g.ESTIMPRO
CORTICAL STIMULATOR

g.tec

CONTROL MANUAL

g.ESTIMPRO

Control Manual g.Estim PRO
Version: 1.24.01 | Revision 1.13

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CONTENTS

1 CONVENTIONS

The following conventions are used to direct the attention of the reader to important safety information.

WARNING

A warning informs about possible injury or death that could result from the use or misuse of the device.

CAUTION

A caution informs about possible injury or malfunctions of the device or other equipment that could result from the use or misuse of the device.

NOTE

Notes provide information such as recommendations, best practices or other information.

2 CONTRAINDICATIONS

WARNING

- The device must not be used directly on the heart.
- The device must not be used for stimulation near or through the chest (transthoracically), as applying electrical stimulus current to any region of the thorax can lead to ventricular fibrillation or other cardiac arrythmias. Never use electrodes contralaterally, i.e. do not use two electrodes on opposite segments of the body.
- The device must not be used for stimulation directly on the eyes or inside body cavities.
- The device must not be used for stimulation when the mouth of the patient is covered.
- The device must not be used for stimulation of the front side of the throat (carotid sinus nerves), particularly in patients with a known sensitivity to the carotid sinus reflex.
- The device must not be used for stimulation of the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- The device must not be used for stimulation with electrodes mounted on the chest and the upper back or crossing the heart.
- The device must not be used during defibrillation.
- The device must not be used in environments that do not meet the environmental conditions defined in the Instructions For Use.
- The device must not be used in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.
- The device must not be used in the presence of magnetic fields (e.g. MRI scanners). Before an MRI test, remove all electrodes from the patient and remove the g.Estim PRO and all accessories, removable components and electrodes from the MRI chamber.
- The device must not be used together with high-frequency equipment. The usage of high-frequency devices together with the g.Estim PRO can result in tissue burns under the electrodes and could damage the stimulator. When using an electrosurgical unit (ESU), remove or disconnect all electrodes that are in the high frequency current path between the ESU tip and return plate.

WARNING

- The device must not be used when the device or its accessories or components show damage of the housing, connectors, sockets, cables or other parts. Damaged parts must be replaced immediately. For repair or replacement, contact g.tec medical engineering GmbH.
- The device must not be used when the electrodes are in contact with or near protruding metal such as surgical surface staples or external pins, because they are excellent conductors of electricity.
- The device must not be used when a patient is non-compliant to planned procedures due to age, cognitive function, or cognitive development stage. Such procedures might depend on the active cooperation of the patient and/or a sufficiently developed brain, and/or other aspects. Generally, patients that are eligible for brain surgery in general and the individual type of surgery (e.g. epilepsy, tumor, or similar) in particular are also eligible for the usage of this device. In the individual case the responsible surgeon has to decide upon the procedures and the usage of the device.

3 WARNINGS, CAUTIONS, AND NOTES

WARNING

- The device must only be operated by medical professionals, who underwent training for g.Estim PRO by g.tec medical engineering GmbH.
- To avoid erroneous diagnoses, the interpretation of stimulation results must be done only by medical doctors.
- Stimulating with a wrong electrode surface area can lead to serious tissue damage. If electrodes are changed and/or mixed during the session, please enter the surface area of the smallest electrode that is used.
- The device must be switched off during battery replacement. The person replacing the batteries must not be in physical contact with the patient.

CAUTION

- The control computer must not be integrated into a network for operating the g.Estim PRO. Any active network connection or any additional software and/or hardware used in conjunction with the control computer can cause risks for the patient and/or other persons, harmful interference to the equipment or cause the equipment to fail to perform its intended function or degrade its intended performance. Therefore, before use, you must determine, analyze, assess, and mitigate those risks and assure the correct functionality of the system. If there is any undesired deviation from the intended operational performance during the operation of the equipment, you must avoid, identify and resolve the adverse effect before continuing to use the equipment. Note that changes like the integration into a network or altering the configuration, connection or removal of elements, updates or upgrades of elements, can induce new risks and may require additional analyses.
- Use the g.Estim PRO only with a personal computer according to the specification given in the Instructions For Use.
- Automatic updates of the operating system or other software installed on the computer are ideally turned off to prevent alteration of the system configuration that could potentially cause the equipment to fail to perform its intended function or degrade its intended performance. Performance settings should be set to maximum performance. Automatic sleep/hibernation/log-out/screensaver functionality should be switched off to prevent disturbances during the operation of the equipment.
- The basic mode must only be used with grid, strip, or depth electrodes according the recommendation in the Instructions For Use. The handheld mode must only be used with a handheld electrode according the recommendation in the Instructions For Use.
- All settings that can be edited in the user interface describe target values that are aimed to be delivered during stimulation and underlie the specified accuracies. Please refer to the Instructions for Use for the respective accuracies and tolerances.
- Make sure that spare batteries are available at any time. If the battery charge display is decreasing, be prepared to exchange the batteries. Always exchange all two batteries. It is not possible to execute stimulation without charged batteries.

NOTE

- Do not connect g.Estim PRO to the computer via a USB hub.

3.1 THE INTENDED USE OF THE EQUIPMENT

The g.Estim PRO is intended for functional brain mapping via electrical stimulation prior to cortical resections in the vicinity of essential cortex. The device must be used by medically trained and qualified personnel within a medical environment.

3.2 THE INTENDED ENVIRONMENT OF USE

The device must not be used in dangerous conditions such as wet rooms or explosive environments. The device must not be used in combination with any high-frequency medical device. The usage of a high frequency device together with g.Estim PRO can result in burning under the electrodes and could damage the stimulator. Please consider the environmental conditions for safe operation, storage and transportation described in the instructions for use of g.Estim PRO.

4 PROPERTIES OF PC OR NOTEBOOK

g.Estim PRO requires a PC compatible desktop, notebook workstation or embedded computer running a Microsoft Windows operating system. While using g.Estim PRO, full power to the PC USB connectors has to be guaranteed. Therefore, do not use any power saving mode. Directly connect the USB connector to the computer. Make sure that your Microsoft Windows operating system works correctly before installing the g.Estim software.

CAUTION

The control computer must not be integrated into a network for operating the g.Estim PRO. Any active network connection or any additional software and/or hardware used in conjunction with the control computer can cause risks for the patient and/or other persons, harmful interference to the equipment or cause the equipment to fail to perform its intended function or degrade its intended performance. Therefore, before use, you must determine, analyze, assess, and mitigate those risks and assure the correct functionality of the system. If there is any undesired deviation from the intended operational performance during the operation of the equipment, you must avoid, identify and resolve the adverse effect before continuing to use the equipment. Note that changes like the integration into a network or altering the configuration, connection or removal of elements, updates or upgrades of elements, can induce new risks and may require additional analyses.

Hardware	Properties
CPU	Intel, 2 cores (or more) at 2.30 GHz (or higher)
Harddisk	> 100 GB
RAM	8 GB
USB 3.0 port	one free USB port for g.Estim PRO

OTS Software	Properties
Operating System	Windows 11 Pro, 64-bit, version 23H2
.NET framework**	4.8
Microsoft Visual C++ Redistributable *	2015-2022
g.Estim PRO driver *	Version 1.24.00.01

* Software is included in the g.Estim PRO Installation package.

Trademark Notice

Windows is a registered trademark of Microsoft Corporation in the United States and other countries.

All brands or product names are the property of the respective owners.

CAUTION

Use the g.Estim PRO only with a personal computer according to the specification given in the Instructions For Use.

CAUTION

Automatic updates of the operating system or other software installed on the computer are ideally turned off to prevent alteration of the system configuration that could potentially cause the equipment to fail to perform its intended function or degrade its intended performance. Performance settings should be set to maximum performance. Automatic sleep/hibernation/log-out/screensaver functionality should be switched off to prevent disturbances during the operation of the equipment.

NOTE

Do not connect g.Estim PRO to the computer via a USB hub.

5 INTRODUCTION

This section describes the basic terminology used in connection with the g.Estim PRO. A pulse can consist of one or two **PHASES** and an optional **INTER-PHASE DURATION** interval. The **PULSE ONSET INTERVAL** describes the whole interval from the start of one pulse to the onset of the following pulse. One or more **PULSES** form a **TRAIN**.

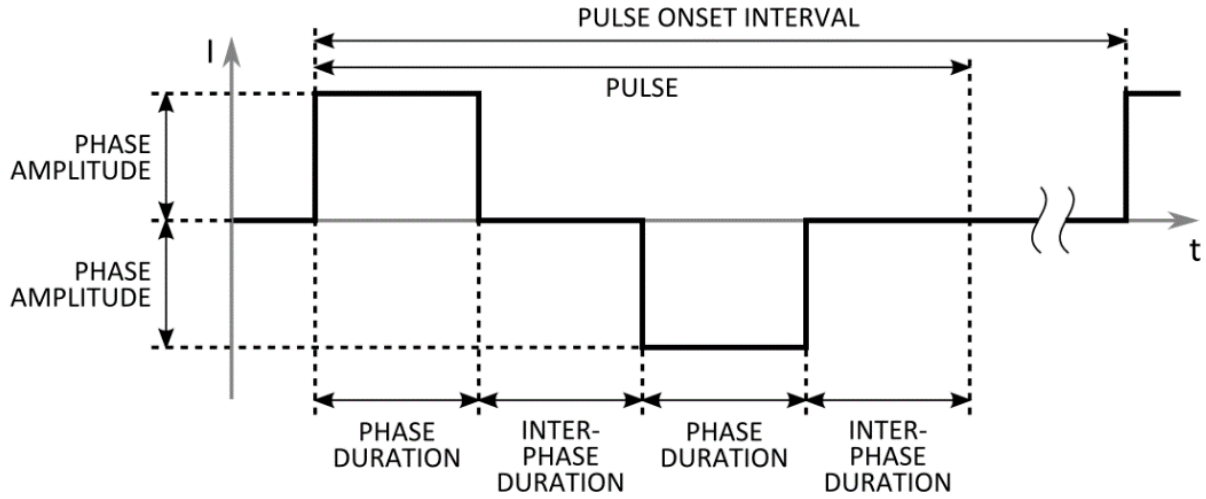


Illustration of a biphasic PULSE

PHASE

A single stimulation phase has a certain **PHASE DURATION** and **PHASE AMPLITUDE**. g.Estim PRO supports rectangular phase shapes. The **PHASE AMPLITUDE** describes the target current aimed to be delivered during stimulation. The **PHASE POLARITY** is either positive or negative, leading to I_{stim} or $-I_{stim}$ mA.

PULSE

A **PULSE** consists of one **PHASE** in monophasic mode or of two reversely polarized **PHASES** in biphasic mode and a specific **INTER-PHASE DURATION**.

INTER-PHASE DURATION

The time between the **PHASES** of one **PULSE**. In monophasic mode the **INTER-PHASE DURATION** is set to zero. In biphasic mode, the **INTER-PHASE DURATION** after the second **PHASE** serves as a minimum time between **PULSES**.

PULSE MODALITY

Either monophasic or biphasic. Monophasic **PULSES** contain one stimulation **PHASE**, biphasic **PULSES** contain two **PHASES** with different **PHASE POLARITY**.

PULSE POLARITY

Either steady or alternating. With steady **PULSE POLARITY** the **PHASE POLARITIES** within a **PULSE** always stay the same within a **TRAIN**. With alternating **PULSE POLARITY** the **PHASE POLARITIES** are 'mirrored' alternatingly within the **TRAIN**.

START POLARITY

Can be either positive or negative. This is the **PHASE POLARITY** of the very first **PHASE** of a **TRAIN**. Together with **PULSE MODALITY** and **PULSE POLARITY** this determines the shape of the **TRAIN**.

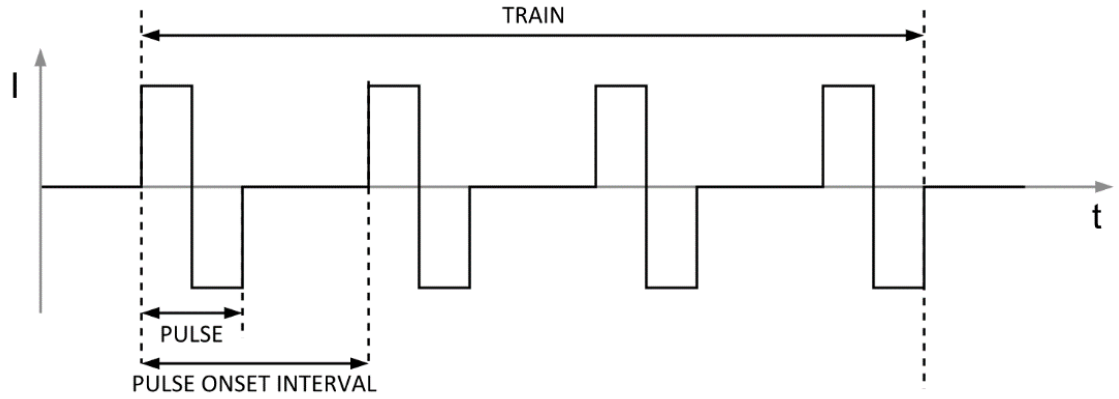


Illustration of a TRAIN with steady PULSE POLARITY

TRAIN

A **TRAIN** consists of one or more **PULSES**. Pulses are delivered either with steady or alternating **PULSE POLARITY**.

PULSE ONSET INTERVAL

The **PULSE ONSET INTERVAL** specifies the distances of the onsets of the **PULSES** within a **TRAIN**.

PULSE RATE

The **PULSE RATE** is the reciprocal of the **PULSE ONSET INTERVAL** and specifies the **PULSES** delivered per second.

6 BEFORE USING g.ESTIM PRO

Before using the device and its control software, make yourself familiar with the *gEstimPRO_InstructionsForUse.pdf* manual and read it carefully. The following sections are of particular importance:

- The intended use of the equipment
- Safe operation of g.Estim PRO

Related documents: gEstimPRO_InstructionsForUse.pdf – a detailed description of the device hardware (sockets, labelling,…)

7 INSTALLATION OF CONTROL SOFTWARE

For installation follow the instructions according to g.tec Suite 2020 – User Manual.

NOTE

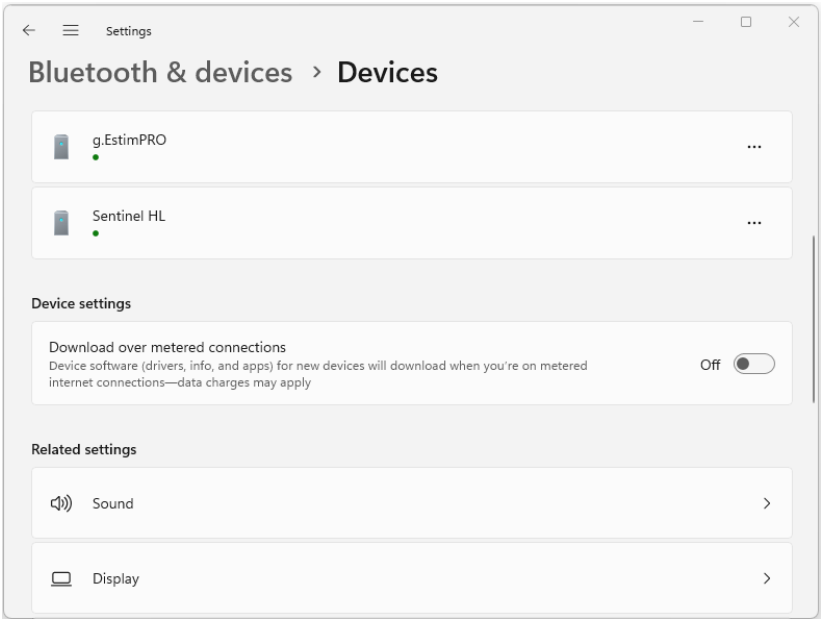
g.Estim PRO Control software has to be installed before attaching the device to your computer.

Perform the following steps in the correct order to attach the g.Estim PRO hardware to your system successfully:

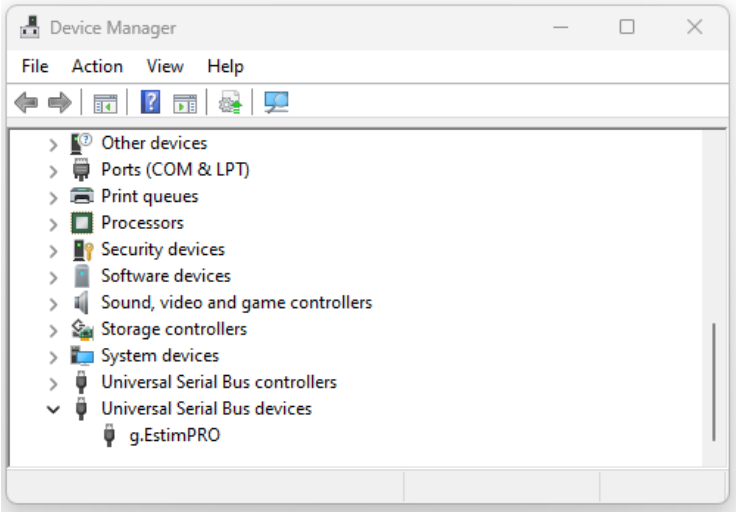
- Connect the USB cable to your g.Estim PRO device and to a free USB 2.0 or 3.0 port of your computer.
- Power up the device using its power switch. The power LED indicates that the device is on.
- The Plug and Play manager will detect the new hardware and starts to install the device driver for g.Estim PRO.
- Note: Driver installation in Windows 10 is done automatically. No user interaction is required.
- A notification icon indicates that the installation procedure starts.
- When the installation has finished another notification, icon informs you that the installation has completed successfully.

8 TEST YOUR INSTALLATION

Open the **Devices** tab from the Windows 11 **Settings** menu. The g.EstimPRO should be listed under **Connected devices**.



Alternatively, you can start the device manager to test your installation. Under **Universal Serial Bus devices**, the g.EstimPRO must be listed.



If you see a question mark beside the g.EstimPRO icon or g.EstimPRO is listed under “Other devices” the installation must be repeated.

9 RUNNING THE CONTROL SOFTWARE

Before running g.Estim PRO Control, ensure that g.Estim PRO is turned on and connected to your computer.

To run g.Estim PRO Control, open the Windows start menu by clicking the button with the Windows logo in the task bar, select **All Programs**, navigate to the **g.tec → g.Estim PRO** group and run **g.Estim PRO Control**.

The **Startup window** opens and prompts for choosing a device.

9.1 HELP AREAS

Throughout the software the **Help areas** (marked by the question mark symbol) provide guidance for using the control elements of the application. To get help for a specific control element, simply hover the mouse over the control. The guidance text is then displayed in the **Help area**.

The **Help areas** additionally contain the buttons **Manual, Instructions** and **About**. A click onto the button **Manual** opens the current document in the pdf reader. A click onto the button **Instructions** opens the Instructions for use document in the pdf reader. Please make sure that the correct version of Adobe Acrobat Reader DC is installed on your computer, see the section Hardware and Software Requirements. A click onto the button **About** opens a dialog showing the version information of the g.Estim PRO Control software.

9.2 STARTUP

The startup window dialog lets you choose the device to operate.

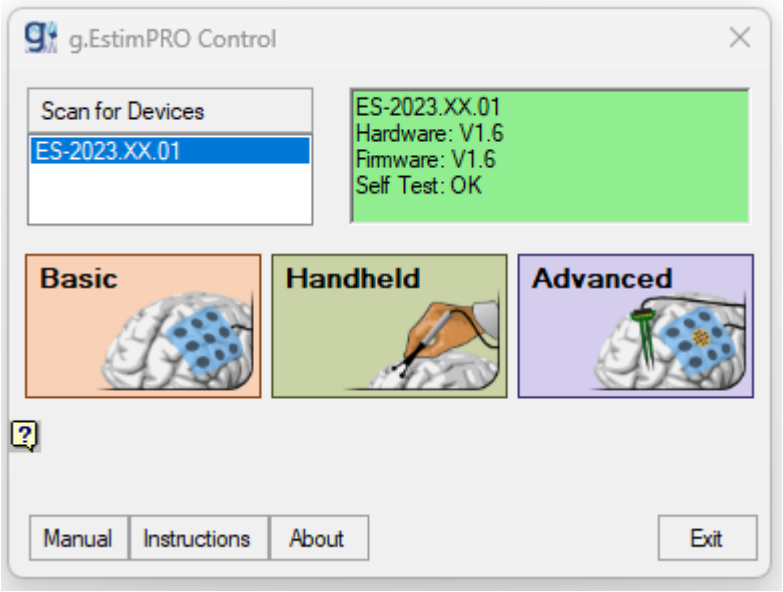


Figure 1: Startup window: Choose the device to use by selecting its serial number.

Every device that is found is listed with its serial number. The serial number of a g.Estim PRO device is of the format ES-XXXX.XX.XX and is printed on its label in the lower left corner (on top of the device).

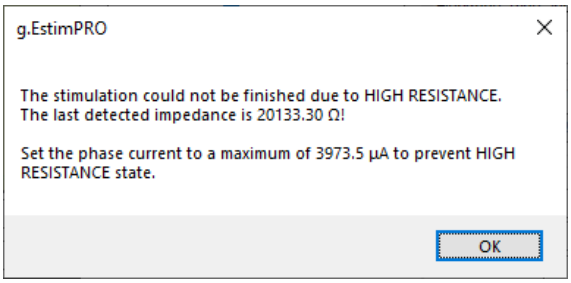
If no serial number is listed, please assure that the g.Estim PRO device is turned on, connected to the computer, and click **Scan for devices**.

As soon as a device is selected an initial self-test is executed on the device to assure correct functionality. During the self-test, the LED indications of the device are switched on and off. The result of the self-test is displayed in the area to the right of the device list. Passing this test is crucial for a safe and accurate operation of the device. In case the self-test is not passed, stimulation will not be possible. If you encounter such a situation, please contact the g.tec customer support. It is irrelevant for the self-test if electrodes are connected to the g.Estim PRO.

Two different session modes named **Basic** and **Handheld** can be accessed from the startup window.

The **Basic Mode** is suitable for standard ECS mapping procedures using standard cortical electrode grids. This mode provides a basic configuration interface with the most important settings.

The **Handheld Mode** is suitable for intraoperative situations where the surgeon wants to stimulate multiple locations of the cortex with a hand-held probe. This mode provides a configuration interface with the most important settings. In this mode, the stimulator constantly measures the resistance between the electrodes. As soon as the resistance is below 50kΩ (i.e. when the electrode tips touch the neural tissue) the stimulation is started. To stop stimulation, remove the electrode tips from the neural tissue. In case a stimulation was started, but the configured current could not be reached due to the high impedance, the stimulation stops and a message box informs you about the current resistance and give advice about the maximum supported stimulation current.



CAUTION

The basic mode must only be used with grid, strip, or depth electrodes according the recommendation in the Instructions For Use.

The handheld mode must only be used with a handheld electrode according the recommendation in the Instructions For Use.

By selecting a session type the **Session configuration** dialog opens.

9.3 SESSION CONFIGURATION

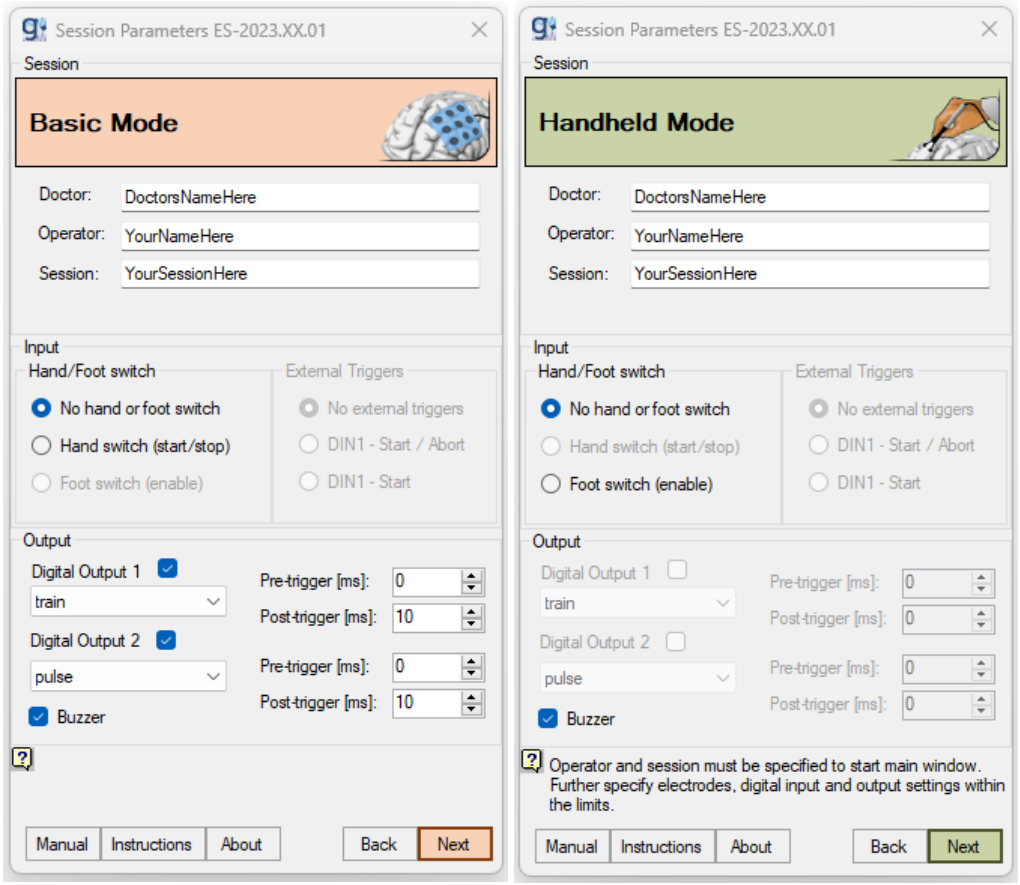


Figure 2: Session configuration dialogs. left: Basic mode, right: Handheld mode

In the **Session Parameters** dialog, the selected session mode is displayed and some general settings for the stimulation session are set.

9.3.1 SESSION GROUP

The **Session group** allows for specifying the doctors name, operator name, as well as the session identifier.

Use the field **Doctor** for entering the name of the responsible doctor for reference. This field must not be empty to enable the start button.

Use the field **Operator** for entering the name of the responsible person for reference. This field must not be empty to enable the start button.

Use the field **Session** for entering an identifier for the stimulation session for reference. This field must not be empty to enable the start button.

9.3.2 TRIGGER INPUT GROUP

The **Trigger input** group allows for specifying whether to use the hand switch, (see Figure 3a), or the foot switch (see Figure 3b), that both come as accessories with the g.Estim PRO. The hand switch allows users to start stimulation by pressing the **STIMULATE** button after the device has been set active via the software and the 'READY' LED is on. During stimulation, it allows users to abort stimulation by pressing the **ABORT** button. When the foot switch is used and pressed, the stimulator accepts a cue to start stimulation from the software. When the foot switch is released, stimulation is aborted.

The usage of external triggers is disabled.

a)  b) 

Figure 3: a) The hand switch. b) The foot switch.

9.3.3 TRIGGER OUTPUT GROUP

Use the checkbox **Buzzer** to decide whether the g.Estim PRO should give auditory signals whenever a stimulation pulse is produced.

The Trigger output group allows for specifying which digital triggers should be available at the digital outputs located on the back of the g.Estim PRO device (see Figure 4). Triggers from the DO connectors can be used to synchronize external equipment to the stimulation delivered by the g.Estim PRO.

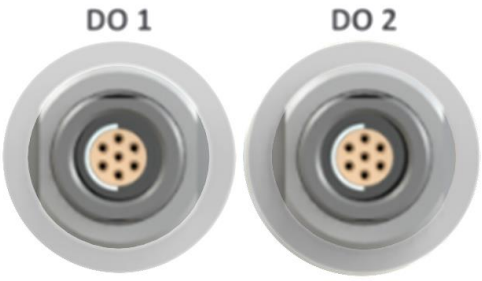


Figure 4: The digital output sockets (DO1 and DO2) at the back of the g.Estim PRO.

Using the checkboxes, you can activate/deactivate the digital outputs. When activated, one of three different modes can be chosen for each digital output.

The setting **Train output** sets the digital output for which it is specified to HIGH whenever a stimulation train is active (see Figure 5a). This mode does not include a possible inter-phase period after the last pulse as defined in the Terminology.

The setting **Pulse output** sets the digital output for which it is specified to HIGH whenever a stimulation pulse is active, which includes the inter-phase duration in between the phases (see Figure 5b).

The setting **Phase output** sets the digital output for which it is specified to HIGH whenever a stimulation phase is active (see Figure 5c).

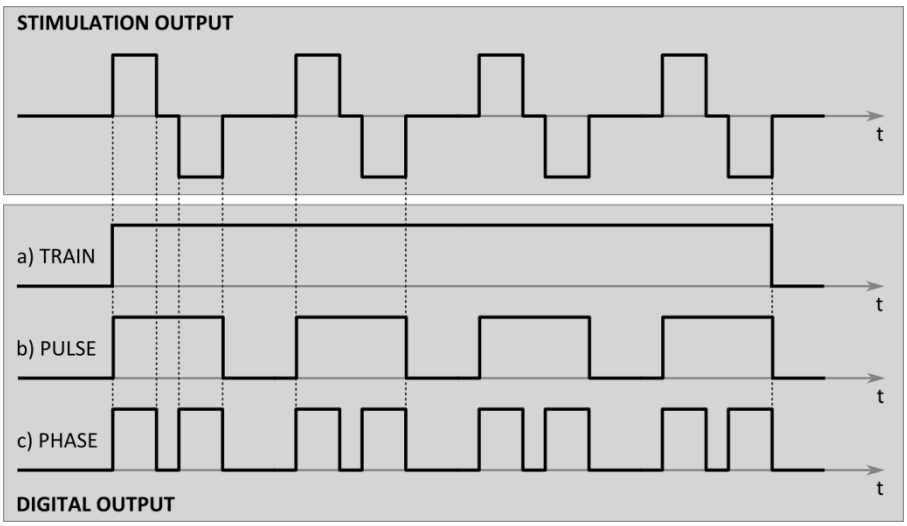


Figure 5: Digital output behavior explained with a biphasic, steady pulse train containing four pulses visualized on the top. a) Digital output with Train output configuration. b) Digital output with Pulse output configuration. c) Digital output with Phase output configuration.

Additionally, for each digital output a **Pre-** and **Post trigger time** can be specified. This is useful if in parallel to the stimulation session also biosignals are recorded. In this case, the amplifier might want to be switched away from the stimulation electrodes for protection some time before and after stimulation is executed. The **Pre-trigger time** specifies how long before the stimulation train/pulse the trigger should be HIGH. The **Post-trigger time** specifies how long after the train/pulse the digital output should remain HIGH before it becomes LOW again. This behavior is visualized in Figure 6 for the **Pulse output** setting.

Pre- and Post-trigger times are not available for the **Phase output** setting.

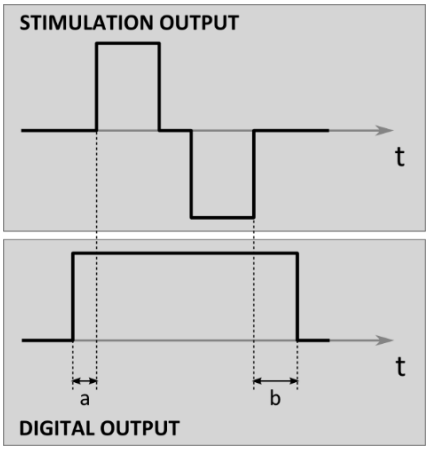


Figure 6: Explanation of Pre- and Post-trigger times with the setting Pulse output. The top box shows the stimulation output. The bottom box shows the resulting digital output. a) The trigger starts before the actual onset of the pulse. This is the Pre-trigger time. b) The trigger stops after the actual offset of the pulse. This is the Post-trigger time.

Pre- and **Post trigger times** in combination with pulse/train settings may lead to overlaps of the digital output signal like indicated in Figure 7. In this case, the software will warn you before preparing the device for stimulation, but will still allow stimulating. In such cases, you should check the effects on devices connected to the digital output port in question, or change the timing settings.

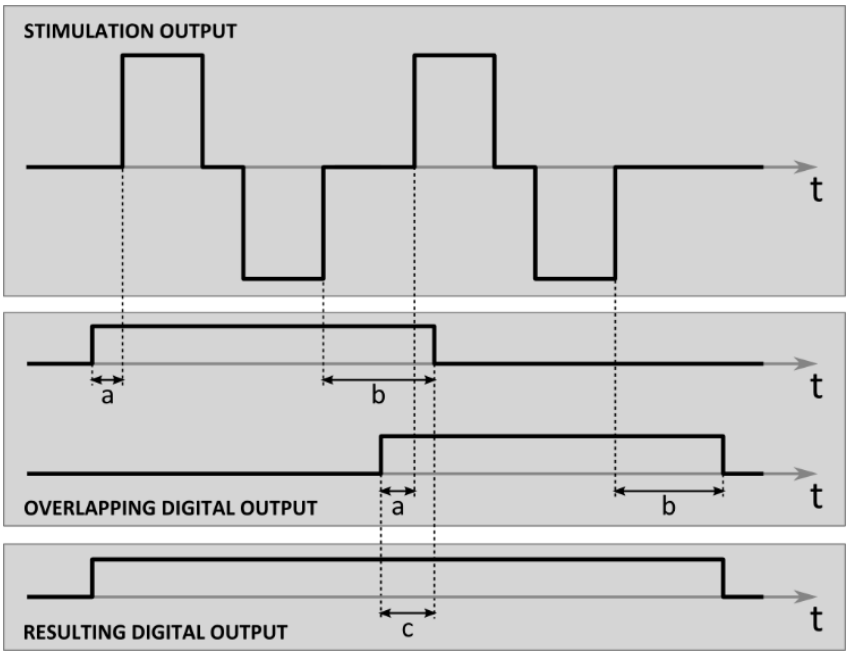


Figure 7: Explanation of Pre- and Post-trigger overlap with the setting Pulse output. The top box shows the stimulation output. The middle box shows the theoretical digital output for each pulse with the Pre- and Post trigger times marked by a and b respectively. The bottom box shows the resulting digital output where the overlap between the theoretical pulse outputs is marked by c.

As can be seen the trigger output does not get LOW in this scenario in between stimulation pulses.

Pre- and **Post trigger times** of **pulse** must be **less or equal** to the according values of **train** of the other output, if both outputs are enabled.
If all the settings are done, a click onto the button **Next** closes the **Session configuration** dialog and opens the **Electrode specification** dialog.

9.4 ELECTRODE SPECIFICATION

The default electrode is a circular electrode with an exposed surface area of 4.15 mm², which is shown in the fields Electrode, and **Surface [mm²]**.

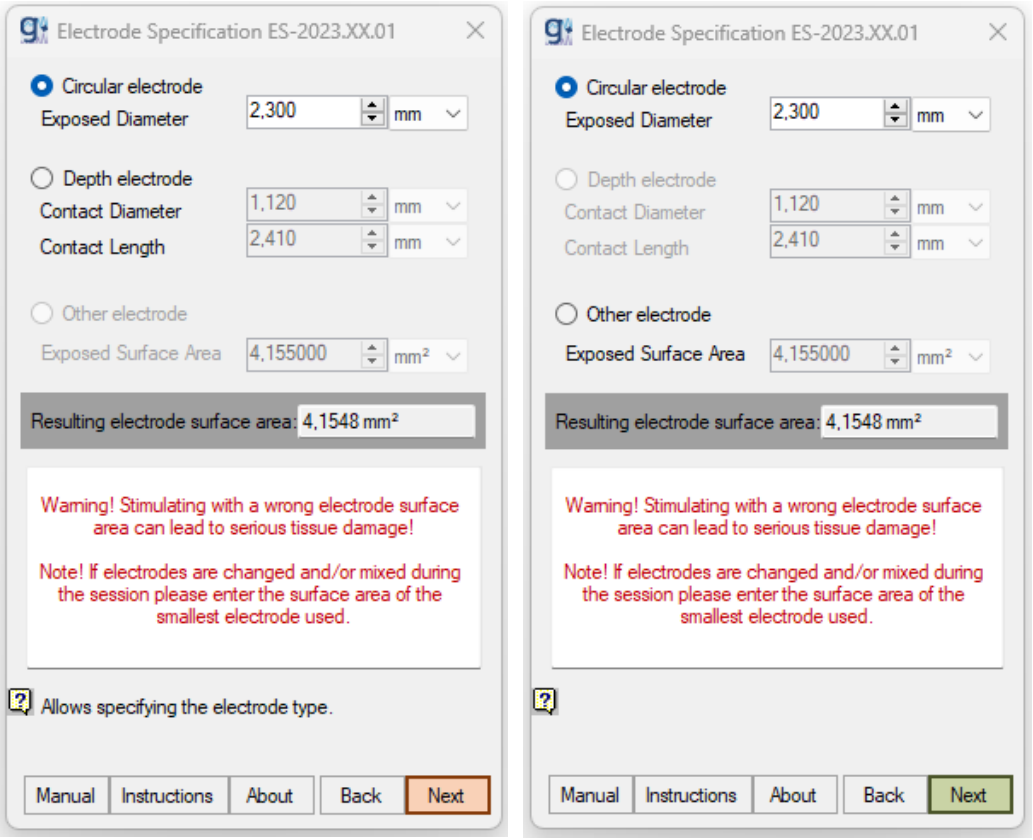


Figure 8: Electrode specification dialog. left: Basic mode, right: Handheld mode

The **Electrode specification** dialog allows for specifying different electrode types and their measures and calculates the resulting electrode surface from those parameters.

The most common electrode type is the circular electrode. To choose circular electrode, click on the radio button **Circular electrode** and enter the exposed diameter of the electrodes you plan to use into the field **Exposed diameter**. Make sure you select the correct unit for your value.

To choose depth electrode, click onto the radio button **Depth electrode** and enter the measures of your depth electrode into the fields **Contact diameter** and **Contact length** according to Figure 9. Make sure you select the correct units for your values.

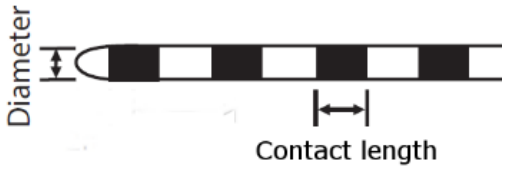


Figure 9: Required depth electrode measures.

If you plan to use another type of electrode, you can enter the exposed surface area also directly by clicking the radio button **Other electrode** and entering the surface area into the field **Exposed surface area**. Make sure you select the correct unit for your value.

In all three cases, the resulting surface area that will be used by the system is displayed in the field **Resulting electrode surface area**.

WARNING

Stimulating with a wrong electrode surface area can lead to serious tissue damage.

If electrodes are changed and/or mixed during the session, please enter the surface area of the smallest electrode that is used.

Click **Next** to apply your changes and start the session.

9.5 HARDWARE CONFIGURATION WINDOWS

When either the hand switch or the foot switch is used the software presents corresponding hardware configuration windows as presented in Figure 10.

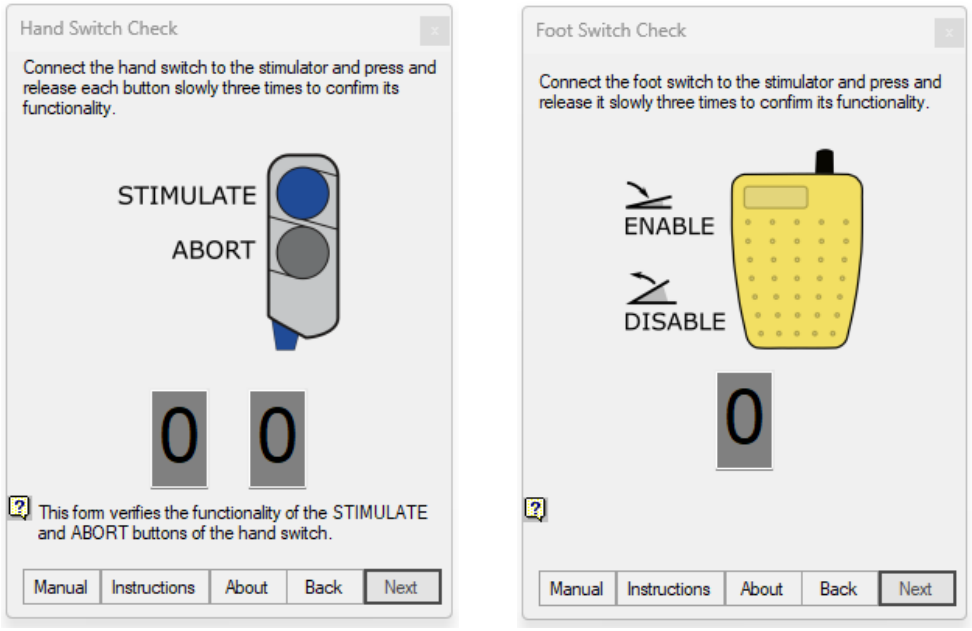


Figure 10: Hardware configuration windows for the hand switch (left) and the foot switch (right)

The purpose of these windows is to verify that the respective component is connected and working properly before starting the session. For the hand switch each of the two buttons has to be pressed three times. The foot switch has to be pressed also three times. The grey areas show how often the activations have been detected. When three activation have been detected, the button **Next** is activated and the session can be started.

9.6 g.ESTIM PRO CONTROL MAIN WINDOW

The **g.Estim PRO Control Main window**, also referred to as the **main window**, shows the controls required for setting the primary stimulation settings for the g.Estim PRO stimulator. The device is stopped at startup and the stimulation current source is disconnected from the electrodes. This situation is referred to as the ***STOP*** state.

The **main window** is organized in three columns. In the left column, the pulse/train/sequence layout is visualized graphically according to the settings in the middle column. The right column contains the tools for controlling the session and the stimulator.

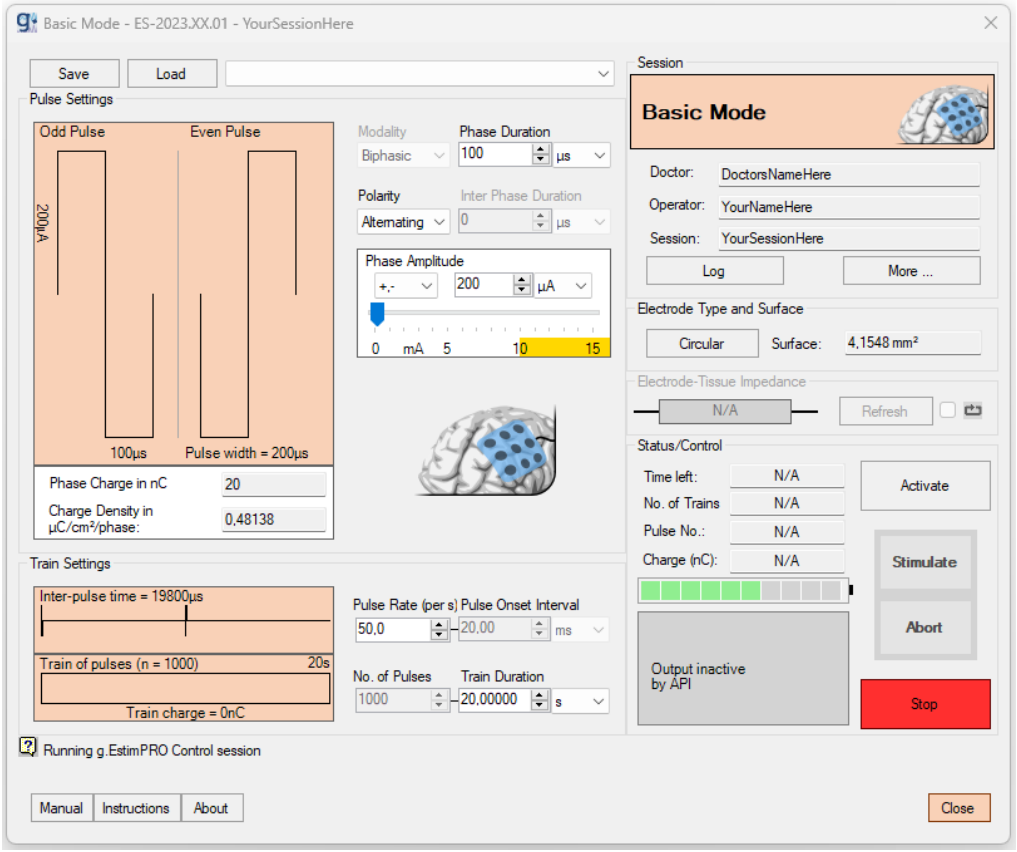


Figure 11: The g.Estim PRO Control Main window in Basic mode.

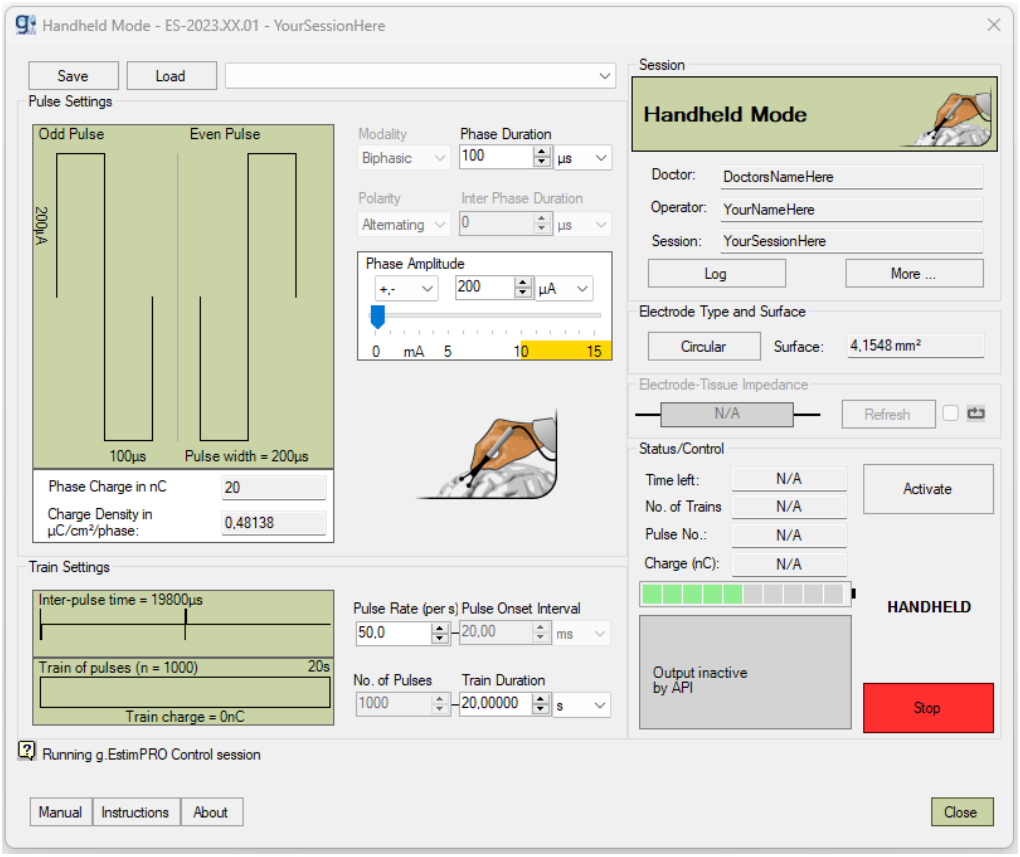


Figure 12: The g.Estim PRO Control Main window in Handheld mode.

9.7 STIMULATION VISUALIZATION

In the **stimulation visualization** column at the left side of the **main window** at the very top, the stimulation pulses are displayed according to the settings in the middle column. Two pulses are displayed to take account for the **Polarity** setting. Thereby the left pulse represents odd, and the right pulse represents even pulses of the train, assuming counting starts at one. The two visualized pulses are identical if **Polarity** is set to **Steady**. They are inverted if **Polarity** is set to **Alternating**. Depending on the **Phase amplitude** setting the first phase of the left pulse starts with either a negative or a positive phase.

Below the pulse shape, the train layout is visualized in a different color. This layout contains a two-pulse diagram to show the distance of the pulses and a full train diagram with the number of pulses as specified in the **Train settings** in the middle column. This second diagram does not show the single pulses if the pulse number is too high to make them discernible on the diagram.

9.8 STIMULATION SETTINGS

CAUTION

All settings that can be edited in the user interface describe target values that are aimed to be delivered during stimulation and underlie the specified accuracies.

Please refer to the Instructions for Use for the respective accuracies and tolerances.

9.8.1 PULSE SETTINGS

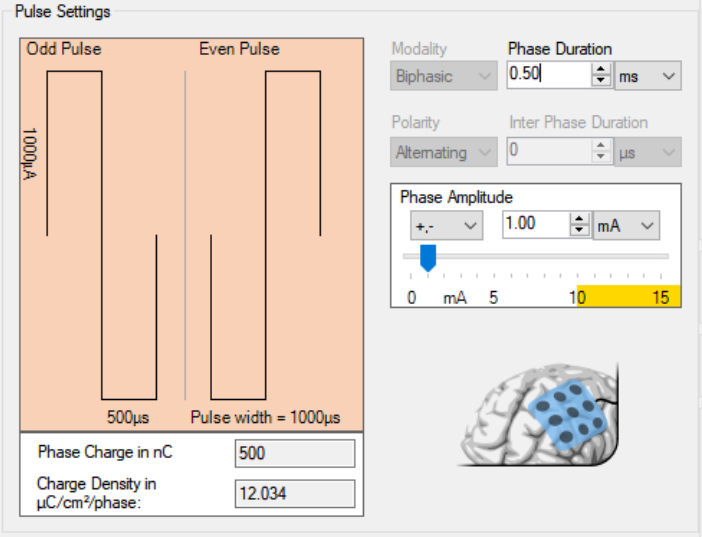


Figure 13: The Pulse settings group.

The **Pulse settings** group contains controls for defining the shape of the stimulation pulses. The combinations of settings are explained according to Figure 14.

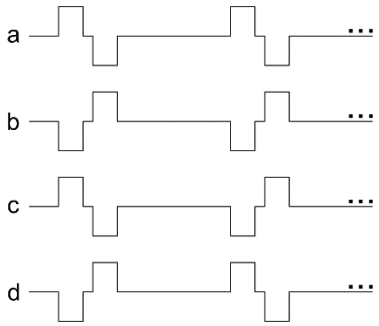


Figure 14: Stimulation waveform according to the settings Polarity, and Phase amplitude sign.

Table 1: Polarity and Phase amplitude sign settings according to Figure 14.

Modality	Polarity	Phase amplitude sign
Biphasic	Steady	+, -
Biphasic	Steady	-, +
Biphasic	Alternating	+, -

Biphasic	Alternating	-, +

To adapt timing and amplitude of the pulse shape the controls **Phase duration,** and **Phase amplitude** are available. The phase amplitude of the two phases in the pulse is always the same value, but inverted.

The pulse settings result in combination with the exposed electrode surface in a current density that is shown at the very bottom of the group. It is important to keep stimulation intensities below certain thresholds to avoid tissue damage. According to [McCreery, et al. 1990] the current density control stays gray for unproblematic densities of up to 50µC/cm^2/phase. It is displayed in yellow for densities up to 150µC/cm^2/phase that bear a certain risk for tissue damage. Finally, it is displayed in red for densities higher than 150µC/cm^2/phase, where the risk for tissue damage is considerably high. The absolute maximum allowed current density is 375µC/cm^2/phase. The system does not allow stimulation with higher charge densities than that.

If the **Phase amplitude** value exceeds 10 mA, the background of the control is displayed in yellow accompanied by the message: "Warning: High current". In this situation, stimulation is still possible; this warning's aim is to ensure that the operator is aware of the actual current level.

The following table shows the ranges that are possible for the Pulse settings in Basic and Handheld mode:

Setting	Range	Resolution	Tolerance
Phase duration	0.1 – 1 ms	10 µs	± 10 % or ± 20 µs, whichever greater
Inter-phase duration	0 ms	-	-
Phase amplitude	0.2 – 15 mA	10 µA	± 10 % or 50 µA, whichever greater

9.8.2 TRAIN SETTINGS

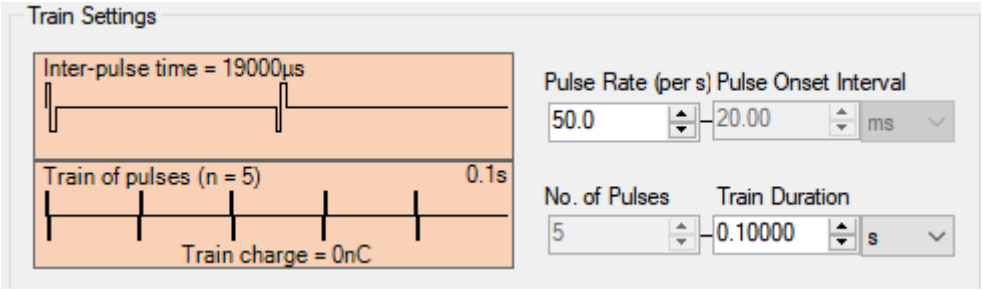


Figure 15: The Train settings group.

If the desired stimulus shall consist of more than one pulse, a train can be set. Therefore, the **Train settings** group contains controls for defining the layout of more than one pulse into a stimulation train.

Use the **Pulse rate (per s)** and/or **Pulse onset interval** controls for defining in which intervals the pulses are presented in the train. Hereby **Pulse rate (per s)** equals `1/Pulse onset interval` where **Pulse onset interval** is given in seconds. If **Pulse rate (per s)/Pulse onset interval** is changed, the **Train duration** is adapted accordingly considering the specified **Number of pulses**.

Use the **Pulses** and/or **Train duration** controls for defining how many pulses the train should consist of or how long the train should be. In the former case, the **Train duration** is adapted according to the **Number of pulses** desired with the specified **Pulse rate (per s)/Pulse onset interval**. In the latter case, the **Number of pulses** is calculated such that the duration can be met with the specified **Pulse rate (per s)/Pulse onset interval**.

The following table shows the ranges that are possible for the Train settings in Basic and Handheld mode:

Setting	Range	Resolution	Tolerance
Pulse rate (per s)	2 – 100 pulses per second	0.1	± 10 %
Train duration	Length of one pulse – 20s	Length of one pulse	N/A

9.8.3 LOAD/SAVE CONFIGURATION

You can save your current configuration settings for later use. To do so, click the **Save** button at the very top of the middle column.

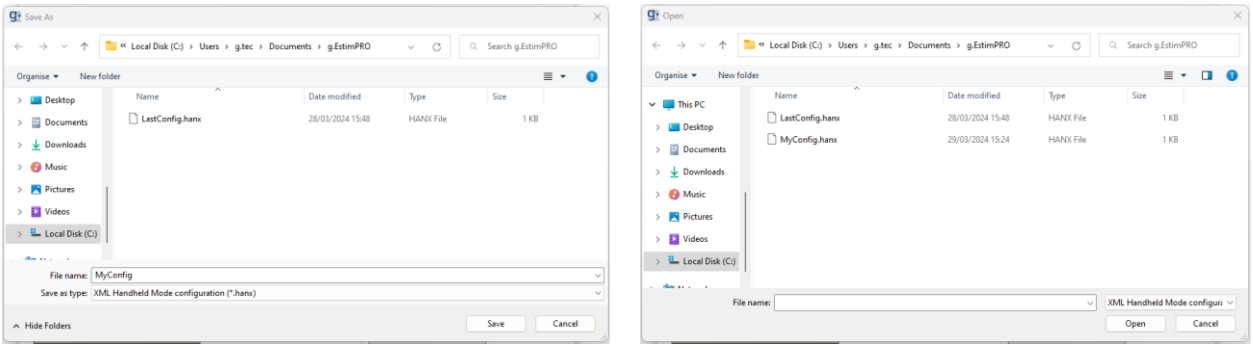


Figure 16: Saving and loading configurations.

To reload your settings, click the **Load** button at the very bottom of the middle column of the main window and choose a configuration file from disk. Alternatively, you can also select a previously saved configuration from the combo box beside the **Load** button.

All files are stored in the personal folder of the logged-in windows user under `Documents\g.EstimPRO`. You can access them from outside the application via your personal Documents folder (navigate to **My Documents → g.EstimPRO**).

Another benefit of the XML file format is that you can view your setup-file using a simple text viewer. You do not have to run the application each time you want to review your parameters.

9.9 SESSION OVERVIEW

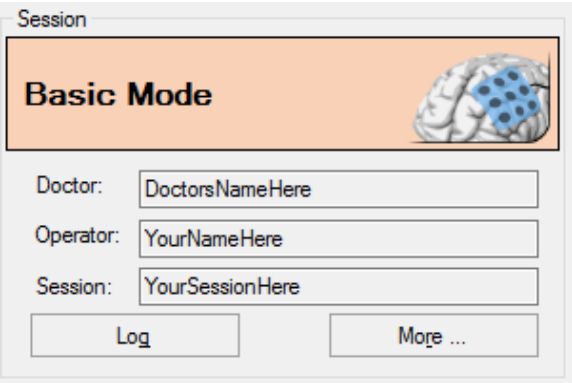


Figure 17: The Session group in basic mode.

The **Session group** provides an overview about the chosen **operation mode**, the **Doctor**, the **Operator** and the **Session** identifier.

A click to **More...** opens a dialog that shows the complete session configuration including the settings for the digital inputs and outputs.

A click to **Log** shows a window that displays all the log messages from the g.Estim PRO Control software (see Figure 18).

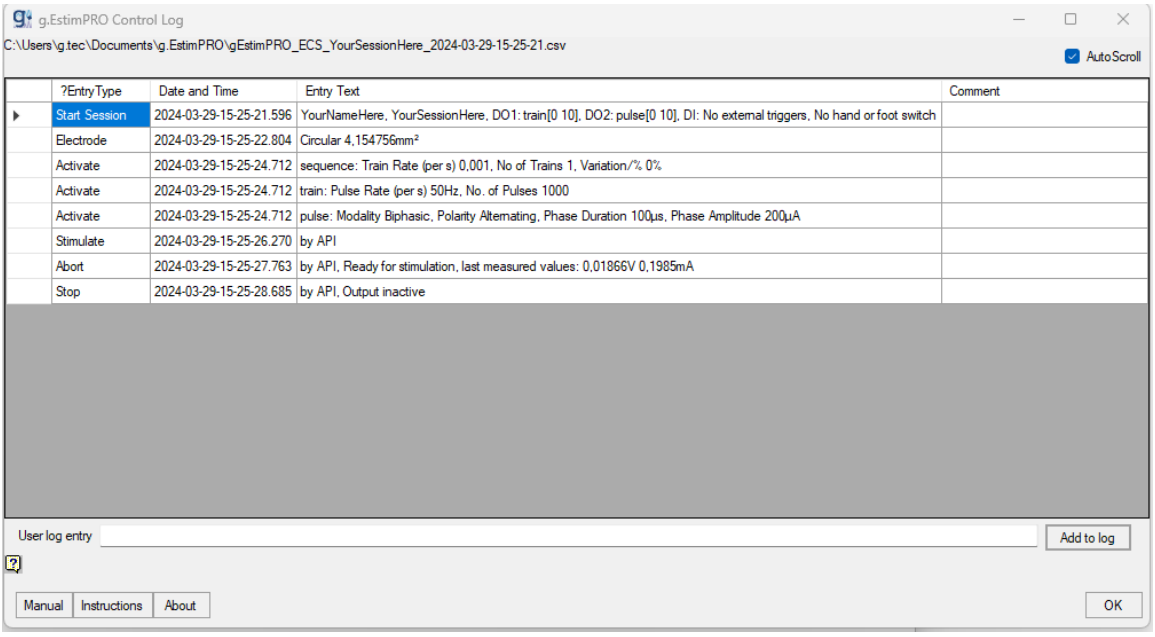


Figure 18: The Log window.

At the very top of the log window, you can see the file path of the log file, which holds the contents of the log file for later reference. The log file is stored as a comma-separated values file (CSV) using a semicolon (;) as separator. The log file can be viewed with a simple text editor or

also with Microsoft Excel. Please refer to the documentation of Microsoft Excel to learn how to import

The spreadsheet area in the middle lists the log messages. It is possible to add a comment to log messages for later reference in the very right column **Comment** by first selecting then clicking on the selected cell.

For adding custom entries use the **User log entry** input field and click **Add to log** after you typed in the desired message. By default, a user log entry is appended to the log list. However, user log entries can also be inserted between existing log entries. To do this, first make sure that the *original order* of the log table is not overridden by custom sorting. This is assured when no column header displays a triangle
(▼ or ▲). Then, select the existing entry that should precede the new user log entry. A selected log entry is indicated by the small triangle at the very left of the list (▶).

Note that user entries will be inserted with their time of creation. If the list is sorted according to the column 'Date and Time', all entries will be displayed in order of their creation.

The log csv file will be exported with the *original order* of log entries, which assures that inserted user entries are displayed at the correct positions but also causes the times of the log entries not being necessarily strictly ascending.

9.10 ELECTRODE

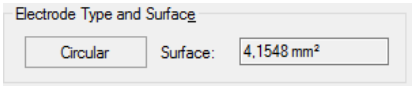


Figure 19: The Electrode group.

The **Electrode Type and Surface group** provides information about the chosen Electrode. The specified **Electrode** type and **Surface** area is shown. A click to the electrode type leads to the **Electrode specification dialog** (described above) and allows for changing the electrode type/surface area.

9.11 STATUS/CONTROL

The **Status/Control** area contains all the elements for controlling the stimulation.

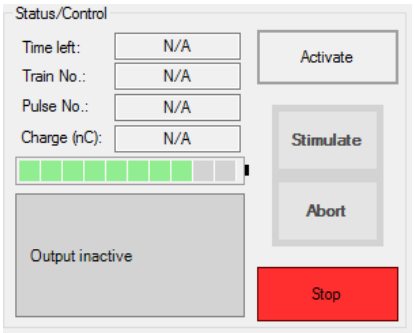


Figure 20: The Status/Control area.

At the top left, the **status information** about the stimulation is displayed (see Figure 20).

In the line with the label **Time left** the remaining stimulation time is displayed until the stimulator will stop stimulating by itself, which means, when the sequence/trains of the current stimulation are completely executed.

In the line with the label **Train No.** the progress of the stimulation sequence is displayed. It shows how many trains of those configured were already executed.

In the line with the label **Pulse No.** the progress of the current stimulation train is displayed. It shows how many pulses of the current train were already executed.

In the line with the label **Charge (nC)** the total applied charge of the stimulation so far is displayed. Note that a biphasic stimulation always leads to a total charge value of 0 as the stimulated tissue does not polarize.

Below the stimulation status, the **battery gauge** shows the battery charge in percent.

WARNING

The device must be switched off during battery replacement. The person replacing the batteries must not be in physical contact with the patient.

CAUTION

Make sure that spare batteries are available at any time. If the battery charge display is decreasing, be prepared to exchange the batteries. Always exchange all two batteries. It is not possible to execute stimulation without charged batteries.

Below the **battery gauge,** the **device status area** is located. In this area, the current state of the device is displayed.

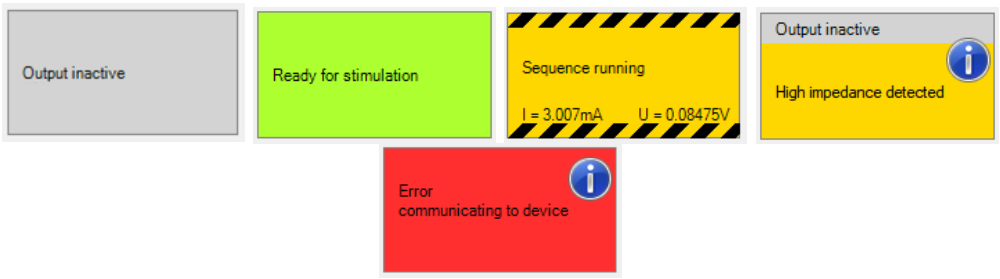


Figure 21: Examples of monitoring the device state: stop, active, stimulation, high impedance, error

The information below gives descriptions for the different device status displays:

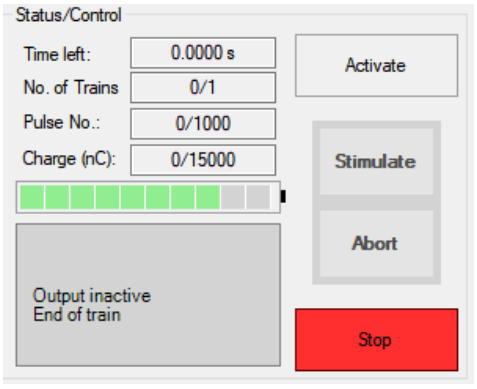
Status	Description
Output inactive	Displayed when the device is turned on but the stimulation output is inactive.
Ready for stimulation	Displayed when the device is ready for stimulation. In this view, also the total charge that was applied in previous stimulations is displayed.
Sequence running	Displayed when the device is currently stimulating. While stimulating the area shows two measured values in the lower part: • left: the average current from the last ~200 ms (measured only during phases) • right: the average voltage from the last ~200 ms (measured only during phases)
High impedance	Displayed when the device detected high impedance, which is likely caused by bad contact of the electrodes to the tissue during stimulation.
Error	An error occurred.

If an information symbol is shown, one can click on the button for more information.

At the right side of the area, the stimulation control buttons are located.

By clicking the **Activate** button, the device changes to the ***ACTIVE*** state and is ready for stimulation. After a click to **Activate,** no settings can be changed. For changing settings, the stimulator has to be brought to the ***STOP*** state by clicking the **Stop** button (see Figure 22).

a)



b)

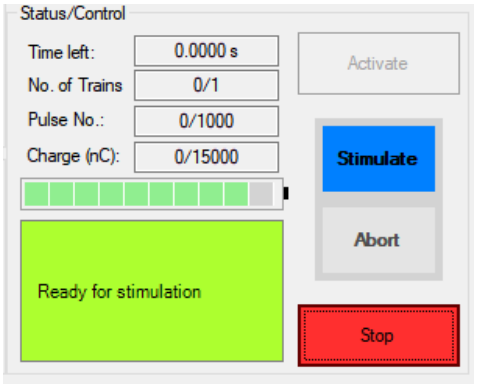


Figure 22: a) The Status/Control area when the g.Estim PRO is in *STOP* state. A click onto the button Activate sets the g.Estim PRO to the *ACTIVE* state. b) the Status/Control area when the g.Estim PRO is in *ACTIVE* state. The Stimulate and the Stop buttons are available.

When the device is in ***ACTIVE*** state, you can initiate stimulation by clicking the **Stimulate** button.

Stimulation lasts either until the task is completed or until **Abort** or **Stop** is clicked. After finishing a stimulation sequence or after clicking **Abort** the device stays in ***ACTIVE*** state and is ready for the next stimulation. When pressing ***Stop*** during stimulation the stimulation is aborted and the device is put into ***STOP*** state. (see Figure 23a).

a) b)

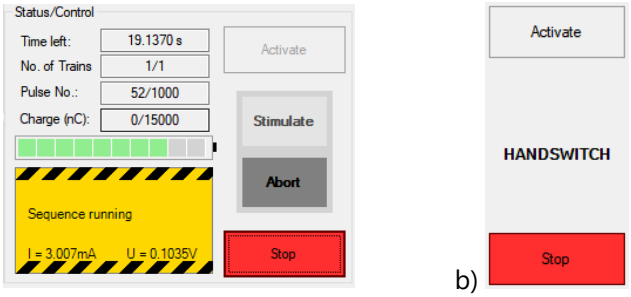


Figure 23: The Status/Control area when the g.Estim PRO is stimulating. The Abort button is available.

In case the *hand switch* is used (see **Session configuration dialog**) the functionality of the **Stimulate** and **Abort** buttons is available on the hand switch (see Figure 23b). Before using the hand switch, you must press the **Activate** button. When the *foot switch* is used, the **Stimulate** button is only enabled if the foot switch is pressed. Stimulation is aborted if the foot switch is released during stimulation.

If a 'High impedance' is detected, stimulation is stopped in any case and the device is in ***STOP*** state until the button **Activate** is pressed again.

10 ERROR MESSAGES

Value	Name	Text	Comment
0	GERROR_SUCCESS	No error occured	
1	GERROR_SELFTEST_NOT_DONE	Self test not done. This is the beginning error state until selftest has finished	
2	GERROR_FUNCTION_NONE	Self test: disconnecting test resistance failed	Device needs inspection.
3	GERROR_SELFTESTMEASURE	Self test: measured values failed	Device needs inspection.
4	GERROR_SELFTESTHIGHVOLTAGE	Self test: high voltage test failed	Device needs inspection.
5	GERROR_SELFTESTRESISTANCE	Self test: resistance test failed	Device needs inspection.
6	GERROR_LOCK_BY_API_NOT_ALLOWED	It is not possible to lock the device via the API	
7	GERROR_MIN_VOLTAGE_LIMIT	voltage limit is too small	Correct the setting.
8	GERROR_MAX_VOLTAGE_LIMIT	voltage limit is too big	Correct the setting.
9	GERROR_MIN_ALTERNATE	alternate is too small	Correct the setting.
10	GERROR_MAX_ALTERNATE	alternate is too big	Correct the setting.
11	GERROR_MIN_PHASE_CURRENT1	phase_current1 is too small	Correct the setting.
12	GERROR_MAX_PHASE_CURRENT1	phase_current1 is too big	Correct the setting.
13	GERROR_MIN_PHASE_CURRENT2	phase_current2 is too small	Correct the setting.
14	GERROR_MAX_PHASE_CURRENT2	phase_current2 is too big	Correct the setting.
15	GERROR_MIN_PHASE_DURATION1	phase_duration1 is too small	Correct the setting.
16	GERROR_MAX_PHASE_DURATION1	phase_duration1 is too big	Correct the setting.

17	GERROR_MIN_PHASE_DURATION2	phase_duration2 is too small	Correct the setting.
18	GERROR_MAX_PHASE_DURATION2	phase_duration2 is too big	Correct the setting.
19	GERROR_MIN_FADE_IN_TIME	fade_in_time is too small	Correct the setting.
20	GERROR_MAX_FADE_IN_TIME	fade_in_time is too big	Correct the setting.
21	GERROR_MIN_FADE_OUT_TIME	fade_out_time is too small	Correct the setting.
22	GERROR_MAX_FADE_OUT_TIME	fade_out_time is too big	Correct the setting.
23	GERROR_MIN_FADE_TYPE	fade_in_time is too small	Correct the setting.
24	GERROR_MAX_FADE_TYPE	fade_in_time is too big	Correct the setting.
25	GERROR_MIN_INTERPHASE	interphase is too small	Correct the setting.
26	GERROR_MAX_INTERPHASE	interphase is too big	Correct the setting.
27	GERROR_MIN_PULSE_RATE	pulse_rate_ is too small	Correct the setting.
28	GERROR_MAX_PULSE_RATE	pulse_rate_ is too big	Correct the setting.
29	GERROR_MIN_PULSES	pulses is too small	Correct the setting.
30	GERROR_MAX_PULSES	pulses is too big	Correct the setting.
31	GERROR_MIN_DO1_PRE_TIME	do1_pre_time is too small	Correct the setting.
32	GERROR_MAX_DO1_PRE_TIME	do1_pre_time is too big	Correct the setting.
33	GERROR_MIN_DO1_POST_TIME	do1_post_time is too small	Correct the setting.
34	GERROR_MAX_DO1_POST_TIME	do1_post_time is too big	Correct the setting.
35	GERROR_MIN_DO2_PRE_TIME	do2_pre_time is too small	Correct the setting.

36	GERROR_MAX_DO2_PRE_TIME	do2_pre_time is too big	Correct the setting.
37	GERROR_MIN_DO2_POST_TIME	do2_post_time is too small	Correct the setting.
38	GERROR_MAX_DO2_POST_TIME	do2_post_time is too big	Correct the setting.
39	GERROR_MIN_DO1_FUNCTION	do1_function is too small	Correct the setting.
40	GERROR_MAX_DO1_FUNCTION	do1_function is too big	Correct the setting.
41	GERROR_MIN_DO2_FUNCTION	do2_function is too small	Correct the setting.
42	GERROR_MAX_DO2_FUNCTION	do2_function is too big	Correct the setting.
43	GERROR_MIN_DIO_ENABLED	dio_enabled is too small	Correct the setting.
44	GERROR_MAX_DIO_ENABLED	dio_enabled is too big	Correct the setting.
45	GERROR_MIN_HIGHVOLTAGE_LED	highvoltage_led can only be set to zero	Correct the setting.
46	GERROR_MAX_HIGHVOLTAGE_LED	highvoltage_led can only be set to zero	Correct the setting.
47	GERROR_MIN_O_FUNCTION	o_function is too small	Correct the setting.
48	GERROR_MAX_O_FUNCTION	o_function is too big	Correct the setting.
49	GERROR_MAX_TOTAL_CHARGE	total_charge can only be set to zero	Correct the setting.
50	GERROR_MIN_OPERATIONMODE	operationmode is too small	Correct the setting.
51	GERROR_MAX_OPERATIONMODE	operationmode is too big	Correct the setting.
52	GERROR_MIN_TRAIN_RATE	train_rate_ is too small	Correct the setting.
53	GERROR_MAX_TRAIN_RATE	train_rate_ is too big	Correct the setting.
54	GERROR_MIN_N_TRAINS	n_trains is too small	Correct the setting.

55	GERROR_MAX_N_TRAINS	n_trains is too big	Correct the setting.
56	GERROR_MIN_JITTER	jitter is too small	Correct the setting.
57	GERROR_MAX_JITTER	jitter is too big	Correct the setting.
58	GERROR_MIN_EL_TYPE	el_type is too small	Correct the setting.
59	GERROR_MAX_EL_TYPE	el_type is too big	Correct the setting.
60	GERROR_MIN_EL_CIRC_DIAMETER	el_circ_diameter is too small	Correct the setting.
61	GERROR_MAX_EL_CIRC_DIAMETER	el_circ_diameter is too big	Correct the setting.
62	GERROR_MIN_EL_DEPTH_DIAMETER	el_depth_diameter is too small	Correct the setting.
63	GERROR_MAX_EL_DEPTH_DIAMETER	el_depth_diameter is too big	Correct the setting.
64	GERROR_MIN_EL_DEPTH_LENGTH	el_depth_length is too small	Correct the setting.
65	GERROR_MAX_EL_DEPTH_LENGTH	el_depth_length is too big	Correct the setting.
66	GERROR_MIN_EL_OTHER_SURFACE	el_other_surface is too small	Correct the setting.
67	GERROR_MAX_EL_OTHER_SURFACE	el_other_surface is too big	Correct the setting.
68	GERROR_CHARGE_DENSITY	Stimulation with charge densities above MAX_CHARGE_DENSITY is dangerous and therefore not allowed.	Correct the setting.
69	GERROR_PULSE_WRONG_PHASES	Phase current/duration 1 and 2, if not zero, must be equal in size and opposite in sign	Correct the setting.
70	GERROR_FADE_OUT	During fade out no stimulation parameter has to be changed	
71	GERROR_RAMP_DURATION	The fade in and fade out time lead to a ramp duration longer than the train duration	Correct the setting.

72	GERROR_PULSE_PERIOD_DURATION	The pulse rate leads to a pulse period smaller than the pulse duration	Correct the setting.
73	GERROR_DO12_PULSE_TRAIN	Pre/post_time for train on one DO must be longer than for phase on the other DO	Correct the setting.
74	GERROR_NO_DO1_PRE_TIME_FOR_PHASE	Setting DO1 pre_time for phase is not possible	Correct the setting.
75	GERROR_NO_DO1_POST_TIME_FOR_PHASE	Setting DO1 post_time for phase is not possible	Correct the setting.
76	GERROR_NO_DO2_PRE_TIME_FOR_PHASE	Setting DO2 pre time for phase is not possible	Correct the setting.
77	GERROR_NO_DO2_POST_TIME_FOR_PHASE	Setting DO2 post_time for phase is not possible	Correct the setting.
78	GERROR_ENABLE_SIMULTANEOUS_HAND_FOOT	Enabling hand and foot switch simultaneously is not possible	Correct the setting.
79	GERROR_RESISTANCE	Unable to do resistance measurement	
80	GERROR_TIMEOUT_FRAME	Communication timeout for next frame (GERROR_TIMEOUT_FRAME)	The computer might be under too much load.
81	GERROR_FTDIAPI	Communication ERROR (FTDI did not return FT_OK)	Check that the USB cable is properly plugged.
82	GERROR_FTDINONEFOUND	No device found	Check that the USB cable is properly plugged and that the device is turned on.
83	GERROR_REQUEST_TIMEOUT_FRAME	Answer to request not within timeout (GERROR_REQUEST_TIMEOUT_FRAME)	Device needs inspection.
84	GERROR_REQUEST_TIMEOUT	Bytes of frame returned with too much delay (GERROR_REQUEST_TIMEOUT)	Device needs inspection.

85	GERROR_MIN_TOTAL_CHARGE	total_charge can only be set to zero	Correct the setting.
86	GERROR_PHASE_WRONG_POLARITY	Phase current 1 or 2, has opposite polarity than current one (if changed during stimulation)	Correct the setting.
87	GERROR_INVALIDDEVICE	Invalid device. SW is not made for this device.	
88	GERROR_RESERVED07	Not used.	
89	GERROR_ACKNOWLEDGE	No acknowledgement for message received.	Device may need inspection.
90	GERROR_CRC	Invalid CRC checksum received	Maybe communication problems due to ESD.
91	GERROR_RESPONSE	Response does not fit to request	Maybe communication problems due to ESD.
92	GERROR_TRAIN_DURATION_EXCEEDED	The maximal train duration exceeded. For FES/CUBE only.	
93	GERROR_TRAIN_PERIOD_EXCEEDED	The train rate is too high, leaving no room for the train	Correct the setting.
94	GERROR_RESERVED09	Not used.	
95	GERROR_WRITESTATE	Invalid state received or invalid state change requested	Correct the setting.
96	GERROR_NOT_ACTIVE	Operation only works in active state, or stopped due to some error (e.g. not enabled due to foot switch not pressed)	
97	GERROR_OPERATION_ABORTED	Operation was aborted before completion	
98	GERROR_TRAIN_DURATION_BELOW_LIMIT	Train duration below minimal limit. For FES/CUBE only.	Correct the setting.
99	GERROR_RESERVED11	Not used.	
100	GERROR_RESERVED12	Not used.	
101	GERROR_RESERVED13	Not used.	
102	GERROR_RESERVED14	Not used.	

103	GERROR_WRITENOTSTOPPED	Write command while device not stopped	
104	GERROR_WRITEATREADONLY	Write command in read only data segment received	
105	GERROR_WRITEDEVINFO	Failed to program device program memory with serial, identifier,...	
106	GERROR_CALIBRATE	Failed to calibrate device ,...	Device needs inspection.
107	GERROR_READSTIMDATA	Read command at stimulation data while device not stopped	
108	GERROR_RESERVED15	Not used.	
109	GERROR_CONTENT	Invalid offset, length or combination of them received	Maybe communication problems due to ESD.
110	GERROR_LENGTH	Invalid length (in combination with the offset) received	Maybe communication problems due to ESD.
111	GERROR_COMMUNICATIONUCS	UART communication between uC1 and uC2 failed	Maybe communication problems due to ESD.
112	GERROR_UC2TIMEOUT	uC2 did not respond within time to uC1	Device may need inspection.
113	GERROR_RESERVED16	Not used.	
114	GERROR_LOWBATSTOP	Device in STOP state till battery replaced	Change the battery.
115	GERROR_LOCKSTATE	Device is in Lock state, no write command is processed	Device needs inspection.
116	GERROR_NOENABLESIGNAL	Device still in ACTIVE state, because foot switch not pressed	
117	GERROR_CHARGELIMIT	Charge limit reached with next stimulation	
118	GERROR_TRANSITIONLIMIT	Transition limit reached --> stimulation is only possible between two read commands	Frequency of state changes must not be bigger than about 5 Hz.

119	GERROR_RESERVED17	Not used.	
120	GERROR_DONGLE	Dongle not detected.	Check the dongle.
121	GERROR_WRITE_HW_FW_VERSION	Failed to program device program hardware- or firmware version, because already programmed	
122	GERROR_MMF	Failed to create memory mapped file for SIMULINK.	Clear the Windows temp folder.
123	GERROR_LOWSUPPLY	Failure due to low voltage supply via USB.	The PC might not be suitable for the device.
124	GERROR_TIMEOUT	communication timeout for next byte in frame (GERROR_TIMEOUT)	The PC might be under too much load.

11 BIBLIOGRAPHY

McCreery, D. B., Agnew, W. F., Yuen, T. G., & Bullara, L. (1990, October). Charge Densitiy and Charege Per Phase as Cofactors in Neural Injury Induced by Electrical Stimulation. *IEEE transactions on biomedical engineering, 37*, 996-1001.

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CORTICAL STIMULATOR