Application Software

Short Manual

Brain Interchange System

Valid for research and clinical investigation:

EU: Exclusively for clinical investigation
USA: CAUTION – Investigational Device Limited by Federal (or United States) law to investigational use.
EU&USA: Scientific research and development

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CorTec
Thinking ahead

1. Content

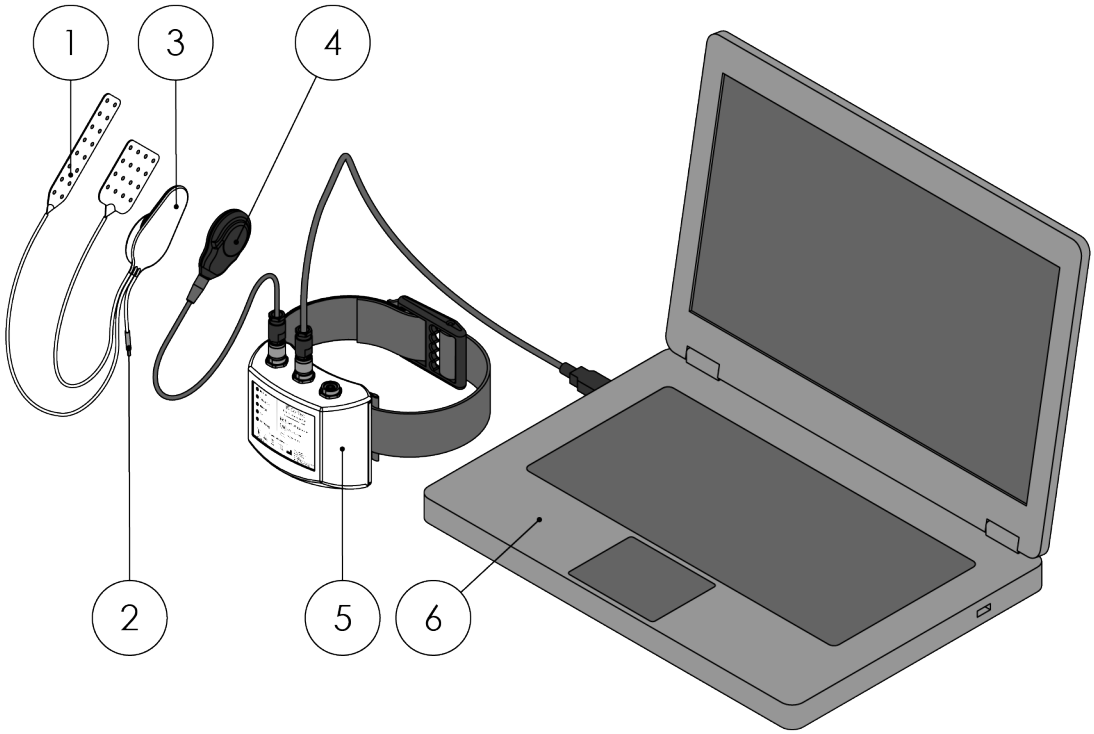
2. Information

Table 1: Information

Topic	Information
Applicable Software Releases:	Implant firmware: 1.0.238 / 1.1.260 Brain Interchange Application: 1.0.238 / 1.1.260

3. System Description

The Brain Interchange (BIC) system consists of Implanted Grid Electrodes connected to an Implanted Electronic Unit. The Implanted Electronic Unit is wirelessly powered from outside the body by a Head Piece and communicates wirelessly to a Communication Unit. The Communication Unit relays information (e.g. neural data and status information) from the implant to a Personal Computer (PC) as well as transfers commands (e.g. electrical stimulation commands) from the PC to the implant. Figure 1 illustrates the main components the system consists of.
The Application Software runs on the PC and offers the control of the implant and gathering of implant data using a graphical user interface.



1: Grid Electrodes
2: Ground Electrode (Optional)
3: Implanted Electronic Unit
4: Head Piece
5: Communication Unit
A - Head Piece Cable Connector
B - USB Cable Connector
C - Trigger Input Connector
6: Personal Computer

Figure 1: Overview of BIC System components

4. Terminology

See *User Manual*, chapter 4.2.

5. Main Functions

The key functions/performance of the system is the recording of neural signals, modulation of neural activity by delivering electrical pulses to the neural tissue (hereinafter referred to as *stimulation*) and measuring of electrode impedance. The latter permits to evaluate the integrity of the technical system as well as the biological response to the Implanted Grid Electrodes.
The application software offers control over the key functions and also visualizes measured data and system status information. The software is launched by clicking the launcher icon (Figure 2)

Figure 2: Application Software launcher icon on MS Windows desktop.

The functional elements of the graphical user interface (GUI) of the Application Software are shown in Figure 3: Signal visualization and control panels.

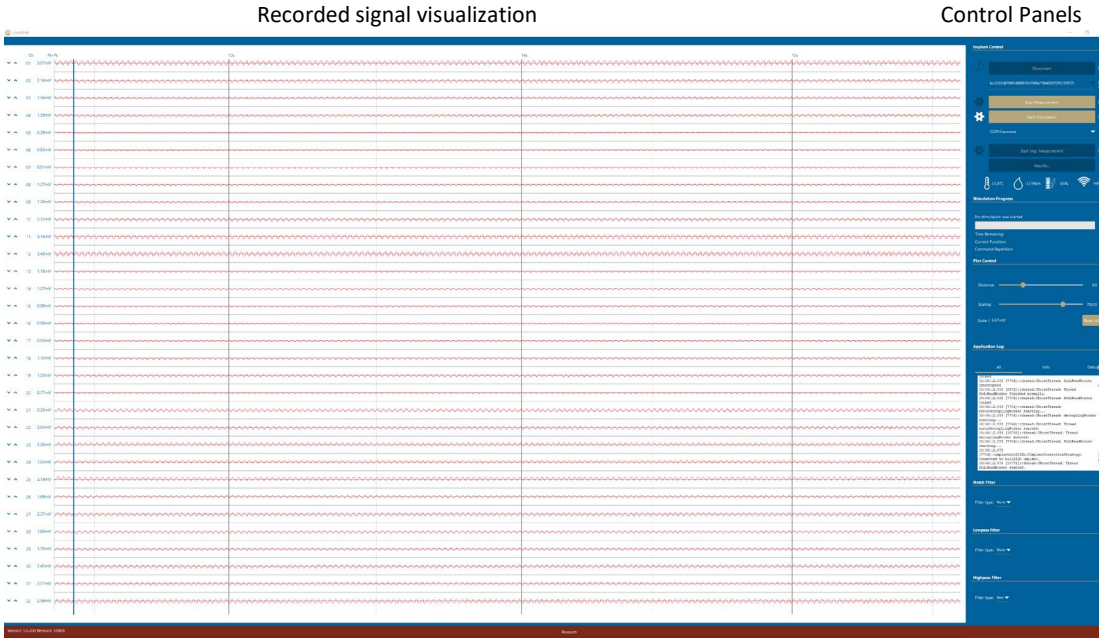


Figure 3: Graphical User Interface of Application Software.

5.1. Connect / Disconnect

Connection to an implant refers to having the implanted and the body-external components communicate to each other. First, implants in reach (inductively powered and addressable by radio frequency communication) need to be discovered by clicking on the magnification lens icon in the implant control panel (Figure 4).

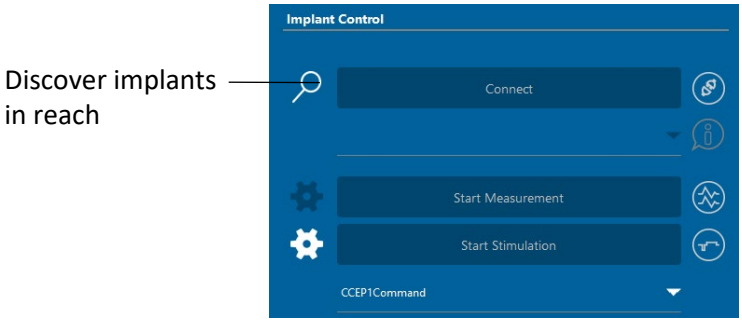


Figure 4: Initiate the discovery of implants by click on the magnification lens symbol.

Once one or more implants are discovered, the implant to be connected needs to be selected from the list of implants in reach (Figure 5). In second step the *Connect* button needs to be clicked on.

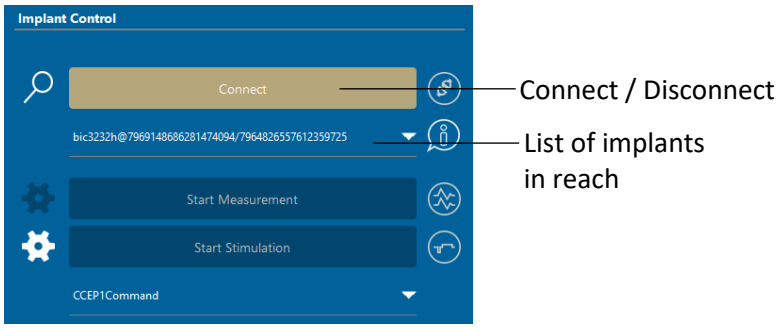


Figure 5: Connect to an implant by selecting the identification number and clicking on the Connect button. The same button is used for disconnection.

Once connected, the label of the connect button changes to *Disconnect*.
Disconnection from the implant by clicking on the *Disconnect* button finishes the tasks carried out by the implant and shuts down the implant power supply. If the Application Software is closed without disconnecting, the implant will be further powered. It will although continuing the current task.

5.2. Implant Status

Once connected status information of the implant is displayed in the status display. A value of '~~???~~' indicates that no data is available. The temperature and relative humidity are measured inside of the implant's hermetic capsule.

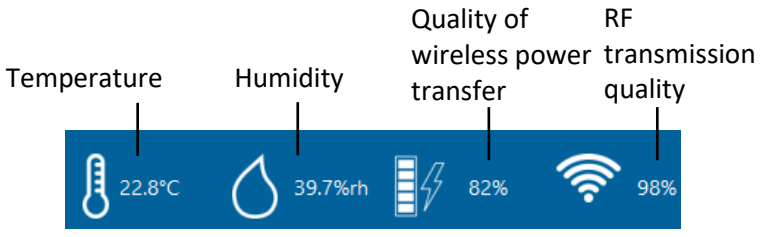


Figure 6 Implant status display

The supply voltage is an indicator for the power coupling between head piece and implant. The quality of wireless power transfer describes how good is the power transferred from the

head piece to the implant. Low wireless power transfer quality indicates that the placement of the headpiece is not optimal.

The RF transmission quality is an indicator for the rf link quality. Low RF transmission quality indicates more RF interferences have occurred.

5.3. Record Neural Signals

5.3.1. Recording Configuration

Recording of neural signals requires the amplification of the electrical potentials seen by each recording electrode referred to the electrical potential sensed by one or more reference electrode contacts.

The recording configuration menu can be opened by left clicking the gear left of the Start Measurement button, which opens the recording configuration menu.

Since each electrode contact can work as recording reference, this selection must be done before recording can be started. In some variants of the implant system, a hard-wired reference electrode contact is used. In this case, the selection of a recording reference adds an additional reference contact to the hardwired reference contact.

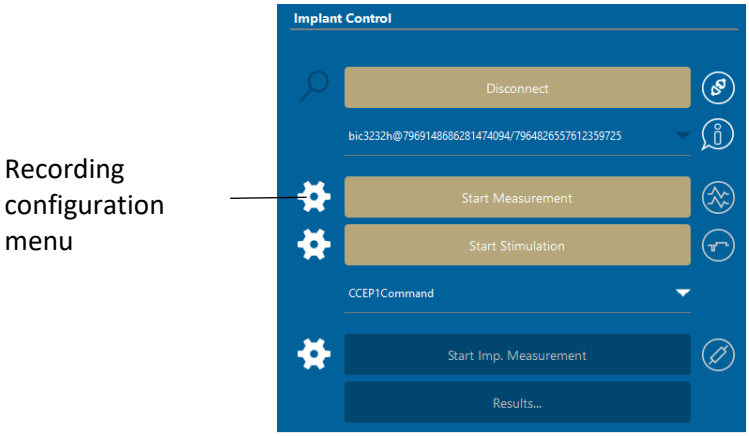


Figure 7: Clicking on the gear symbol opens a new window that permits the configuration of the recording system.

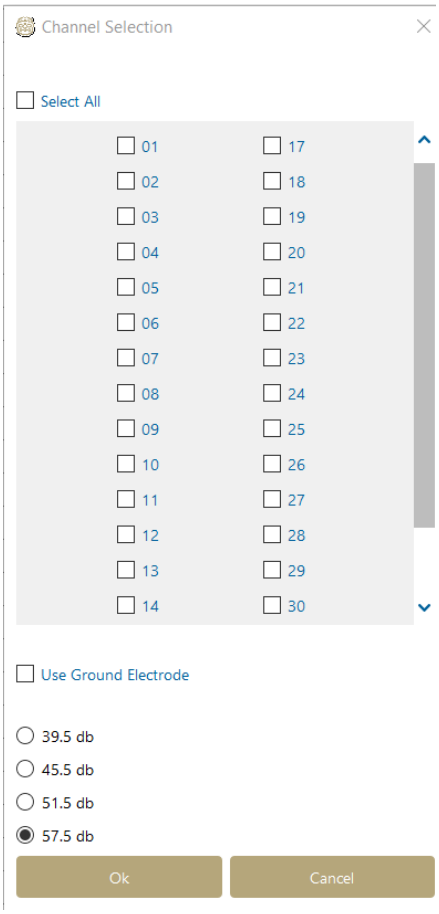


Figure 8: Recording configuration menu

The ground electrode contact can be low-impedance coupled to the electrical ground of the system by selecting “Use Ground Electrode” during measurement. This can improve the common mode behavior of the recording system under certain circumstances.

The amplification of the measurement can be modified by selecting the amplification factor. Use lower db values if the signals are clipped (at maximum/minimum) during stimulation.

Once all recording settings have been chosen, close the menu by clicking on *Ok*. The measurement is started by clicking on *Start Measurement* in the Implant Control Panel.

5.3.2. Start / Stop Measurement

Once the recording reference is defined, the recording can be started.

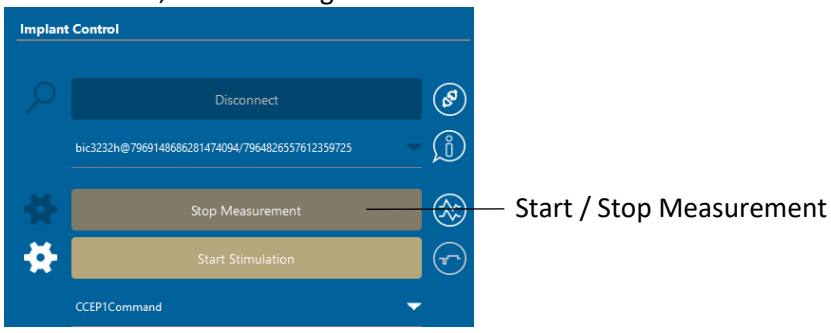
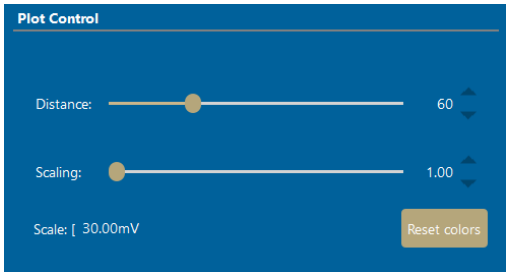


Figure 9: Recording is started by clicking on the button Start Measurement. The same button is used to stop the measurement.

5.3.3. Plot Control

The display of the data stream can be adjusted by the user:

- **Distance**
  The distance between two channels can be adjusted.
- **Scaling**
  The amplitude scale of all channels can be adjusted.

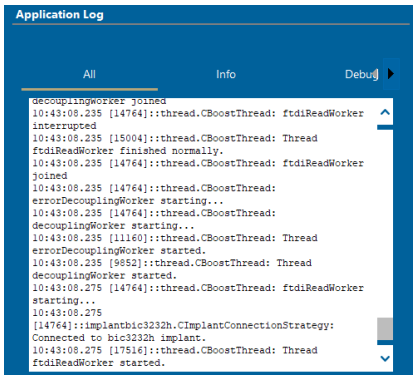


Note: These settings have no influence on the data stored to file.

The recorded digitized data is displayed on the screen (Figure 3).

5.3.4. Application Log

All logs (status reports, error messages etc.) are displayed in this section. These logs are also stored to a file.



5.3.5. Frequency Filters

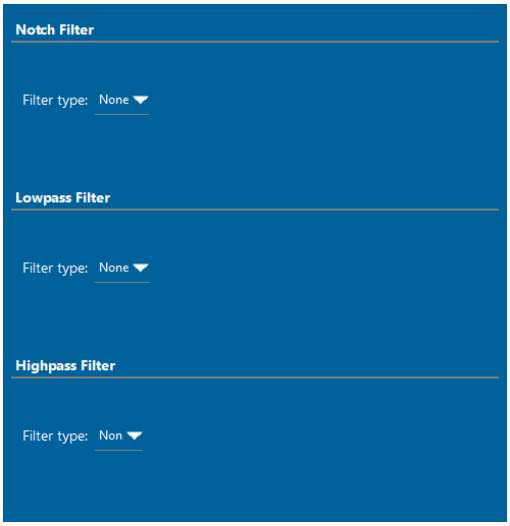


Figure 10: Control panel for frequency filter settings

The recorded data can be frequency filtered before display.

- **Notch Filter**
  Notch filters remove artifacts associated with one frequency. Often used to reject mains frequency (50 Hz in Europe, 60 Hz in the USA).
- **Low Pass Filter**
  The filters permit to reject signal content at selected frequencies and above. (100Hz, 200Hz, 300Hz, and 400Hz can be selected)
- **High Pass Filter**
  The filters permit to reject signal content at selected frequencies and below. (1Hz, 5Hz 10Hz, 20Hz can be selected.)

Note: These settings have no influence on the data stored to file.

5.3.6. Data Storage

See *Appendix3 bip2x Short Manual.*

5.4. Apply Electrical Stimulation

5.4.1. Define Stimulus

Stimulation commands can either be selected from a pre-defined list of commands or newly defined (Figure 12).

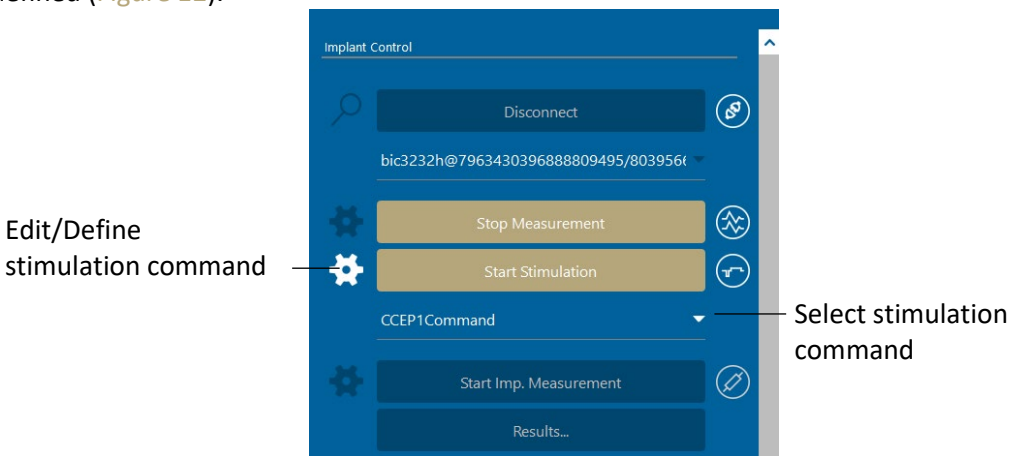


Figure 11: Clicking on the gear symbol opens a new window that permits the definition of the stimulation pattern.

New definition or editing of stimulation commands is done using the Stimulation Command Editor (Figure 12). When opening this dialog for the first time, a list of pre-defined commands is created.

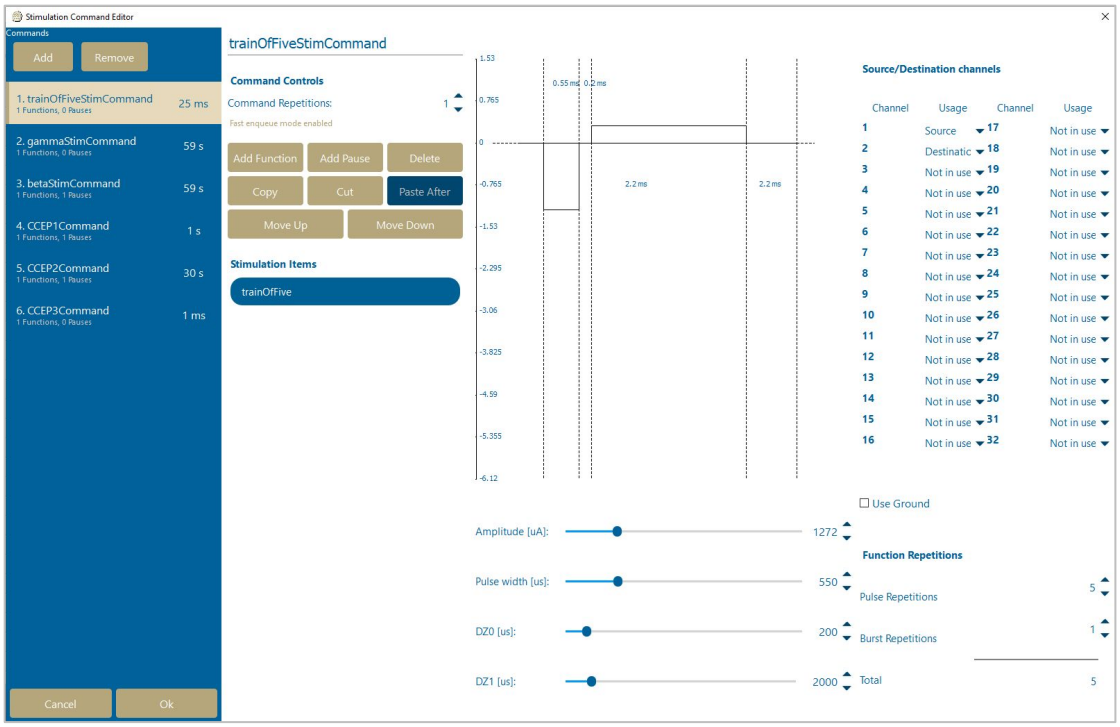


**Figure 12: Stimulation Command Editor.
Stimulation commands can be edited, or new command can be added.**

The Stimulation Command Editor permits the selection of pre-defined stimulation commands as well as the definition of a new stimulation command (select the *Add* button).

The timing and amplitude parameters define the stimulation pulse according to Figure 13. A Pulse is defined by its amplitude (amp), pulse width (PW), deadzone 0 (DZ0) which is a configurable pause before and after the counter pulse. Deadzone 1 (DZ1) is a pause in between two pulse repetitions. The selection of Source/Destination channels defines the actual stimulation electrode function: The current leaves the implant through the source contact(s), pass the tissue and re-enter the implant through the destination contacts, and/or the Ground contact.

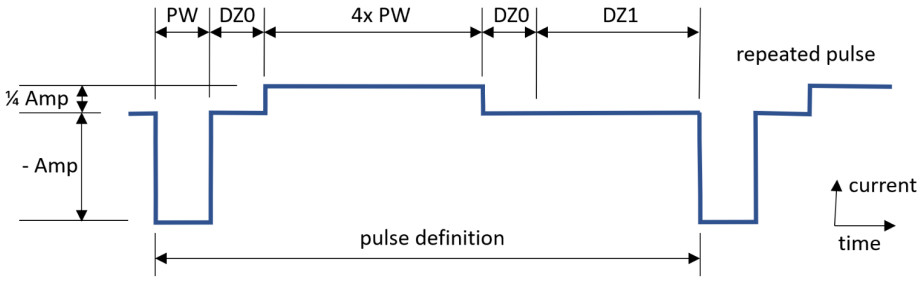


Figure 13: Definition of a pulse by timing (PW, DZ0, DZ1) and amplitude (Amp) parameters.

Function repetitions defines how often the stimulation pulse is applied. The exact number of repetitions is calculated with two parameters: *pulse* and *burst repetitions*. The system interprets the two values by delivering the stimulation pulse pulse repetitions times as shown in Figure 13 with no pause between the pulses. This group of repeated pulses is called a burst. The burst is applied burst repetitions times with a pause of 10 µs between each burst execution. The total number of times a stimulation pulse is applied can simply be calculated as follows:

Function repetitions = pulse repetitions x burst repetitions

Note: Due to the 10 µs pause between the execution of stimulation pulse bursts, the overall runtime of a command can differ between configurations, even though the total number of executions stays the same.

By selecting the *Ok* button on the lower left corner, the drop-down menu (Figure 9, Figure 11) is filled with the commands that are available in the Stimulation Command Editor. They are now ready to be executed using the corresponding panel (Figure 14) on the graphical user interface main window.

5.4.2. Start / Stop Electrical Stimulation

The stimulation command shown below the *Start Stimulation Button* in the implant control panel can be started by selecting the *Start Stimulation* Button (Figure 14). For the duration of stimulation, the button changes its label to *Stop Stimulation*. In case the stimulation needs to be stopped, this button needs to be clicked on. After the stimulation command is finished (or was stopped) the label of the button switches back to *Start Stimulation*.

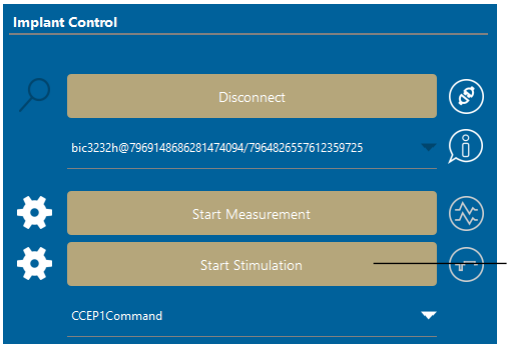


Figure 14: Stimulation is started by clicking on the button Start Stimulation. The same button is used to stop the stimulation in case it is to be interrupted before the intendent end of the stimulation pattern.

5.4.3. Stimulation Progress

The progress of an ongoing stimulation is tracked and visualized in the *Stimulation Progress* control panel (Figure 14). It tells the user which command is executed or notifies him if no stimulation was started before. The progress information is shown in the form of a progress bar that is annotated with an estimate of the remaining time until the end of the stimulation, the stimulation function that is currently executed on the implant and how often the command was repeated already.

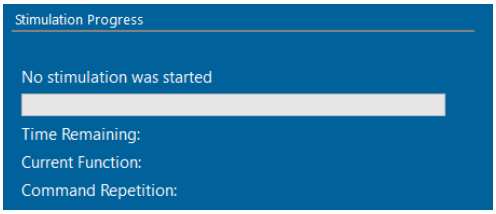


Figure 15: State of the stimulation

5.5. Measure Impedance

The impedance of each electrode including the Ground electrode (exception: hard-wired reference electrode - if existent in the given system variant) can be measured using the application software.
To measure the impedance, the electrode contact(s) to be measured must be defined first in the channel selection menu. Then the impedance measurement is started by clicking on the button *Start Imp. Measurement*. The last results of the measurements are displayed by clicking on the button *Results*.

The result will be displayed as an ohmic value, in case it is within the measurement range. The message “Too high” (> 37.8 kΩ) or “Too low” is displayed if measurement outside the range. These out-of-range messages are documented in the log files as *-inf* and *+inf*.

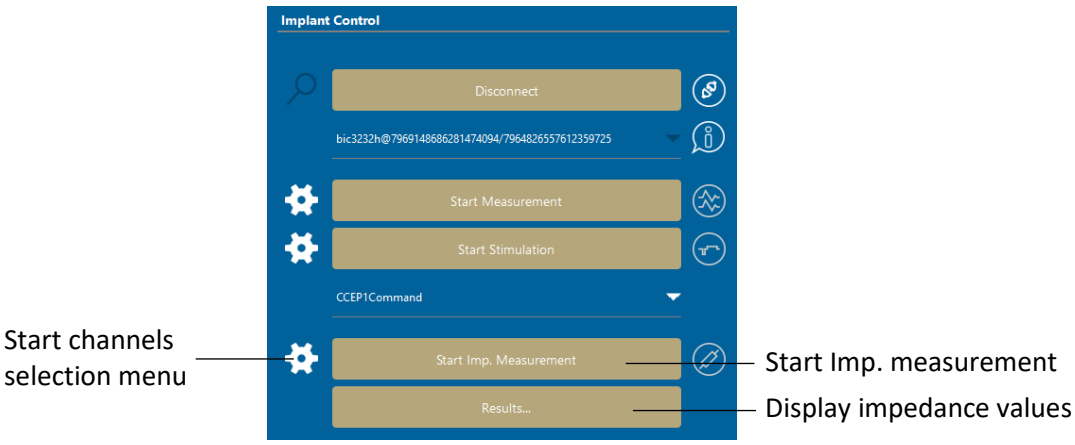


Figure 16: Functions of control panel related to impedance measurement of electrode contacts.

Note: The impedance values measured correlate to the ohmic resistance calculated by measuring the voltage step height in response to a short current pulse divided by the pulse amplitude. This value is strongly influenced by change of the electrode environment, e.g. by fibrotic tissue growth as well as by electrode contact surface area and cable resistance, allowing to discover onset of electrode breakage.

Note: The accuracy of the Ground electrode impedance values cannot be guaranteed if there are less than four electrodes connected. Connected in this context means an impedance value of less 37.8 kΩ.

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