Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

Avoid any placement:

- On the bony part of the cranium, near the mouth, throat, or larynx,
- Near the throat / carotid artery,
- Near the genitals,
- On acutely or chronically diseased (injured or inflamed) skin (e.g., in the event of painful and painless inflammation, reddening, skin rashes (e.g., allergies), burns, bruises, swellings, open wounds, and wounds or operation scars in the process of healing).

⚠ Any electrode placement that causes current flow at the front of the neck (especially the carotid sinus) or through the neck should be avoided unless under strict guidance from a qualified physician.

To remove or move the electrodes – first switch off the stimulation to avoid unwanted reaction. Always remove the electrodes from the skin with a moderate pull to avoid irritation of highly sensitive skin.

For reasons of hygiene, the electrodes should only be used on one person.

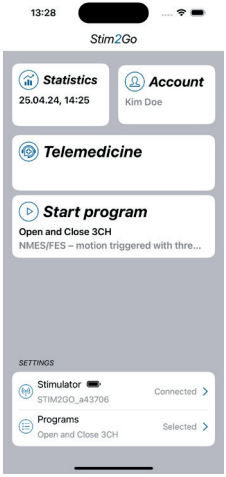
2.3 The App

The App is available from the App Store / Play Store. Type in “Stim2Go”.

The App is the main way to control the Stim2Go.

Log in with a valid email and choose a secure password to prevent unauthorized access. The App connects to the stimulator wirelessly through Bluetooth, and the connection is protected with encryption (ECC and AES). Most functions require an internet connection, which is secured with SSL encryption. It is within the responsibility of the user, to identify, analyze, evaluate and control the risks of any network or data coupling connection other than initiated by the Stim2Go App.

2.3.1 Home Screen



→ Stimulator settings and connections

→ Program settings
- Select programs
- Create, modify, delete programs

→ Account settings
- Sign in, Sign out, Sign up
- Edit your personal data, change your account type
- Access group administration

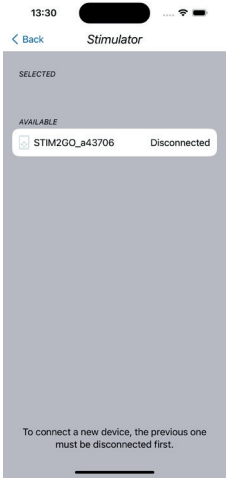
→ Statistics
- Access to statistical usage data

→ Start Program
- Quick stop test
- Electrode placement wizard
- Execute therapy programs

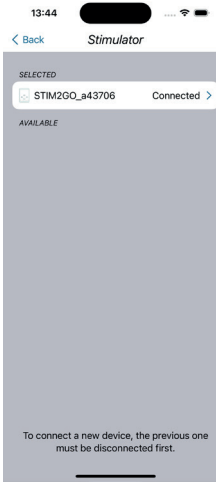
→ Telemedicine
- Notification handling for program sharing
- Consent activities
- Get access to assigned program by entering a one-time-code generated by the therapist

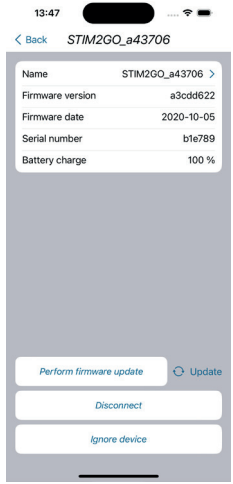
The Home screen shows the stimulator status, battery status, selected program, user information and a brief description of the selected therapy program to be started.

2.3.2 Stimulator Settings



The Stimulator screen offers the user access to features concerning the stimulator. Initially, connect the stimulator. Turn on the stimulator and wait until the device appears as available. Tap the device name to start pairing. Enter the PSK code (printed on the nameplate). This step is only needed once. When you tap on a connected stimulator, you can access different features.



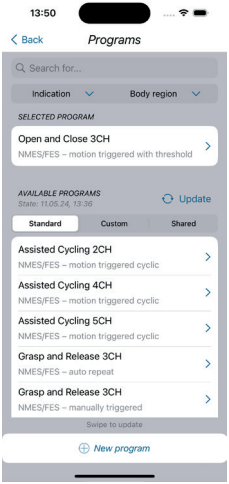


→ Name
The default name for the stimulator is STIM2GO_6 digit unique address.
If you have more than one stimulator, give them a more speaking name.
→ Information
Here you can find safety information like the firmware version, firmware date and serial number.
→ When you open this screen, Stim2Go will check if the firmware is up to date. If not, you can update it.

→ Finally, the device can be disconnected or ignored.

2.3.3 Program Settings

The program screen gives access to therapy programs.



→ Select a program
Search, filter, program at a glance, selection, deletion

→ New program
Template selection, naming, creation

→ Modify program master data
Stages / properties, channel settings, stimulation settings, phases

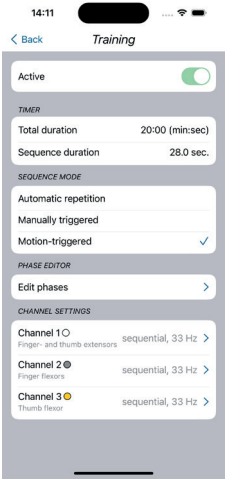
To execute a therapy with Stim2Go requires a program. The product is shipped with a set of standard programs. Users with the account type therapist can create new customized programs, which are based on templates. Lay users are advised to contact a medical professional in case they do not understand the product or a specific therapy program.

2.3.3.1 Program Master Data

Stim2Go maintains for any program several master data like name, description, tags, patient info. When you create new programs, record the data in a way it can be found when users search for a suitable program. Programs have up to 3 stages and use different channels for stimulation. It is part of the program specification to select which of up to 5 stimulation channels are involved and to give each channel a therapy specific name and description. The description could, e.g., state which limb is concerned (e.g., left/right leg) and to which muscle group the electrodes shall be attached with (e.g., quadriceps).

Programs can be set for solo mode, where the smart device disconnects, and the stimulator is controlled directly using its keypad. The solo mode can be activated at any time after the start of the program. After the program is finished, or the user stopped the stimulation, or an error occurred, the solo mode is terminated, and a new therapy program can only be started via the smart device. The solo mode is only possible if the sequence mode of the program is “Auto-repeat” or “Motion triggered” and if only the training stage is used.

2.3.3.2 Program Stages

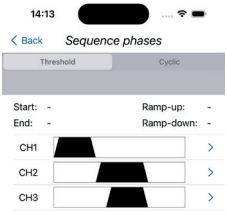


Any program can have up to 3 stages – warm up, training, cool down.

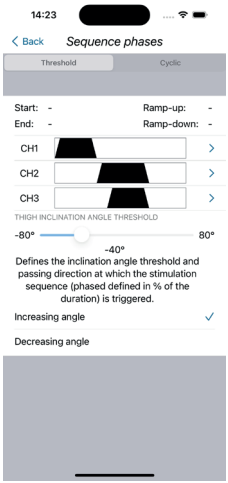
Stages last from 1 to 60 minutes. Each stage has a sequence setting for all channels in "sequential" mode. Sequences are patterns for stimulation. The sequence duration depends on the sequence mode. You can set it to "auto-repeat," what means that sequences are permanently repeated, “manually triggered” – a sequence ill be manually triggered via the App and executed once or “motion triggered” – preconfigured inclination angle values can be used as thresholds to evoke FES stimulation sequences (see chapter 2.2.5 - Built-In Sensor).

For cyclic limb motions, stimulation sequences can be defined based on the cycle percentage that is derived from the limb’s inclination angle (see chapter 2.2.5 - Built-In Sensor).

2.3.3.3 Phases



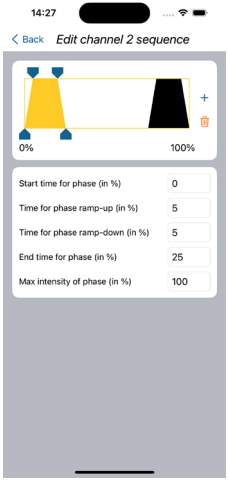
Each sequence has up to three phases per channel. The stimulation pattern is the alignment of phases across all applied channels. All values are specified in % of sequence duration.



Phases need to be specified: Start time, ramp-up, ramp-down, end time, and max. intensity.

When the program is “motion triggered” and the option “threshold” is chosen, the trigger threshold (inclination angle) of the internal sensor can be set from -80° to +80°. Furthermore, the direction of triggering can be chosen (increasing or decreasing angle).

When you touch a phase on the screen, it turns yellow and the values appear. To edit a value, press the ">" button. When the program is "motion triggered" and the option "cyclic" is chosen, the stimulation is defined by the percentage of a cyclic limb movement. There is no fixed sequence duration. See chapter 2.2.5 - Built-In Sensor for details.



To add a new phase, press the “+” button right of the graphical window. You can define up to three phases. To delete a phase, touch it – it will turn yellow. Touch the recycler icon to delete a phase. To modify a phase, you can change the shape or values. Values are specified in percentage of the “sequence frame”.

Phases cannot overlap and must be set within the “sequence frame”. Any setting will immediately be valid.

2.3.3.4 Channel Settings

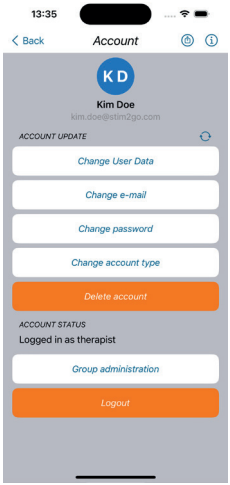
The mode refers to the stimulation pattern and can be set to:
“Always On” – the sequence settings are not relevant, or
“Sequential” – stimulation pattern (“phases”) according to the sequence settings are applied.

The characteristics of the current are determined by “Pulse Width” (width of the rectangular pulse), “Max Current” (maximum intensity the user can adjust), “Frequency” (number of pulses per second) and “Pulseform” (biphasic rectangular with pause or without pause).

The “Max Current” parameter serves as a recommended orientation for the intensities considering the proposed electrodes of a certain type and size and determines the granularity of the increase and decrease steps. The increment value is 1% of the “Max Current”.

2.3.4 Account

The App guides new users through a sign-up process to get initial credentials. Once signed in, the user will have access to all functions, necessary to maintain a user account:



→ “Change User Data”
Change user master data (Name, optionally date of birth, sex, title)

→ “Change e-mail“
Every account is tied to a valid email address. When you change the email address (e.g., for personal or job reasons) you will need to update your Stim2Go account data as well

→ “Change Password”
Whenever you suspect that your password is no longer secure, you should change it immediately.

→ “Change Account Type”
Stim2Go distinguishes between roles patient and therapist / physician. Being therapist / physician will give you access to extended features like creating customized programs. Any change of the account type can be initiated here.

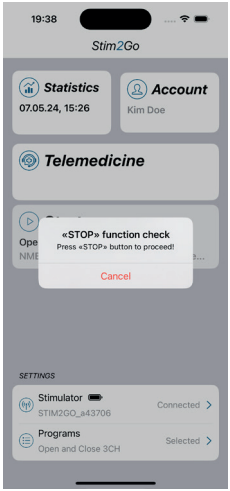
→ The deletion of an account and associated data can be done by pressing the button “Delete Account” or may be requested at account@stim2go.com.

When Stim2Go is used in a clinical setup, users can become members of a group. At least the creator of the group has access to group management. For creation, deletion, or administration of groups press the button “Group Administration”.

2.3.5 Start Program

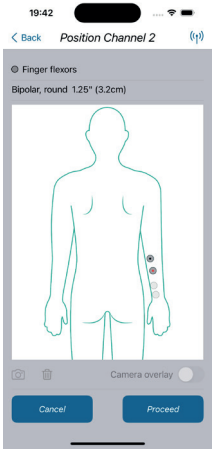
2.3.5.1 Stop Function Test

A major safety feature is the “STOP” button.

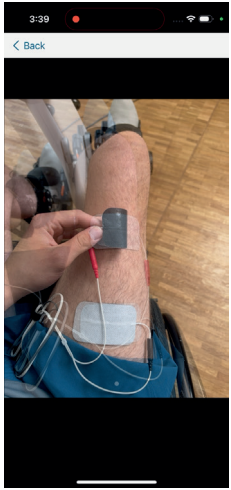


The stimulator has a safety feature that stops stimulation when there is a connection interruption. After each start a stop function check is performed to prove the connection. When the connection is confirmed - prove you can stop quickly at any time. Press the "STOP" button on the stimulator or the "STOP" / "PAUSE" button in the App to stop stimulation.

2.3.5.1 Electrode Wizard



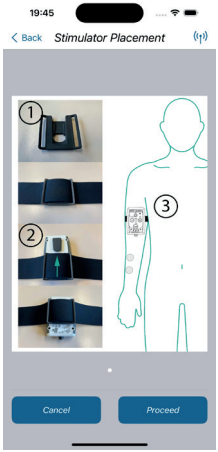
The correct placement of the electrodes is crucial for a successful therapy. The optional electrode placement wizard provides information like electrode size and type, the recommended location and additional information such as pictures uploaded by the user in previous sessions.



The Camera overlay mode will support you to refind the right electrode position. Saved photos that show good electrode placement are compared with the camera overlay to ensure new precise electrode placement.

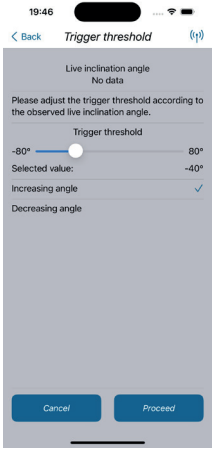
The electrode placement depends on the program and cable type.

2.3.5.3 Stimulator Placement Wizard



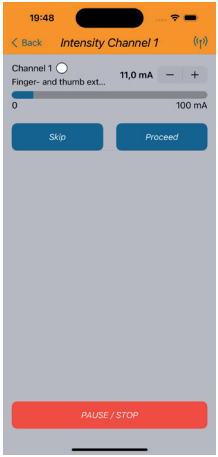
The graphics illustrate how to position and orient the device at the limb and how to mount the strap at the stimulator.

2.3.5.4 Threshold Wizard



This wizard appears for biofeedback programs and helps you to select the threshold inclination angle for triggering the stimulation. The measured inclination angle is displayed live and can be assessed while the patient performs voluntary movements without stimulation. Values above 80° or below -80° are shown as >80° and <-80°, respectively. Based on these observations, a patient-individual threshold for triggering the stimulation sequences must be manually determined. This threshold must be reachable by the patient and should challenge the patient to reach their residual motor limits. The threshold can be set using the slider.

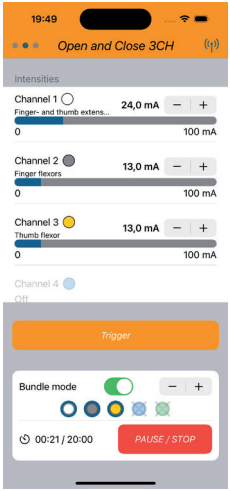
2.3.5.5 Intensity Wizard



Set an intensity level per channel that is expected to be comfortable when initiating a triggered stimulation. In case the program aims for functional movement, check the effect of a certain intensity with the current setup. This can be done for all program stages (Warm-up, Training and Cool Down).

If you skip this wizard, it will start with zero intensity on all channels when invoking stimulation. The intensity for all channels can then be adjusted on the fly.

2.3.5.6 Stimulation Screen



→ Status bar
Yellow back colour indicates one or more channels with intensities >0mA.
Left widget shows which of three stages is active. (Warm Up, Training, or Cool Down)

→ Channel area
Each channel is visually represented. Unused channels are greyed out. The buttons “+” and “–” will increment/ decrement the intensity by steps of 1% of the maximum intensity (shown as s grey bar).→ Bundle area The “+” and “-” buttons will affect all bundled channels.

The blue bar shows the intensity. The icon to the right of the channel name matches the colours of the cable and the indicators of the stimulator keypad.
The channels can be toggled – to be included or not, the actual and configured stage time are displayed, the “PAUSE” / “STOP” button will stop the stimulation at any time

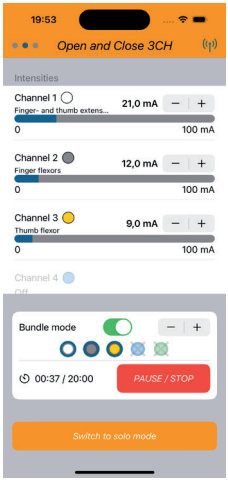
→ Bundle area
The “+” and “-” buttons affect all bundled channels. The channels can be toggled.

The bundle mode is off by default. You can switch on Bundle Mode when at least one channel is enabled.

The "+" and "-" buttons in the "Bundle area" affect all bundled channels. You can also set the intensity of each channel separately.

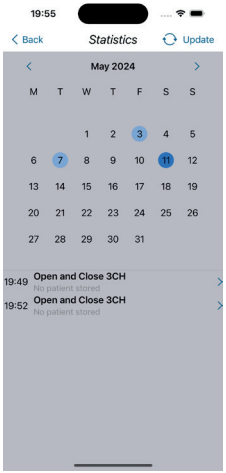
The actual and configured stage time are displayed.

You can stop stimulation at any time with the PAUSE/STOP button.



Solo Mode: You can operate the stimulator with the membrane keypad and an App control is not required. If the program allows solo mode, you can switch to it by pressing the “Switch to solo mode” button. The stimulator and smart device will be disconnected and the basic control functions (increase, decrease, “STOP”) are executed via the keypad on the stimulator.

2.3.6 Statistics



The “Statistics Button” will give users access to statistical meta data.

These data are organized by calendar and log durations, intensities, completed stages and error events for any execution of therapy programs. Access is restricted to the corresponding users or user groups.

3 FAQs and Troubleshooting

3.1 Operating the App

The program list is empty or not up to date.

The program list is updated from the cloud.

If you lose your internet connection, you cannot use the app. Check your phone's internet settings. To update the program list, swipe down in the middle of the program list.

3.2 Connection Issues

The stimulator has unexpectedly disconnected from the App.

Wireless connection may be interrupted. If this happens, the blue Connection-LED on the keypad blinks and the app shows "No Stimulator connected".

→ Make sure the stimulator is switched on and the Connection-LED is flashing.

→ Check the App: Go to the Stimulator screen and try to connect again.

↔ If the issue persists, check your Bluetooth connection on your smart device.

The stimulator has unexpectedly disconnected from the App.

The stimulator may be connected to a different smart device.

The Stimulator can be connected to only one smart device at a time. If the Connection-LED on the Stimulators keypad is flashing, the Stimulator is advertising (looking for a smart device to connect); if it is permanently on – a Bluetooth connection is established.

If your App's home screen indicates: "No Stimulator connected" but the Connection-LED on the stimulator is permanently on, most probably a different smart device is connected.

3.3 Errors

I try to switch on the stimulator - when pressing the Power button the Battery-LED light is flashing red.

The stimulator battery may be completely discharged.

→ Charge the stimulator by connecting it to the power supply plugged into a mains outlet.

→ The Battery-LED is flashing green – wait until it is permanent green.

→ Nothing seems to happen – wait 5 minutes and then reconnect the charging cable.

The stimulation is paused and one or more Channel-LEDs are permanent red.

An electrode error occurred.

→ Check whether the electrodes are properly attached to the skin as advised in the electrode manufacturers IFU.

→ Check the connection of the cable with the electrodes. The connector may have loose contact.

4 Maintenance and Service Instructions

4.1 Cleaning and Disinfection

Clean the device, cables, and strap holders regularly for hygienic reasons. Use a dry or slightly damp cloth. For stains, you can also soak the cloth in alcohol. The strap can be machine washed at 30 °C.

⚠ Never use strong cleaning agents, soaps or solvents or disinfectants containing trichloroethylene, acetone, button, benzene methanol or nitro thinners.

Contact the manufacturer if there is any heavy-duty dirt that cannot be removed. Disinfect Stim2Go and straps before every patient treatment session, thus preventing cross-contamination between patients. Wipe the device's surfaces, cables and strap holders with disinfectant. Disinfect the strap with a disinfectant spray. Clean and disinfect parts in direct contact with the patient's skin after each training session. We strongly recommend that you use disinfectants and disinfection procedures conforming with a state-of-the-art disinfection protocol.

4.2 Charging

Use the power supply unit provided by the manufacturer to recharge the stimulator. Ensure that the power supply matches the voltage and frequency in your country.

⚠ Do not connect the product's power supply to the mains via an extension cable or a multiple socket.

If the battery is charged with less than 10%, the battery status indicator is shown in red. The indicator lights up yellow between 10% and 20% charge level. Use the power supply unit to recharge the stimulator if the battery status indicator is shown in yellow or red.

The battery indicator flashes green during the charging process. If the battery is fully charged, the indicator will light green permanently. It takes about 180 minutes to recharge the stimulator completely. When the stimulator is charging, no stimulation is possible.

LiPo rechargeable batteries are "comfortable" when the capacity is between 20% and 80%. Avoid extreme temperatures and follow the storage instructions. When the stimulator is not used for more than 3 months - charge the battery regularly.

4.3 Maintenance and Technical Safety

The lifetime of the device is set to 5 years, based on the maximum charge cycles of the integrated LiPo battery. The internal battery guarantees up to 500 full charge cycles with over 80% capacity. The battery cannot be replaced by the user nor during maintenance. Proper disposal of a device with a built-in LI-ION battery involves certain risks. To avoid risks, return the device to the manufacturer.

⚠ If the stimulator has been subjected to mechanical stress - e.g., after a fall - switch it off and on again to force a selftest and do a visual inspection. If damaged, replace components.

For repair, the customer must obtain a RMA number before returning the device or accessories to the manufacturer. To obtain a valid RMA number contact support@stim2go.com.

The separate battery charger is part of the product and must not be replaced with a different type. You are recommended that the charger undergoes a regular check-up and is replaced if necessary.

If used in clinical or health care facilities, regular checks of the device must be carried out in accordance with the relevant national regulations (e.g. IEC 62353: Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment).

4.3.1 Maintenance in Home Use

Maintenance of this product in Home Use is limited to the most basic routine functions - simple cleaning by wipe disinfection (see chapter 4.1 - Cleaning and Disinfection) and recharging of the battery (see chapter 4.2 - Charging).

Inspect the stimulation device, cable, electrodes and accessories before each use. If there is a defect, contact the manufacturer.

4.4 Service Period

The product does perform a self-test after charging or before starting a therapy. If the self-test fails constantly, the customer should send in the product to the manufacturer for repair. If a customer's safety regulations require recurring testing, e.g. every 2 years, the power supply can be subjected to a common standard test.

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