Transcranial Electrical Stimulator
for tDCS, tACS, tRNS

User Manual

REV. IN-tESm 1.6

CE 2274

Transcranial Electrical Stimulator for tDCS, tACS, and tRNS.

This device is in compliance with the requirements of Directive MDD 93/42/EWG and is compatible with the requirements of the following standards: PN-EN 60601-1:2011 + PN-EN 60601-1:2011/A1 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance and PN-EN 60601-1-2: 2015 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests as well as the basic requirements of MDD 93/42/EEC.
The product is a medical device.

nurostym tESm™ is manufactured by Neuro Device Group S.A.
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Information about compliance can be obtained from the manufacturer.

Nurostym tESm User Manual
Original Issue: 04/2021

The information contained herein is subject to change without notice. Neuro Device Group S.A. shall not be liable for technical or editorial errors or omissions contained herein. Nothing within this User Manual can be considered as an offer, warranty, promise or contractual condition.

The device and the software which is supplied with the device belongs to the manufacturer. Upon receipt of the equipment, the user acquires only the right to use the software.

By installing, copying, downloading or otherwise using the nurostym tESm software application that accompanies this device, you agree to be bound by the terms of the End User Licence Agreement (EULA). If you do not accept these licence terms, your sole remedy is to return the entire used device (hardware and software) within 14 days for a refund subject to the refund policy of the distributor of the device.

It is also necessary to seek written permission from the manufacturer before making changes for the use of the device for purposes other than those established.

This guide describes the features on the nurostym tESm device and refers to nurostym device version 1.0.0 and newer. Some functions or accessories described herein may not be available in older versions of the device

Before starting the device, please read these instructions carefully. Keep this document for future reference. Follow warnings and instructions marked on and given by the product.

Table of Contents

1 About nurostym tESm

The Nurostym tESm is designed for non-invasive brain stimulation (NIBS) and central nervous system (CNS) stimulation with electrical currents ranging from ±100 μ A to ±4 mA (in 1 μ A intervals) by placing electrodes on the scalp. The device provides stimulation in transcranial direct current stimulation, transcranial alternating current stimulation and transcranial random noise stimulation, (tDCS, tACS and tRNS respectively). Alternatively, Analog Input Mode allows the user to use any analogue signal from an external source. In this case, the stimulation current is adjusted proportionally to the external signal and stimulation is delivered using patient-safe transcranial non-invasive brain stimulation. Using transcranial electrical stimulation, cortical activity can be stimulated or inhibited to modulate plastic changes in the brain. The effects achieved depend on the duration of stimulation, the shape of the current waveform, the current density and the frequency of stimulation. The electrical charge and current density delivered by tES stimulators is well below the charge needed to induce neuron activation and only affects neuron excitability.

The device is designed for use by professional users (doctors, Rehabilitation, psychologists) or under their supervision. The tESm stimulator is used in treatment:

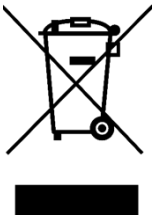
- **Neurological disorders:**
  - neurological rehabilitation [tDCS],
  - memory disorder [tDCS],
  - aphasia [tDCS],
  - chronic pain [tDCS, tACS, tRNS],
  - migraines [tDCS],
  - Parkinson's disease [tDCS, tACS],
- **Mental disorders:**
  - depression [tDCS],
  - schizophrenia [tDCS],
  - addictions [tDCS].

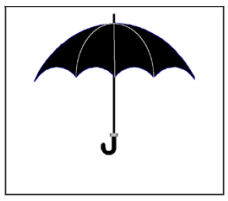
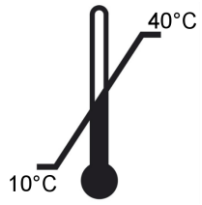
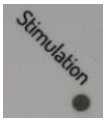
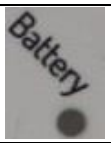
The Nurostym tESm, like other stimulators of this type, is not recommended for use in patients with epilepsy or diagnosed anxiety disorders and continuous stimulation should not last longer than 30 minutes.

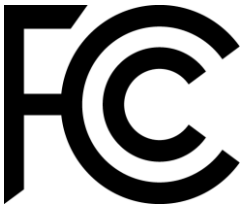
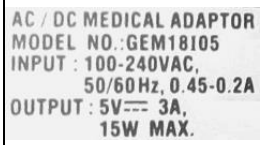
The nurostym tESm features exceptionally low noise levels, a wide range of parameter settings and a built-in ergonomic user interface for stimulation without the need for external devices such as a computer or tablet.

2 Icons and Labels on Device and Packaging

	Follow the user instructions
	BF applied part. BF applied part is a type B part with additional isolation of the patient circuit from the remaining part of the electrical medical device.
	Special care required. Pay attention.

	Class II device (power unit). Protection of a class II device consists of separating any accessible conductive parts from hazardous parts with double insulation with specified parameters or reinforced insulation to the same level of protection as double insulation. It does not use any earthing measures and is not dependent on the electrical system conditions.
	Manufacturer's address
	Power 'Standby' button. This button does internally not disconnect the device power. Pressing this button turns on or turns off the device.
	Waste electrical and electronic equipment (WEEE) should not be discarded together with other types of waste.
	Serial number
IP41	IP class identification: ○ 4 - protection from solid objects equal or greater than 1.0mm diameter ○ 1 - protected against vertical falling water drop
	CE marking constitutes the manufacturer's declaration of the product's conformity with the requirements of Directive 2014/30/WE and 2014/35/UE.
	Handle with care.

	Keep the device dry. Store in a dry place.
	Acceptable storage temperature restrictions (from 10 to 40 °C)
	Direct current (device charging unit)
	Digital in/out triggers terminal (also used to couple to nurostym Interface) (See: 5. Triggers and Analogue I/O)
	USB port (USB port - used only for communication with the device)
	Stimulation - continuously lit (blue) during stimulation and impedance check.
	Battery - continuously lit (yellow) when the device is being charged or green when it is fully charged. The LED goes off when the charger is disconnected.
	Power - continuously lit (green) whenever the device is on.
	Charger terminal 5V DC, max 3A (15W max)
	Medical safety approved (2xMOPP) according to ANSI/AAMI ES60601-1
	Medical safety approved (2xMOPP) according to IEC60601-1

	For indoor use only
	Polarity of DC power connector
	WEEE; waste electrical and electronic equipment
	FCC Declaration of Conformity
	Mains power unit parameters: - AC input power, DC output power, - manufacturer model: GEM18105 medical adaptor, - input power: 100-240VAC at 50/60Hz, - output power: 5V DC, max 3A (15W max)

3 General Device Information

The nurostym is designed for use by or under supervision of specialists.

3.1 Safety, Risks and Prevention of Side-effects

The device is fitted with numerous safeguards to limit the possibility of subjecting participants to any undesired effects. The key variables which may lead to unwanted side-effects include: current dose and the size and positions of electrodes. Recommended limits of stimulation in tDCS are 2mA of current applied via electrodes with an operating surface of 35cm² in a single session of no more than 30 minutes. The user is required to enter data, prior to stimulation, about the surface area and shape of electrodes being used.

The device measures the current intensity continuously ensuring performance and safety of each stimulation. The device also has a current density control mechanism which is used to adjust the stimulation value and notifies the user of any safe operating limits being reached or exceeded.

The nurostym must not be used on subjects with implanted devices such as a pacemaker and/or deep brain stimulator, as well as intracranial metals such as clippings, coilings, ventriculo-peritoneal shunts and endoprothesis (amongst others) as the device can interfere or cause damage to such metals/devices and/or cause injury to the subject.

An electrostatic discharge may be caused by touching the subject or the device. Such an electrostatic discharge whilst electrodes are attached to a subject's scalp could lead to a mild shock sensation similar to that experienced in everyday life. These currents are not dangerous but can cause an unpleasant sensation. Care should be taken to avoid touching a subject during stimulation.

The most common side-effect occurring as a result of tESm is skin irritation, which presents itself in the form of transient redness or, less frequently, as erythema and eschar. To reduce the risk of these side-effects, the use of well moistened salinised sponges under the electrodes or a thick layer of conductive gel is recommended.

Frequently reported experiences for most participants of tES include tingling or a slight burning/itching sensation on the scalp which is caused by skin resistance. This sensation weakens or disappears after approximately 30 seconds. Gradually increasing the current intensity to the target level (fade-in) and a gradual reduction at the end of a stimulation period (fade-out) can help to alleviate these sensations. The nurostym implements a fade-in and fade-out model for power intensity adjustment.

Certain non-specific side-effects have also been described by subjects, such as localised pain and headaches. However, these are not thought to be directly related to stimulation and only appear to occur in subjects who are also suffering from sleep deprivation or hunger.

The risk of inducing an epileptic seizure remains negligible due to the fact that no harmful neuronal hyperpolarization occurs through subcortical stimulation. For safety reasons, subjects who suffer from epileptic episodes are typically excluded from transcranial stimulation studies.

The operator should not touch the subject during stimulation.

The device is designed for transcranial stimulation only. It should not be used for any other types of stimulation, e.g. subdural stimulation. Use of the device for any other purposes may cause tissue damages or may lead to low efficacy of intervention.
Apart from stimulation functionality, device provides analogue input, analogue output, trigger input and trigger output functionalities for interfacing with external devices. Operation of these functionalities is safe for patient and follows requirements of PN 60601-1.

Stimulation of selected narrow areas of the brain could cause short-term interruption of activity in this area, with disruption of cognitive functions and motor/sensory processes.

The device is fitted with an integrated, rechargeable battery which cannot be removed or replaced. Any attempts to

tamper with or remove/replace it can lead to fire, leakage of aggressive substances or explosion. For power unit servicing please contact your distributor.

WARNING: Unauthorised opening of the device will void any warranty and may cause electric shock.

3.2 Essential performance, frequently used functions and contraindications

The essential performance of the device is to transcranially stimulate the brain of a subject (patient, research study participant) with given stimulation current parameters for a given amount of time, as defined by the stimulation protocol.
The device may be used for clinical research, comprising of tDCS, tACS, tRNS stimulation or other types of electrical current stimulation through use of the Analog Input Mode.
General contraindications of tESm use include skin inflammations and epilepsy seizures history. The use of the device in clinical research and the study protocol shall be approved by appropriate entities.

3.3 Device Specifications (Technical description)

Number of channels	1
Stimulation modes	tDCS, tACS, tRNS, Analogue Input Mode
Sham mode	Single-blind and Double-blind
tDCS Parameters	
Stimulation current	max ±4 mA (increment 1µA)
Stimulation duration	1-1800s (increment 1s)
Fade-in/out	0-60s (increment 1s)
tACS Parameters	
Amplitude of stimulation current (peak-to-peak value)	max 4 mA (increment 1µA)
Offset	max ±3 mA (increment 1µA)
Stimulation duration	1-1800s (increment 1s)
Fade-in/out	0-60s (increment 1s)
Frequency (carrier)	0.01-600Hz (increment 0.01Hz)
Frequency (modulation)	0-300Hz (increment 0.01Hz)
Modulation index	0-100%
Samples per period	256 (for carrier frequency <300Hz and 128 for carrier frequency ≥300Hz)
tRNS Parameters	
Sample value range	±(200 - 4000)µA (increment 1µA)
Stimulation duration	1-1800s (increment 1s)
Fade-in/out	0-60s (increment 1s)
Noise distribution	rectangular, gaussian
Predefined filters	LP: 100Hz, 250Hz, 640Hz, OFF HP: 50Hz, 100Hz, 250Hz, OFF
Analogue Input Mode Parameters	

Transfer ratio	2mA per V
Current range	±4 mA
Analogue Bandwidth	1kHz (-3dB)
Triggers IN and OUT parameters	
Signal parameters	TTL or 5V CMOS compatible
Other Features	
User programs	1. Creating predefined stimulation programs (PRESET) 2. Directly controlling the protocol through the application interface (API)
Accuracy of current setting	<5% for current <1mA, <1% for current >1mA
Voltage max.	35V
Device rated power	3W
Interface	Touch screen display, control by PC-USB
Digital inputs and outputs	2 digital inputs 3 digital outputs
Analogue Outputs	Main: 0.5V per mA (single ended output) Low level: 2.5mV per mA (differential +,- & GND)
Power supply	Built-in rechargeable battery, total charge typ. 10Ah operating time up to 10h
Mains power adapter (Charger)	Included in the set (Mean Well part number GEM18I05-P1J), 5V/3A DC output 2x MOPP medical safety 80-264VAC 47-63Hz mains input, AC current 0.45A at 115VAC, 0.25A at 230VAC Touch current < 100µA/264VAC
USB	USB micro B plug type, 5V DC, USB 2.0 compatible (12Mbps) (communication only)
Dimensions	150 x 115 x 32mm
Safety control	1. Current density control for a defined electrode; 2. Measurement of impedance (modes: continuous monitoring without stimulation, continuous monitoring with stimulation, single impedance check before stimulation)
Operation of impedance control	Possibility to define a threshold for interrupting stimulation: 10kΩ - 50kΩ Possibility to define user alert threshold: 5kΩ - 15kΩ/off
Electrodes sockets	touchproof DIN42802 1.5mm
Measurement accuracy (stimulation current and voltage)	5%

3.4 **Default Parameters Values (Technical description)**

Type of setting	Parameter name	Starting value of the parameter
General	Electrode shape	Rectangular
	Maximum impedance	10kΩ
	Impedance alarm	On; 8kΩ
	Sham	None
Electrode rectangular	Dimension a	5cm
	Dimension b	5cm
Electrode round	Diameter	2cm
Electrode shape undefined	Surface area	25cm²
tDCS	Amplitude	2mA
	Duration	20min
	Fade In	10s
	Fade Out	10s
tACS	Peak to Peak	2mA
	Frequency	10Hz
	Offset	0µA
	Duration	20min
	Fade In	10s
	Fade Out	10s
tRNS	Amplitude	2mA
	Highpass filter	None
	Lowpass filter	250Hz
	Noise type	Gaussian
	Duration	20min
	Fade In	10s
	Fade Out	10s

3.5 **Operating, Handling, Transporting and Storage Conditions (Technical description)**

The following conditions must be adhered to for the operation, handling and storage of the nurostym. Following these instructions will help to ensure that the device remains functional and minimise any risk of damage to the device or injury to users and subjects.

Keep the device out of and away from:

- Areas where there is a high level of dust, moisture and/or humidity.
- Sources of heat and direct sunlight.
- Strong magnetic or electrical field sources (at least 30cm away).
- Liquid, corrosive chemicals and flammable gasses or liquids.
- Highly pressurised atmospheres (above 1060hPA)

The ambient temperature should be between 10ºC – 40ºC (50-104ºF).
Relatively air humidity should be between 20-95%
Air pressure should be between 700hPA – 1060hPA

Condensation formed in the atmosphere whilst the stimulator is stored, transported or used at low or highly fluctuating temperatures can cause damage to the device. For safety reasons, allow the stimulator to be gradually brought up to room temperature before use (wait minimum one hour before using).

Take care when operating, handling and storing the device to avoid damage to the housing, screen and connection terminals; and to prevent wires being detached.

Do not use the device in a manner other than that outlined in this instruction manual or as advised by the manufacturer. Doing so may damage the device and increase the risk of injury and/or electric shock.

The device is fitted with an integrated, rechargeable battery and is supplied with a mains power unit for charging. Use of a 3rd party power unit other than the one supplied with the device or provided by the manufacturer can cause damage and/or malfunction and increase the risk of injury.

The integrated, rechargeable battery does not need periodic testing or calibration. If the device is stored for more than 12 months, it is recommended to perform re-charging of internal battery.

Do not store the device with less than 50-60% charge in the integrated, rechargeable battery.

Store the device in a secure location, in its original packaging in a cool, dry place free from dust and humidity; and away from unauthorised personnel.

Transport the device in its original packaging free from dust, moisture and humidity. Transport the device in its original packaging, free from dust, moisture, and humidity. Land, sea, and air transport is permissible (battery compliant with UN38.3). Maximum altitude of transport is 2000m.

The device is designed for self-checking its critical functions and will alert if manufacturer's service is required.
There's no need for scheduled maintenance or re-calibration. Any service actions within the device should be performed by the manufacturer's service and engineering department or the authorized and trained representative of the manufacturer only. There are no user-serviceable parts in the device.

The intended life of the product is five years from the date of manufacture.

Dispose the device as required by the legislation of disposal of waste electrical and electronic equipment (WEEE) within the country of use.

WARNING: No modification of this device/equipment is allowed.

3.6 Electromagnetic environment

The intended environment for device's usage is professional healthcare facility environment.
The system the device is certified for consists of the stimulator with or without and interface box, with or without a splitter and with up to five electrodes.
Any cables connecting interface box with external devices (such as EEG amplifier, signal generator, oscilloscope, signal recorder etc.) should not be longer than 3 meters.
All interfaces designated as 'outputs' shall be coupled with external high-impedance input ports.
All interfaces designated as 'inputs' shall be driven from low impedance sources.

3.7 Operation

The device is intended for a continuous operation. Practical operation time is limited by batteries capacity.

3.8 **Cleaning**

The device does not require any sterilisation.

Clean the device with a warm, damp cloth moistened with water and then dry with a separate cloth. Do not use products which contain acetone.

Rubber electrodes with outer sponge should have the cloths removed. The sponges should be washed in 60 degrees water with standard textile washing detergents and rinsed.
Rubbers should be cleaned with isopropanol or disinfectants for medical products (e.g. Schülke Mikrozid AF liquid) afterwards.

When used with rubber electrodes and Ten20 Paste, clean the electrodes with tap water, gently rubbing them. Use isopropanol or disinfectants for medical products (e.g. Schülke Mikrozid AF liquid) afterwards.

Leave the electrodes to dry in room temperature.
If other types of electrodes are in use – refer to user manual of electrodes manufacturer.

3.9 **Use**

NOTE: The manufacturer or its authorised representative accept no responsibility for any faults and/or injuries a result of misuse of the device.

General recommendations:

- There is no age limitation for subjects undergoing stimulation.
- Settings of the procedure should be consistent with the instructions in this manual.
- Do not expose the device to ionizing radiation, non-ionizing radiation or vibration.
- Use of any accessories or cables other than those supplied with the device or specified in this manual could increase the emission rates or reduce the immunity to external disruption and may consequently cause the device to malfunction.
- Do not put any portable radio communication equipment within 30cm of the device or any of its parts, including the cabling supplied with the device. Otherwise, the device can malfunction.
- The device, when it is in use must not be covered with any materials, such as papers, clothing, notebooks or any type of sheeting.
- If the display is blinking, stop using the device immediately, as you will not be able to control the device functions.
- As a result of significant disruptions caused by such factors as electrostatic discharge, communication with the device display can be interrupted. When this kind of condition is discovered, the device will refresh the view and the display can blink temporarily. After refreshing, the device will continue working normally. In similar circumstances, battery status indication can be interrupted. In this case, contact your distributor.
- When operating the device, it must be placed on a flat and stable surface, with its display facing upwards, outside the range of the subject's hands, so that the operator can read the messages displayed on screen. The device orientation should facilitate disconnection of applied parts (such as electrodes), and the device should be protected from falling from height onto the operator or subject.
- Do not stack the device on top or under other units (except for manufacturer-provided Interface), as this may cause the device to malfunction.
- If any mechanical damage is found on the device housing, the device should be returned to your distributor for servicing. If any damage occurs during work, interrupt the treatment immediately. Many of these cases involve broken displays.

3.10 Display Messages - Colour Coding

The device displays certain messages concerning its operation to the user.

- Green indicates correct readings.
- Yellow indicates a warning against incorrect stimulation parameters, however without exceeding the preprogrammed safety level.
- Red indicates the highest level of warning, when stimulation cannot proceed or is interrupted if the warning appears during the process. In this case, either the parameters exceed the preset safety level, inadequate settings are used, or the device is inadequately prepared for service (shorted electrodes, too high impedance or impedance ≤300Ω, charger connected).

Any diagnostic operator with impaired colour perception should pay special attention to the text message and sound signals.

3.11 Package contents

The package contains:

- Main unit (identified by name and serial number)

NOTE: Use only the original charger supplied by the manufacturer. Use of a non-authorized charger may result in a device malfunction or unacceptable risk.

- Accessories:
  - Mains power adapter with plug adapter (Charger-5V/3A, medical grade Mean Well GEM18I05-P1J)
  - USB cable (MULTICOMP MC002473)
- Optional accessories:
  - Interface box (inputs and output extender -identified by name and serial number)
  - Splitter box (identified by name and serial number)
  - Extender cables for connecting splitter (Spes Medica BEC152626S12 or equivalent)
  - Cable to couple main unit to Interface (L-Com CS2NB15MM-1 or equivalent)
  - Cables to couple Interface box with external recording devices (Spes Medica BEC152126S3 or equivalent)
  - Electrode cables (Spes Medica BEC152126S12 or equivalent)
  - Reusable silicon electrodes (Spes Medica SIL0005050 or SIL0005070 or equivalent)
  - Disposable electrode support cap (Spes Medica D00000SA000 or equivalent)

3.12 Device Layout

Figure 1 shows the front view of the device, with the following components:

1. Charger terminal
2. Power 'Standby' button

3. Device status LEDs
    a. Power - continuously lit (green) whenever the device is on.
    b. Battery - continuously lit (yellow) when the device is being charged or green when it is fully charged. The LED goes off when the charger is disconnected.
    c. Stimulation - continuously lit (blue) during stimulation and impedance check.
4. USB communication port
5. Digital in/out triggers terminal (also used to couple to nurostym Interface)

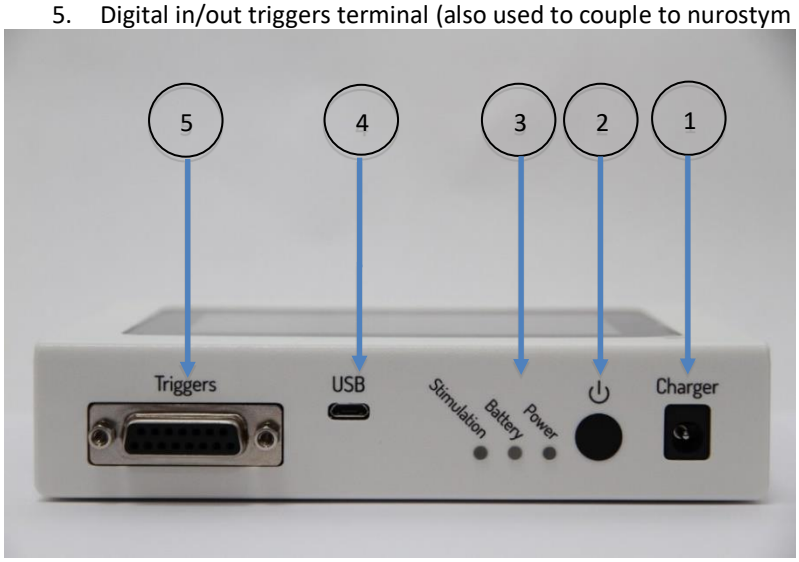


Figure 1 nurostym tESm front view

The markings and labels are readable from 30 cm by a person without a visual impairment.

Figure 2 shows the top view of the device, including its 4.3” touch screen user interface (GUI).

Figure 2 tESm top view

Figure 3 shows a view of the device from the left, with visible 1.5mm terminals for red electrode - anode (+) and black electrode - cathode (-).

Figure 3 Nurostym tEm's left-hand-side view

Figure 4 shows a typical arrangement of nurostym tESm, nurostym Interface and Interface Splitter when the accessories are used in a system.

Figure 4 Nurostym tESm, Interface and Splitter

3.13 **Power Supply and Charging**

Power supply to the nurostym is provided from an integrated lithium rechargeable battery. The battery may not be fully charged on delivery and should be charged before first use. The charging status is shown as a percentage in the upper part of the screen.

When the battery charge is low (<5%) the device displays a low battery screen containing a relevant message. The device will automatically turn itself off after 10 seconds.

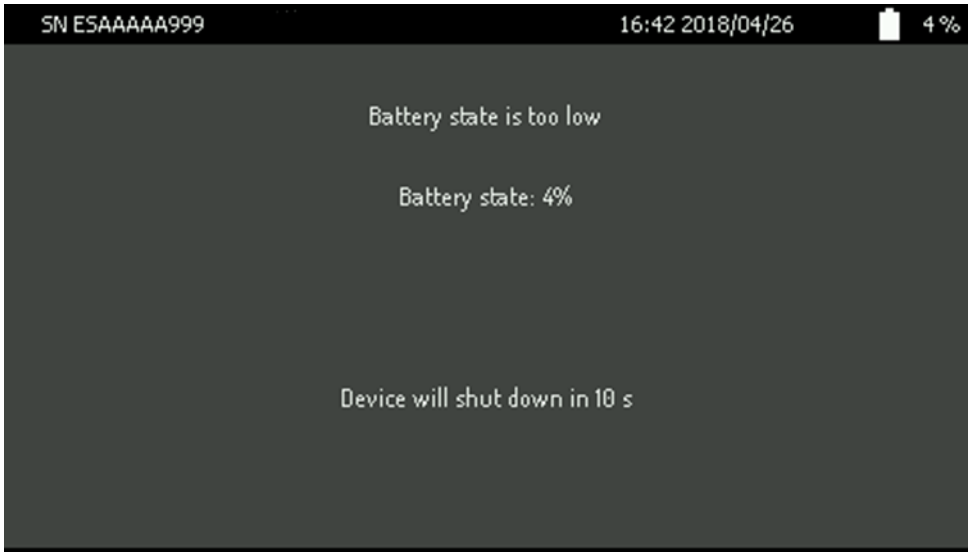


Figure 5 Battery state is too low

Figure 6 Proper connection of power supply

To charge the battery, connect the power unit supplied with the device to the charger terminal (Figure 6).

A power unit connected to the device will be detected automatically and a charging screen will be displayed (Figure 7). After 10s the device is shut down automatically. Charging is indicated by the Battery LED which will be continuously lit. A yellow LED means the device is being charged and green indicates when it is fully charged. The LED goes off when the charger is disconnected. The charging screen displays whether the charger is connected/disconnected, the charging percentage, the charging process, and time left to device shutdown (seconds).

As a safety precaution, the device cannot be charged and operated at the same time. The user or subject must not touch the electrodes while the charger is connected or while the device is charged.

Allow approximately 10 hours to fully charge the battery.

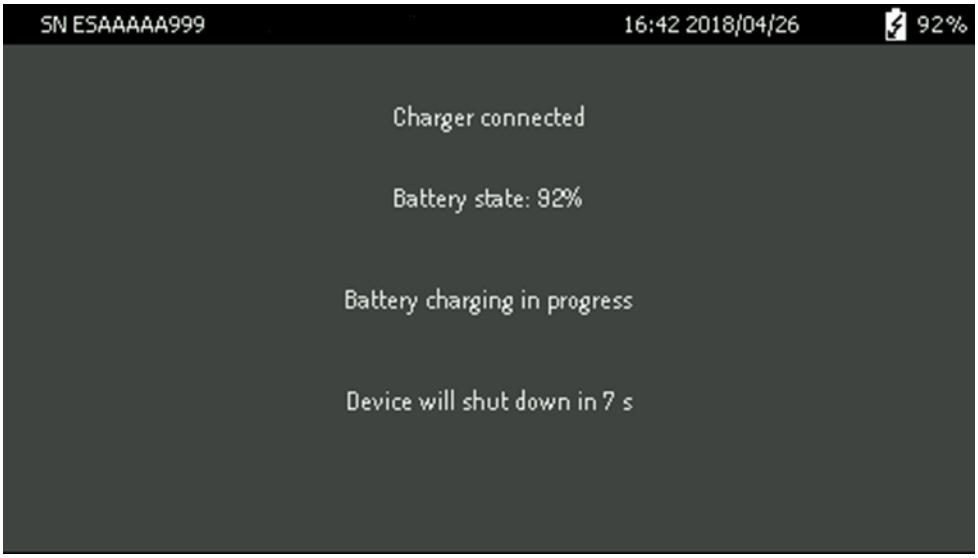


Figure 7 Charging screen

3.14 Starting the Device

To start the device, press the Power button (Figure 1) and hold for approx. 2 seconds, or until the green Power LED goes on (Figure 1). A welcome screen will be shown on the device (Figure 11).

3.15 Switching Off the Device

To switch off the device, press and hold the Power button for approx. 2 seconds or until the green Power LED goes off. You can shut down the device after making sure that the stimulation process is over.

3.16 Storing Last Settings

The last custom settings of the user will be stored at shutdown and restored at the next start-up.

3.17 Connecting Electrodes

Electrodes should be connected to their corresponding electrode terminals (Figure 8) using 1.5mm pin cables. To disconnect an electrode, hold the pin and pull. **Never remove electrodes while stimulation is in process**. For safety reasons, it is recommended that the cables be plugged into the correct inputs according to their colour - insert the **red cable into the red socket** (Figure 8).

Figure 8 Correct electrodes cables connection

NOTE: All electrodes and cables must have a CE declaration of conformity to be approved for use with this device. Rubber carbon electrodes or sponge electrodes are acceptable if they are specifically manufactured for use with transcranial electric stimulator devices. Spes medica 50x70 mm electrodes are recommended (Figure 9). **Before use, check that the electrodes are dedicated to transcranial electrical stimulation and are not broken.**

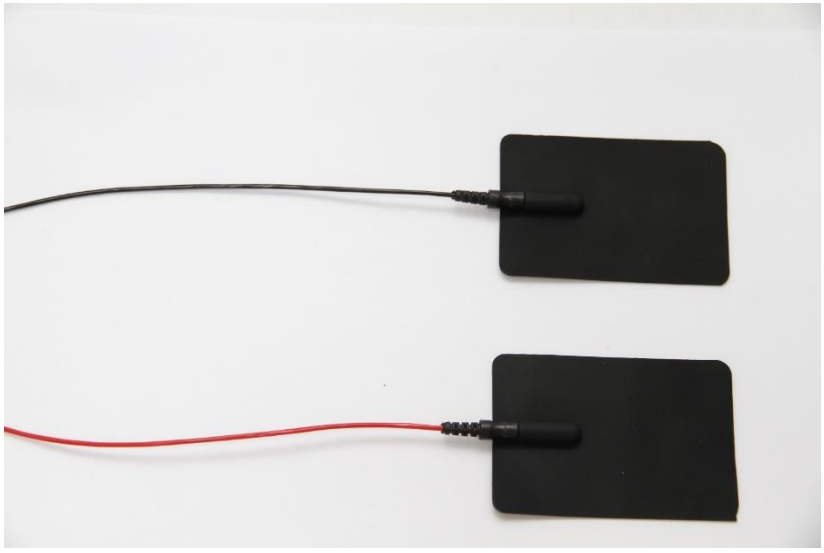


Figure 9 Electrodes connected

Figure 10. Arrangement of the gel on the electrodes

Special conductive gel should be applied to the electrodes (Figure 10). **Never use tap water to wet electrode sponges**.

3.18 Impedance Control

The unit is fitted with an integrated impedance control mechanism. Impedance measurement begins before the start of every stimulation and continues during the stimulation. In addition, users can initiate impedance measurement from the stimulation summary screen. An acceptable impedance threshold and impedance alert level can be programmed into the device (see: 4.10.3 Impedance Alarm). Stimulation is not possible when the impedance value exceeds the threshold at 50kΩ.

In addition, stimulation will stop when impedance value falls below 300Ω, indicating a shorting in the electrodes. The impedance control function will also verify whether the preset values can be reached with the current level of impedance. To control impedance, the device generates a low-intensity electric signal. For details, contact your distributor.

4 Graphic User interface (GUI), Parameter Selection and Stimulation

The nurostym tESm device has been designed with a unique graphic user interface which means that it can be controlled directly via the integrated touch screen. This makes it ideal for studies that require mobile tESm.

4.1 Welcome Screen

On start-up the device will display the Welcome screen (Figure 11).

The upper bar of the screen contains the device serial number, operating mode, date and time, and battery status. The nurostym logo is displayed in the centre.

After a few seconds, the device will automatically switch to the Home screen.

Figure 11 GUI Welcome screen

4.2 Home Screen

On the Home screen three buttons are available for the user.

- Custom stimulation – allows selection of the stimulation method (parameters);
- Presets – where predefined stimulation settings can be selected.
- Analogue Input Mode – allows special stimulation mode controlled via external analogue source
- Settings – where the device date and time can be change and where stimulation logs can be managed.

To setup a new stimulation select 'Custom Stimulation'.
To start a previously saved preset select 'Presets'.

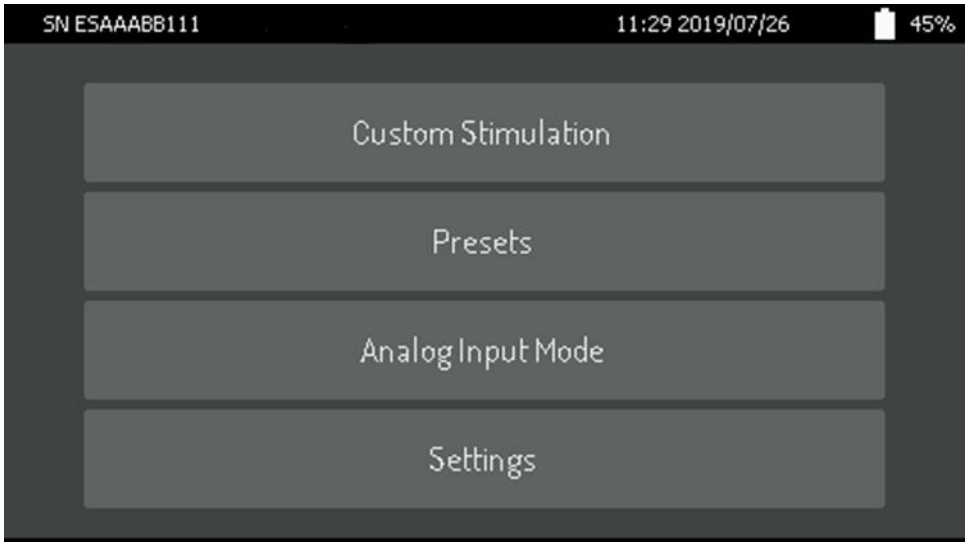


Figure 12 Home screen

4.3 **Settings**

Press 'Settings' to redirect to the Settings screen.

Figure 13 Settings screen

The Settings screen displays firmware and hardware version information.

Beneath the version details you will see information about the logs that have previously been saved. A 'Log' is "a registration of every started stimulation (stimulation parameters, time, settings, measurement and end stimulation status). The device can store a maximum of 1000 logs.

Pressing 'Clear' will delete all saved logs.

Logs are recorded even when the device is used without PC the application. They can be downloaded using the software application supplied with the device or by using any serial terminal and SCPI protocol described later in this manual. Users can disable logging in settings by choosing OFF. The user is able to determine the status of stimulation by polling stimulation via SCPI protocol in real time.

The format of the time and date setting is set out below. To edit these on the device select the parameter you want to change.

- hh – hours,
- mm – minutes,
- ss – seconds,
- dd – day,
- mm – month,
- yyyy – year.

Pressing + or – will either increase or decrease the value.
Press 'Save Date' to save the new time and date.

Pressing the arrow will redirect you to Home screen.

4.4 Custom Stimulation Screen

When 'Custom Stimulation' is selected, the stimulation setup screen is displayed (Figure 14).

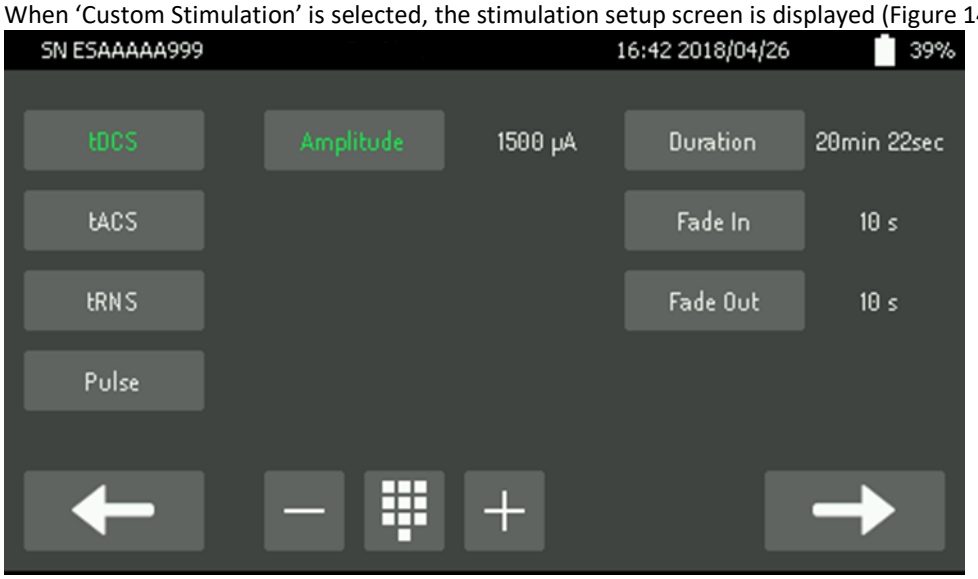


Figure 14 Custom Stimulation screen

Available stimulation modes are listed as buttons in left column.
The currently selected stimulation mode is highlighted in green.
To switch the stimulation mode, select the desired mode by pressing the relevant button.

To return to previous screen, press the left arrow on the bottom of the screen.

When changing the stimulation mode, different sets of parameters are available, as shown below. (Figure 15, Figure 16 and **Błąd! Nie można odnaleźć źródła odwołania.**)

Figure 15 tACS highlighted showing different parameters

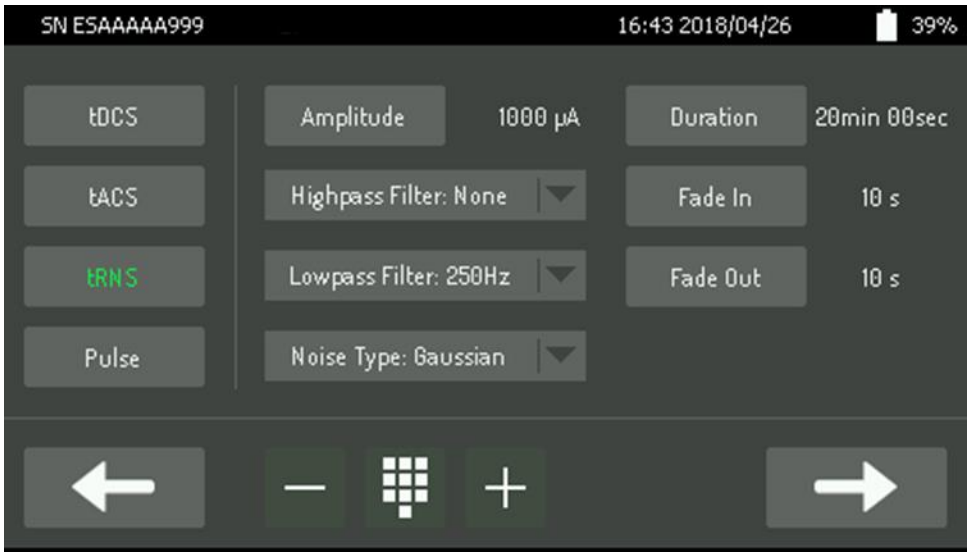


Figure 16 tRNS highlighted showing different parameters

4.5 Editing Stimulation Parameters

To customize the stimulation, select the desired stimulation method. The method will be highlighted in green once selected.

There are three ways of editing parameters:

a) + and – to increase/decrease parameter value

b) Keypad– when the keypad button  is pressed – the desired levels can be entered via the keypad.

c) Dropdown menu – some parameters have a fixed number of options selected from a dropdown menu.

To start editing parameter values, first press button/dropdown item with its name. Then use one of the methods to set new value.

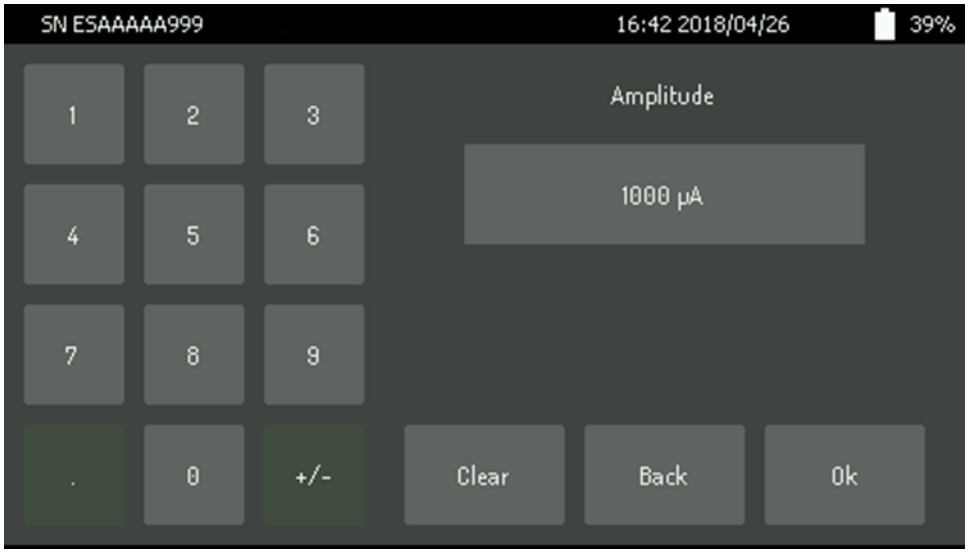


Figure 17 Amplitude entered using the keypad

4.6 General Settings for all Methods of Stimulation

Setting the stimulation time (excluding duration, fade-in and fade-out) for all methods of stimulation is identical (Figure 18). See part 4.6.1 and 4.6.2.

Other parameters differ depending on the selected type of stimulation (see part 4.7, 4.8, 4.9 and **Błąd! Nie można odnaleźć źródła odwołania.**).

Figure 18 General settings

4.6.1 Duration

Duration is a parameter that determines the time of a proper stimulation with a given current value (Figure 19). The units of this parameter are minutes [min] and seconds [sec]. The highest possible value to be set for this parameter is 30mins and the lowest possible value is 1sec.

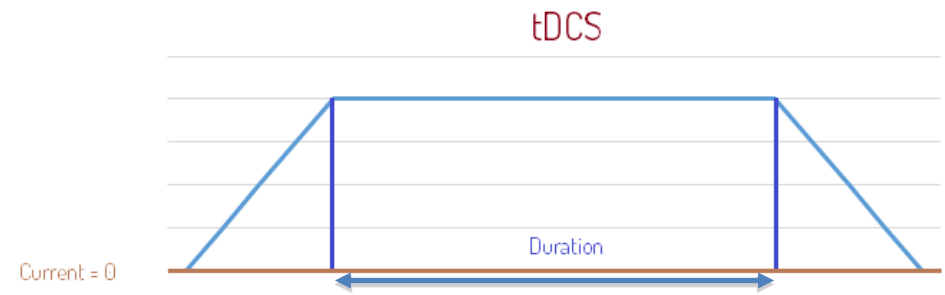


Figure 19 Duration

To edit, press 'Duration' having selected the stimulation method. The + and - buttons increase/decrease value. Pressing the keypad will display the keypad screen (Figure 20).

Figure 20 Duration setting screen

To enter seconds, press the 'sec' button (Figure 21). Should a value be entered that exceeds the permitted maximum, it will be automatically corrected to the highest permissible value. If the maximum number of digits for minutes is entered, the numeric keypad will be deactivated, however it is possible to continue to enter seconds by pressing 'sec' (Figure 21 and Figure 22). When all digits for minutes and seconds are entered the numeric keypad will be deactivated (Figure 23).

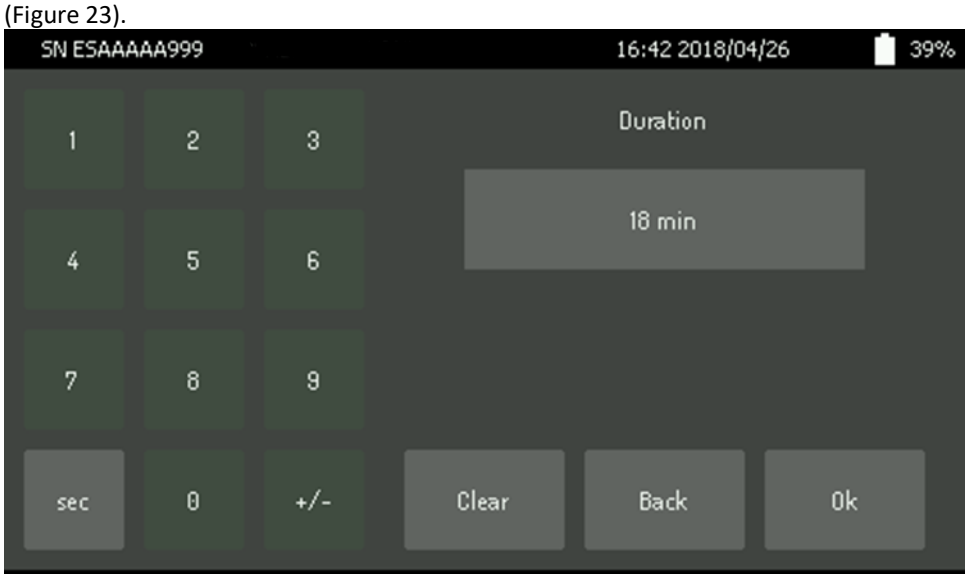


Figure 21 Maximum number of digits for minutes of stimulation reached. Press 'sec' to increase duration by seconds.

Figure 22 Seconds now appear as 00. Continue to enter desired stimulation duration.

Figure 23 Total number of digits for minutes and seconds entered. Numeric keypad is now disabled.

'Ok' is available when an appropriate value is entered.
'Back' closes the keypad and return to the previous screen without saving.
'Clear' erases entered value so that a new value can be entered.

4.6.2 Fade-in and Fade-out

Fade-in and Fade-out is a time value for the signal to rise before stimulation and fall after the stimulation has finished (Figure 24). This is a key safety feature and is a systematic increase of the current so that it will not burn the subject. The unit of this parameter is a second [s]. Fade-in and Fade-out can be set between 0-60 seconds.

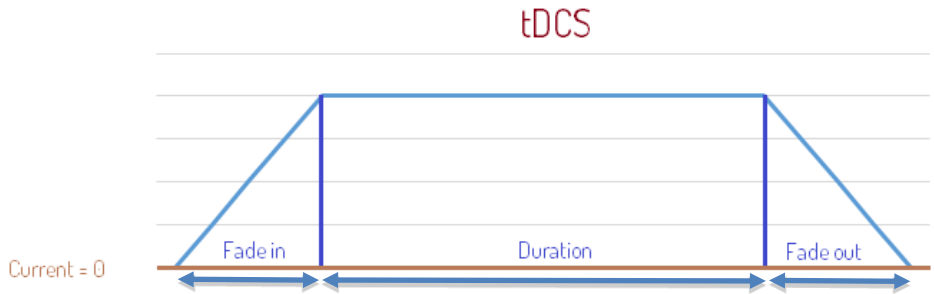


Figure 24 Fade in and fade out

Fade-In or Fade-Out can be edited once the stimulation method had been selected. The + and – buttons will increase/decrease by 1 second the duration of the Fade-In or Fade-Out, which will be highlighted in green to show which is being edited.

Pressing the keypad icon will bring up the keypad screen (Figure 25).

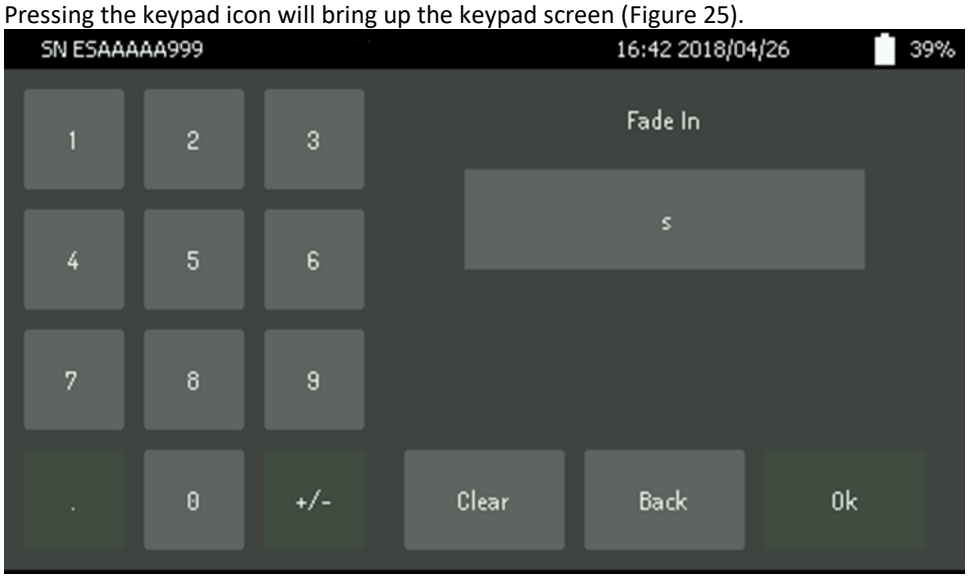


Figure 25 Fade in setting screen

Should a value be entered that exceeds the permitted maximum, it will be automatically corrected to the highest permissible value. If the maximum number of digits is entered, the numeric keypad is deactivated (Figure 26).

'Ok' is available when an appropriate value is entered.

'Back' closes the keypad and return to the previous screen without saving.

'Clear' erases entered value.

Figure 26 Maximum number of digits entered. Numeric keypad is now disabled.

4.7 Specific tDCS Parameters

tDCS (transcranial direct current stimulation) is a form of stimulation that uses direct current.

4.7.1 Amplitude

Amplitude is the only parameter for tDCS. It represents the value of the tDCS electrical current (Figure 27). The unit of this parameter is a microampere [µA]. The value range for Amplitude is between 100µA and 5000µA.

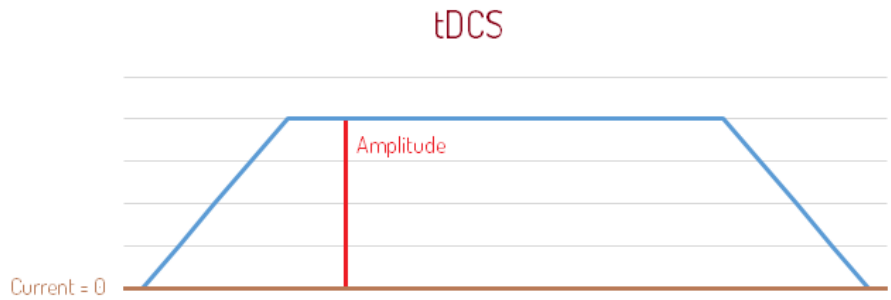


Figure 27 tDCS Amplitude

To edit the amplitude parameter, press the 'Amplitude' button. Use the + and - buttons to change amplitude levels at increments of 100µA. Pressing the keypad will access the keypad screen, where exact amplitude levels can be entered (Figure 28).

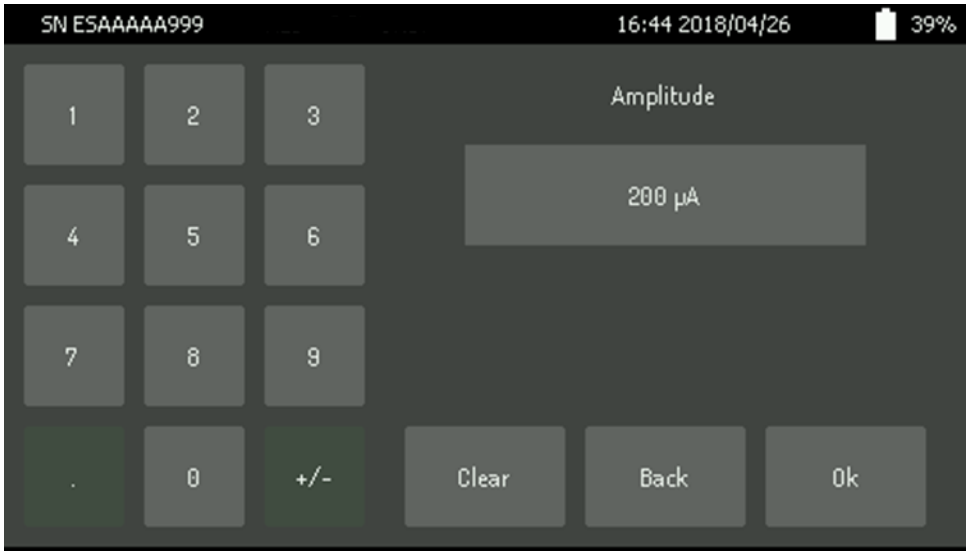


Figure 28 Amplitude setting screen using the keypad

Should a value be entered that exceeds the permitted maximum, it will be automatically corrected to the highest permissible value. If the maximum number of digits is reached the numerical buttons will be deactivated.

'+/-' changes current polarity (if applicable).
'Ok' is available when an appropriate value is entered.
'Back' closes the keypad and returns to the previous screen without saving.
'Clear' erases the entered value.

Figure 29 Amplitude entered using the keypad

4.8 Specific tACS Parameters

tACS *(transcranial alternating current stimulation)* conducts a sinusoidal current at a chosen frequency, amplitude and offset. Amplitude modulation signal is also available.

4.8.1 Amplitude

Amplitude is the change between peak (highest signal value) and trough (lowest signal value, which can be negative). (Figure 30)

To edit the Amplitude parameter go to section 4.7.1.

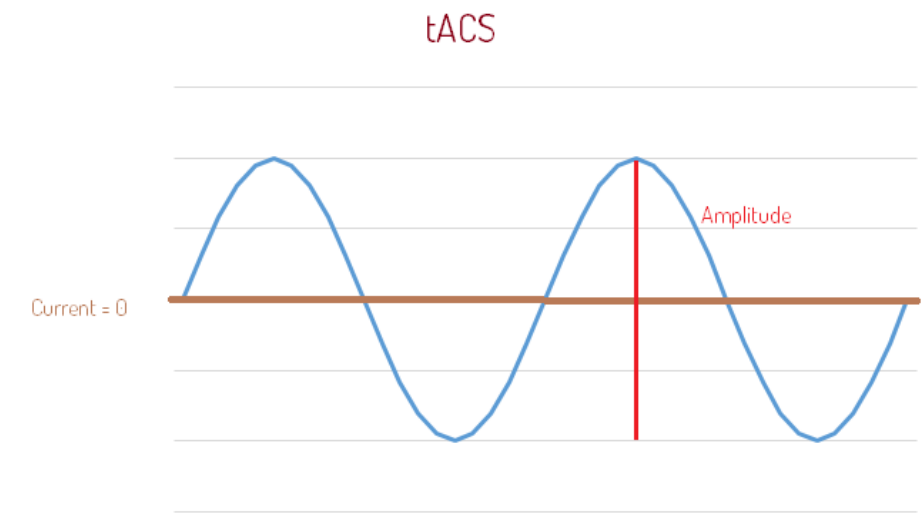


Figure 30 tACS Amplitude

4.8.2 Frequency

The Frequency parameter in tACS is the number of cycles of the periodic phenomenon occurring in a unit of time (Figure 31).
The unit of this parameter is a hertz [Hz]. The value range for this parameter is between 0.01Hz and 600Hz.

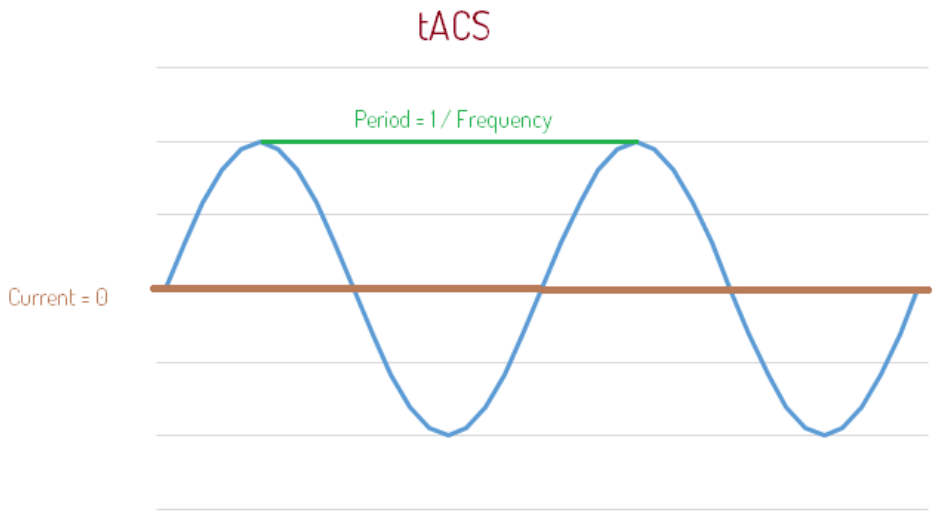


Figure 31 tACS Frequency

To edit the 'Frequency' parameter in tACS mode, use + and - to increase/decrease the frequency in increments of 10Hz. Pressing the keypad will access the keypad screen, where exact frequency levels can be entered (Figure 32).

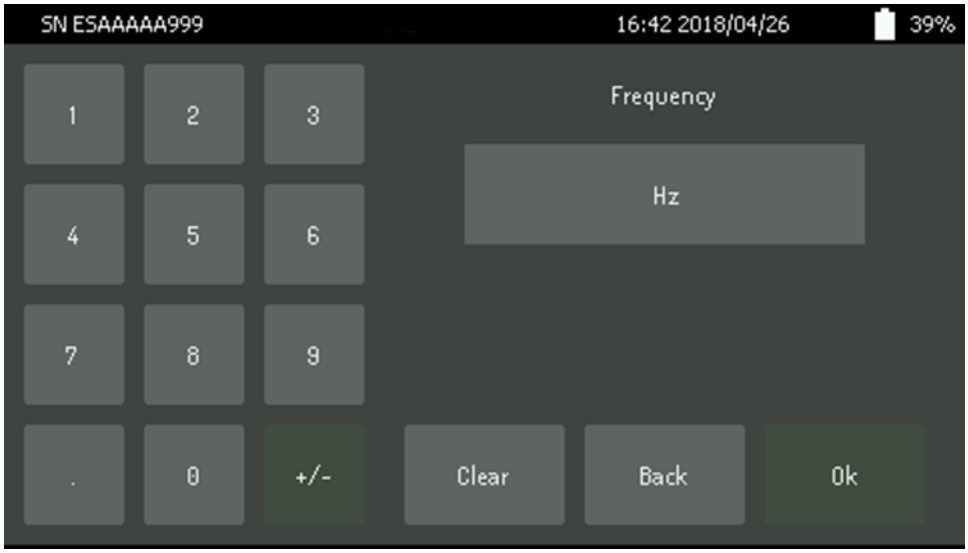


Figure 32 Frequency setting screen

To enter a fractional value, press the decimal button. Should a value be entered that exceeds the permitted maximum, it will be automatically corrected to the highest permissible value. If the maximum number of non-fractional digits is reached, the numeric keypad is deactivated, but the user can add 2 decimal places after pressing the decimal button.

'Ok' is available when an appropriate value is entered.

'Back' closes keypad and returns to the previous screen without saving.

'Clear' erases the entered value so that a new value may be entered.

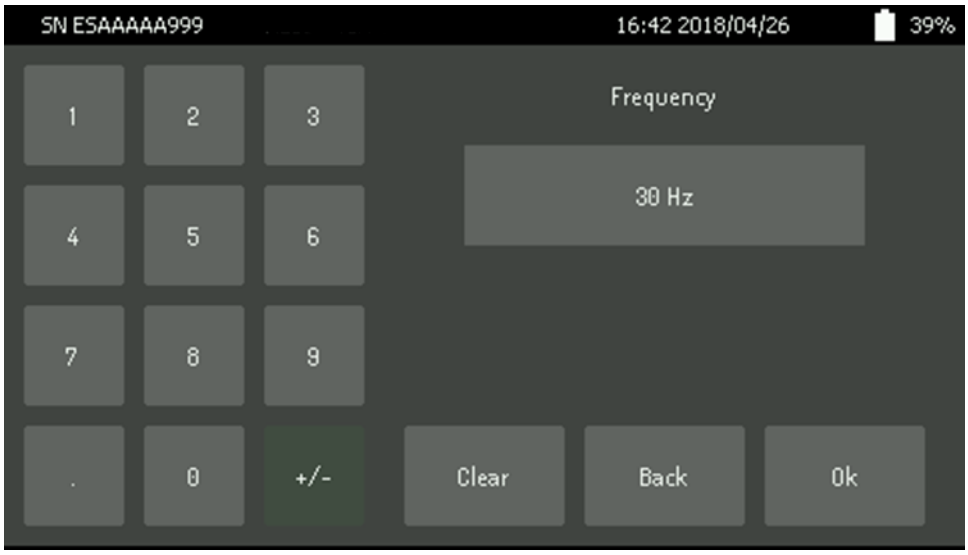


Figure 33 Frequency entered using the keypad

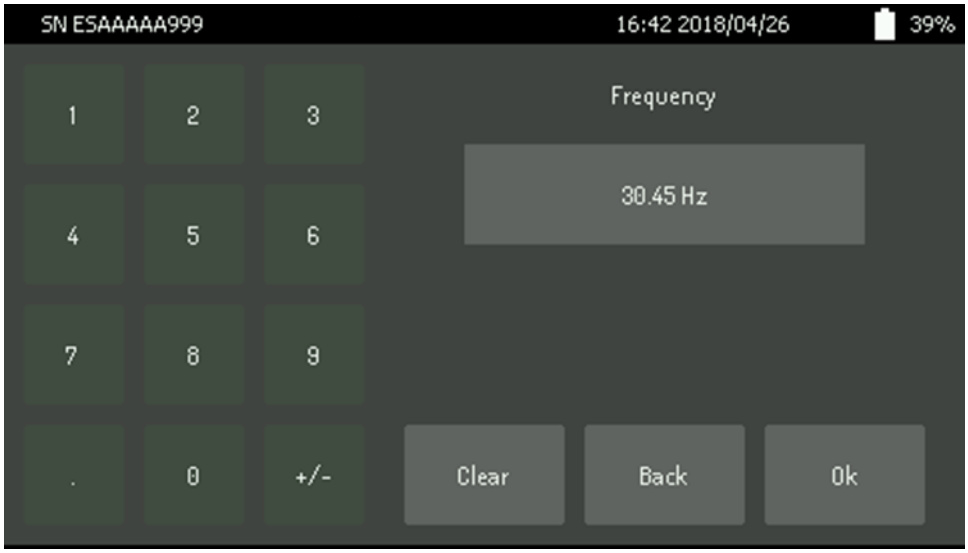


Figure 34 Frequency entered using keypad with fractional part

4.8.3 Offset

Offset is the movement of the entire sinusoid by a given value along the axis of value. In practice, this means giving an initial value to the tACS stimulation.
The unit of this parameter is a microampere [µA]. The value range for this parameter is between minus 3000µA and 3000µA. Should a value be entered that exceeds the permitted maximum, it will be automatically corrected to the highest permissible value.

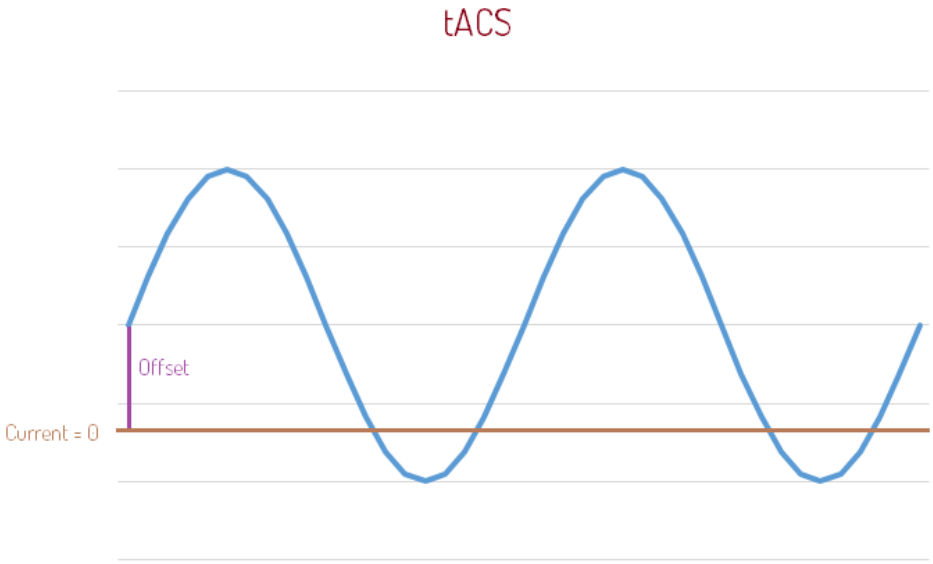


Figure 35 tACS Offset

The offset parameter is only available for tACS.

To edit Offset parameters, press 'Offset' and use + and – to increase/decrease values by 100µA. Pressing keypad will bring up keypad screen (Figure 36).

The sum of Offset and Amplitude values cannot exceed the maximum permitted current (it has to be in the range of ±5000µA). Should the entered value cause a violation of that restriction, the other parameter is decreased to avoid it.

Figure 36 Offset setting screen

'+/-' changes offset polarity.
'Ok' is available when an appropriate value is entered.
'Back' closes the keypad and returns to the previous screen without saving.
'Clear' erases entered value so that a new value may be entered.

4.8.4 Envelope Amplitude

Envelope amplitude is the depth of modulation of the tACS signal, which changes the value of the amplitude given to the stimulation (Figure 37).

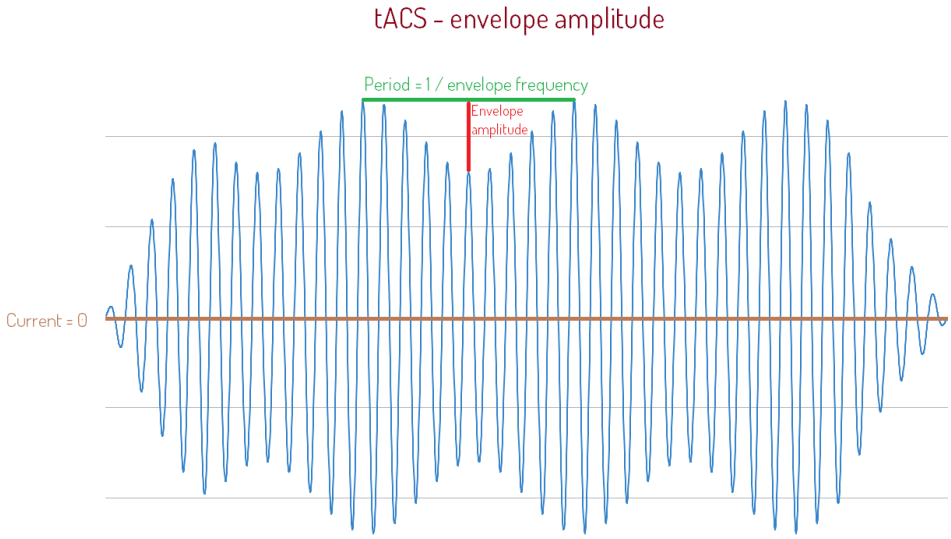


Figure 37 tACS Envelope amplitude

The unit of this parameter is a microampere [µA]. The envelope amplitude value shall not be bigger than half of the stimulation amplitude.
To edit, press 'Env. ampl.' in tACS mode. Use + and – to increase/decrease the value by 100µA. Pressing keypad will bring up keypad screen (Figure 28).

The value of envelope amplitude cannot exceed half of the amplitude of the carrier. Should the entered value cause a violation of that restriction, the envelope amplitude is decreased to avoid it.

'Ok' is available when an appropriate value is entered.
'Back' closes the keypad and returns to the previous screen without saving.
'Clear' erases entered value so that a new value may be entered.

4.8.5 Envelope Frequency

Envelope frequency is the frequency of modulation signal (Figure 37).

The unit of this parameter is a hertz [Hz]. The value range of this parameter is between 0Hz (where no modulation will occur) and 100Hz. The value of envelope frequency cannot exceed the half of the carrier frequency (tACS frequency). Should the entered value cause a violation of that restriction, the envelope frequency is decreased to avoid it.

To edit, press 'Env. freq.'in tACS mode. Use + and – to increase/decrease the envelope frequency by 10Hz. Pressing keypad will bring up keypad screen (Figure 33). The envelope frequency value shall not be bigger than half of the stimulation frequency.

'Ok' is available when an appropriate value is entered.
'Back' closes the keypad and returns to the previous screen without saving.
'Clear' erases entered value so that a new value may be entered.

4.9 Specific tRNS Parameters

tRNS (transcranial random noise stimulation) mode utilises alternate current along with given maximum current value, spectrum and distribution.

4.9.1 Amplitude

The Amplitude parameter in tRNS mode defines the current range from which all samples will be generated (peak-to-peak value). (Figure 38)
Setting any filter or setting Gaussian rather than rectangular noise type may decrease (or under some circumstances even increase) the actual amplitude due to a random nature of the signal.

To edit the amplitude parameter go to section 4.7.1.

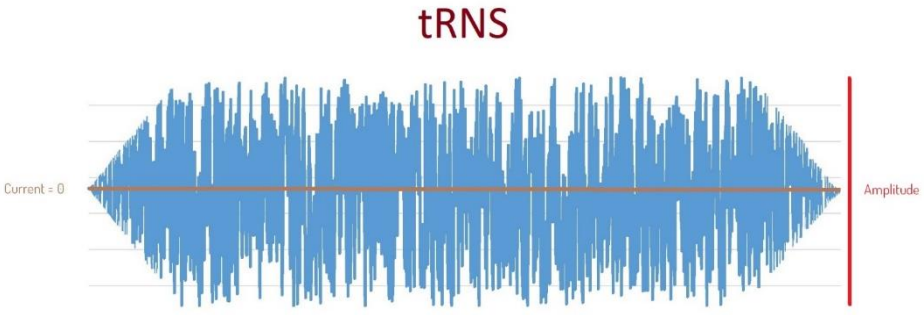


Figure 38 tRNS Amplitude

4.9.2 Highpass Filter

The Highpass Filter is available specifically for the tRNS signal. A highpass filter attenuates frequencies below the selected value.
Edit the Highpass Filter cut off frequency by selecting the required cut-off frequency from the Highpass Filter drop down menu.

Note: A highpass filter cannot have a cut-off frequency equal to or higher than that of the lowpass filter.

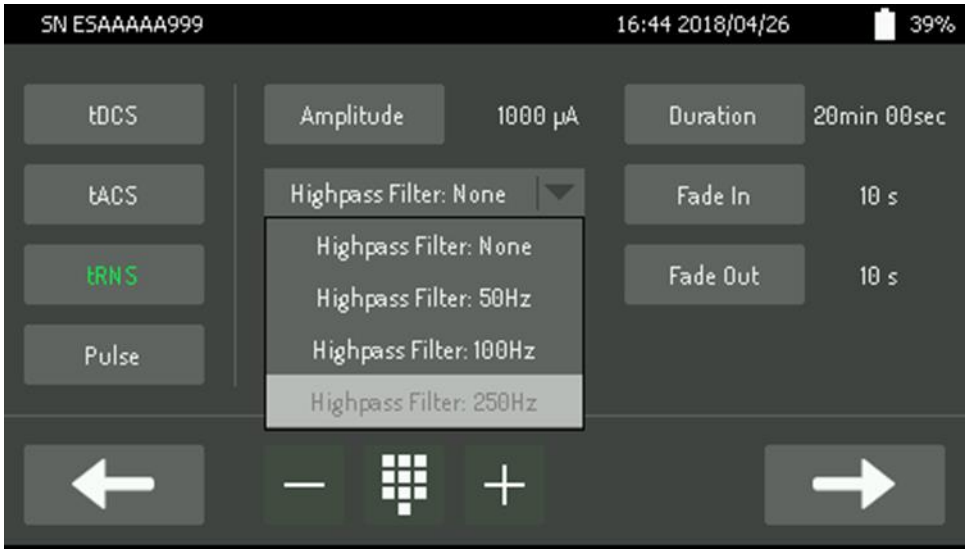


Figure 39 Setting highpass filter for tRNS

4.9.3 Lowpass Filter

The Lowpass Filter is available specifically for tRNS Signal. A lowpass filter attenuates frequencies above the selected value. Edit the Lowpass Filter cut off frequency by selecting the required cut-off frequency from the Lowpass Filter drop down menu.
(Figure 40).

Note: The lowpass filter cannot have a cut-off frequency equal to or lower than that of the highpass filter.

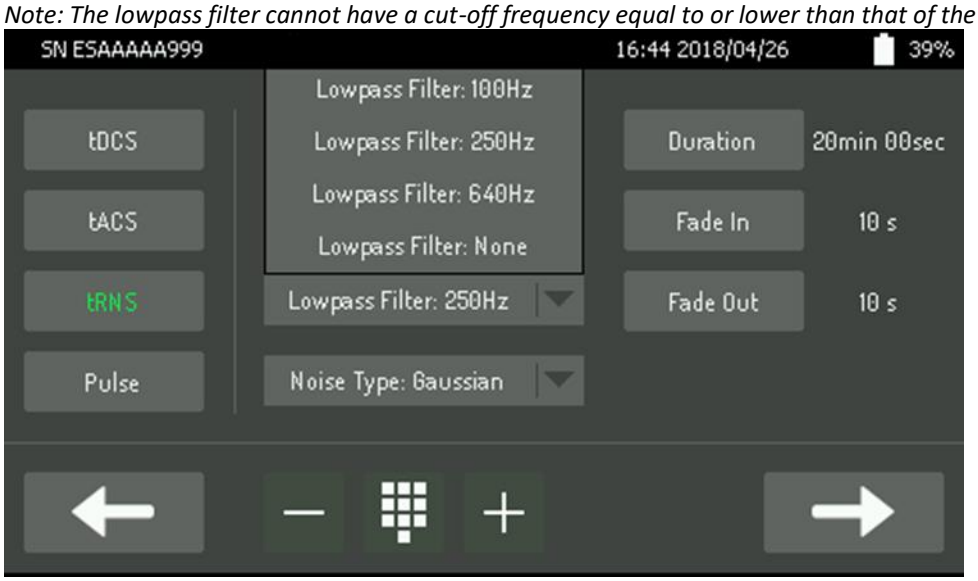


Figure 40 Setting lowpass filter for tRNS

4.9.4 Noise Type

There are two types of noise distributions available for tRNS.

- Rectangular – causes samples to be generated evenly over the whole signal current range.
- Gaussian – weights samples more to the middle of the current range than at either extremity.

To choose a noise type, first select the desired tRNS method, then select the desired noise type from the two options available (Figure 41).

Figure 41 Noise type selection dropdown

Frequency parameter can be edited described in 4.8.2.

4.10 Advanced options

Once all stimulation parameters have been set, press the right arrow button at the bottom right corner of the screen to proceed to the advanced options screen.
The following options are not directly related to the signal to be used in stimulation. However, it is still necessary that they are set.

4.10.1 Electrodes

This option relates to the type of electrode to be used in the next stimulation. The surface area of the electrode is calculated using provided parameters so that a current density calculation can be made. This step can be skipped; however, for safety reasons skipping this step is not recommended.

Note: If your electrodes are of different sizes, always use the size of a smaller electrode.
To choose an electrode type, select the electrode type dropdown menu and choose the desired option (Figure 42). There are 4 types of electrode shape possible:

- rectangular
- round
- shape undefined
- ignore electrode size

Figure 42 Electrode type dropdown shown at the top left

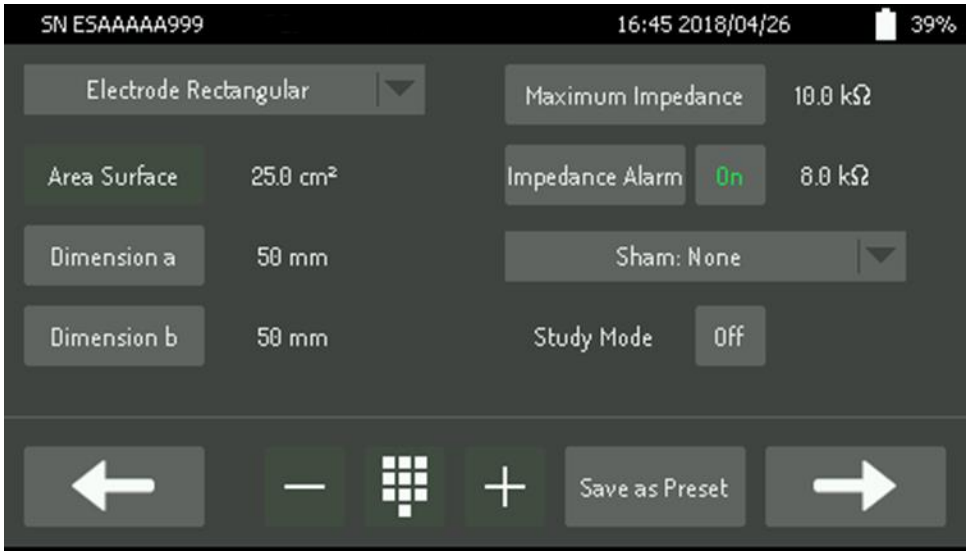


Figure 43 Electrode Rectangular

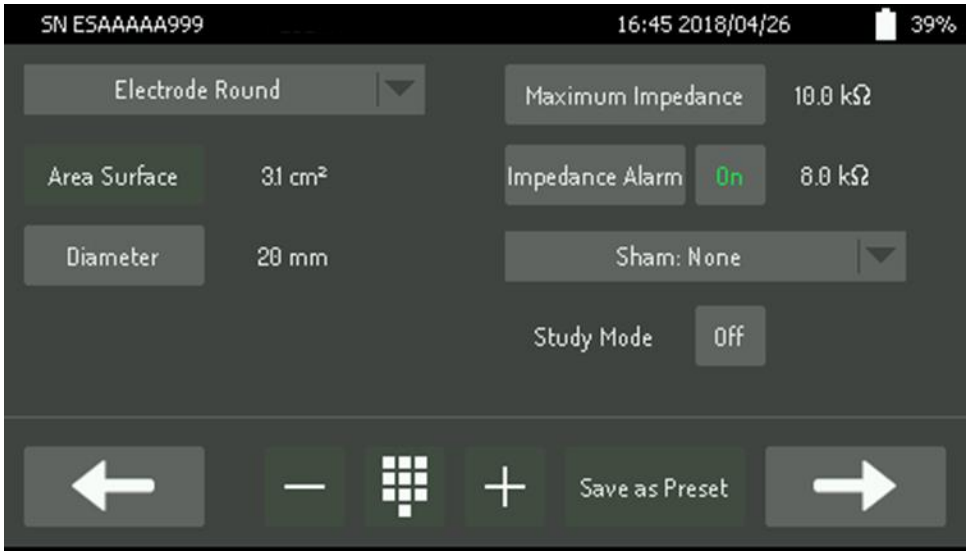


Figure 44 Electrode Round

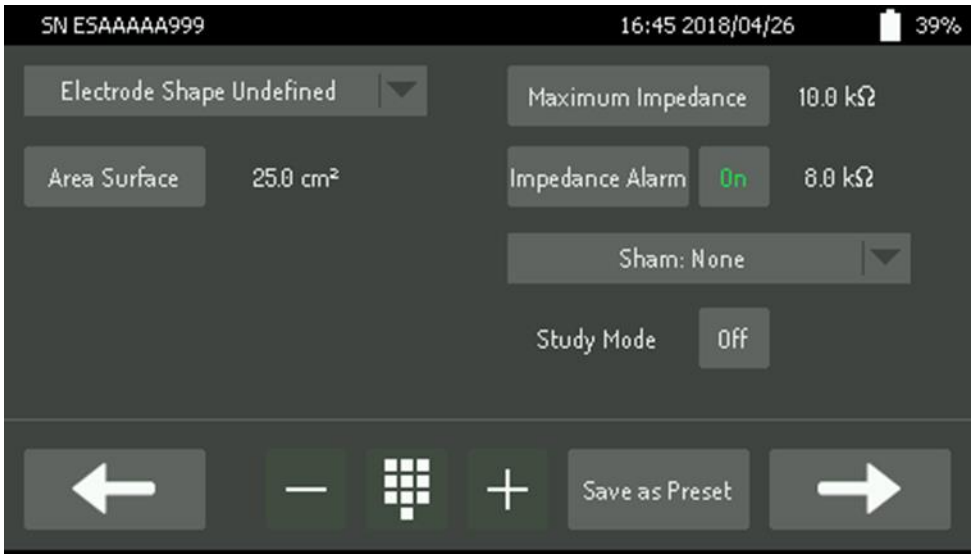


Figure 45 Electrode Shape Undefined

The electrode shape can be left as undefined, but the surface area of the electrode must still be entered.

When selecting a rectangular electrode shape, enter two dimensions (a and b) to change surface area. Once selected the letter in the box will change to green Use + and – to change dimensions by 5mm (min. 5mm, max. 300mm). Pressing the keypad icon will allow the user to enter the exact number (Figure 46). The area is calculated automatically.

To edit the surface area of round electrodes it is necssary to enter the diameter. Use + and – change dimensions by 5mm (min. 12mm, max. 300mm). The keyboard may also be used.

To edit the surface area of an undefined electrode shape press 'Area Surface'. Use + and – change dimensions by 1cm^2 (min. 1cm^2, max. 900cm^2). The keyboard may also be used.

Should a value be entered that exceeds the permitted maximum, it will be automatically corrected to the highest permissible value. If a maximum number of digits is entered, the numeric keypad is deactivated.
Selecting the 'ignore size of electrode' option means that the device will not check the parameter's propriety. For example, using too big a current for small electrodes may cause burn or electric shock to the subject. Before choosing the "ignore electrode size" option check if the set parameters will not harm the subject.

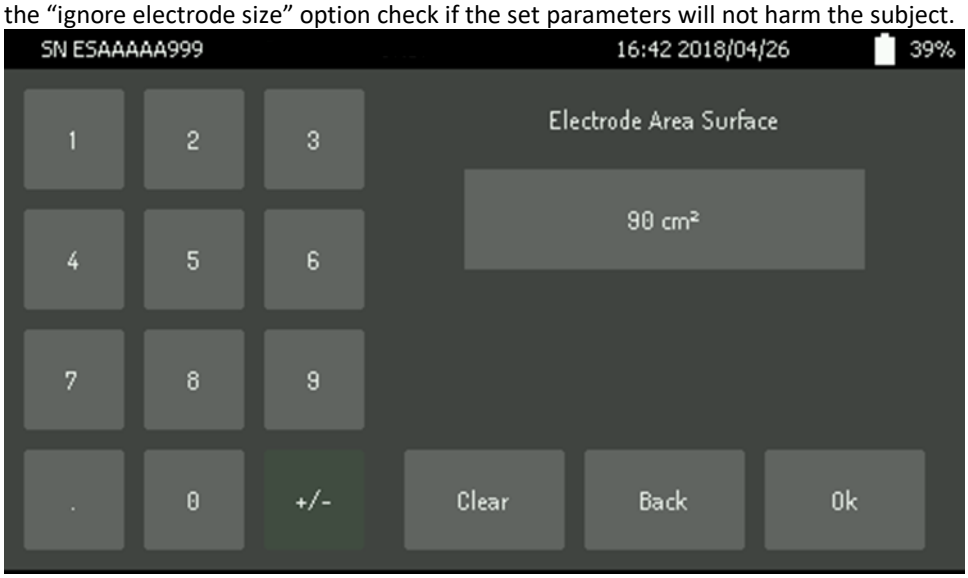


Figure 46 Electrode surface area setting

'Ok' is available when an appropriate value is entered.
'Back' closes the keypad and returns to the previous screen without saving.
'Clear' erases the entered value so that a new value may be entered.

4.10.2 Maximum Impedance

This option relates to the maximum permissible impedance between two electrodes. Should the impedance exceed the entered value, the stimulator signals an error and terminates the stimulation.

Note: The stimulation can still be terminated or prevented from starting if the current level and impedance cause an overvoltage error, even if the maximum impedance level has not yet been reached.

To edit the impedance level, select 'Maximum impedance' from the advanced options menu. Use + and – to increase/decrease the level in increments of 1kΩ. Pressing the keypad icon will bring up the keypad screen (Figure 47).

The valid range of maximum impedance is from 10kΩ to 50kΩ. To enter fractional values, press the decimal key on the keypad. If an entered value exceeds the permitted maximum, it will be automatically corrected to the highest permissible value. If two digits are entered for the non-fractional part, the numeric keypad will be deactivated, however you can continue to enter decimal places, by pressing the decimal key (Figure 48). When the total number of digits is entered, numeric keypad will be deactivated.

Figure 47 Maximum impedance setting

Figure 48 Maximum number of digits entered for maximum impedance

'Ok' is available when an appropriate value is entered.
'Back' closes the keypad and returns to the previous screen without saving.
'Clear' erases the entered value so that a new value may be entered.

4.10.3 Impedance Alarm

An impedance alarm will sound if the impedance exceeds the value entered here. Stimulation will not be interrupted.

This parameter is optional. It can be enabled/disabled by selecting on or off on the advanced options screen. If the on/off button displays green 'on', the alarm is enabled (Figure 49). It can be edited in a similar manner as the maximum impedance parameter. The acceptable range is 5kΩ to 20kΩ.

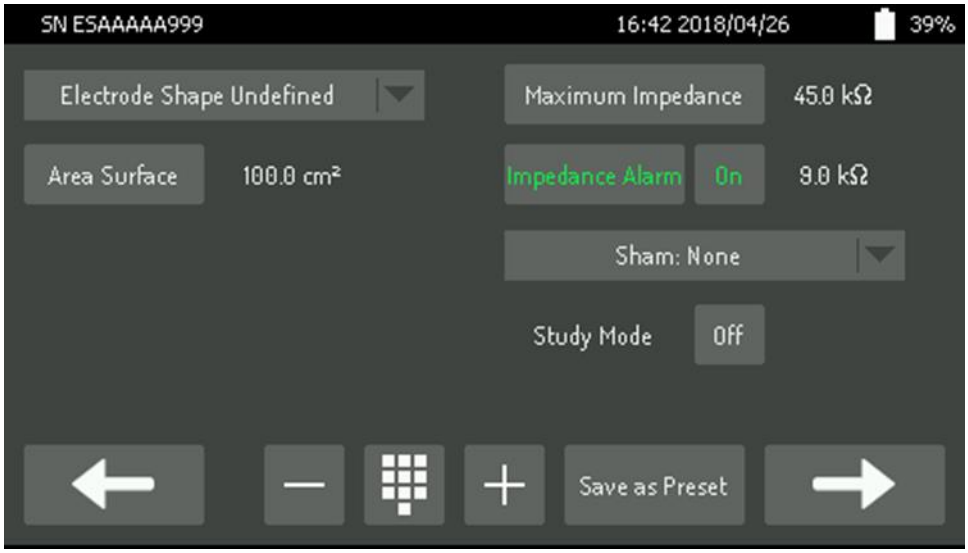


Figure 49 Impedance alarm text showing "on" in green. Alarm has been enabled with user set value shown to the right

4.10.4 Sham Mode

The sham feature allows the user to determine whether genuine or faux stimulation is administered. Three options are available to select in the drop down.

- None – Normal stimulation.

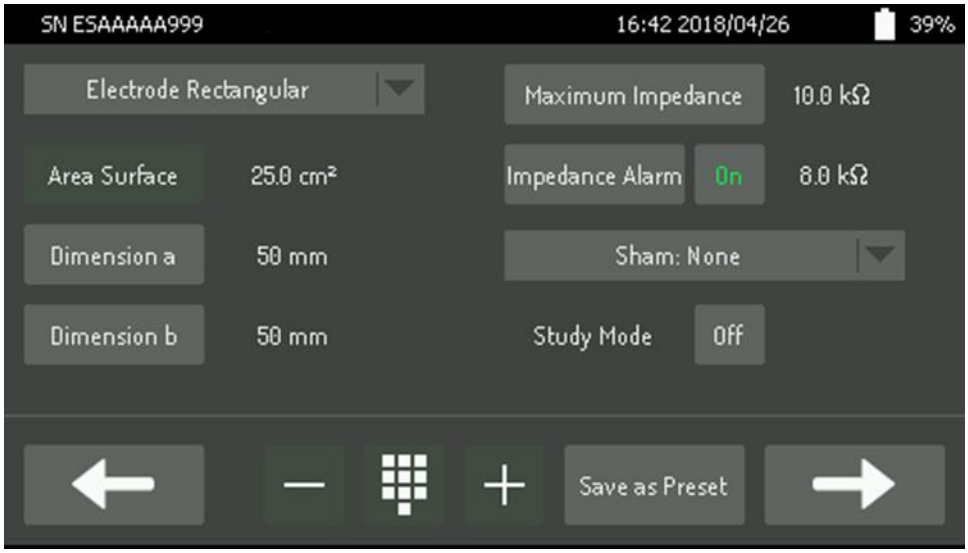


Figure 50 Sham: None

- Single Blind – Always sham stimulation. The recipient does not know whether stimulation is occurring or not, but the researcher does.

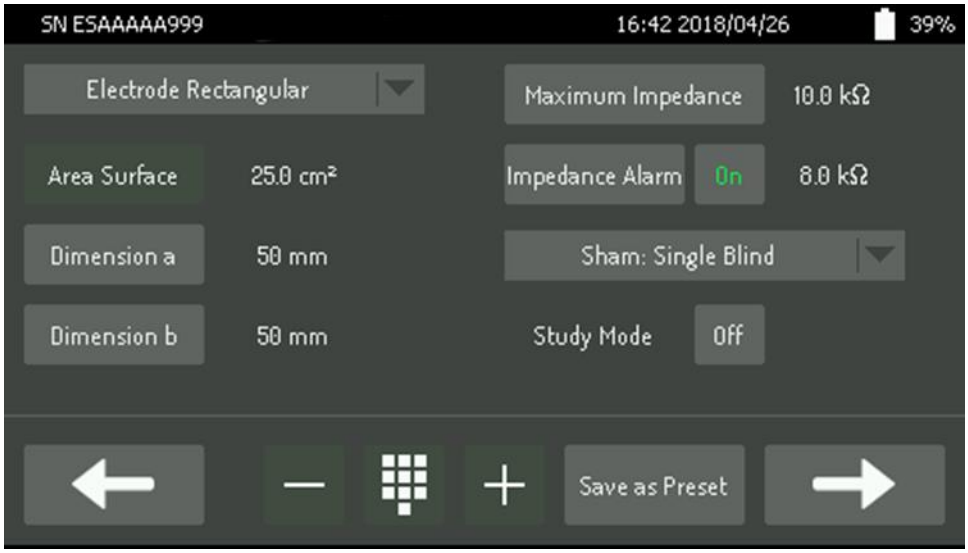


Figure 51 Sham: Single Blind

- Double Blind – normal or sham stimulation determined by a PIN code. Double Blind mode maintains complete reliability of the research - the subject does not know what kind of stimulation and what stimulation parameters are administered. The researcher/operator, in turn, knows the settings, but does not know whether the proper stimulation or placebo stimulation will be given. Only the research manager decides what the study scenario is: whether it is a proper stimulation or a placebo one.
  During the Double Blind sham stimulation some of the parameters will not be displayed or will be displayed in an obscured way.

  The operator only enters an appropriate PIN code (defined by the research manager) to start the stimulation. Some PIN codes trigger normal stimulation and others trigger the placebo one. A list of 30 five-digit PIN codes needed to initiate Double Blind is included with this manual. For more PIN codes, please refer to the distributor.

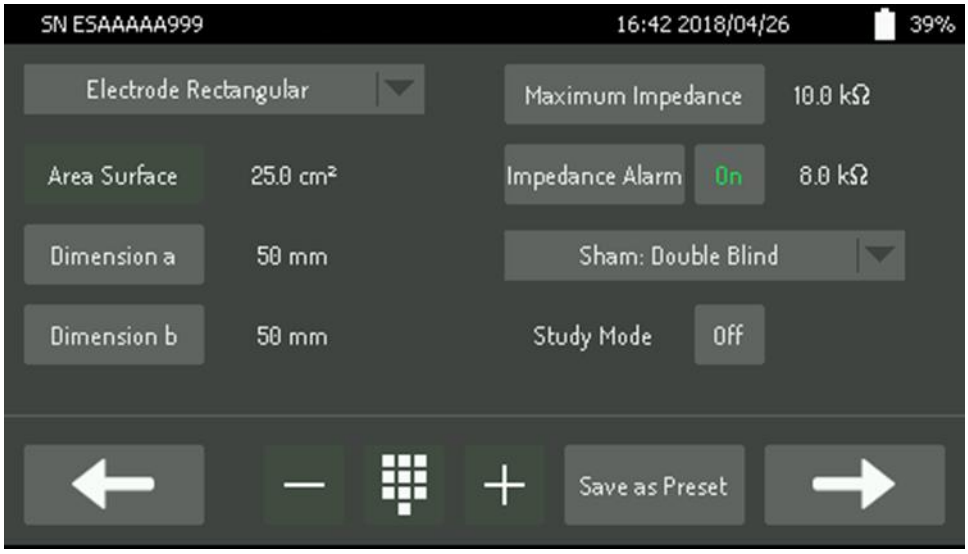


Figure 52 Sham: Double Blind

Figure 53 Enter PIN to choose sham mode

During stimulation the operator can check whether sham stimulation is turned on or not by polling stimulation status via SCPI protocol. To set a sham option, select from the sham drop down menu. Information about sham mode and eventually given PIN code are stored in log files on the device (if enabled) and can be used for further post processing of data.

4.10.5 Study Mode

Study mode is an advanced option that hides the stimulation parameter details during stimulation. When study mode is active, there are no parameters such as amplitude or frequency displayed on the Summary screen (see 4.13 Summary) – only impedance check is visible for safety reasons (Figure 54).
Impedance display in Study Mode is limited to colour-code, displaying a red bar when maximum impedance is exceeded, yellow bar when impedance alarm is exceeded and green bar when neither is exceeded. Numerical value is hidden on purpose.

Study mode is used in stimulation situations where the subject must not see the stimulation parameters so as not to influence the results of the experiment.

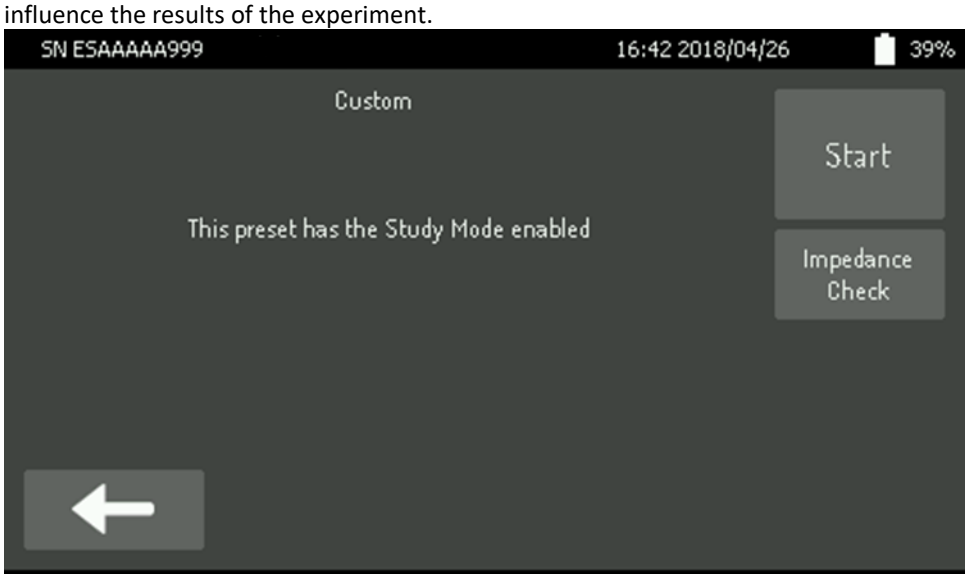


Figure 54 Study mode summary screen

4.11 Saving Presets

Once all of the above parameters have been selected, the user is able to save them as a preset which can be selected in first screen (Figure 12). To do this, press ‘Save as Preset’. This will direct the user to the presets window (Figure 55).

Figure 55 Presets screen

To save a preset, select any of the buttons which show a preset slot. The selected slot will then be highlighted green and the ‘Save’ button in the bottom right corner will become available (Figure 56).

When the preset is saved, it will be stored in the chosen slot. If the selected slot is not empty, any previously saved preset data will be overwritten. Presets saved this way will be given a generic name (“Preset_4” for example). It is not possible to change the name of these presets via the touch screen.

Saving a preset and giving it a custom name can only be done via the USB interface using the serial terminal and SCPI protocol or via the device computer application.
Connecting via SCPI protocol is described later in this manual.
Deleting stored presets must also be carried out via SCPI protocol.
After setting all the stimulation parameters in the Custom Stimulation window, you can save the stimulation prepared in such a way as a preset, which will then be visible in the "Presets window" of the main menu.

Figure 56 Saving the preset

A preset cannot be saved if the maximum safe current density is exceeded. When this is the case, the Save button will not be illuminated. Whether or not stimulation is possible is shown in the Summary window.

To exit the presets screen, press the arrow in the bottom left corner.

4.12 Limit Mode

It is possible to restrict the functionality of the device to only load presets that had been saved earlier. In this mode the parameters of stimulation and electrode cannot be adjusted and it is only possible to invoke a preset without any alterations.

Switching limit mode on or off is only possible by connecting to computer by USB cable and using nurostym application (or low-level terminal), which is outside the scope of this manual. Switching the mode on and off is PIN-code protected.

Figure 57 Preset selection as main screen in limit mode

4.13 Summary

Once all of the parameters have been set and the user is ready to proceed to stimulation, press the arrow in the bottom right of the advanced options screen (Figure 58).

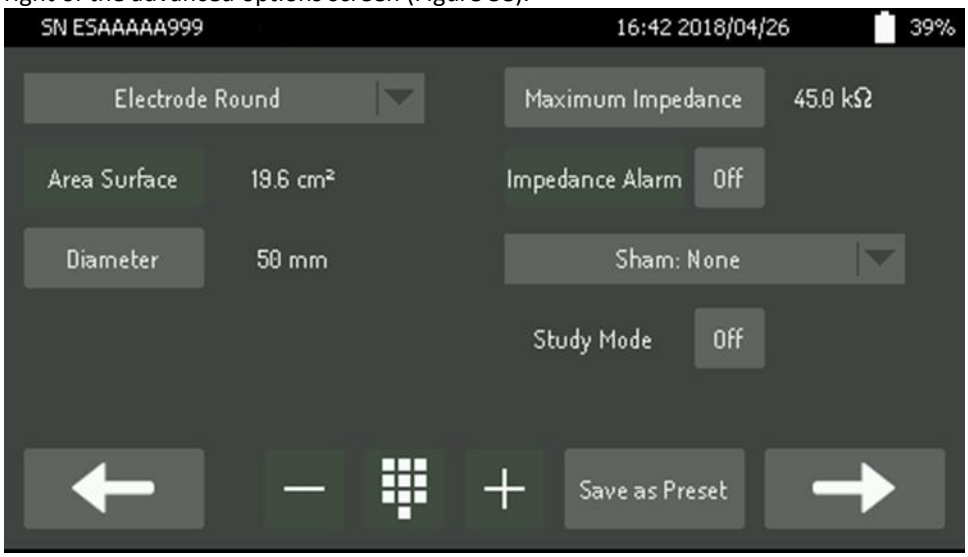


Figure 58 Advanced options screen. All parameters have been set so stimulation can proceed via the right-hand arrow.

Before starting stimulation, a screen summarising the parameters to be administered will be shown (Figure 59). If the maximum safe current density is exceeded, the 'Start stimulation' button will be unavailable, and the parameter will be highlighted in red (Figure 60). If the electrode size was not entered whilst setting the advanced options (the ignore electrode size option was chosen), a warning will be shown (Figure 61) but stimulation can still be started.

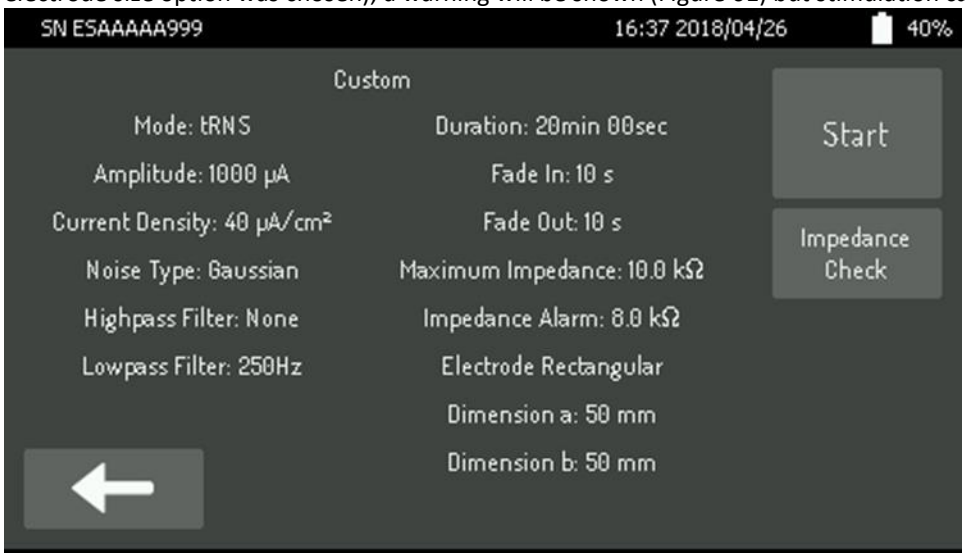


Figure 59 Summary screen showing stimulation settings

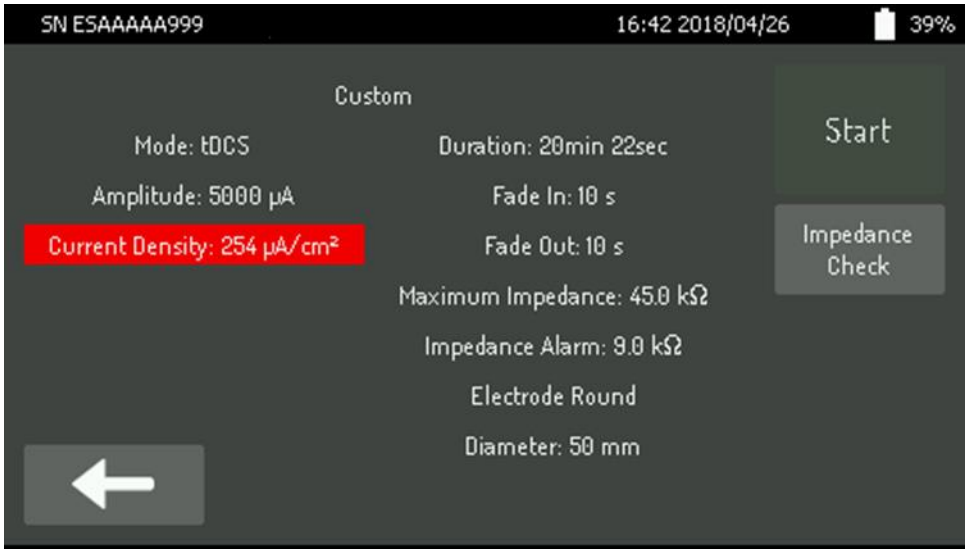


Figure 60 Current density is too high, so stimulation cannot proceed

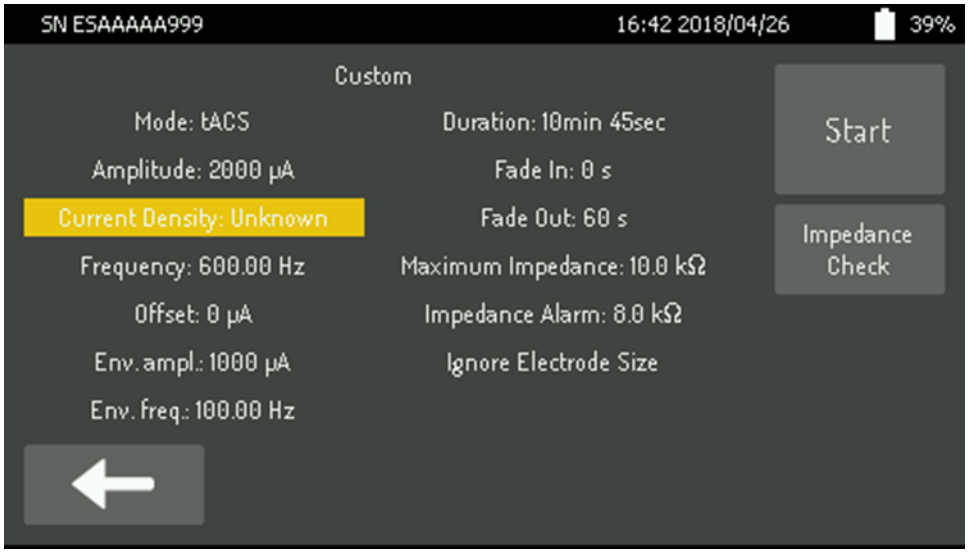


Figure 61 Current density is unknown as electrode size has not been entered. Stimulation can still start.

4.14 Impedance Check

Before starting stimulation, it is recommended that a manual impedance check is carried out. This will ensure that electrodes are mounted correctly, the required stimulation current can be reached, and overvoltage cannot happen. Pressing 'Impedance Check' button will direct the user to the impedance check screen (Figure 62) and a continuous impedance measurement will start.

If the level of impedance is low, which is a correct and desirable value, a green bar will be shown.

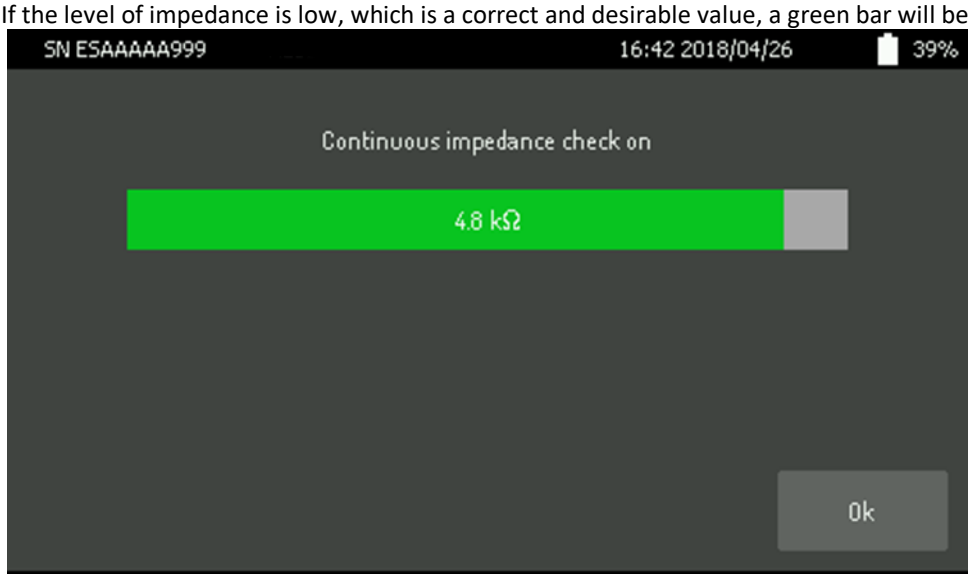


Figure 62 Impedance check screen. Green bar shows a low level of impedance.

If the impedance level exceeds the user defined threshold, the impedance bar will be yellow, and a warning message will be displayed (Figure 63).

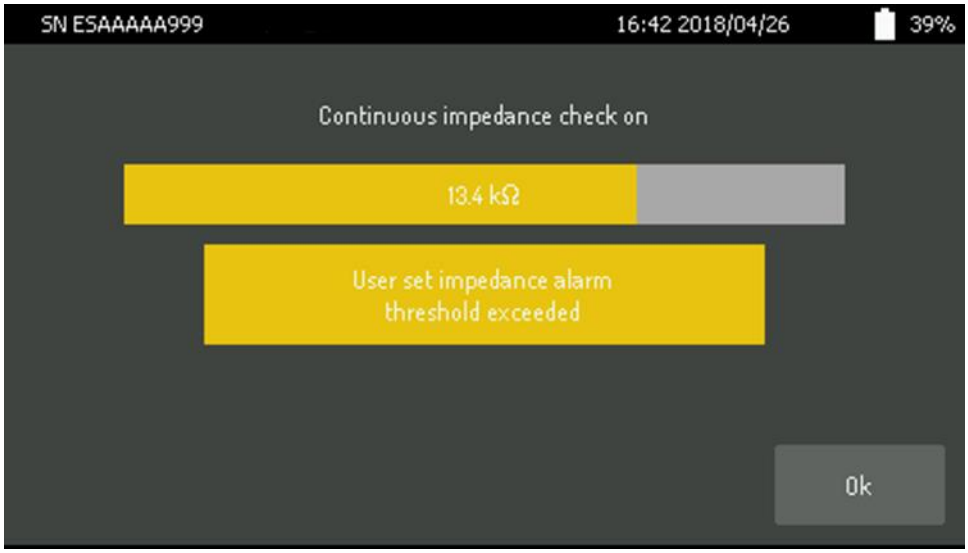


Figure 63 User set impedance level has been reached. Impedance bar is yellow, and a warning message is shown.

If the measured level of impedance is so high as to cause overvoltage, the impedance bar will be red, and a second warning will be shown (Figure 64).

Figure 64 Specified parameters would not be achievable, so secondary warning message is displayed in red.

If the measured impedance exceeds the maximum level, both warning messages will be shown in red (Figure 65).

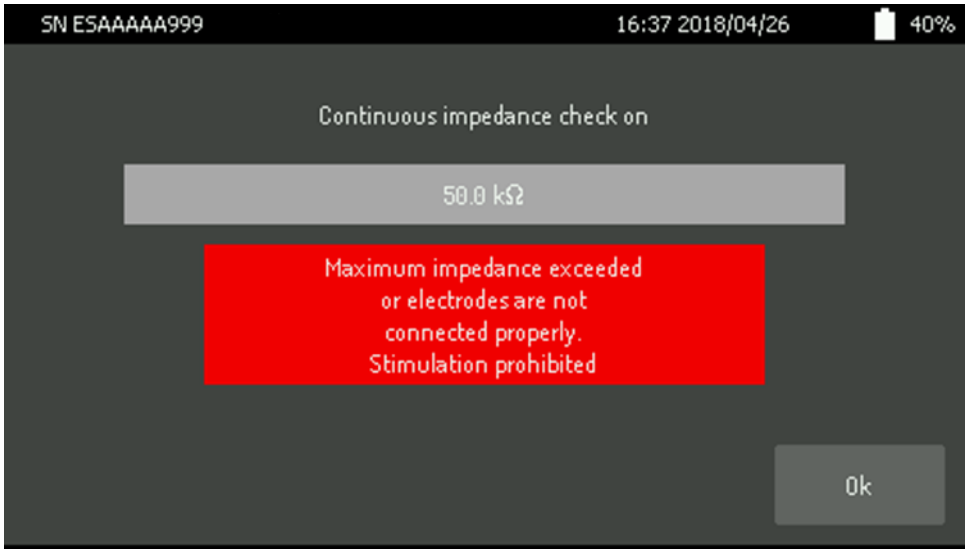


Figure 65 Maximum level of impedance reached. Both warning messages show in red.

If the impedance level measured is too low or electrodes are shorted, the impedance bar will be shown in red and a dedicated warning message will be shown in red (Figure 66).

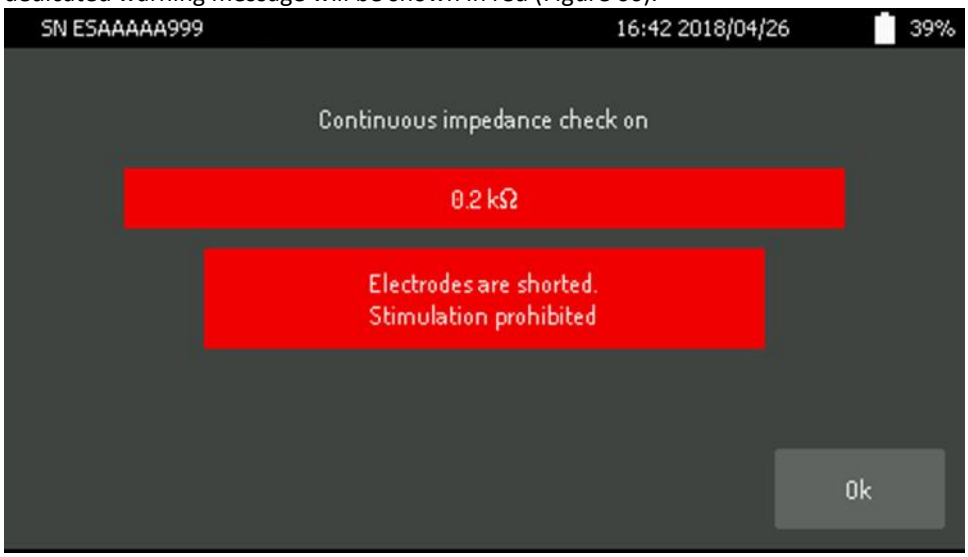


Figure 66 Short circuit detected - impedance bar shown in red with a specific warning message.

The measured impedance value during impedance check and during proper stimulation can differ due to the characteristics of the measuring signal.
If impedance level is deemed to be an acceptable level, press the 'Ok' button in the bottom right corner to return to the preset summary screen. To start stimulation, press 'Start Stimulation'.

4.15 **Stimulation**

Stimulation starts with a single impedance check. If it is within accepted levels, actual stimulation begins. This feature can be turned off via SCPI protocol, but for safety purposes, each dose of stimulation requires an impedance check.

The stimulation screen shows current preset name, measured values, user set values where applicable (frequency and duty cycle, for example), progress bar and stop buttons. During Fade in/Fade out the measured values are unavailable (Figure 67). Impedance bar shows colour-coded indication of impedance with no numeric value.

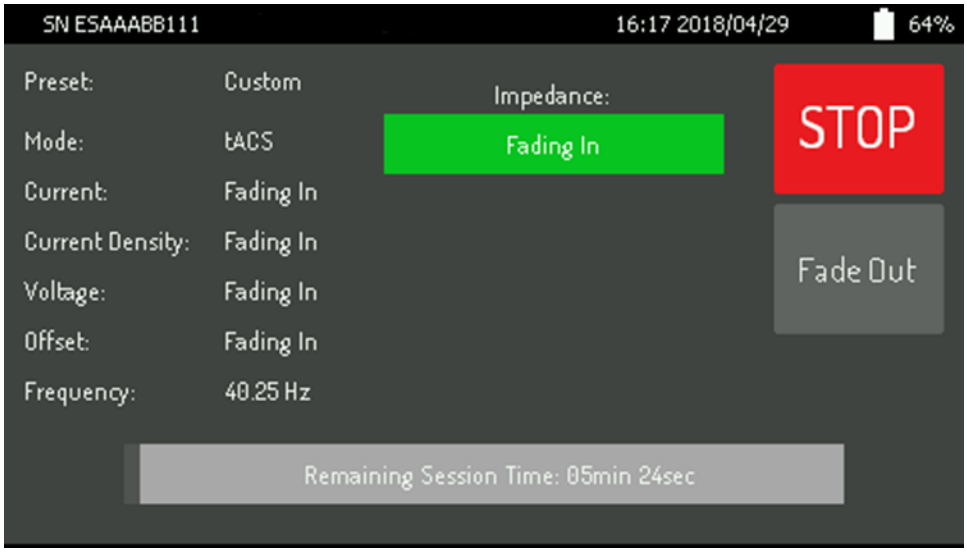


Figure 67 Stimulation screen showing mode, impedance bar. Measured values are shown as "Fading in" or "Fading out" during the fade in and fade out periods.

During normal stimulation, all measured parameters are displayed (Figure 68). In some cases (like very low tACS frequencies) parameters are shown as 0 until first valid measurements are gathered. In 0.01Hz tACS this could take up to 50 seconds.

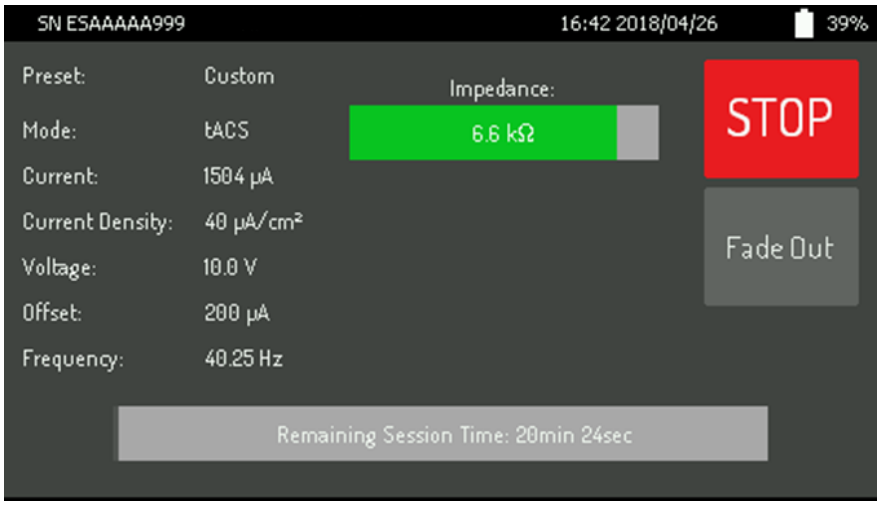


Figure 68 Stimulation screen during normal stimulation. All parameters are displayed.

If the impedance alarm has been set, which is triggered during stimulation or impedance becomes too high or low, the impedance bar will turn the relevant colour and the corresponding warning message will be shown, as seen in the impedance check screen in 4.14 and Figure 69.

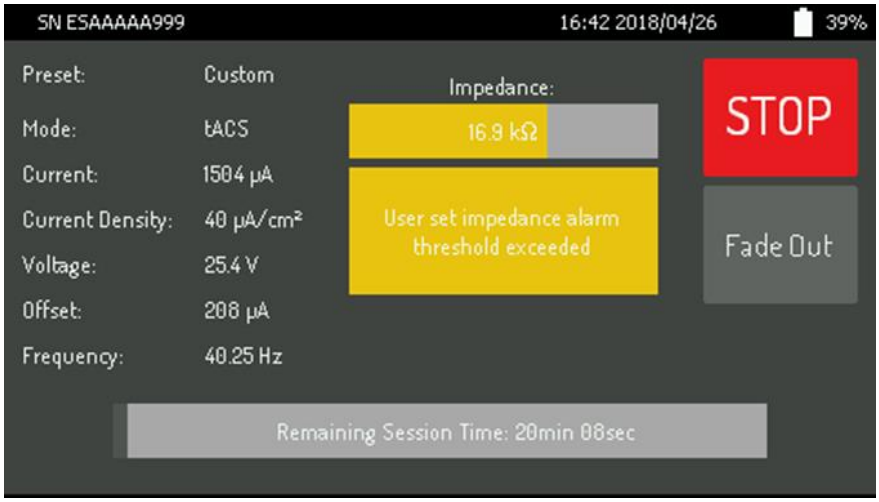


Figure 69 Impedance warning shown during stimulation. Stimulation will still be administered at this point.

If the measured impedance levels become too high, regardless of the set user limit, stimulation will be aborted, and the emergency fade out will begin (Figure 70).

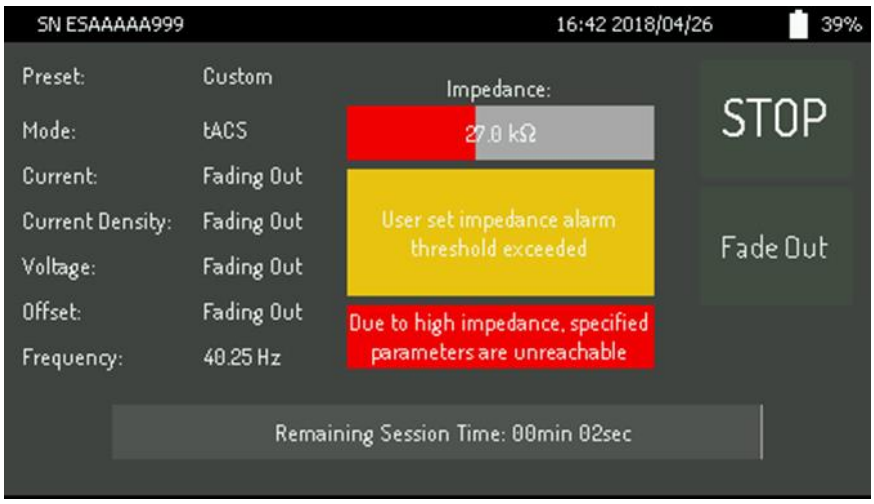


Figure 70 Stimulation has been aborted due to high impedance levels. Emergency fade out is underway.

To stop stimulation manually, press either 'STOP' or 'Fade out'. Pressing 'Fade out' will cause stimulation to cease and proceed to a pre-defined fade out length selected in the stimulation settings screen and then stop.

The 'STOP' button initiates an emergency fade out (2 seconds) and should only be used in an emergency, when it is necessary to stop the stimulation as fast as possible. The use of the 'Fade out' button is recommended so as not to cause discomfort to the subject.

The stimulation will not start if:

- parameters are unreachable,

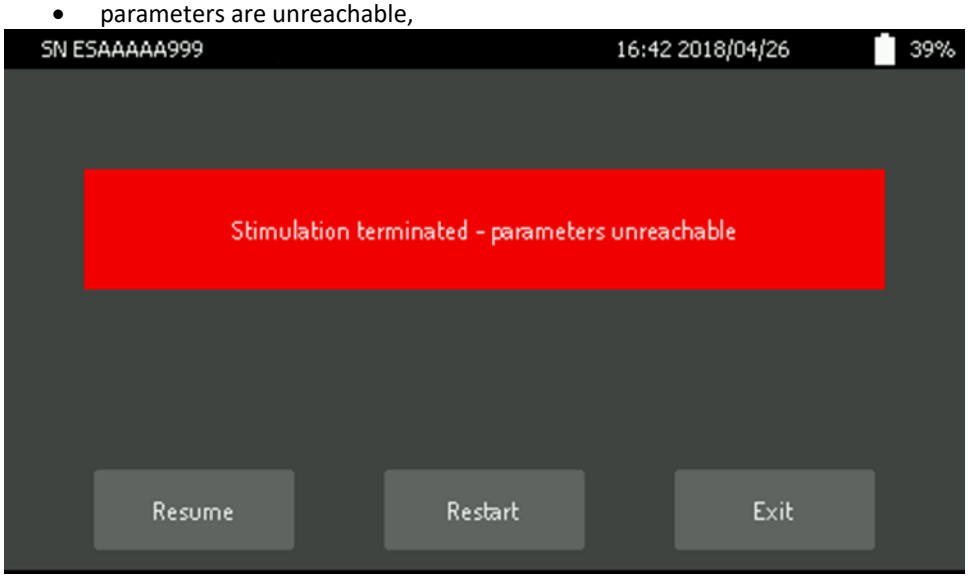


Figure 71 Stimulation terminated - parameters unreachable

- impedance measurement is outdated,

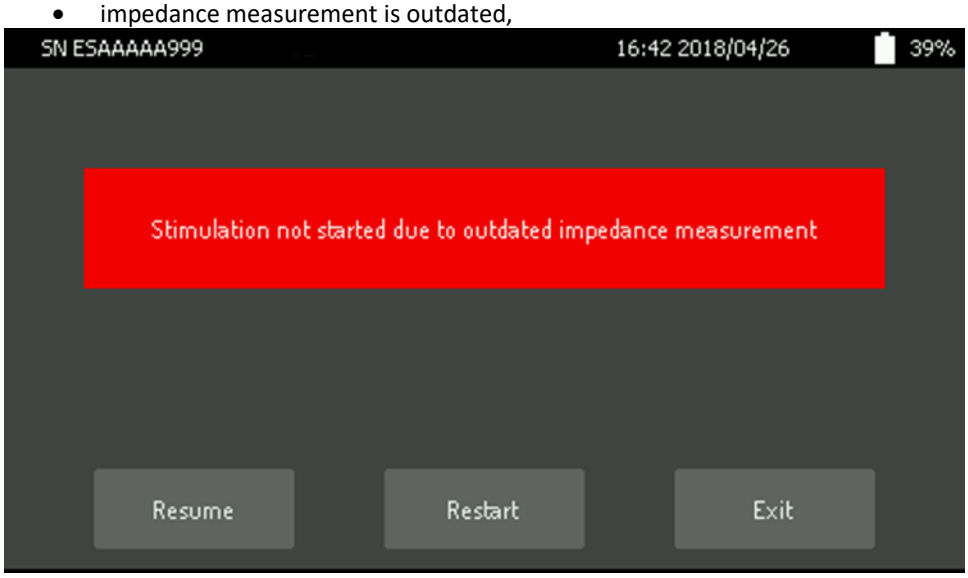


Figure 72 Stimulation not started due to outdated impedance measurement

- battery is low.

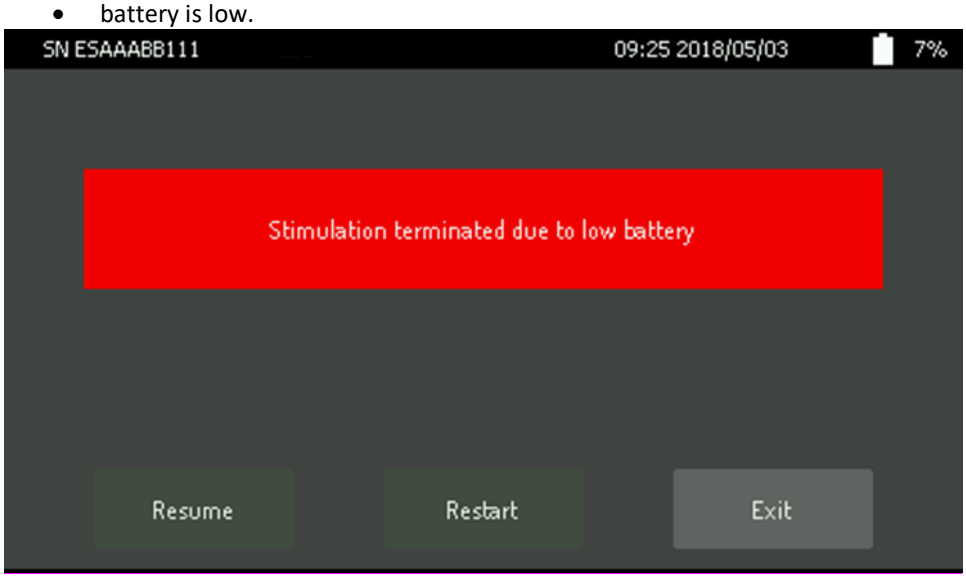


Figure 73 Stimulation terminated due to low battery

4.16 End of Stimulation

After a successful stimulation dose, the exit screen is shown with a message confirming the end of stimulation (Figure 74).

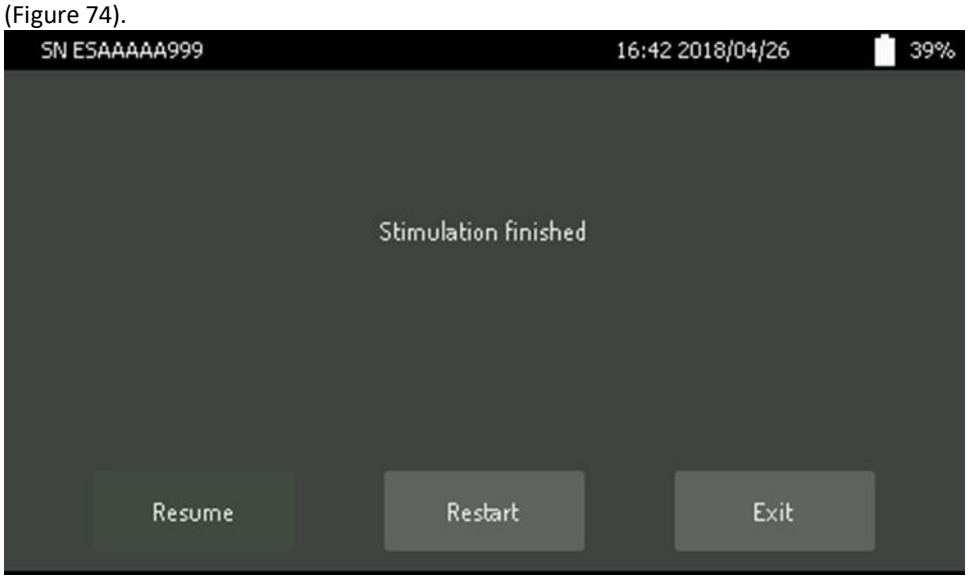


Figure 74 Screen showing that stimulation has finished without errors.

If stimulation was terminated automatically (by a warning) or early (manually) the appropriate alarm message is show in the exit screen.
If a stimulation has ended prematurely it can be resumed (if it is possible to stimulate) by pressing 'Resume' which opens a preset summary screen (Figure 59). However, stimulation time will be decreased by the amount of time that elapsed in the aborted session (Fade in and Fade out are not counted as stimulation time).

The stimulation will finish automatically if:

- the programmed stimulation was successful,
- impedance value falls below or above safe range.

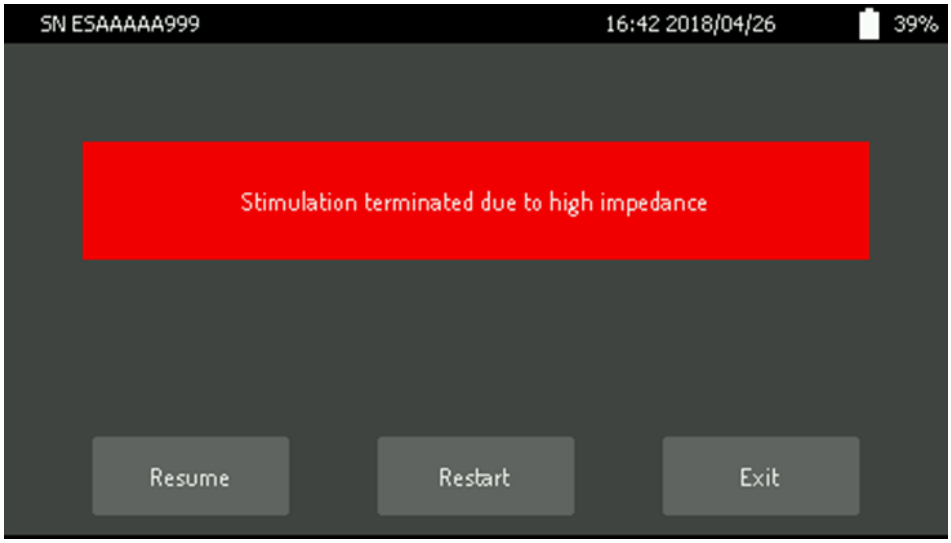


Figure 75 Stimulation terminated due to high impedance

The stimulation will finish before scheduled time if:

- user connects a power unit to the device,

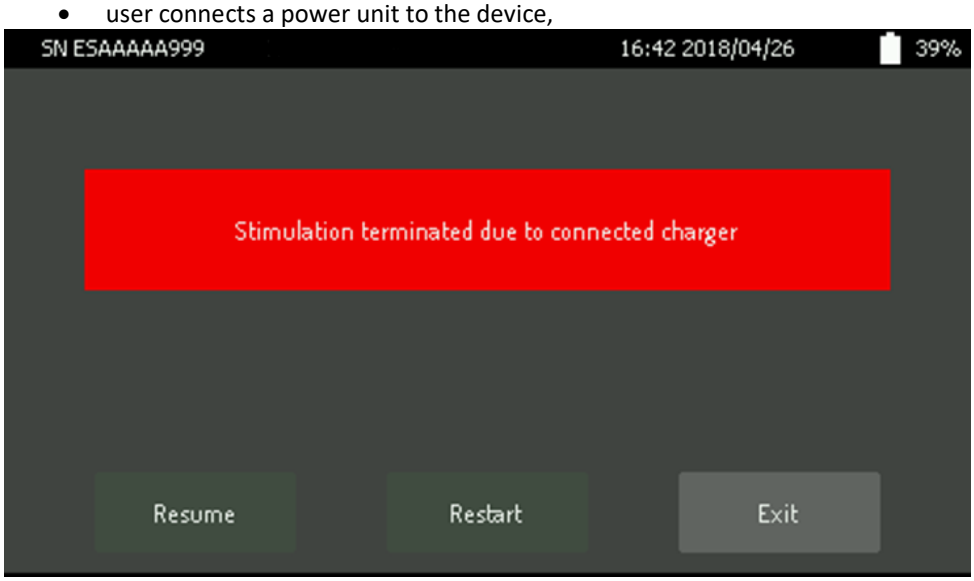


Figure 76 Stimulation terminated due to connected charger

- user disconnects electrodes or pin cables,

Figure 77 Stimulation terminated due to disconnected electrodes – visible as high impedance

- user presses 'STOP',
- user presses 'Fade out'.

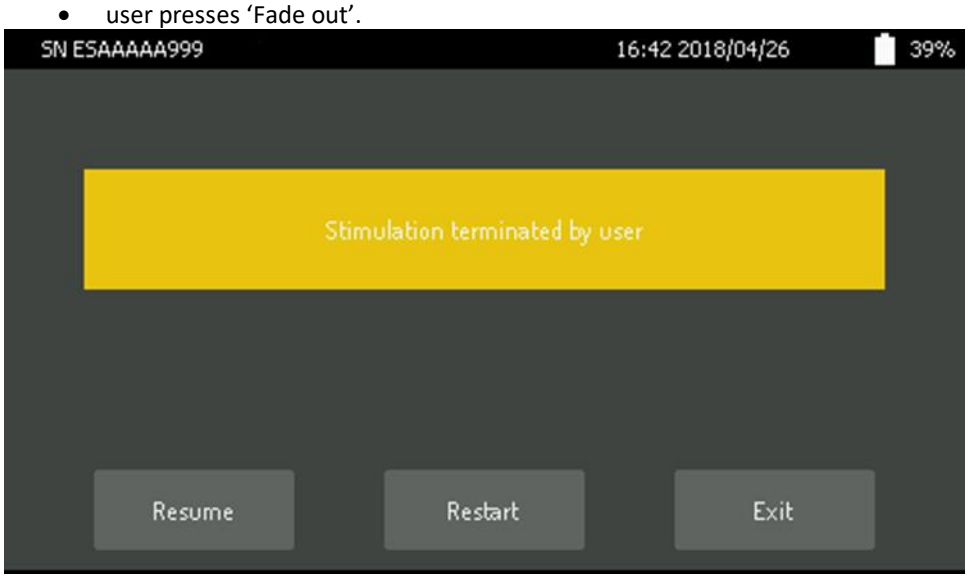


Figure 78 Stimulation terminated by user

If the reason for the aborted stimulation was due to an impedance error, a new impedance check will have to be carried out. This should be completed before going to the preset summary screen.

Stimulation can be restarted (if it is possible to stimulate) by pressing the 'Restart' button. This will take the user to a preset summary screen (Figure 59). Stimulation time will have been reset to the original value established in the stimulation parameters.

'Exit' takes the user back to the home screen (Figure 12).

4.17 Loading a Previously Saved Preset

To load a stimulation protocol from a preset, select 'Presets' from the home screen (Figure 12).

Stored presets will be shown as available buttons with preset names. Select the preset to be used. The chosen preset

will then be highlighted green and the 'Load' button will become available (Figure 79).

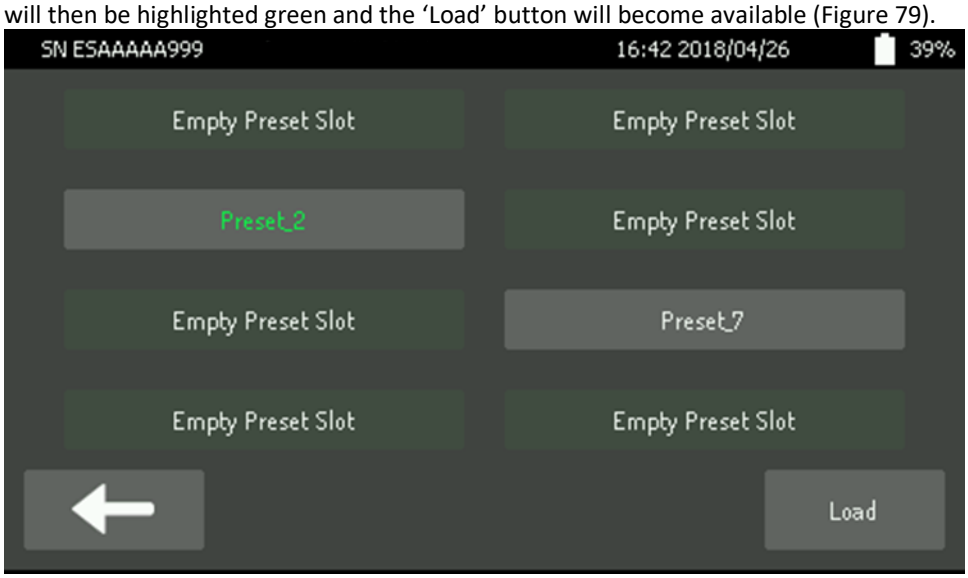


Figure 79 Preset selection screen. Preset 2 chosen for loading.

Once 'Load' has been pressed, the user is taken to a new summary screen, showing the parameters about to be administered. Note that on the summary screen, Preset 2 is shown as selected (Figure 80). To load a different preset, press the bottom left arrow.

Figure 80 Preset summary screen. Note that Preset_2 has been chosen.'

4.18 **Analogue Input Mode**

Analog input mode is a special mode of operation, in which patient's current is generated in direct proportion to an externally-provided analogue control voltage.
Analog Input Mode can be entered from the device's home screen (Figure 12) .

The device in this mode operates as follows:

- accepts analogue voltage signal from -2.5V to +2.5V range from an external source, such as signal generator
- generates current stimulation waveform directly proportional to external signal, at conversion factor of 2mA of patient per 1V of external signal voltage, up to -5mA to +5mA range
- provides adequate medical-grade galvanic isolation between external analogue source and patient

In Analog input mode there are no parameters to be set. Once chosen, the stimulation can start or Manual impedance

check may be invoked (Figure 81). Maximum impedance accepted in this mode is set to 50kΩ and may not be adjusted. As a safety feature, this stimulation mode can be terminated by open-circuit or overvoltage detection like in other stimulation modes.

Figure 81 Summary screen in Analog Input Mode

During analog input mode stimulation there's no duration limit and elapsed stimulation time is displayed instead. Additionally, current, voltage and impedance indication is provided(Figure 82)

Figure 82 Stimulation screen in Analog Input Mode

4.19 **Remote Mode**

Remote mode enables the device to be controlled via SCPI protocol using USB port. The device is visible by the computer as a serial port. This makes it possible to run nurostym tESm using Nurostym Application. As a low-level alternative it is possible to use any serial port terminal application (although it is recommended to use RealTerm). Connection parameters are irrelevant. **Please ensure that STM Virtual COM Port Driver has been installed before connecting the device in this way.**

When the device is connected to a computer 'REMOTE' is displayed on the upper bar. If the device is not stimulating, the screen changes to the Preset summary screen with the last set parameters. Buttons are hidden, and all control is done remotely on the computer (Figure 83). The screen is refreshed with every change to Preset.

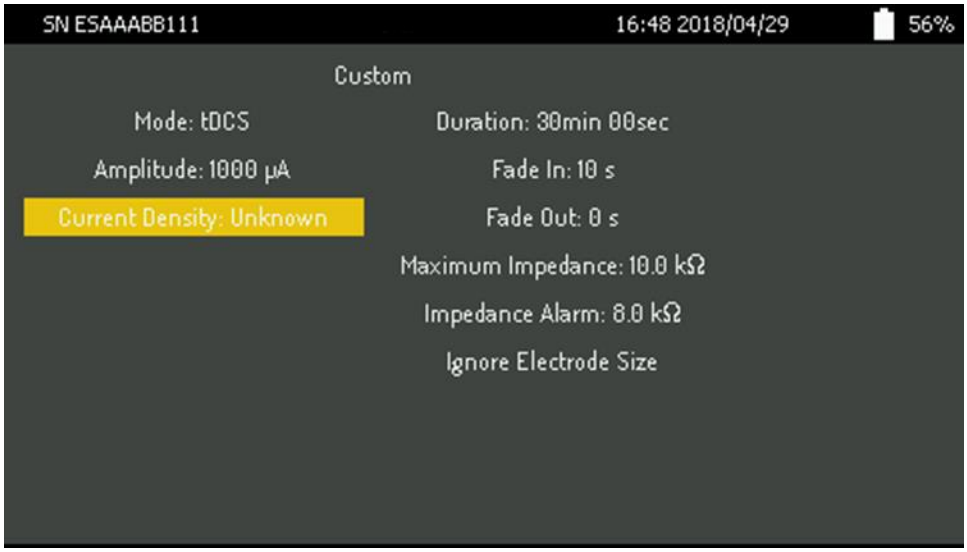


Figure 83 Preset summary screen in Remote Mode

During stimulation, for safety reasons, 'Stop' and 'Fade Out' buttons are still active (Figure 84). When stimulation ends, the screen reverts back to summary screen.

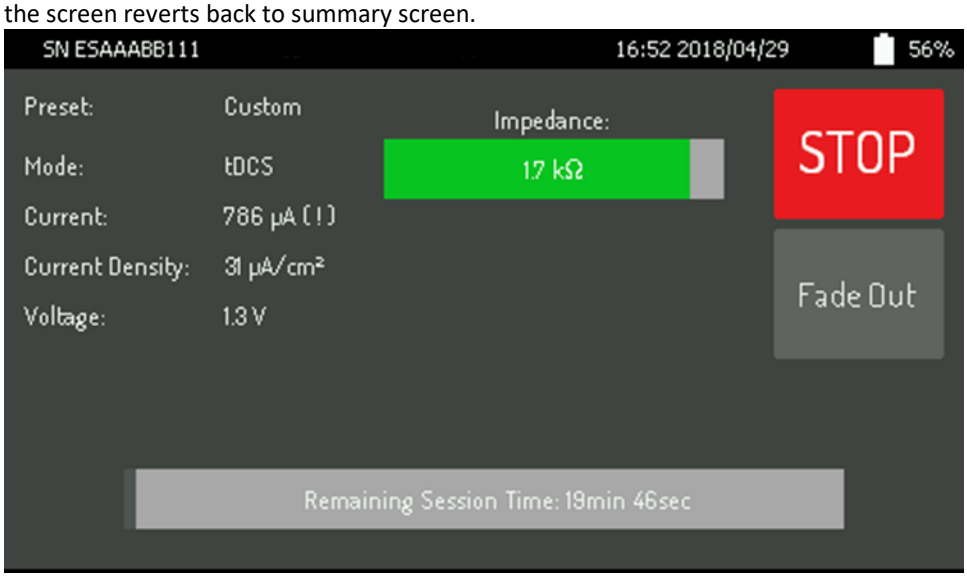


Figure 84 Stimulation screen in Remote Mode

Remote mode allows full control of all device functions, some of which are not otherwise available from the touch screen user interface (such as Triggers). For a list of all commands, with examples of use, see Appendix to this manual.

It is recommended that the original device software application be used to connect the device to a computer.
Any deviation from this recommendation is at the users risk and neither the manufacturer nor distributor can be held responsible for issues that arise as a result.

Before disconnecting the USB port of the nurostym device, it is recommended to turn the device off.

5 Triggers and Analogue I/O

Triggers are discrete or digital input and output signals that allow nurostym to synchronise with other devices such as EEG, TMS etc.
Analogue Input signal is used for stimulation governed from external signal source.
Analogue Output signals are used to monitor the patient current and further process or record it.

5.1 Triggering

The SCPI protocol allows the user to operate the device remotely with a triggering function or to use certain events during the course of a stimulation protocol to trigger a third-party application. These are known as Trigger In and Trigger Out functions. Triggering will only work whilst the stimulator is in remote mode (connected to a computer via USB cable using SCPI protocol). Once the stimulator has been disconnected from the PC any trigger options will no longer be configurable.

5.2 Analogue Input

Analogue input signal is used along Analogue Input Mode stimulation. In this mode patient stimulation current is closely following the voltage waveform at the Analogue Input provided from the external source. The transfer ratio is non-adjustable at 2mA of stimulation current per 1 volt at analogue input.

The waveform presented to the analogue input may be arbitrary (AC, DC, noise etc.) as long as the signal stays within ±2.5V range and is bandwidth limited to 1kHz (at -3dB attenuation).

'Fast' signals near 1kHz and above will be transferred with considerable attenuation, with visible slope and/or phase shift.

Analogue Input Mode cannot be used simultaneously with the Remote Mode. Neither application nor SCPI commands allow to manage Analogue Input Mode.

Nurostym tESm provides measurements in of output current, voltage and estimated impedance, thus ensuring to control skin-electrode contact. Indications of measurements in Analogue Input Mode are based on root-mean-square (RMS) values averaged over a period of time, thus indicated values are always positive values and have definitive relations to other parameters, such as factor of 0.707 to peak value in case of a pure sine wave or equal to absolute DC value in case of DC input.

5.3 Analogue Output of 500mV per mA

Analogue output is a single-ended directly proportional representative of patient stimulation current.

This output is active at every mode of stimulation (TDCS, TACS, TRNS, Analogue input).

Output level is typically convenient for oscilloscope examination of patient current.

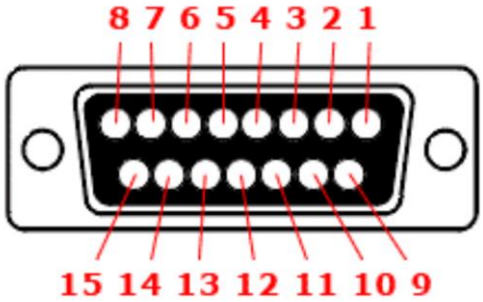
Output transfer is also complementary to Analogue Input, therefore allowing for different configurations of multiple nurostym tES device in multichannel stimulation (mirroring current, daisy-chaining, parallel operation etc.)

5.4 Analogue Outputs of 2.5mV per mA

Low level Analogue Outputs are differential scaled-down outputs. The level and differential format make the signal convenient for usage with EEG amplifier or similar processing.

5.5 Pin Layout

The diagram below shows the layout of the pins in the trigger port and their uses.



Pin 1 – Analogue Input
Pin 2 – GND - Ground for triggers
Pin 3 – Analogue Output 2.5mV/mA Negative
Pin 4 – Analogue Output 2.5mV/mA Positive
Pin 5 – GND - Ground for triggers
Pin 6 – Trigger Out channel 3
Pin 7 – Trigger Out channel 2
Pin 8 – Trigger Out channel 1
Pin 9 – 5V Source (max short circuit current: 30mA)
Pin 10 – Analogue Output 500mV/mA
Pin 11 – GND - Ground for triggers
Pin 12 – GND - Ground for triggers
Pin 13 – GND - Ground for triggers
Pin 14 – Trigger In channel 2

Pin 15 – Trigger In channel 1

5.6 Interface box

It is recommended to use the Nurostym Interface Box as an expander of the signals described above, rather than connecting directly to the pins of the Triggers port.
Interface is connected to tES using a D-subminiature connection cable and provides convenient connectors to external equipment:

- BNC for triggers in/out
- BNC for analogue input
- BNC for analogue Output 500mV/mA
- 3 off touchproof connectors for Analogue Output 2.5mV/mA Positive (OUT+), Negative (OUT-) and Ground (GND)

Figure 85 Nurostym Interface views

5.7 Trigger In

Trigger in channels are used to start and stop a stimulation protocol via an external CMOS level compatible source (TTL or 5V CMOS compatible signals). Each trigger channel is configurable independently and works independently. Each channel can be configured so that it can either start or stop the stimulation or do both.

To start the stimulation with a trigger the 'start trigger event' must be configured and a 'start stimulation command' must be sent to the device. The device will then display a 'Stimulation will start after trigger' message and once a trigger event occurs the stimulation will start.

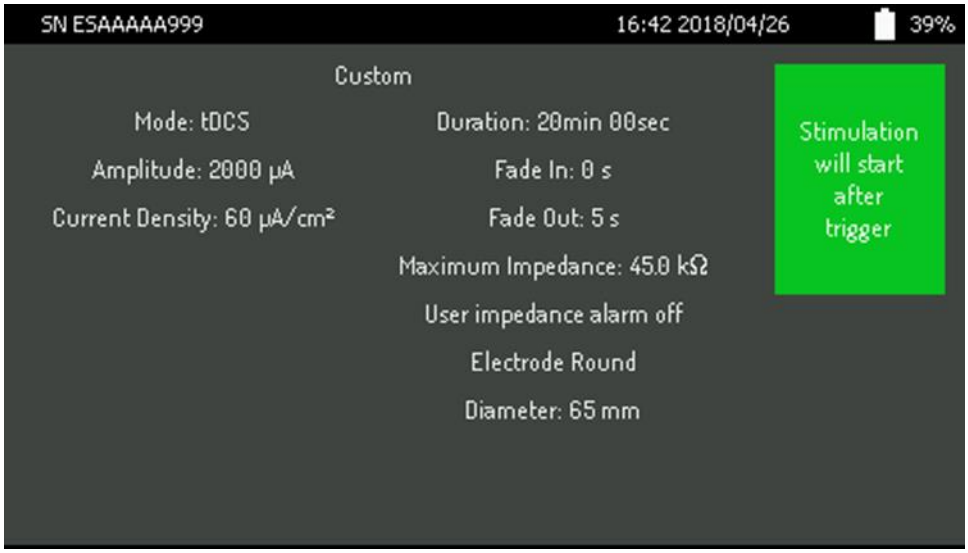


Figure 86 Stimulation will start after trigger

To stop the stimulation with a trigger the same rules apply: a 'stop trigger event' must be configured and the device must be administering a stimulation.

Each channel can be configured so that it reacts to the following:

- Rising Edge

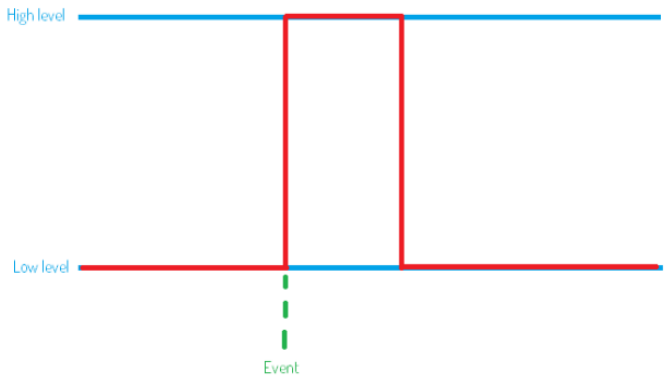


Figure 87 Trigger in setup for rising edge

- Falling Edge

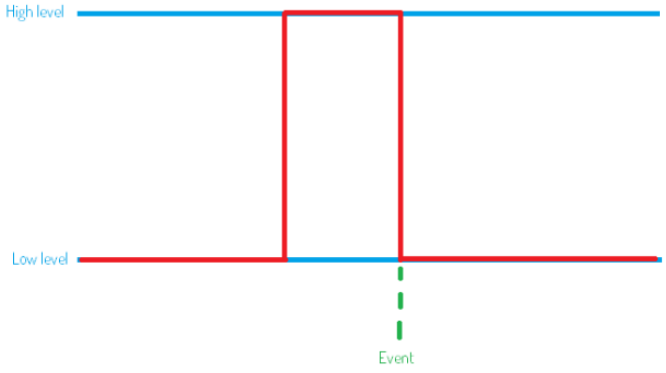


Figure 88 Trigger in setup for falling edge

- Both Edges

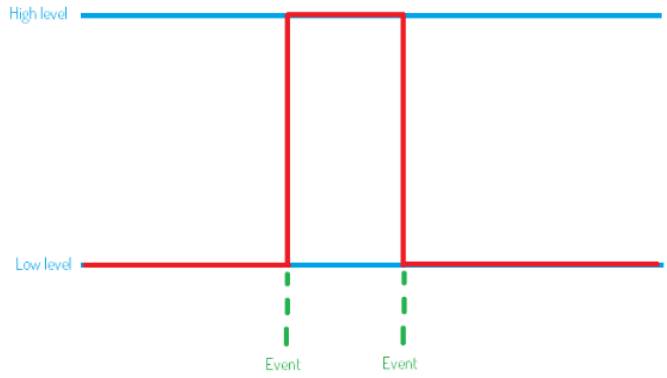


Figure 89 Trigger in setup for both edges

5.8 Trigger Out

Trigger out channels are used to signal various events during the stimulation to an external device using TTL or 5V CMOS compatible signals. Again, each channel is configurable independently and operates independently. Each channel can be configured with any combination of available events and can be configured to signal events with one of four available modes, such as:

- Pulse High (PH) - Each event is signalled by a signal transition from low to high, then shortly high to low.

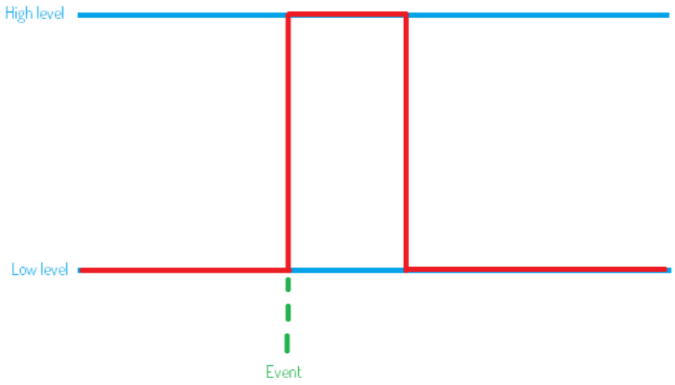


Figure 90 Trigger out setup for pulse high

- Pulse Low (PL) – Each event is signalled by a signal transition from high to low then shortly low to high.

Note, that the pulses are very short to accommodate a possible high density of such pulses generated by various events. Any equipment recording such pulses must ensure to have good time resolution not to miss a short pulse.

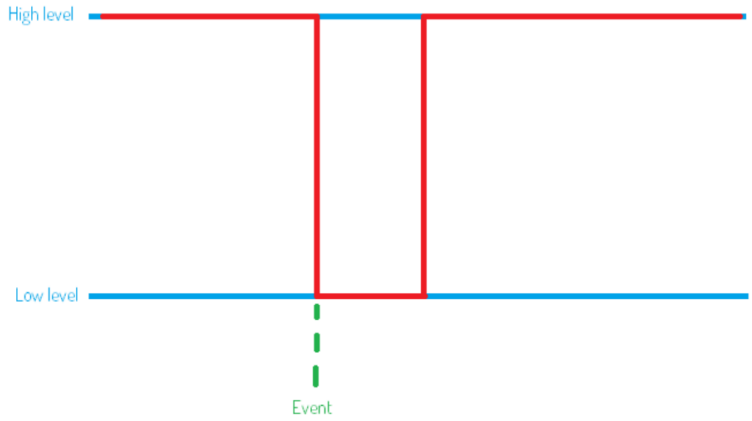


Figure 91 Trigger out setup for pulse low

- Level High (LH) – Only used for signalling the following events: Start or Stop of the stimulation. When stimulation is being administered the signal level is high. When there is no stimulation the signal level is low.

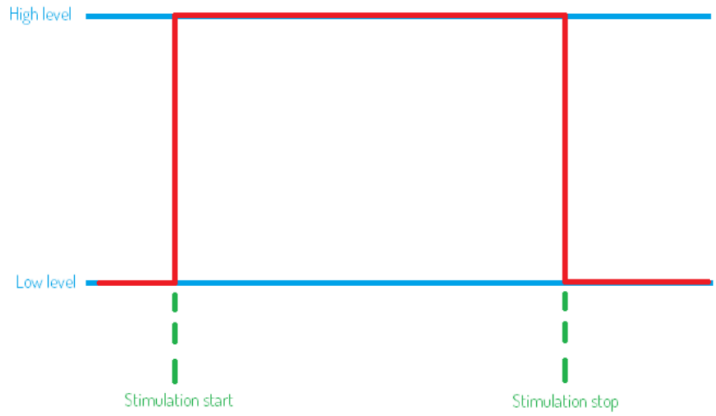


Figure 92 Trigger out setup for level high

- Level Low (LL) – As above, only used for signalling the following events: Start or Stop of the stimulation. When stimulation is being administered the signal level is low. When there is no stimulation the signal level is high.

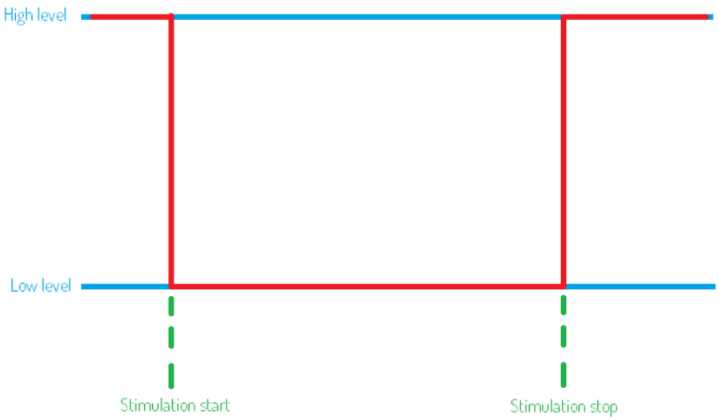


Figure 93 Trigger out setup for level low

Available events:

- MAX (maximum) – A signal reached its maximum (only applicable to tACS)

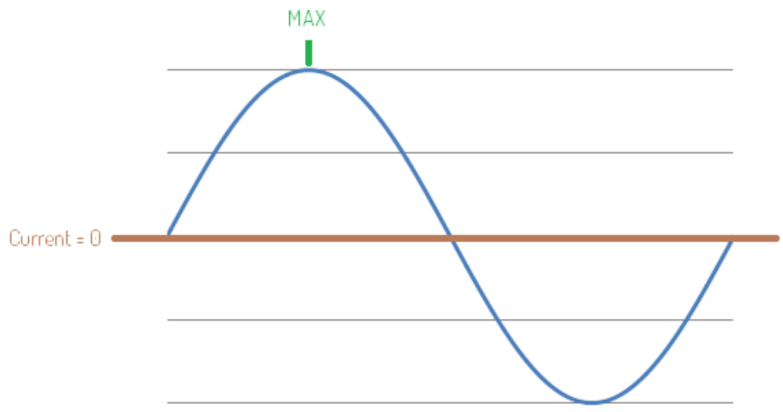


Figure 94 Trigger out event - signal maximum

- MIN (minimum) – A signal reached its minimum (only applicable to tACS)

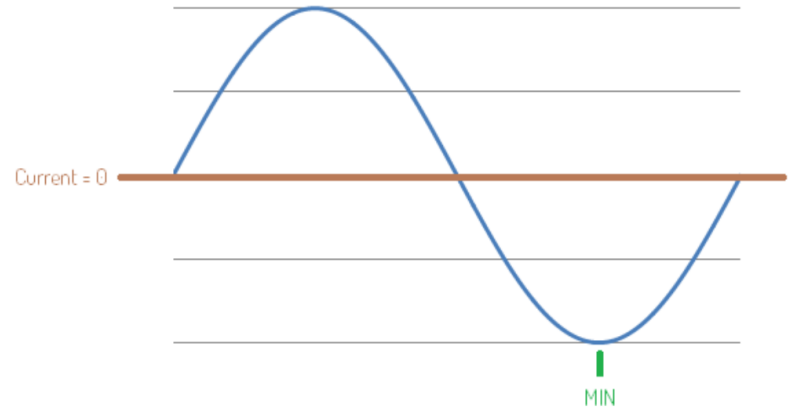


Figure 95 Trigger out event - signal minimum

- ZERO (zero level) – A signal changed the polarity (only applicable to tACS)

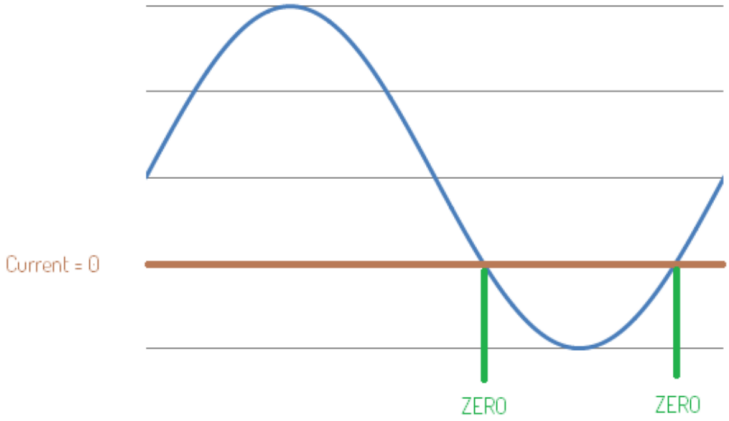


Figure 96 Trigger out event - zero level crossing

- NOC (number of cycles) – An event triggered following a specified number of signal cycles (only applicable to tACS)

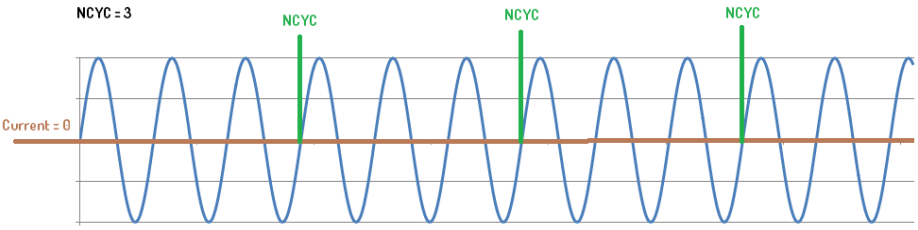


Figure 97 Trigger out event - number of cycles

- PIT (point in time) – After a specified period of time, a trigger event occurs ‘n’ times with a predetermined interval between each other.

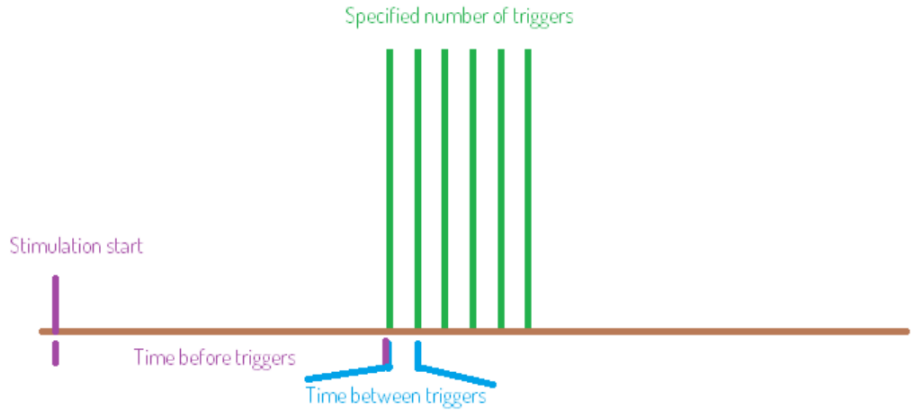


Figure 98 Trigger out event - point in time trigger

- STRT – Stimulation Started
- STOP – Stimulation Stopped

Figure 99 Trigger out event - start and stop stimulation

6 Splitter

Nurostym Splitter passive accessory provides an option to use one ‘active’ electrode and up to 4 ‘return’ electrodes. Each return channel can be switched on or off using associated switches. To use splitter it is required to connect Splitter’s input sockets to tES electrodes sockets and electrodes to Splitter’s Output sockets.

To crudely equalize the currents though the multitude of return electrodes, each channel contains a series 10kΩ resistor in series. This typically keeps the currents in the return electrodes reasonably similar, however individual currents generally flow according to laws of electrical circuits and are not individually monitored.
Series 10kΩ resistors in the return paths will impact the overall circuit impedance in the experiment, as observed on the tES screen.

Figure 100 Nurostym Splitter general view

7 Firmware update

The firmware of the device is constantly improved by a team of engineers. The device is analysed and user feedback is considered on an ongoing basis. To ensure a positive experience with the device users are offered free system updates.

7.1 Firmware distribution

Firmware update notifications will be sent to customers via email messages by the distributor. The message will contain a link to the file to be downloaded by the user.

The firmware update is distributed as a single IMG file.

7.2 Firmware update

Firmware update is done in two stages. The first stage is uploading the file to the device via SCPI protocol using the USB cable and nurostym application or any serial terminal application. The second stage is flashing the device by the bootloader. While the second stage is done automatically by the device, the first stage requires user activity. We strongly recommend using our dedicated application as a much easier way to update the device.

To upload the new firmware to the device, plug the device to the USB port. The device should appear as a new serial port. Connect to the device via a serial port terminal that allows file sending (**WARNING: be sure to use a terminal that sends the whole file as it is, without converting it to text or adding additional special characters**). Connection parameters are irrelevant.

To upload the file, send the command: ":SYST:BOOT X", terminated with a carriage return, where X is the file size in bytes. If the device returns an OK message, it is ready to receive the file. Now the file can be sent to the device. While uploading the file, progress can be tracked on the bar on the device screen. When the upload is complete (the specified number of bytes is sent), the device will reboot.

When the device reboots, firmware flashing is conducted. After a successful update the Welcome screen is displayed on the device with an 'Update completed' message.

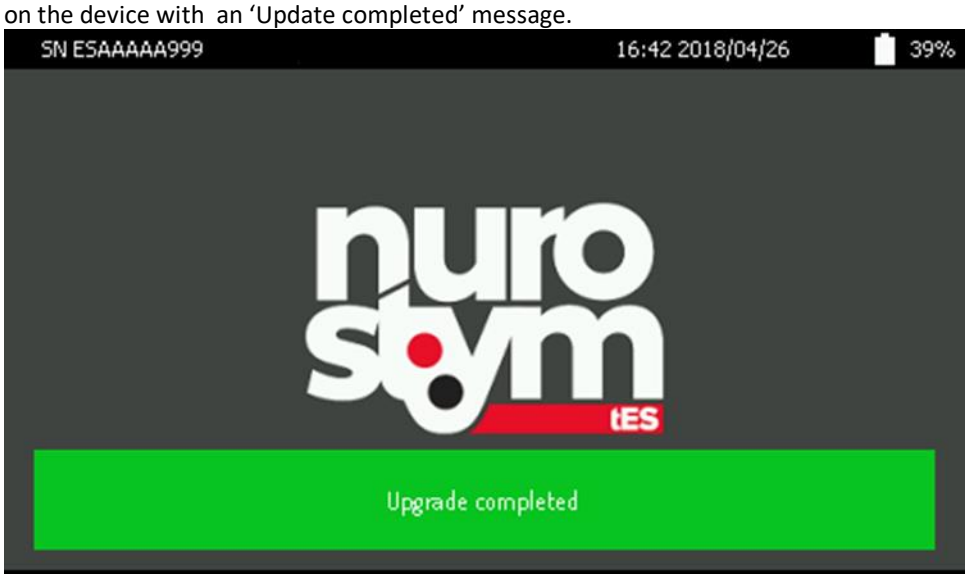


Figure 101 Firmware update completed

Device updating may take up to one minute. During the update, the device's screen is black, and the blue Stimulation LED is on. **WARNING: Do not turn off the device during the firmware update process as this may make the device unusable.**

7.3 Firmware Update Error Control

The device has strict firmware update error control. Several errors may occur during an update, due to hardware or software failures. Should this happen, an error message is displayed on the welcome screen.

List of error messages:

- 'File with upgrade was corrupted. Upgrade aborted!' – Uploaded file is incorrect or incomplete.

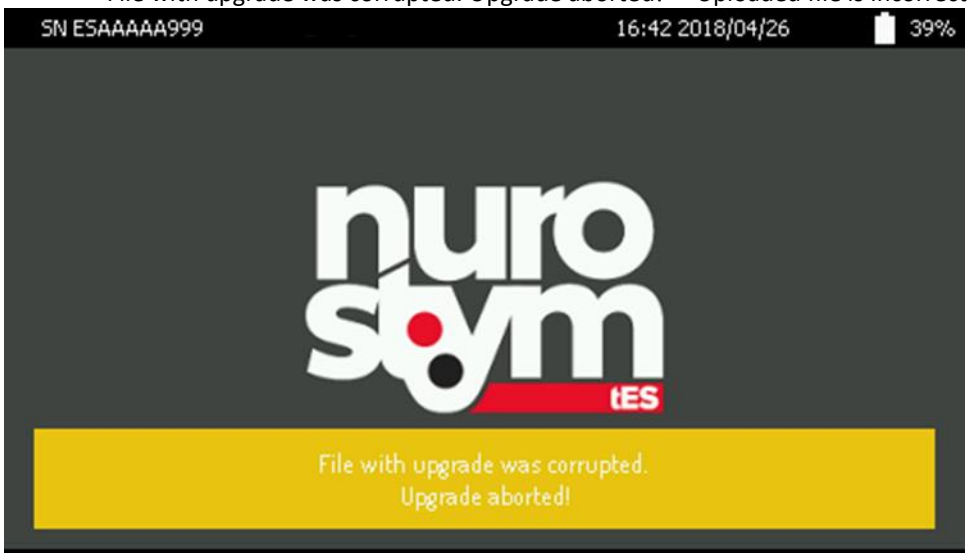


Figure 102 Firmware update error - corrupted file

- 'Uploaded firmware version is older or does not match hardware. Upgrade aborted!' – Wrong version of firmware was uploaded. It is not applicable to the user's hardware or is older than the current firmware.

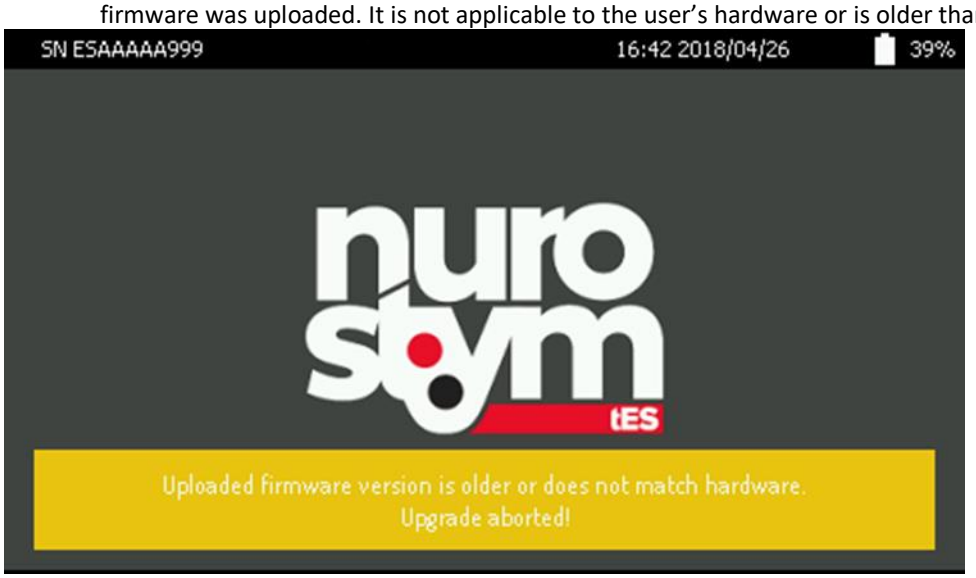


Figure 103 Firmware update error - older firmware version

- ‘Error occurred while updating. Upgrade aborted!’ – Internal error. If it is recurring, contact the distributor – the device is malfunctioning.

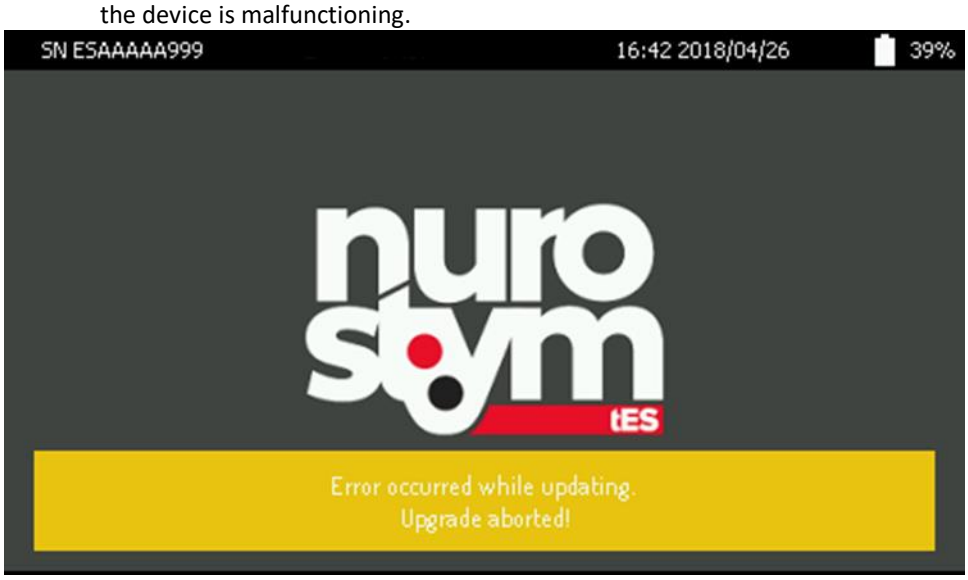


Figure 104 Firmware update error - error while updating

- ‘Firmware in device was corrupted. Backup restored.’ – The device discovered corruption in its firmware and restored a backup program – **WARNING: The backup program is the previous working version of firmware!**

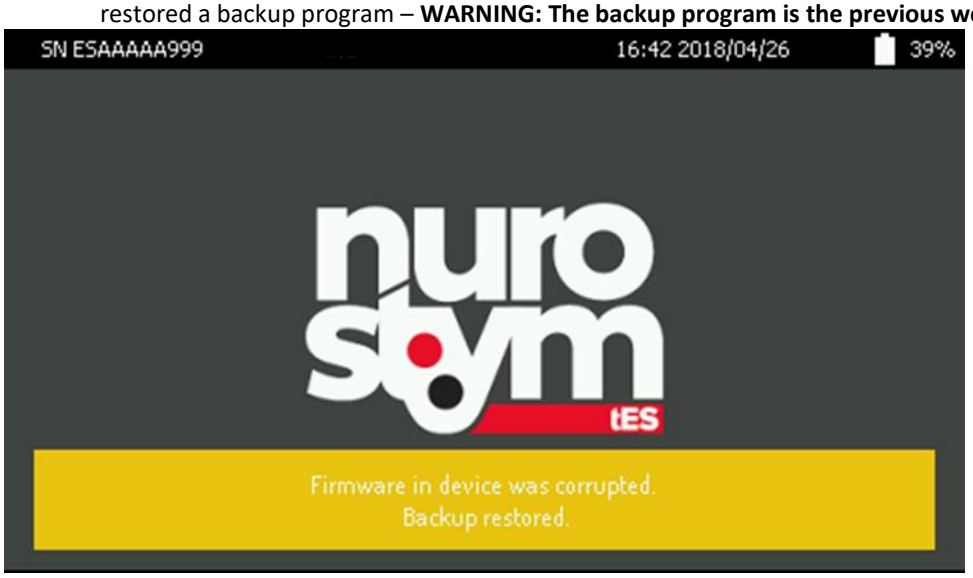


Figure 105 Firmware update error - corrupted firmware

In case of an error, the previous firmware version is restored.

If the error is due to malfunction the device has no means to start a correct program, the blue Stimulation LED starts to blink at device start-up. When this happens, contact your distributor.

8 Troubleshooting and maintenance

8.1 Device-specific issues

8.1.1 Device interface

1. The device screen is not working
    - The device is shut down automatically for the duration of charging
2. The device screen is not responding
    - The operator is wearing gloves.

8.1.2 Stimulation

3. Stimulation does not start exactly on pressing the 'START' button.
    - There is a delay before proper stimulation starts. An impedance measurement is optionally performed before starting the stimulation, followed by a momentary delay before the diagnostic procedure begins.
4. Stimulation does not start (wrong impedance message dialog is displayed).
    - Verify the positioning of the electrodes, check electrode connections, check or remove adapters if any were used to connect the electrodes.
5. User-defined impedance cannot be set to a higher value.
    - User-defined impedance must always be lower than the security threshold, which can also be set in a limited range (not exceeding the maximum of 50kΩ).
6. The device stops working during stimulation.
    - Electrode connection conditions have changed, impedance has exceeded the acceptable value, e.g. exceeded 50kΩ or dropped below 300Ω.
7. 'Parameters unreachable' message is displayed.
    - This message indicates that the impedance is so high that the current settings cannot be achieved due to hardware and safety limitations.
8. A sound signal is emitted
    - This is normal activity of the device, indicating that the user-defined impedance level has been exceeded or another stimulation error occurred (check the messages on the device screen or the status received using SCPI protocol).

8.1.3 Device operation

9. The charging LED remains on, despite that 15 hours have passed after connecting the device to a charger.
    - Disconnect the device from the charger immediately and contact your distributor.
10. Battery charging indicator LED is continuously on.
    - Do not connect the device to a charger, contact your distributor.
11. Battery empty (5%).
    - Connect the device to a charger. (connecting USB does NOT result in charging!)
12. Charging indicator LED is off.
    - Check the charger connection, use an original charger, the device will not charge when connected to a PC via SCPI protocol.

8.2 Maintenance

The device is designed for self-checking its critical functions and will alert if manufacturer's service is required.
If a critical function of the device is non-functional, the device will lock and alert on service needed.

There's no need for a scheduled maintenance or re-calibration.

Any service actions within the device should be performed by the manufacturer's service and engineering department or the authorized and trained representative of the manufacturer only.

There are no user-serviceable parts in the device.
All safety fuses inside the device are fixed to internal printed circuit boards and are not replaceable or resettable.

Internal batteries are in-built and are not replaceable by the user. In case of an evident loss of operational time due to battery ageing, the device should be serviced by the authorised service personnel only.

Any wear and tear of the accessories, such as cables and electrodes should be noted and a new accessory should be ordered to replace a worn one.

Electrodes, charger and some cables are off-the-shelf parts available on the market and may be replaced by a new one of exactly the same model by the same manufacturer.

All worn or damaged cables must be re-ordered from the manufacturer.

Using any replacement parts other than those specified in this manual is prohibited.

9 Manufacturer and servicing information

The MANUFACTURER will make available on request: circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

SERVICE PERSONNEL must be an authorized and trained representative of the manufacturer or the manufacturer's service or engineering department.

The manufacturer and support provider for the medical device is:

Neuro Device Group S.A.
Address: Warszawa 01-510, Gen. Józefa Zajączka 28 Street
Telephone: + 48 513 121 977
kontakt@neurodevice.pl
http://www.neurodevice.pl

10 Revision history

Revision	Date	Autors	Description
1.0	05.02.2021	AJ, SM	First relese
1.1	05.03.2021	MG, SM, KM	2 Icons and Labels on Device and Packaging – new records 3.3 Device Specifications – new records 5.7 – Update
1.2	10.03.2021	MG, SM, KM	2 Icons and Labels on Device and Packaging – new records 3.3 Device Specifications – new records 3.11 Package contents – new records
1.3	15.03.2021	SM	3.12 Adding a way to read the label
1.4	14.04.2021	SM	Whole document: Pulse mode deleted 1 added information on which current modes treat which diseases 5.6 added description of designations
1.5	08.06.2021	KM	Added recommendation to turn off device while disconnecting USB. Added information about measurement method in Analogue Input Mode.
1.6	02.11.2021	SM	Changed company address.