BrainSTIM Transcranial Stimulator

Operating Manual

CE
0476

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The following symbols are used to bring some important information to your attention:

Warning! This symbol indicates that not following these instructions might be harmful to you and other users or might damage your BrainSTIM or other equipment.

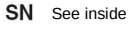
Warning! This symbol indicates that before using the BrainSTIM stimulator you must read the operating instructions.

This symbol identifies the manufacturer and must be accompanied by the manufacturer's name and address.

This symbol identifies the BrainSTIM stimulator code.

This symbol indicates the production batch and must be accompanied by the manufacturer's batch code. The code must be adjacent to the symbol.

This symbol indicates the serial number of the BrainSTIM stimulator and must always be accompanied by the manufacturer's serial number.



This symbol indicates that the serial number of the BrainSTIM stimulator is stamped inside.

This symbol indicates the upper and lower storage temperature limits recommended by the manufacturer.

This symbol indicates the upper and lower limits of humidity recommended by the manufacturer.

This symbol indicates that the BrainSTIM stimulator is electric and electronic waste and therefore cannot be disposed of in normal domestic waste bins, and must be treated as "waste

This symbol indicates that the stimulator conforms to the Medical Devices Directive 93/42/EC.

This symbol indicates that the stimulator conforms to the BF type of electromedical equipment.

Out	Exit
Battery Powered	Battery powered

The plate data of the device, including some of the symbols shown above, is given on the plate attached to the back of the BrainSTIM.

The following commands and LEDs are also shown on the equipment.

2. Pack contents

On opening the pack, check that it contains all the items listed below:

- A BrainSTIM bidirectional current transcranial stimulator
- Two connection cables to connect the stimulator to the electrodes, one red and one black, with 2mm safety banana plugs on one side and 2 mm banana plugs on the other (length 150 cm)
- A battery charger for AA accumulators
- Eight AA accumulators with a capacity greater than or equal to 2Ah
- A User Manual for the BrainSTIM stimulator
- A User Manual for the battery charger
- Two medium size pairs of conductive rubber electrodes (50mm x 50mm)
- Two pairs of electrode sleeves
- Two fixing bands
- Two fixing band buttons
- A CD with a copy of the software (DVD case, DVD/CD, Dongle licence, Bluetooth dongle)
- A stimulator carry bag

The following accessories may be ordered separately:

- External trigger unit, to synchronize several stimulators
- Cable to connect the BrainSTIM stimulator to the external trigger unit (length 100 cm)
- Cables to connect the external trigger unit to other devices (length 400 cm)
- Conductive rubber electrodes, medium size (50mm x 50mm)
- Conductive rubber electrodes, large size (50mm x 100mm)
- Sponge electrodes (55mm x 75mm) complete with adapter

If the pack does not contain all the items listed above, contact the distributor immediately.

Warning:
the use of ACCESSORIES, transducers and cables other than those specified, except for the transducers and cables sold by EMS as spare parts for internal components, may cause an increase in emissions or a reduction in the immunity of the BrainSTIM

3. The BrainSTIM bidirectional current stimulator

The BrainSTIM bidirectional current stimulator was specifically designed to facilitate ease of use both for research purposes and for clinical therapy performed at home or in the outpatient department. Specifically, the stimulator may be programmed to apply the chosen treatment protocol to the patient for a predetermined period of time and may therefore be given to the patient to use, as he/she will be unable to change any of the stimulation parameters. When the treatment protocol has ended, the stimulator will cease to function and must be re-programmed. When the stimulator is returned, the healthcare worker, provided with a calculator on which the BrainSTIM operating software has been installed, can view and save the report of the stimulation sessions effectively performed by the patient, to check whether the patient has adhered to the treatment protocol. The stimulator may then be re-programmed and used for a new treatment protocol at home or in the outpatient department.

INTENDED USE:
The BrainSTIM stimulator supplies low-intensity uni- and bi-directional transcranial electrical stimulation. It is used to treat different neurological and psychiatric disorders. In particular it has been validated for the following conditions: Depression, Alzheimer, Aphasia, Chronic pain, Dystonia, Parkinson, Epilepsy, Migraine, Hypertension, Stroke, Ischaemia, Addictions, Memory disfunctions, Tinnitus.

The stimulator is programmable, thus enabling the operator to select a stimulation waveform from the following:

- **Continuous,** consisting of a rising ramp, a constant high level and a falling ramp. The rising ramp enables the stimulation current to be progressively increased up to the programmed value within the required time; the level has a programmable duration during which the stimulation current is constant and is followed by a falling ramp which enables the stimulation current to be reduced gradually, within the required time, from the value reached in the course of the level, down to zero.
- **Pulse,** consisting of a sequence of rectangular impulses of which the intensity, duration and interval between successive impulses may be selected.
- **Sinusoidal semicycle,** consisting of repeated sinusoidal curves of which the duration, number of repetitions and intensity may be selected.
- **Single sinusoidal cycle,** consisting of a sinusoidal cycle of which the duration and intensity may be selected.

- **Sinusoid with offset,** consisting of repeated cycles of sinusoids to which an offset of variable width has been superimposed, thus allowing the frequency, intensity and width of the offset to be selected.
- **Colored noise,** consisting of repeated excerpts of full-band colored noise.
- **HF noise,** consisting of repeated excerpts of colored noise. Band limited to the low frequencies at approximately 100Hz.
- **LF noise,** consisting of repeated excerpts of colored noise. Band limited to the high frequencies at approximately 100Hz.
- **Sham unidirectional (positive only),** consisting of a rising ramp, a level, an interval with zero stimulation current, a level and a falling ramp. The rising ramp enables the stimulation current to be increased progressively up to the programmed value in the required time; the duration of the level is programmable, during which time the stimulation current is constant; a zero stimulation interval of a programmed duration; the duration of the level is programmable, during which time the stimulation current is constant; the falling ramp enables the stimulation current to be reduced gradually, in the required time, from the value reached during the course of the level, down to zero.

The significance of the parameters which define the single waveforms will be defined below.

The stimulator has three, mutually exclusive, functioning modes:

a) Setting the stimulation protocol by means of a wireless connection between the stimulator and a personal computer on which the software belonging to the stimulator is installed. In this mode, the stimulation protocol defined in advance on the healthcare worker's personal computer is transferred to the stimulator, which from then on will be able to deliver the stimulation. During the data transfer the stimulator's internal clock is synchronized with that of the personal computer to which it is connected. The details relating to the programming of the treatment protocol on the personal computer and to the transfer of the protocol to the stimulator will be given below.
b) Delivering the stimulation: after programming, the stimulator is ready to deliver the stimulation in accordance with the treatment protocol set by the healthcare worker. Details of the treatment protocol will be given below.

c) Transferring the data regarding the description of the treatment effectively performed by the patient to the personal computer. Details will be given below in this case too.

The BrainSTIM operating software enables the operator to:

a) Enter and manage the patient's personal and clinical details.
b) Create and manage personalized stimulation protocols. It is also possible to view protocols already pre-set in the protocol archive.
c) Define the therapeutic cycle: the healthcare operator can define the required stimulation protocol for a pre-determined period, both in terms of the duration of the treatment and in terms of the number of sessions per day to perform.
d) Program the stimulator: the treatment cycle set in advance is transferred to the simulator, which from that moment onwards will be able to deliver the stimulation. The stimulator can then be handed to the patient to use, although he/she will not be able to change any of the stimulation parameters.
e) Transfer and save data: the healthcare operator can transfer the data stored in the stimulator. The recorded data are viewed in calendar format: the days without sessions will be white, those in which everything went well will be green, those in which there were problems will be yellow and those in which the session was missed will be red. By selecting the day it is also possible to see details of the information stored (relevant dates and times, any alarms due to electrode detachment or high impedance of the same, battery alarms and interruption of the stimulation format).
f) Export data: information on a patient can be exported in a file in excel format. It is also possible to create a file containing all the data of active patients, or similarly, all the archived patient data.

4. Safety

The BrainSTIM stimulator was designed and is manufactured in compliance wtih the Medical Devices Directive 93/42 and its revision 47/2007 and with General, Collateral and Particular Standards of Electrical Safety in force in the European Economic Community.
Specifically therefore, the electrostimulator complies with:

- The Medical Device Directive 93/42/EEC of June 14, 1993
- Directive 47/2007/EEC of September 5, 2007
- Electromagnetic Compatibility Directive 336/89/EEC of 1989
- Directive 1999/5/EC
- General Standard for Medical Electrical Equipment Safety IEC EN 60 601 – 1:2007
- Collateral Standard for Medical Electrical Equipment Safety IEC EN 60 601 – 1 – 1:2003 (Electromedical Systems)
- Collateral Standard for Medical Electrical Equipment Safety EN 60 601 – 1 – 2:2007 (Electromagnetic Compatibility)
- Collateral Standard for Medical Electrical Equipment Safety IEC 60 601 – 1 – 4:2000 (Programmable Medical Electrical Devices)
- EN 60601-1-6:2007 Medical Electrical Equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC EN 62304:2006 - Medical device software - Software life cycle processes
- EN ISO 14971:2009 Medical devices - Application of risk management to medical devices /
- EN 980:2008 Symbols for use in the labeling of medical devices/
- ISO 15223:2007 Medical devices - symbols to be used with medical device labels, labelling and information to be supplied/
- EN 1041:2008 Information supplied by the manufacturer of medical devices/
- ISO 780:1997 Packaging -- Pictorial marking for handling of goods.

The BrainSTIM stimulator must not be used on patients with a pacemaker or a brain stimulator as such devices may interfere with or be damaged by the BrainSTIM.

The Manufacturer does not assume responsibility for any damage.

The BrainSTIM stimulator is not protected against liquid spillage. You must therefore avoid handling any liquids while you are using it. Should any liquid be spilt on the device, you must switch the stimulator off immediately and inform the retailer or manufacturer.

The BrainSTIM stimulator must not be used together with a defibrillator as it does not have adequate protection. The Manufacturer does not assume responsibility for any damage in such cases.

It is advisable to keep the stimulator out of the reach of children.

Electrical medical devices such as the BrainSTIM are subject to particular precautions regarding the EMC and must be installed and run according to EMC Regulations which are included inside the attached documents.

Only the Manufacturer or personnel authorized by the Manufacturer may repair and make changes to the BrainSTIM stimulator.

The BrainSTIM must not be opened for any reason. The Manufacturer does not assume any responsibility for any damage in this case. If you are experiencing technical problems with your stimulator, always inform your retailer or the Manufacturer.

The stimulator must never be used in the presence of inflammable atmospheres or in oxygen-enriched environments.

It is advisable not to apply the electrodes to irritated or grazed skin, on mucous membranes, injuries or lesions.

It is advisable to clean the electrodes before each use.

It is advisable to check the patient's tolerability of the stimulation parameters set before starting a therapeutic treatment.

Additional Warnings

The safety aspects to bear in mind when using any bidirectional current transcranial stimulator concern mainly the intensity of the current and the duration of the stimulation.

There are two main dangers: 1) damage to the skin beneath the stimulation electrodes; 2) damage to the brain tissue through which the current passes.

Given the characteristics of the output stage of the BrainSTIM stimulator and the dimensions of the electrodes generally used, the most common of these two dangers is the first, as the energy the stimulator can transfer to the tissues is, according to reports in the literature and discussed below, limited so that it is unable to heat the brain tissue.

Damage to the skin beneath the stimulation electrodes

The damage depends on different factors, some of the most significant being a) the intensity of the stimulation current expressed as an efficacy value, b) the duration of the stimulation, c) the surface of the electrodes, d) the material of which they are made and e) the characteristics of the medium (conductive gel, saline solution) placed between the skin and the electrode to ensure even skin-electrode contact at a sufficiently low impedance.

Only the healthcare operator's experience will be able to establish whether a specific mode of stimulation can be considered sufficiently safe from the point of view of skin damage, but some general rules can help to avoid potentially dangerous situations.

The following warnings must be borne in mind:

A. **Limit the density of the current to the minimum necessary to achieve the desired therapeutic effect.** The current density is obtained by dividing the mean value of the stimulation current by the stimulation electrode's contact surface area. For example, a rectangular electrode measuring 5cm x 5cm (area 25 cm^2) used to apply a current of 1 mA causes a current density of 1mA /25 cm^2 , therefore 0.04 mA/cm^2 (the equivalent of 40 $\mu A/cm^2$). Current densities of lower than 0.1 mA/cm^2 are generally considered safe if

the period of stimulation is limited to a few minutes, whereas lower values should be used for extended stimulations. The use of a current density that is too high compared to the length of stimulation encourages the accumulation of caustic substances under the stimulation electrodes and can consequently cause chemical-type burns which could involve the epidermis and dermis.

From the point of view of the feeling experienced by the patient during the stimulation, it is considered that this can vary considerably based on individual sensitivity: on average a current density of around 30 $\mu A/cm^2$ can be perceived as a burning feeling. As some patients may have relatively low skin sensitivity, the fact that the patient does not feel any unpleasant sensations during the treatment must not be considered sufficient to guarantee that no chemical-type burns will appear.

Normally, in order to reduce the possibility of damaging the patient's skin, it is best to clean the skin under the electrodes carefully at the end of the treatment, using a neutral detergent and rinsing well with tap water.

A slight reddening of the skin under the electrodes is normal, but it should not feel unpleasant for the patient (itching, burning sensation, …) and should fade spontaneously in no more than two hours.

B. **Limit the mean charge density transferred to the tissues to the minimum required to achieve the desired therapeutic effect.** The mean charge density transferred to the tissues is measured in Coulombs per square centimeter (C/cm^2) and is obtained by multiplying the mean current density of stimulation by the duration, expressed in seconds, of the stimulation itself. For example, a stimulation lasting 30 minutes using a mean current density of 0.1 mA/cm^2 corresponds to a charge density of 30min x 60s x 0.1 mA/cm^2 = 180 mC/cm^2 = 1800 C/m^2. Values higher than 100 mC/cm^2 must be avoided if possible, as they can cause permanent skin lesions.

C. **Limit the length of stimulation to the minimum required to achieve the desired therapeutic effect.** Stimulation protocols using current densities of lower than 0.1 mA/cm^2 for durations of fewer than 20 minutes (charge density lower than 120 mC/cm^2) are generally described in the literature. Applications lasting more than 20 minutes must be performed only after checking that they are not, on the specific subject and considering the chosen current density, a possible cause of skin damage.

D. **Use electrodes with surface areas that will ensure a current density low enough not to cause skin damage.** If you intend to use, for example, a mean current density of 0.05 mA/cm^2, having a current with a mean value of 2 mA, you will need to use electrodes with a surface area equal to or greater than $S = I_{DC}/\delta I_{DC} = 2/0{,}05 = 40\ cm^2$. The stimulator can be used with electrodes of different dimensions to satisfy different assembly requirements.

E. When using conductive rubber electrodes, always use a conductive gel spread evenly over the electrode so that it forms a smooth interface between electrode and skin or, alternatively, use a sleeve of cloth soaked in water or saline solution to contain the electrode. Take care to choose a conductive gel specifically developed for electrical stimulation. The use of unsuitable gel increases the probability of damage to the skin under the electrode. When using sponge electrodes or cloth sleeves be careful of the choice of liquid used to moisten the sponge; physiological solution is advised. The use of different solutions can facilitate the development of skin lesions beneath the electrodes.

F. At the end of the stimulation session, the electrodes should be cleaned carefully and stored properly so that they cannot be damaged. Conductive gel electrodes must be washed with tap water and a neutral soap, carefully rinsed and dried delicately. Sponge electrodes should be rinsed in tap water and absolutely not squeezed out; they should be left to dry before being stored in their box. To hasten the drying process, it is possible to place the sponge on a sheet of white absorbent paper and delicately press all over the surface of the sponge to remove the excess water.

G. Should the surface of an electrode be dirty or damaged, the electrode must be replaced immediately with a new one. The use of damaged electrodes can cause skin lesions under the electrode. In any case, bearing in mind the frequency of use of the stimulator, it is best to replace the electrodes at least every six months, even if they are apparently still in good condition.

Damage to the brain tissue the current passes through

It has recently been reported in the literature (Establishing safety limits for transcranial direct current stimulation, Marom Bikson, Abhishek Datta and Maged Elwassif) that a continuous flow of current density of approximately 15 mA/cm^2 lasting for a period of 10 minutes would be capable of heating tissue with characteristics similar to those of brain tissue, from a baseline temperature of 37°C up to approximately 47°C, potentially capable of causing damage to the cells involved.

It is necessary to bear in mind that only a part of the current passing into the skin from the electrodes passes through the brain tissue, whereas a large part of the current flows between anode and cathode through the epidermis and the dermis without penetrating into the skull.

The maximum current the BrainSTIM stimulator is capable to applying is approximately 5 mA, which, even if it were applied to the subject through electrodes of an area of only one square centimeter, would provide a current density of a third of the amount that is potentially harmful

for heating the brain tissue, of which, however, only a fraction would be applied to the brain tissue itself.

Even in this borderline case – normally the electrodes have a much greater surface area – it would not however be possible to produce an appreciable heating of the tissues inside the skull. All the more so, with the electrodes normally in use, the current density would be several dozen times lower and the current density in the brain tissue would therefore be at least one hundred times lower than the amount which could be harmful.

With regard to the danger arising from brain tissue heating, in the light of current knowledge, it may be concluded that the BrainSTIM stimulator is absolutely safe. It is hovewer advisable that the user keeps himself updated on the clinical and terapeutical aspects of the transcranial direct current stimulation, in order to assure for the time being a safe and effective use of the medical device.

5. Software User Guide

The following paragraphs explain the operations performed most frequently using the BrainSTIM stimulator's operating program.

Installation

Select the file SetupBrinSTIM_XXX.exe (where XXX represents the software version), select the language to use during the installation procedure and continue the installation of the software by selecting Next.

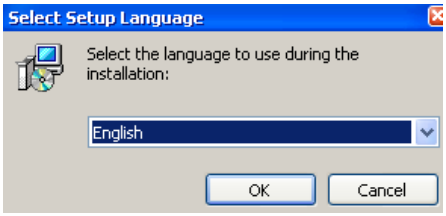


Figure 1 – Installation startup

Press Cancel to stop the installation.

Select the folder in which you want to install the program and press Next.

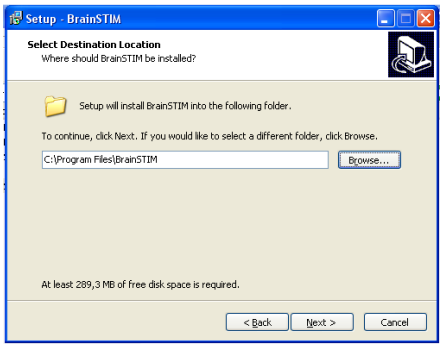


Figure 2 – Installation folder

Press Cancel to abort the installation, which will stop.

Or press Back, to return to the previous page.

The software is ready to be installed on your personal computer.

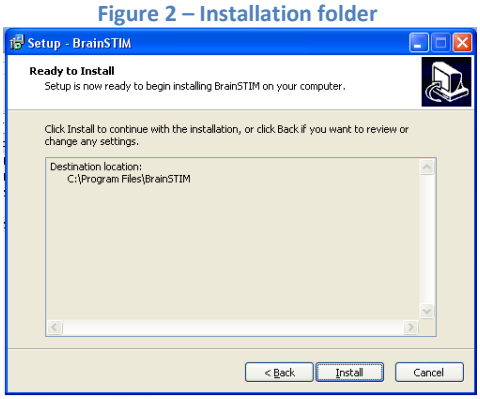


Figure 3 – Ready for installation

Press Install to continue the installation.

Press Cancel to abort the installation, which will stop.

Or press Indietro Back, to return to the previous page.

Installation in progress

The program will automatically install the BrainSTIM software on your personal computer.

Wait until installation is complete.

To stop the installation at any time, press Cancel.

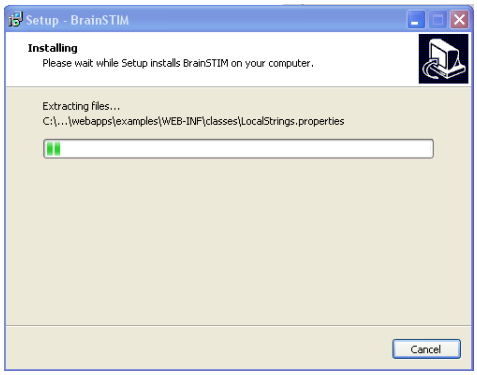


Figure 4 – Installation in progress

Installation complete

When the software has been installed, select Finish.

The program will automatically create the startup icon for the BrainSTIM software.

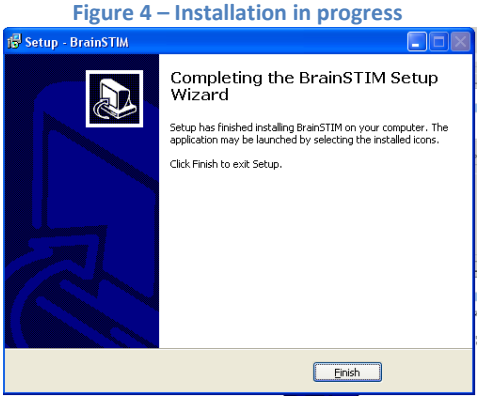


Figure 5 – Installation complete

To start the program click on:

Installing Bluetooth Dongle drivers (only for Windows XP)

Start the SETUP.EXE file contained in the BrainSTIM software CD, located in the folder "Eminent Bluetooth Dongle". At the end of the installation procedure, a "Bluetooth Places" will appear on the Desktop.

This step is not needed for users of the Windows Vista/7 operating systems.

Bluetooth connection

Connect the Bluetooth key to your personal computer and open the folder Bluetooth web resources.

Switch on the BrainSTIM stimulator and press the blue key to start the Bluetooth connection. The stimulator will await connection for 90 seconds in this condition. Carry out a search for available Bluetooth resources.

The stimulator recognition icon will appear on screen, with the name "EMS BrainSTIM XXX-XX", where XXX-XX is the serial number of the stimulator.

If the connection does not take place within this time, switch the Bluetooth connection on again, and repeat the operation.

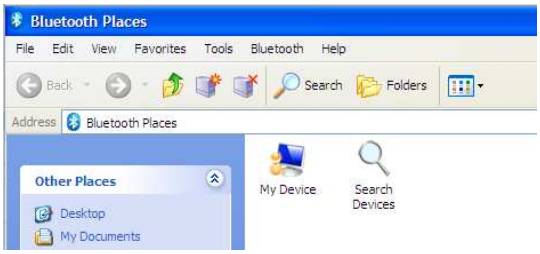


Figure 1 –Bluetooth places

It is necessary to acknowledge the stimulator when it is first switched on.

Right click with the mouse and press Add a Bluetooth device.

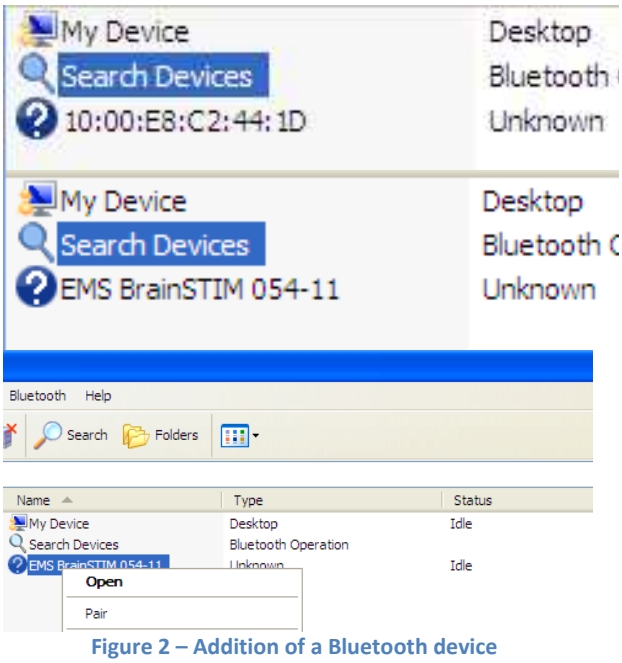


Figure 2 – Addition of a Bluetooth device

To complete the pairing of the stimulator, type:
0000 (four zeros)
and select OK.
To abort the operation, press Cancel.

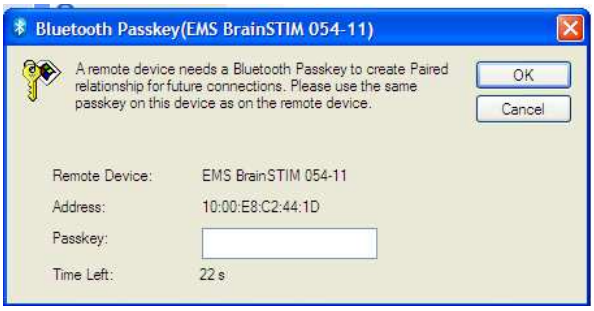


Figure 3 – Pairing Bluetooth

If the acknowledgement operation was successful, the device will appear as "paired" and displayed with a different icon. It is now necessary to install the serial communication port, in order to do this right click the BrainSTIM icon and select Open

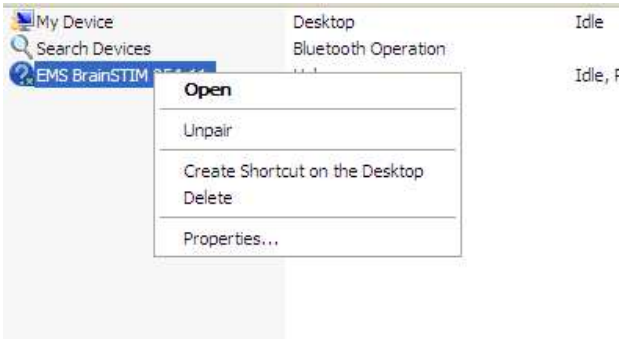


Figure 4 – Open stimulator services

If the pairing was succesfull, a "Bluetooth serial port" entry will appear in the services lst, right cick it and select Connect.

Before connecting the serial port, make sure to put the stimulator in Bluettoth mode (wich lasts 90 seconds), if it is not in Bluetooth mode, then press the blue button on the stimulator.

When completed, press End.
To abort the operation, press Cancel.

Figure 5 –listing the serial port

If the pairing was succesfull, a "Bluetooth serial port" entry will appear in the services lst, right cick it and select Connect.

Before connecting the serial port, make sure to put the stimulator in Bluettoth mode (wich lasts 90 seconds), if it is not in Bluetooth mode, then press the blue button on the stimulator.

When completed, press End.
To abort the operation, press Cancel.

Figure 6 – Connecting the serial port

At the and of the connection, the serial port will change its state to **connected**.

Turn off and then on again the stimulator.

Figure 7 – successful connection

Note:

It will not be necessary to repeat the acknowledgment of the stimulator for subsequent startups.

Connection error

If there are any problems connecting via the Bluetooth, an error message will appear similar to the one in Figure 8.

Figure 8 – Connection error

Repeat the connection, checking that:

1. You have connected the Bluetooth key;
2. You have switched on and connected the stimulator.

If the problem persists, contact the technical assistance service.

Starting up the program

To start the program, just use the mouse to click on the "*BrainSTIM*" icon on the Desktop.

Once you have done this, a window will appear on screen, enabling you to access the system. As access to the system is password protected, you will have to enter your *Username* and *Password* and press Access (fig. 1).

Use the following credentials for the first access:

Username:	System
Password:	brainstim

After the first system access, it is highly advisable to change the SYSTEM user's password. The Patient management page will appear on screen (fig. 2); this contains the list of active patients and enables you to add data for a new patient, access and, if necessary, change the data of an active patient or one who has been filed in the archive, open the list of protocols and export data.

Figure 1 - Access

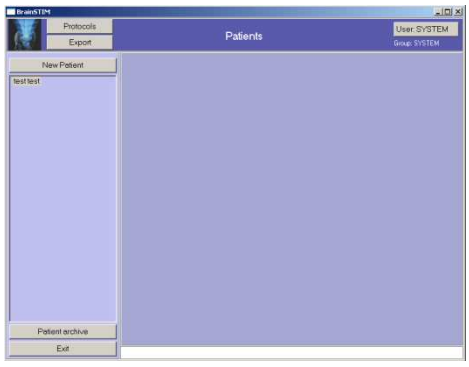


Figure 2- Patient management

Sessions closed incorrectly – User System

When the program starts up, the system detects any sessions left open, so the "Choosing a session" (fig. 3) page will open instead of the "Patient management" page.

It is possible to select a session that is still open, open a new session, delete a session or make a new access by changing user.

If you choose to open a session that is still open, you will return to the page in which the decision to exit incorrectly was made. In the case of a new session, you will return to the Patient management page (fig. 2).

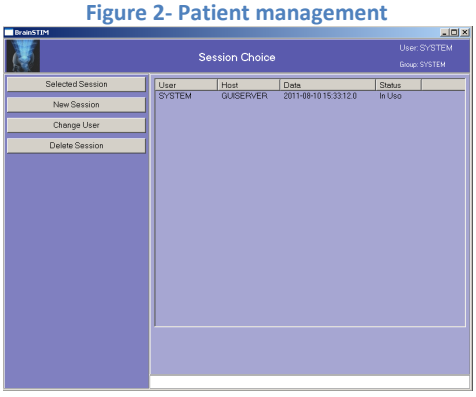


Figure 3 – Choosing a session

New patient – personal details

Press the "New Patient" key to enter a new patient's details.

A page will then appear (fig. 4) on which you can enter the patient's personal details. The following: NAME, LAST NAME, DATE OF BIRTH and PLACE OF BIRTH are all mandatory fields.

Press *"Save"* to save the data you have entered. **Once saved they cannot be changed**. A confirmation message will ask you to confirm you wish to save the entered data.

It is also possible to enter other information such as the tax code, address and place of residence, telephone and fax numbers, email address and any notes. Once you have entered the data, press ***"Save"*** .

There is a search function for the place of birth, as well as the address and place of residence (fig. 5). However, you can enter the data without using this function by placing the cursor inside the box and entering the data manually, using the keyboard.

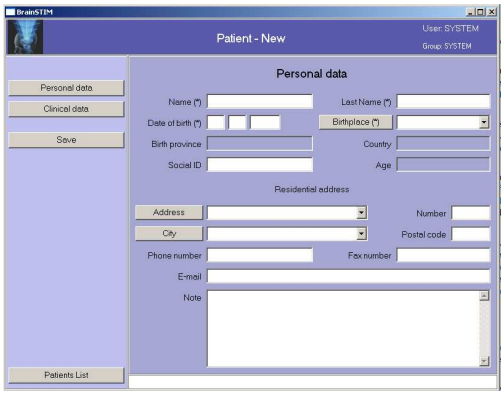


Figure 4 – New Patient

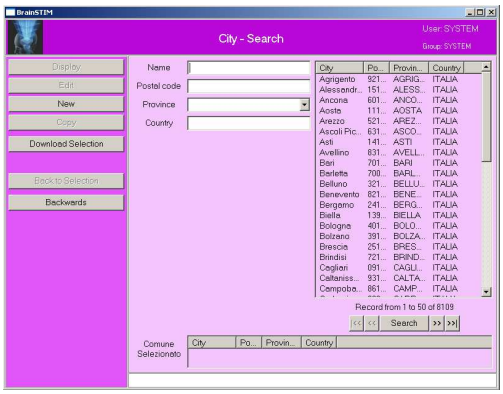


Figure 5 – City search

New patient – clinical data

Click on Clinical Data to enter the clinical data (fig. 6). These fields are not mandatory. Once you have entered the data, press "Save" .

Until the patient has been saved, only "Personal data", "Clinical Data", "Save" and "Patient List" will be active.

Once saved, the patient will be added to the list of active patients and it will be possible to start a new treatment cycle by selecting "New Cycle", which will become active.

To exit without saving the data, press either "Cancel" or "Patient List".

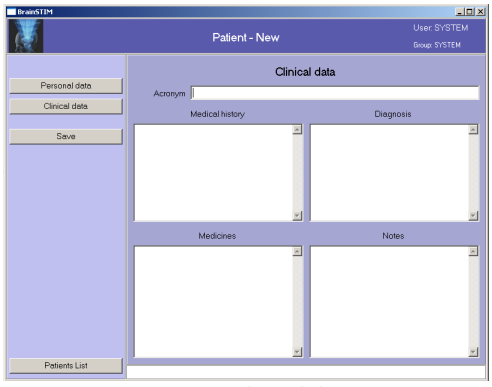


Figure 6 – Clinical data

Changing patient data

To change a patient's data, select the required patient, then press *Edit*. It will then be possible to change the fields (fig. 7). Once you have finished the changes, press "Save".

The following buttons are also active:

Personal data – enables you to change the patient's personal details,

Clinical Data – enables you to change the clinical data,

New Cycle – enables you to start a new treatment cycle,

Therapeutic Cycles – enables you to view the treatment cycles which have already ended,

Save – enables you to save the changes,

Delete – enables you to delete a patient, only if there are no active cycles or treatment cycles associated to that patient,

Archive– enables you to move a patient who is no longer being treated into the archive,

Patient list – enables you to return to the list of active patients.

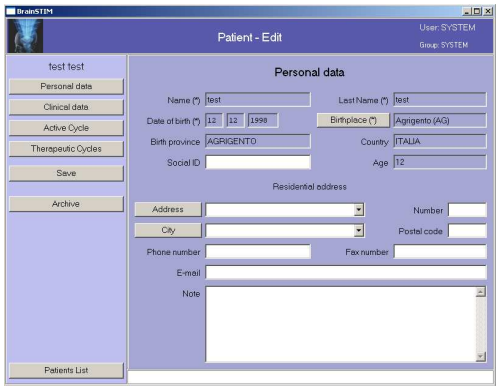


Figure 7 – Patient edit

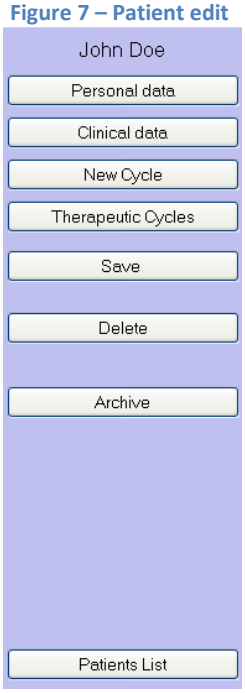


Figure 8 – Details of active buttons

New treatment cycle

After selecting the required patient, press "New Cycle" to start a new treatment cycle.
A window will open enabling you to set up a new treatment cycle (fig. 9).

The healthcare operator can then set the parameters for the treatment cycle, which is then saved. The date the treatment cycle was created is automatically entered by the program and cannot be changed.

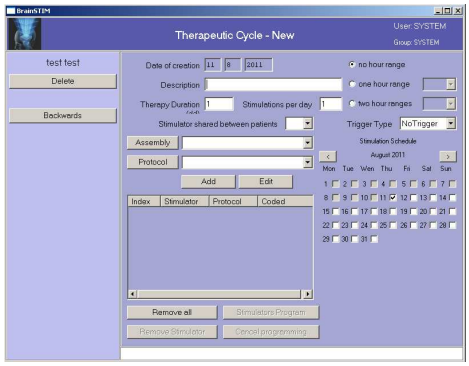


Figure 9 – New treatment cycle

Choosing the parameters

The following must be set:

Description – the treatment cycle's name or code

Therapy duration – expressed in days

Stimulations per day – number

Stimulation Schedule – specify on which days the treatment is to be carried out, noting the days on the calendar. The treatment duration counter is updated automatically.

Protocols – to choose the protocol, open the drop-down menu by clicking on the down key, then choose a protocol from those on the list (fig. 10). Once you have selected a protocol a window will open to the side (white box), representing the waveform you have chosen in diagram format. Press the *"Add"* button and the protocol will be entered and shown in the central window. Moreover, clicking on the *"Protocols"* button activates the function for searching for and creating new protocols.

Stimulator shared between several patients – yes/no, to distinguish between Outpatient Department and home use,

Time slots – enter any mandatory time slots for the stimulation.

Trigger – indicate whether you wish to use a trigger and if so, which one.

Assembly – enter a description. Press the "*Assembly*" button to activate the search and creation function for new assemblies.

The *"Stimulator programs"*, *"Cancel programming"* and *"Remove stimulator"* are not active until the stimulation protocol has been chosen.

There are several commands on the left hand side of the window: "*Delete"* and *"Backwards"* enable you to delete the program you have carried out and return to the previous screen.

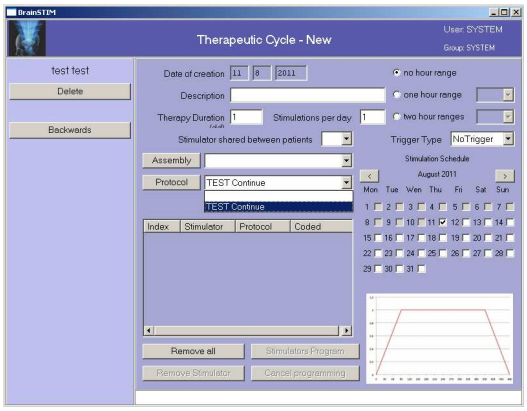


Figure 10 – Choosing parameters

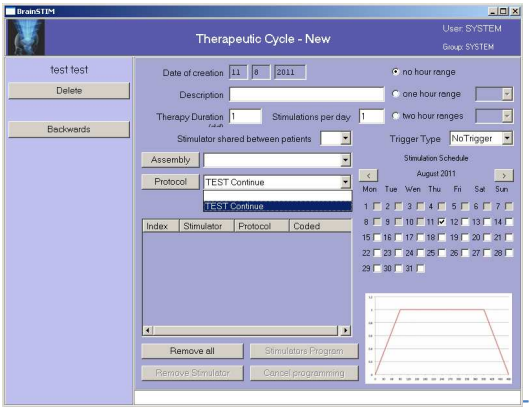


Figure 11 Choosing protocol

Once the treatment cycle has been activated it is no longer possible to change the parameters set.

Protocol search

To start a search, press the *"Protocol"* button indicated on the last page (fig. 11).

The protocol search page will then open (fig. 12), enabling you to search by *code* (entering numbers or letters), *name, waveform, active or not active, used or not used.*

By entering the search parameters and clicking on the "*Search*" button, the screen will refresh, listing the protocols matching your search (fig. 12).

There are also some functions available on the left hand side of the screen (fig. 13).

Display – view the type of waveform and the relevant parameters set,

Edit – enables you to change the waveform and the relevant parameters set,

New – creates a new protocol,

Copy – enables you to create a copy of your chosen protocol,

Download selection/return selection – starts the export function.

Backwards – to return to the chosen page of treatment cycle parameters.

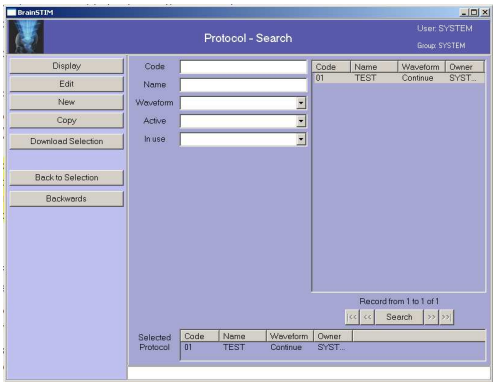


Figure 12 – Protocol search

Figure 13 – Protocol search: details of functions

Stimulation protocols

Select the "*Protocol"* button in the patient management page (fig. 2) to open the *protocols management* page (fig. 14).

On the left hand side of the screen there is a list of all the protocols in use (fig. 14), identified according to the code and description they were saved under.

Select a protocol (fig. 12) to obtain the following information:

Main data – shows the type of waveform and the relevant parameters set (fig. 15),

Used by … – shows the list of treatment cycles in which it was used, including the patient's name (fig. 16),

Copy – enables you to create a copy of the chosen protocol,

Archive – enables you to file the protocol. This function is not allowed if any treatment cycles associated with the protocol are still active,

Protocols list– enables you to return to the protocols list,

Stimulator Program – for quick programming of the stimulator.

When the *"Edit"* and "Delete" buttons are already in use in at least one active treatment cycle, they are not active. It is not possible to delete a protocol after using it in at least one treatment cycle.

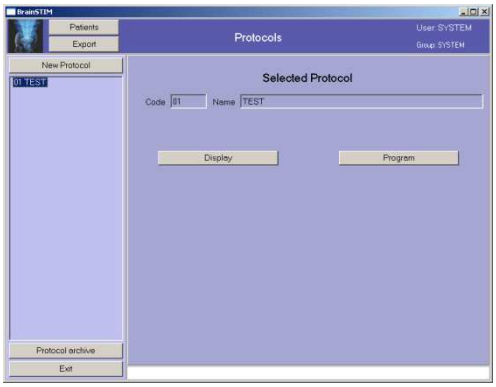


Figure 14 – List of Protocols

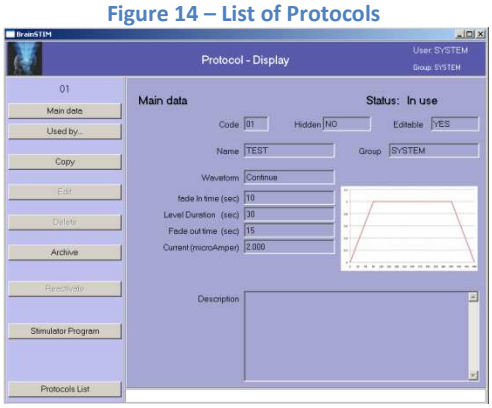


Figure 15 – Main data

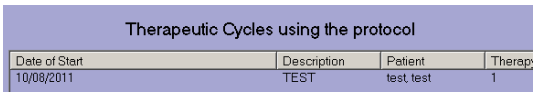


Figure 16 – Used by....

Create a new protocol

Press the *"New"* button to see the *Main data* page to fill in (fig. 17).

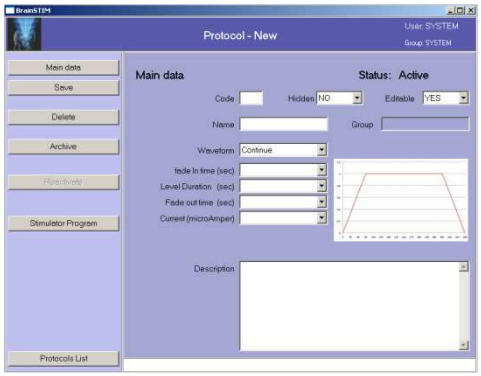


Figure 17 – Create a new protocol

Stimulation parameters (fig. 18)

In order to create a new stimulation protocol it is necessary to define the following:

code – numbers or letters which identify the new protocol,

Hidden (yes/no) – enables you to define whether the protocol must be hidden or not. If it is, once programmed it will not be possible to view the stimulation parameters trasmitted to the stimulator, on the stimulator's screen,

Editable (yes/no) – the choice of modifiable or non-modifiable enables you to create protocols which cannot subsequently be modified,

Name - numbers or letters which describe the type of protocol defined,

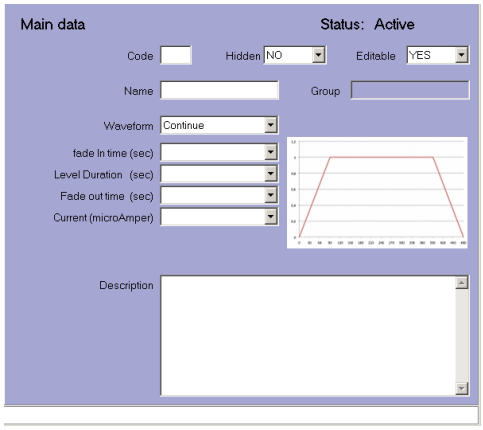


Figure 18 – Stimulation parameters

Waveform – click on the button to the right of the string (down arrow], to open a drop-down menu listing all the waveforms available for selection (fig. 19):

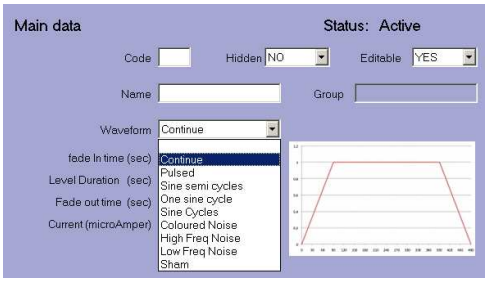


Figure 19 – Waveform

continua, pulsata, semiciclo di sinosoide, un ciclo di sinusoide, cicli di sinusoide, rumore colorato, rumore alta frequenza, rumore bassa frequenza, sham. [continuous, pulse, sinusoidal semicycle, a sinusoidal cycle, sinusoidal cycles, colored noise, high frequency noise, low frequency noise, sham]

By selecting a waveform from those listed, the window will be updated and all the specific stimulation parameters of the chosen waveform will be shown underneath; the chosen waveform is shown as a diagram in the window at the side (white box).

The waveforms and the relevant stimulation

parameters to set are described below:

- **Continue**, consisting of a rising ramp, a level and a falling ramp. The rising ramp enables the stimulation current to be progressively increased up to the programmed value within the required time; the level has a programmable duration during which the stimulation current is constant and is followed by a falling ramp which enables the stimulation current to be reduced gradually, within the required time, from the value reached in the course of the level, down to zero.

  Fade In – expressed in s
  A value of between 1s - 180s may be entered

  Duration level – expressed in s
  A value of between 1s - 180s may be entered

  Fade out – expressed in seconds. A value of between 1s - 180s may be entered
  Current – expressed in µA
  A maximum value of ±5000µA, adjustable in steps of 25µA, may be entered, with the ramps starting from 0 (zero current).

  Description – free annotation field.

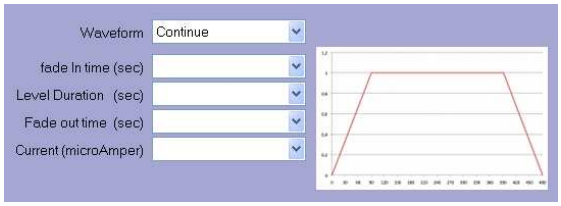


Figure 20 – Continuous waveform

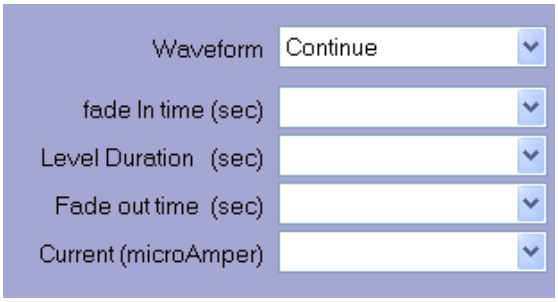
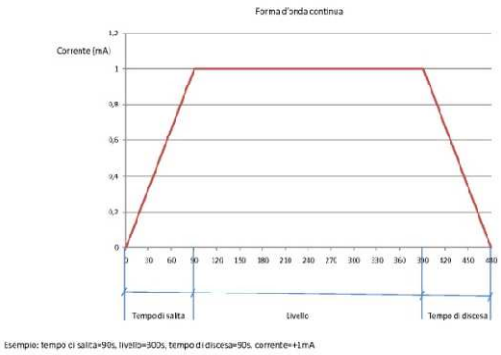


Figure 21 – Parameters for continuous waveform



- **Pulsed**, consisting of a sequence of rectangular impulses, of which it is possible to select the intensity, the duration and the interval between subsequent impulses.

  Pulse duration – expressed in ms
  A value of between 50ms-2500ms, in steps of 50ms may be entered.

  Inter-pulse time - Times between 2 impulses – expressed in ms.
  A value of between 100ms – 2500ms may be entered, in steps of 50ms.

  Repetitions – number of repetitions
  A value of between 1-500, may be entered, in steps of 1.

  Current – expressed in µA
  A maximum value of ±5000µA, in steps of 25µA, may be entered.

  Description – free annotation field.

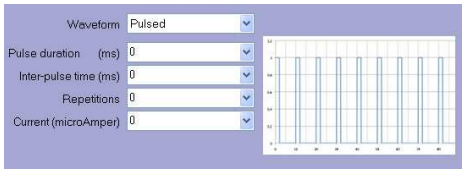


Figura 22 – Pulse waveform

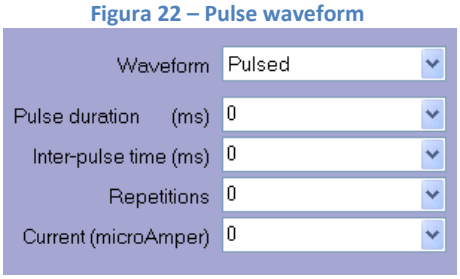


Figura 23 – Pulse waveform parameters

- **Sine semi cycles**, consisting of repeated sinusoidal semicycles of which the duration, number of repetitions and intensity may be selected.

  Semi-cycle duration – expressed in s
  A value of between 1s and 3600s may be entered, in steps of 1s.

  Repetitions - number
  A value of between 1 and 3600 may be entered.

  Current – expressed in µA
  A maximum value of ±5000µA may be entered, in steps of 25µA.

  Description – free annotation field.

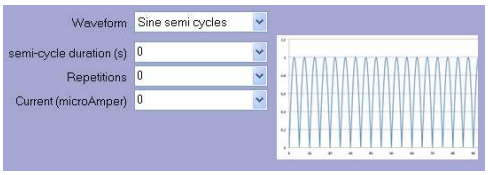


Figure 24 – Sinusoidal semicycle waveform

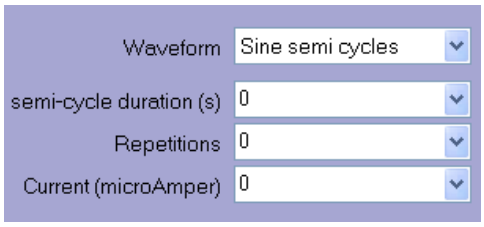


Figure 25 – Sinusoidal semicycle parameters

- **One sine cycle**, consisting of a sinusoidal cycle of which the duration and intensity may be selected.

  Stimulation duration – expressed in ms
  A value of between 10ms – 100s may be

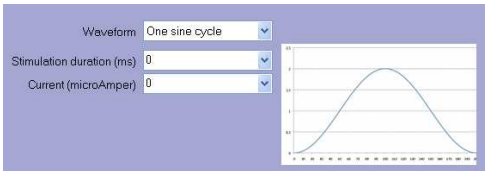


Figure 26 – A sinusoidal cycle waveform

entered (in steps of 10ms).

Current – expressed in µA
A maximum value of ±5000µA may be entered in steps of 25µA, starting from 25 µA.

Description – free annotation field.

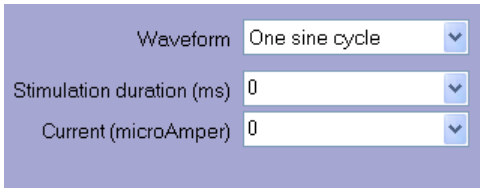


Figure 27 – A sinusoidal cycle waveform parameters

- **Sine Cycles**, consisting of repeated cycles of sinusoids to which an offset of variable width has been superimposed, thus enabling the frequency, intensity and width of the offset to be selected.

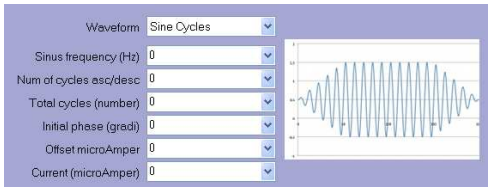


Figure 28 – Sinusoidal cycle waveform

Sinus frequency – expressed in Hz
A value of between 0.1Hz to 250 Hz may be entered, in steps of 0.1Hz.

Number of cycles asc/desc– number
A number of between 0 and 100 may be entered, in steps of 1 cycle.

Total cycles (number) – number
A number of between 1 and 50000, may be entered, in steps of 1 cycle.

Initial phase – expressed in degrees
A value of between 0 and 360 degrees may be entered, in steps of 5 degrees.

Offset – expressed in µA
A maximum value of ±1000 µA may be entered, in steps of 10 µA.

Current – expressed in µA
A maximum value of ±5000µA may be entered, starting from 100 µA and in steps of 100 µA.

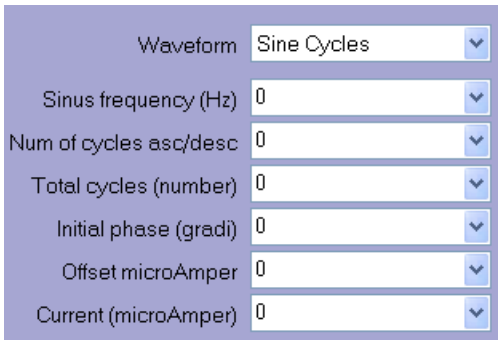


Figure 29 - Sinusoidal cycle waveform parameters

Description – free annotation field.

- **Coloured noise**, consisting of repeated excerpts of full band colored noise consistente nella ripetizione di brani di rumore colorato a banda piena.

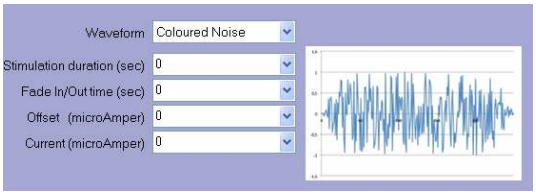


Figure 30 – Colored noise waveform

Stimulation duration – expressed in sec.
A value of between 5s and 3600s may be

entered, in steps of 5s.

Fade In/Out time – expressed in sec.
A value of between 0s and 120s may be entered, in steps of 1s.

Offset – expressed in µA
A maximum value of ±1000 µA may be entered, in steps of 10 µA.

Current – expressed in µA
A maximum value of ±3000 µA may be entered, in steps of 25 µA.

Description – free annotation field.

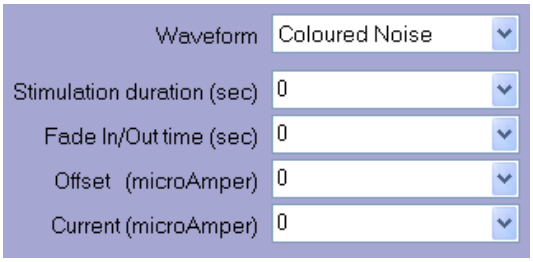


Figure 31 - Colored noise waveform parameters

- **High Frequency Noise,** consisting of the repetition of excerpts of colored noise limited to high frequencies (approximately 100Hz upwards).
Stimulation duration – expressed in s
A value of between 5s and 3600s may be entered, in steps of 5s.

Fade In/Out time – expressed in s
A value of between 0s and 120s may be entered, in steps of 1s.

Offset – expressed in µA
A maximum value of ±1000 µA may be entered, in steps of 10 µA.

Current – expressed in µA
A maximum value of ±3000 µA may be entered, in steps of 25 µA.

Description – free annotation field.

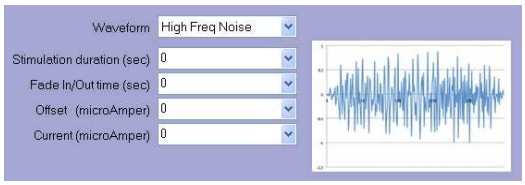


Figure 32 – High frequency noise waveform

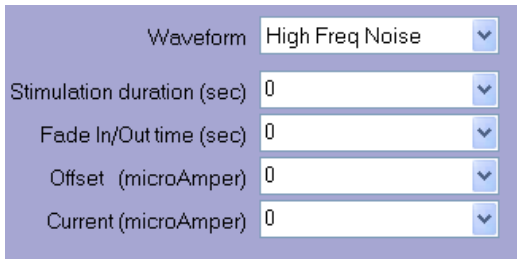


Figure 33 - High frequency noise waveform parameters

- **Low Frequency Noise**, consisting of the repetition of excerpts of colored noise limited to low frequencies (below approximately 100Hz).

Stimulation duration – expressed in s
A value of between 5s and 3600s may be entered, in steps of 5s.

Fade In/Out time – expressed in s
A value of between 0s and 120s may be

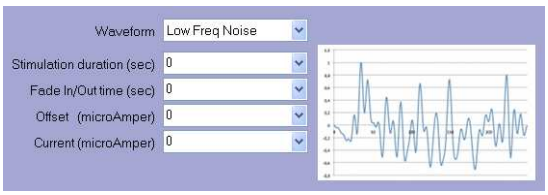


Figure 34 – Low frequency noise waveform

entered, in steps of 1s.

Offset – expressed in µA
It is possible to enter a maximum value of ±1000 µA, in steps of 10 µA.

Current – expressed in µA
A maximum value of ±3000 µA may be entered, in steps of 25 µA.

Description – free annotation field.

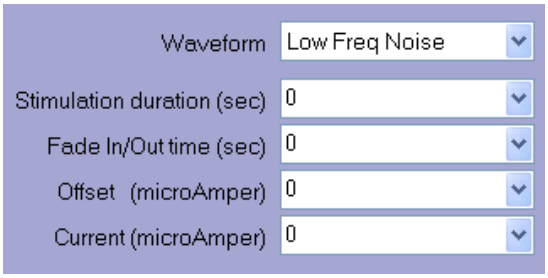


Figure 35 - Low frequency noise waveform parameters

- **Sham, uni-directional (positive only),** consisting of a rising ramp, a level, an interval with no stimulation current, a level and a falling ramp. The rising ramp enables the stimulation current to be progressively increased up to the programmed value within the desired time; the level has a programmable duration during which the stimulation current is constant; the interval with stimulation current has a programmable duration; the level has a programmable duration during which the stimulation current is constant and is followed by a falling ramp which enables the stimulation current to be reduced gradually, within the desired time, from the value reached during the level down to zero.

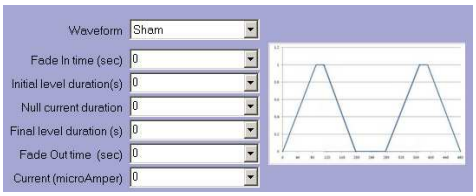


Figure 36 – Sham waveform

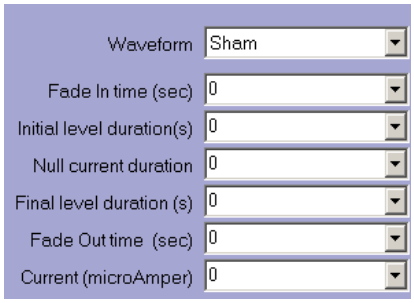


Figure 37 - Sham waveform

Fade In time – expressed in s
A value of between 1s - 180s may be entered

Initial level duration – expressed in s
A value of between 1s - 300s may be entered

Null current duration – expressed in s
A value of between 1s - 3600s may be

entered

Finale level duration – expressed in s
A value of between 1s - 300s may be entered

Fade Out time – expressed in s
A value of between 1s - 180s may be entered

Current – expressed in µA
A maximum value of ±5000µA, adjustable in steps of 25µA with the ramps starting from 0 (zero current).

Description – free annotation field.

Having defined the stimulation parameters, press *"Save"* to save the protocol. Once the protocol has been saved, the protocol list will be updated.

Therefore, to return to our open treatment cycle, click on *"Protocols List"*. The protocol search window will open (fig. 12). Down below, the new protocol you have just saved will appear under "*Selected record*" (fig. 30).

Double click to select the new protocol or to perform a new search.

By clicking on the chosen protocol, you will return to the page of the treatment cycle from which you started (fig. 11).

Lastly, the following buttons are available on the left hand side of the screen (fig. 39):

Used by...– shows the list of treatment cycles in which it was used, including the patient's name,

Save – enables you to save the parameters set,

Delete – enables you to delete the new protocol and return to the protocol management page (fig. 14). Before finally deleting the data, the operator is asked for

Code	Name	Waveform	Owner
01	TEST	Continue	SYST...
02	SHAM	Sham	SYST...

Figure 38 – Selected record

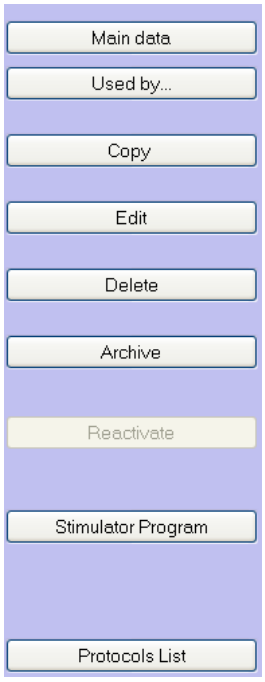


Figure 39 – Details of active buttons

further confirmation,

Archive– enables you to file the protocol. This function is not allowed if there are still any active treatment cycles associated with the protocol,

Stimulator Program – for quick programming of the stimulator.

Protocols list – to return to the protocols list,

When they have already been used in at least one active treatment cycle, the *"Modify"* and *"Delete"* buttons are not active. It is not possible to delete a protocol after using it in at least one treatment cycle.

Press "*Protocols list*" to return to the treatment cycle

Program Stimulator

Once you have set up the treatment cycle, as described above, it is possible to program the stimulator.

In fact, by pressing *"Add"*, the chosen protocol will be shown in the table in the center of the screen (fig. 32) and the *"Stimulators Program"* button becomes active again.

In order to program the stimulator, **it is necessary to check that the stimulator is on and that the Bluetooth is connected**. See the chapter "**Stimulator User Guide**" for instructions on how to switch on the stimulator and Bluetooth.

Click on "*Stimulators Program*" and the control message "*Connect the first stimulator"* (fig. 41) will appear.

By selecting Yes the previously defined treatment cycle will be transferred to the stimulator. During the data transfer the stimulator's internal clock will be synchronized with that of the personal computer to which it is connected.

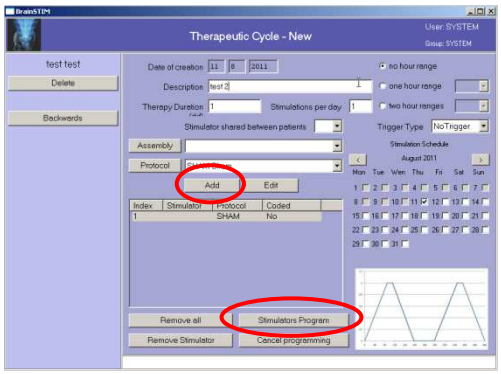


Figure 40 – Programming the Stimulator

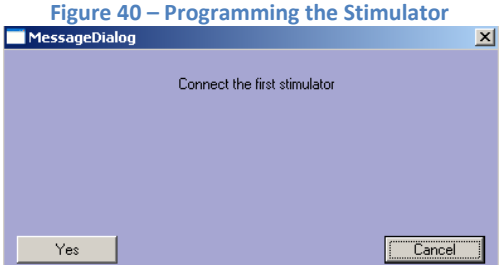
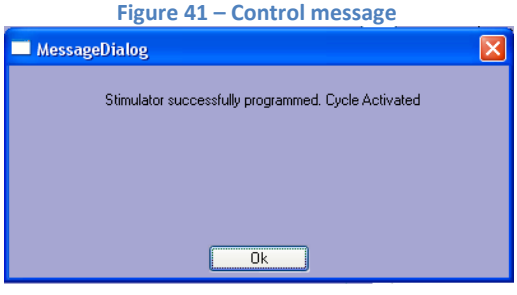


Figure 41 – Control message



Once the transfer has been completed sucessfully, a message of confirmation will appear *"Stimulator successfully programmed. Cycle Activated"* (fig. 42). From now on the stimulator will be capable of delivering the stimulation.

Programming several stimulators

Should you wish to program several stimulators, repeat the instructions given above.

In fact, by pressing "Add" a second time, the chosen protocol will be added to the table in the center of the screen (fig. 43) and the *"Stimulators Program"* will remain active.

Repeat the operation for the required number of stimulators.

By clicking on *"Stimulators Program"* the control message "Connect the first stimulator] will appear (fig. 41).

Select [Yes] to program the first stimulator. Once the transfer has been completed sucessfully, a message of confirmation will appear *"Stimulator successfully programmed. Connect the stimulator number 2"* (fig. 44)

Repeat the operation for the required number of stimulators. When all the required stimulators are programmed, they will be capable of delivering the stimulation.

The following buttons are also available on the left hand side of the screen:

Delete – to delete the treatment cycle and return to the patient management page,

Backwards – to return to the management page of the selected patient.

Figure 42 – Stimulator programmed successfully

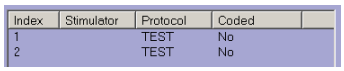


Figure 43 – Programming several stimulators

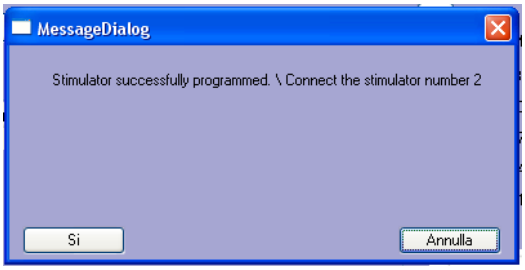


Figure 44 – Program confirmed message

Figure 45 – Details of buttons

Error message

In the event of problems connecting to the stimulator the program will give the following error message: *"Error while programming the stimulator. Stimulator not present. Reconnect stimulator number XX"* (fig. 46)

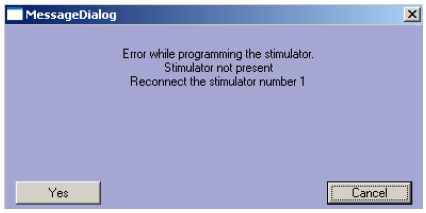


Figure 46 – Problems connecting with the stimulator

Check that the stimulator is switched on.
If it is not on, repeat the operation by clicking on "Yes" after switching on the stimulator and connecting the Bluetooth.
Alternatively go to the instructions in the **"Bluetooth Connection"**chapter.

Error message 2

Should you try to program a stimulator that is still associated to another active cycle, the program will give the following message: "Stimulator associated to another active cycle, connect another stimulator! Stimulator number 1 being programmed"

Due to safety and data protection reasons it is not possible to program a stimulator while it is associated to an active cycle, so you must close it and repeat the programming.

Active Cycle

After programming the stimulator, the treatment cycle becomes an active cycle.

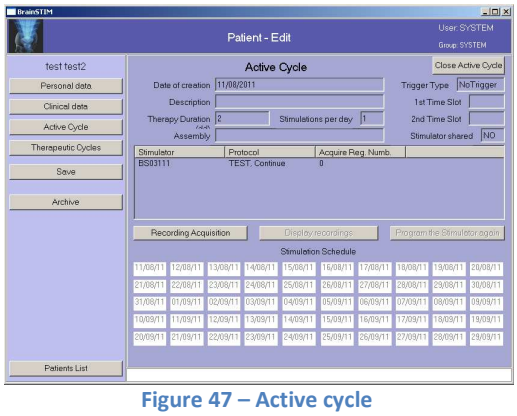


Figure 47 – Active cycle

A page (fig. 40) will then appear with the serial number of the programmed stimulator, the code and name of the chosen protocol and the number of recordings made, in the center. This number will remain 0 until the data has been downloaded (fig. 41).

The "Recording Acquisition" button which enables you to download the data acquired from the stimulator, is active.

There is a calendar scheduler in the lower part of the screen, which will be used to highlight the days in which treatment was carried out.

The following buttons on the left hand side of the screen area also active: (fig. 49)

Personal Data – to display the patient's personal details,

Clinical Data – to display the clinical data,

Active Cycle – to return to the page for the open active cycle,

Therapeutic Cycles – to display the treatment cycles which have already ended,

Edit – to modify the patient's personal and clinical data,

Archive – to file a patient's details, only if the treatment cycle has finished,

Patients List – to return to the list of active patients.

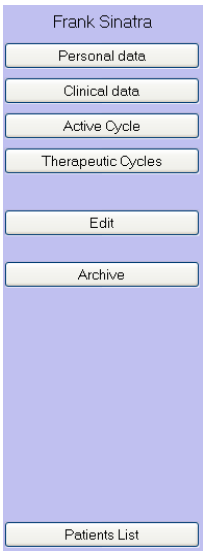


Figure 48 – Details of buttons

Data transfer

Once the stimulation sessions have been carried out, it will be possible to transfer the recorded data.

In order to transfer the stored data **it is necessary to check that the stimulator is on and that the Bluetooth is connected**. Refer to the chapter "**Stimulator User Guide**" for the instructions on how to switch on the stimulator and the Bluetooth.

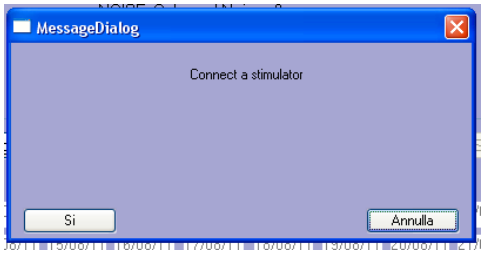


Figure 49 – Data transfer

Click on "Recording Acquisition" and the control message will appear: "Connect a stimulator " (fig. 50). Controlla rif a fig.

By selecting "Yes", the stored data will be transferred to the personal computer.

If the transfer is successful, a confirmation message witll appear "Acquisition ended. X new events acquired, associated to X new stimulations. Acquisition ended successfully."

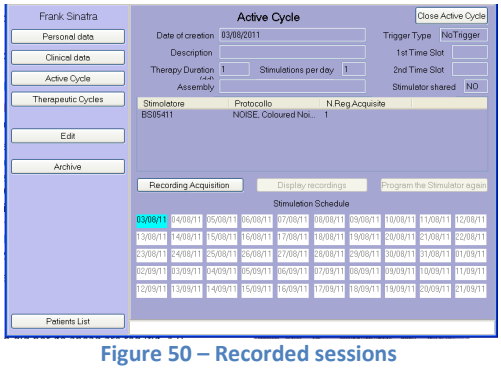


Figure 50 – Recorded sessions

The recorded data is displayed in calendar form: the days without sessions are white, those in which all went well are green, those in which there were problems are yellow, those in which the session did not go ahead are red (fig. 51).

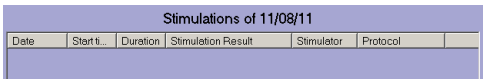


Figure 51 – Session details

Lastly, by clicking on a day, a window will open containing details of the stored information: relevant dates and times, any alarms due to detached electrodes or high impedence of the same, battery alarms and forced interruptions to the stimulation (fig. 52).

To go back, select the "*Backwards"* button.

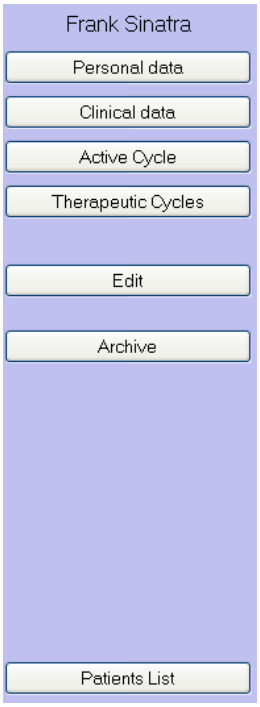


Figure 52 – Details of buttons

The following buttons on the left hand side of the screen area also active: (fig. 53)

Personal Data – to display the patient's personal details,

Clinical Data – to display the clinical data,

Active Cycle – to return to the page for the open active cycle,

Therapeutic Cycles – to display the treatment cycles which have already ended,

Edit – to modify the patient's personal and clinical data,

Archive – to store a patient's details, only if the treatment cycle has finished,

Patients List – to return to the list of active patients.

Error message

In the event of problems connecting to the stimulator the program will give the following error message: *"Stimulator not connected. Connect the stimulator".*

Check that the stimulator is switched on.

If it is not on, repeat the operation by clicking on "Yes" after switching on the stimulator and

connecting the Bluetooth.

Alternatively refer to the instructions in the **"Bluetooth Connection"**chapter.

Export

In order to export the data, press on the *"Export"* button on the first patient management page.

A page will appear (fig. 55) in which the list of all the active patients is shown on the left.

The following data may be exported in excel format:

Database – select the Database button to export the entire patient database,

Patient name – click on patient name to export all the data concerning that patient.

After selecting the *patient name* or pressing the *Database* button, a dialogue box will open, enabling you to save or open the file (fig. 56).

Data saved in excel format contain:

identification code, name, surname, date of birth, place of birth, date cycle was created, description of treatment cycle, duration of cycle (days), number of stimulations per day, date treatment cycle closes, stimulator, protocol, date-time-start-recording, recording date, recording outcome (fig. 57).

The following buttons are also active:

Protocols – to go to protocol management,

Patients – to return to patient management,

Archive – to export the patient data to the archive,

Exit – ends the program.

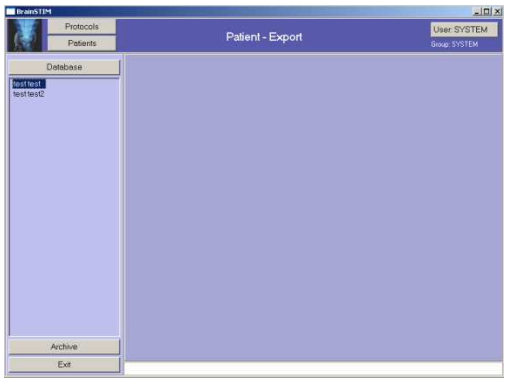


Figure 53 – Export

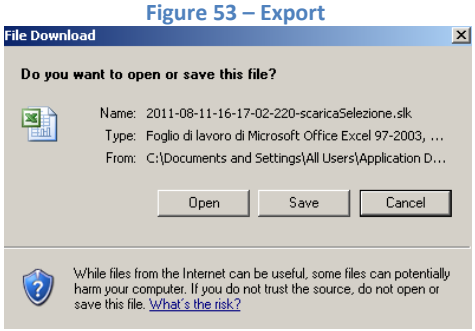


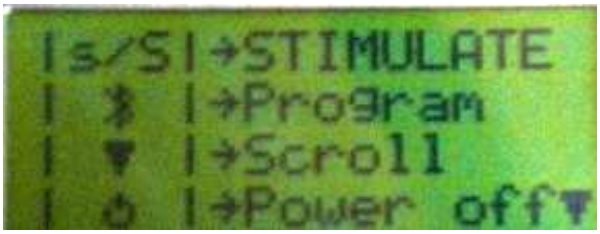
Figure 54 – Message for exporting data

Figure 55 – Example of exported data

6. Stimulator User Guide

In order to start up the stimulator, press the on/off button (green) for more than 4 seconds. After 4 seconds of pressure the green LED positioned above the switch will light up and the stimulator will display a welcome page for approximately 4 seconds.

It will then enter wait mode, displaying the following page

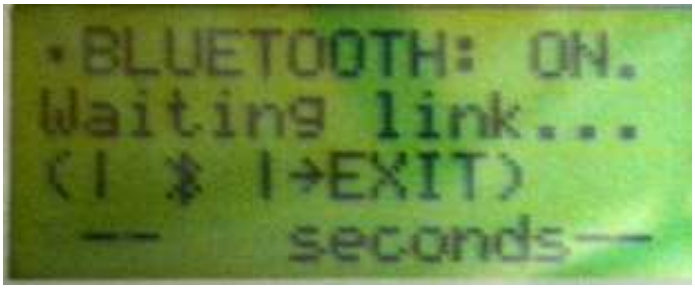


At this point there are four possible choices:

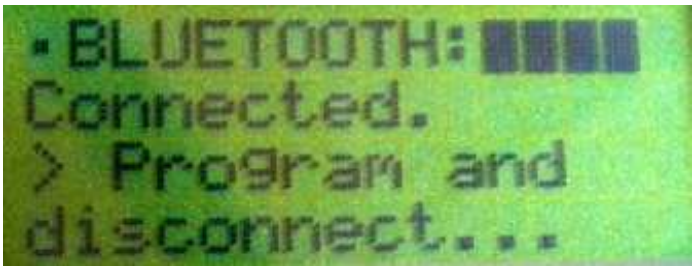
1. If the stimulator has previously been programmed, start a stimulation session by pressing the yellow **START/STOP** button.
2. If the stimulator has not already been programmed, program it, connecting it to a personal computer provided with a Bluetooth connection on which the software for managing the BrainSTIM stimulator has been installed. Then press the blue button bearing the Bluetooth symbol. Program the stimulator in the same way each time you wish to enter a new treatment protocol.
3. Scroll through the programming data, by pressing one of the two black buttons with a white arrow.
4. Switch off the stimulator, keeping the green on/off button pressed down for more than 4 seconds. When the button has been pressed for more than 4 seconds the green LED situated above the green key goes off, indicating that the stimulator has been switched off.

PROGRAMMING

In order to program the stimulator, after activating the BrainSTIM management software as indicated previously and having paired the stimulator with the Bluetooth channel of the personal computer, press the blue button bearing the Bluetooth symbol. The page below will be displayed

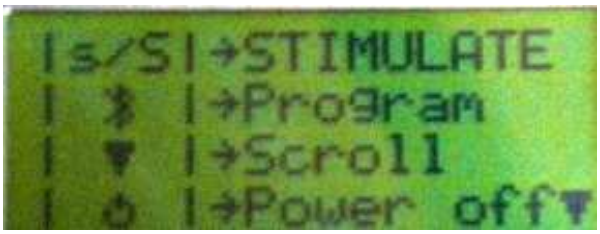


The stimulator will wait to be connected for 90 seconds in this condition. If the connection does not take place within this time, the previous page will be shown, or the page below will appear



During the programming phase the blue LED situated over the blue button will flash very briefly to indicate that data is passing between the stimulator and the personal computer. When the management software has programmed the stimulator, the following page will be shown

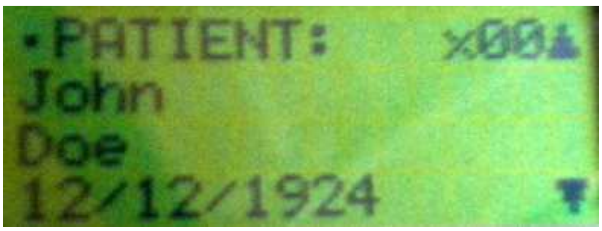
After approximately 4 seconds the main page will appear again



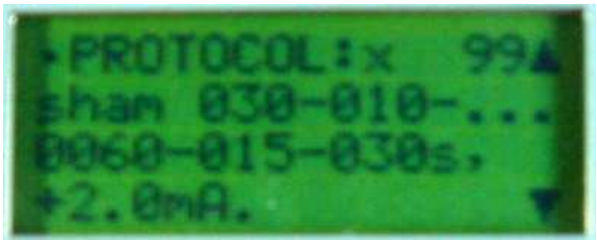
Checking the parameters describing the treatment protocol

In order to check the parameters describing the stimulation program, press the black button bearing the white triangle pointing downwards. The first page will appear, containing the following:

The patient's name and surname, date of birth and number of stimulations performed, in this case 1.



The two arrows shown on the right hand side of the screen indicate that it is possible to scroll up – to return to the main window – or down, to move on to the second page, which starts the description of the treatment protocol

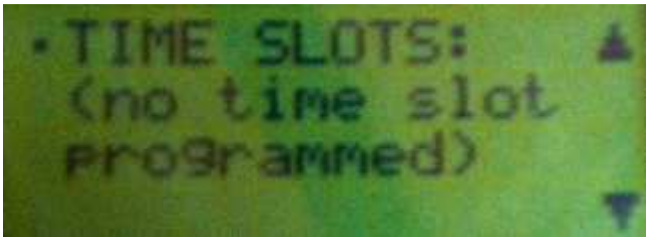


First of all the number of stimulations programmed is shown – in this case 2.

The row below shows the stimulation waveform – in this case continuous – then, the line below shows the parameters describing the waveform – in this case the duration of the ramp-up (1s) the constant level (60 s) and the ramp-down (1s) – and lastly, in the line below, the intensity of stimulation – in this case corresponding to the constant level (-5 mA) –

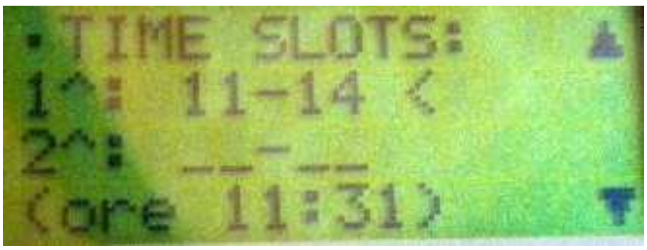
Press the up arrow to return to the previous page.

By pressing the down arrow again a new page will appear



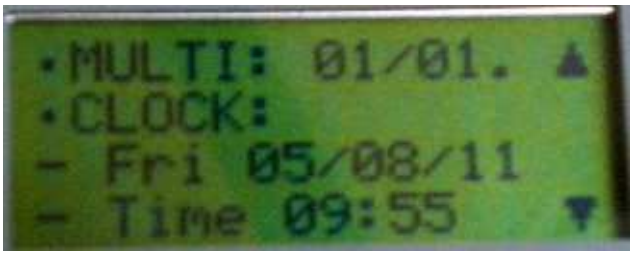
which lists, where present, the programmed time slots. The time slots may be one or two and are binding, so that the treatment must be carried out within the time slots defined. If no time slots have been defined, the treatment may be carried out at any time of day.

In the example given here, only one time slot has been programmed, between 11 a.m. and 2 pm . The second time slot is indicated, if present, in the line below – in this case it has not been chosen. The last line gives the current time.



Press the up arrow to return to the previous page.

By pressing the down arrow again the following page will appear



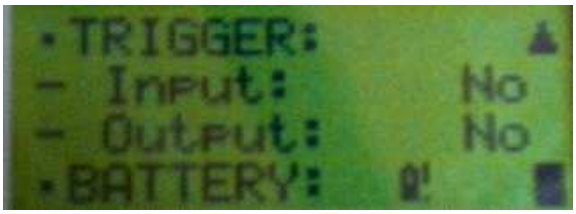
relating to the number of the stimulator (MULTI) – in this case 2 – with respect to the number of stimulators used at the same time, where applicable – in this case 3. Guidelines for using several stimulators at the same time and their possible synchronization will be given below.

It also contains information on the system clock, which indicates the current date and time. The system's clock is synchronized to the personal computer's clock during the stimulator programming phase. The stimulator's clock is powered by a specific battery (CR2032) inserted in a support on the stimulator's printed circuit and guarantees that the clock can work for years even if the stimulator's batteries are low or have been removed from the battery slot.

Press the up arrow to return to the previous page.

Press the down arrow again and the last page will appear.

which describes the trigger status – in program, out program, both or neither – and the battery pack status. Do not start treatment unless the battery status is given as **OK**.

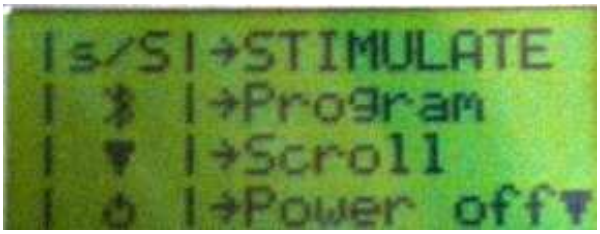


Should this not be the case, replace the battery pack or accumulators with a new one – if batteries – or charged – if accumulators.

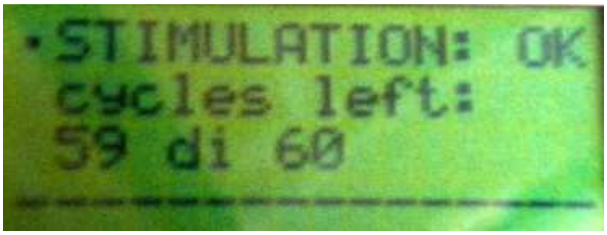
It is only possible to go back to previous pages from this mask.

Stimulation

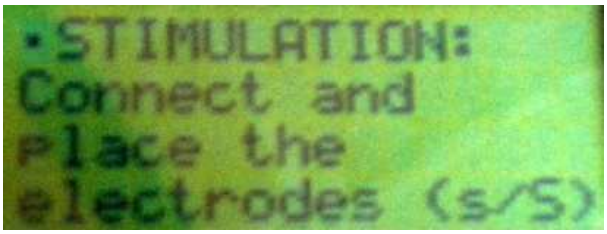
From the main page



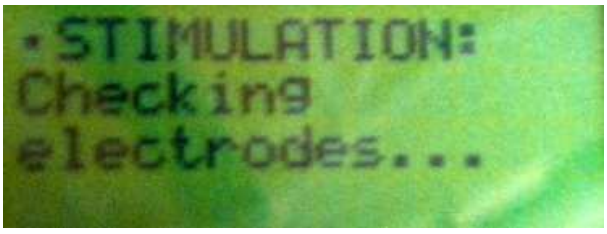
Press the yellow **START/STOP** button to begin a treatment. The following page will appear



which indicates the number of stimulations that are still possible – in this case 97 of 99 stimulations. After a few seconds the following page will appear

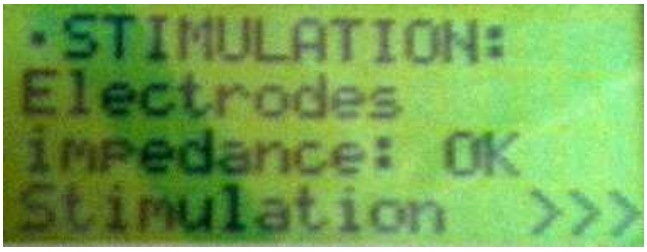


which asks you to position the stimulation electrodes. When the electrodes are positioned on the skin, press the yellow **START/STOP** button again to start the stimulation. At this point the following page will appear

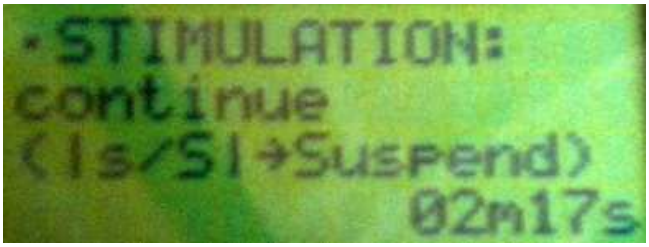


In this phase, the stimulator will measure the impedence of the electrodes by letting a continuous current of an intensity of 500µA flow for approximately 1 second. At the end of the check, if the impedence of the electrodes is lower enough to allow the generation of current

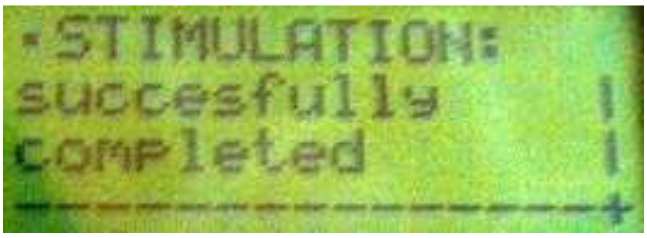
intensity set by the current protocol, a warning beep will sound and the stimulation will begin. The following page will also appear



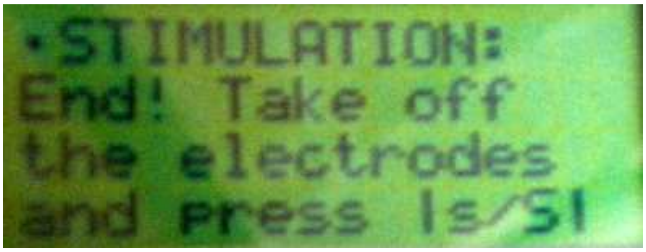
The stimulation begins after a warning given by a short beep, followed by the page



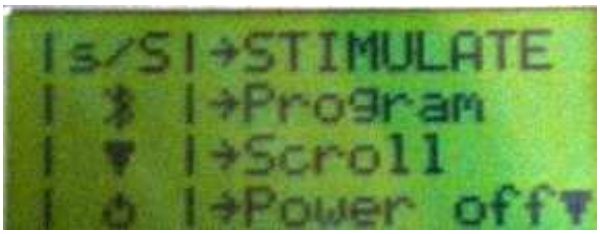
showing the activity (STIMULATION), the chosen waveform – in this case continuous – and the instruction to press the **START/STOP** button to interrupt the stimulation temporarily. During the stimulation the yellow LED situated above the yellow **START/STOP** button is on. If the stimulation continues until the end without the operator stopping it and without the electrodes becoming detatched from the skin, the yellow LED will go off at the end of the stimulation and the following page will appear



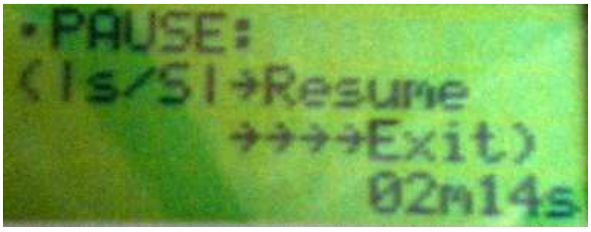
which will be replaced by the following page after 4 seconds:



Now the operator can detach the electrodes from the stimulator, and press the **START/STOP** button and reach the main page.

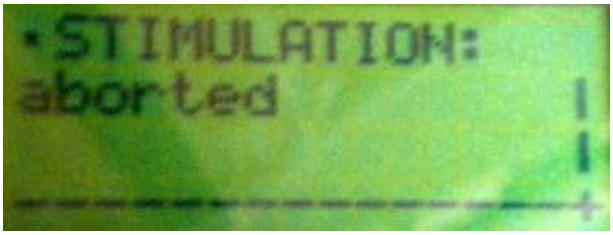


If the yellow **START/STOP** button is pressed during the stimulation, the stimulation is temporarily interrupted, the yellow LED goes off and the following page appears

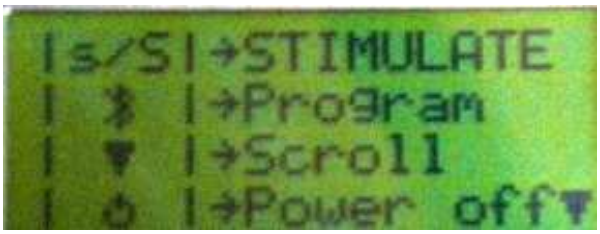


At this point, if the yellow **START/STOP** button is pressed again, the stimulation will continue, the yellow LED will go on again and the stimulation mask shown previous to the interruption will return. The stimulation will then continue until the end, unless it is interrupted again; in any case, the actual duration of the stimulation, if ended correctly, will be exactly as programmed, in the sense that any pause time during interruptions will not be counted.

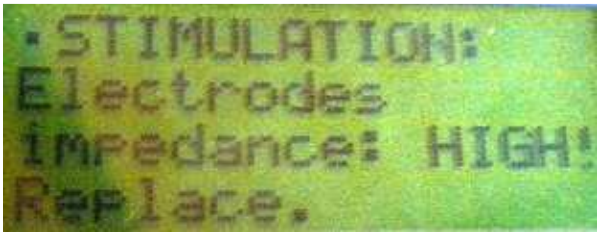
However, if the patient wishes to finally stop the stimulation session, the yellow **START/STOP** button must be pressed for more than 4 seconds. When the button is released the stimulation session will end and the following page will appear



which will disappear automatically after approximately 4 seconds to be replaced by the main page

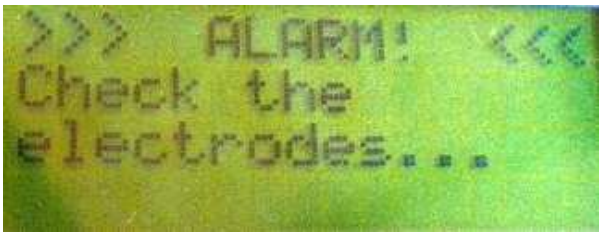


However, if the impedence of the electrodes is found to be too high (greater than 5 kΩ) before starting the stimulation, the following page will appear



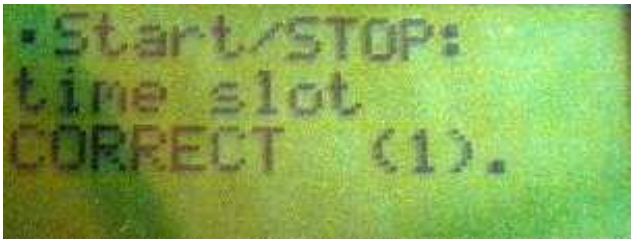
which requires verification of the positioning of the electrodes and the check to be repeated.

Should the electrodes disconnect or become appreciably detatched from the skin during the stimulation, on reaching saturation in the final stage, the following page will appear

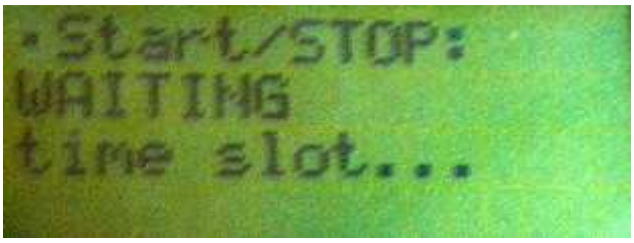


which requires an inspection of the electrodes to ensure they are positioned correctly and which allows the stimulation to continue by pressing the yellow **START/STOP** button briefly or to terminate the session by pressing the same yellow button for more than 4 seconds.

If time slots have been set, the time of stimulation will also be checked before proceeding with the stimulation. At the end of the check, if all is correct, the following page will appear

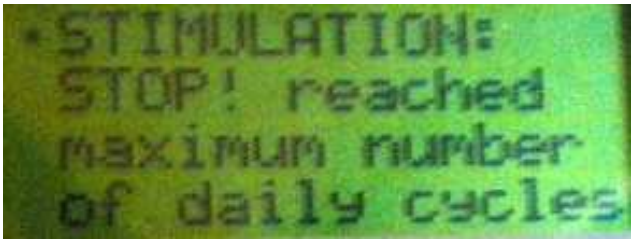


Otherwise it will not be possible to deliver the stimulation and the following message will appear



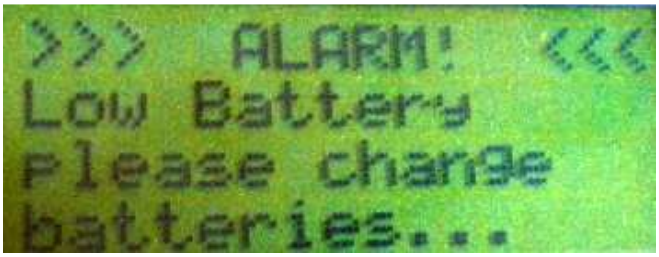
asking the operator to wait for the correct time.

At the end of the treatment cycle, the following page will appear



and it will no longer be possible to deliver further stimulations.

The following alarms are also present



When this message appears, the battery pack or accumulators must be replaced with a new one – if batteries – or charged – if accumulators.

To switch off the stimulator, from any page, press the green on/off button for more than 4 seconds.

7. Maintenance and cleaning

The BrainSTIM stimulator does not require any ordinary maintenance by the user.

CLEANING: the stimulator container must be cleaned, if necessary, with a soft cloth dampened with a neutral detergent, taking care to avoid wetting the connectors of the stimulator cables and that of the trigger.

To remove traces of grease from the methacrylate covering the display, due to handling the stimulator, rub the surface delicately using chamois leather or a microfibre cloth of the type used to clean spectacle lenses.

CLEANING THE ELECTRODES: use water and neutral soap to clean conductive rubber electrodes, rinsing them carefully and drying them delicately with a dry, clean cloth.

The sponge electrode sleeves should be cleaned by immersing them in a solution of water and neutral soap, rinse carefully and leave them to dry in the air, without squeezing them. Do not put the sponge electrode sleeves back in their plastic covers while they are still damp as this can encourage mould to develop in the sleeves.

VISUAL INSPECTION OF THE INTEGRITY OF THE CABLES: before the stimulation sessions and at least every six months on a routine basis, check the integrity of the insulation of the stimulation cables and connectors. Replace any worn material immediately.

VISUAL INSPECTION OF THE INTEGRITY OF THE ELECTRODES: before each treatment check that the stimulation electrodes are clean and the surface which comes into contact with the skin is visually even and whole. Replace any damaged electrodes immediately, as using them increases the probability of producing chemical-type burns on the patient's skin beneath the electrodes.

REPLACING THE ACCUMULATORS: replace worn out accumulators when necessary with a pack of recharged accumulators or non-rechargeable AA-type batteries, taking care to respect the polarity indicated in the battery housing.

	Take care to respect the polarity of the accumulators when replacing them: Warning: the stimulator may be damaged if the indicated polarity is not respected.

WARNING: in order to access the battery housing, it is necessary to remove the lid first, using a suitable tool (for example a screwdriver) only.

Do not dispose of accumulators that are no longer usable or worn out batteries in the environment; use the appropriate waste disposal collection bins available in eco-centers or electrical retailers.

	Warning: if you are not intending to use the BrainSTIM for a long time, you must remove the batteries from the battery housing.

8. Respect for the environment

If you want to dispose of a stimulator you no longer use, or one which is no longer working, treat it as “electronic material” and return it to the distributor or take it to the appropriate consortium, instead of putting it in an urban refuse container.

Likewise do not dispose of spent batteries, or rechargeable accumulators which have reached the end of their life, into the environment; use the containers available at eco-centers or at many electrical retailers instead.

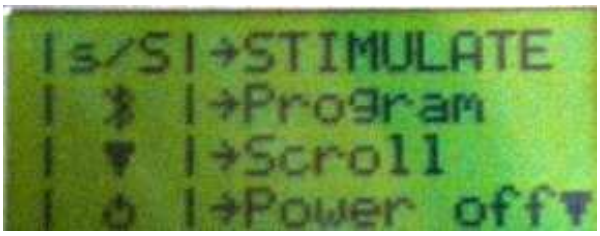
9. Operating instructions for patients

Once the stimulator has been programmed by the physician, it contains the maximum number of stimulations to be delivered during the course of the treatment program, and, if the physician deems it appropriate, the time slots in which the stimulation sesssions are to be performed and all the parameters defining the stimulation program which must be followed. None of this data can be changed by the patient. When all the stimulation sessions programmed by the physician have been carried out, the stimulator will cease to function and must be returned to the physician who will read the memory and if necessary re-program a new cycle of stimulation sessions.

1. Switching on the stimulator

Press the on/off button (green) for more than 4 seconds to switch on the stimulator. After four seconds of pressure the green LED positioned above the button will light up and the stimulator will display a welcome page for approximately 4 seconds.

It will then enter wait mode, displaying the following page



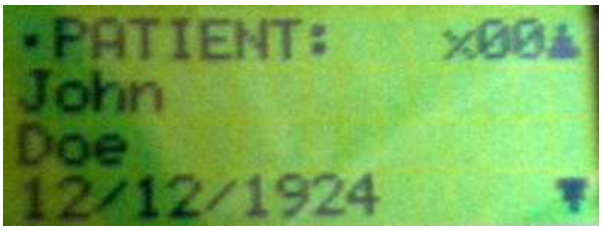
At this point the patient has three of the four possible choices:

1. If the stimulator has previously been programmed, start a stimulation session by pressing the yellow **START/STOP** button.
2. Scroll through the programming data, by pressing one of the two black buttons with a white arrow.

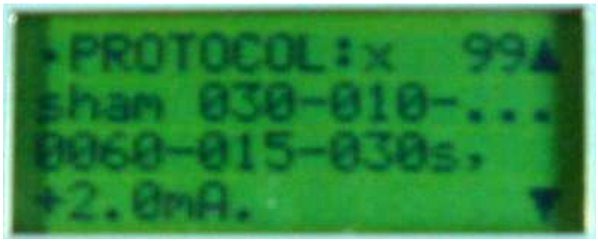
3. Switch off the stimulator, keeping the green on/off button pressed down for more than 4 seconds. When the button has been pressed for more than 4 seconds the green LED situated above the green key goes off, indicating that the stimulator has been switched off.

2. Scroll through the program data

In order to check the parameters describing the stimulation program, press the black key containing the white triangle pointing downwards. The first page will appear, containing
The patient's name and surname, date of birth and in the top right hand corner, the number of stimulations already delivered, in this case 1.



The two arrows shown on the right hand side of the screen indicate that it is possible to scroll upwards – to return to the main window – or downwards, to the second page, which starts the description of the treatment protocol

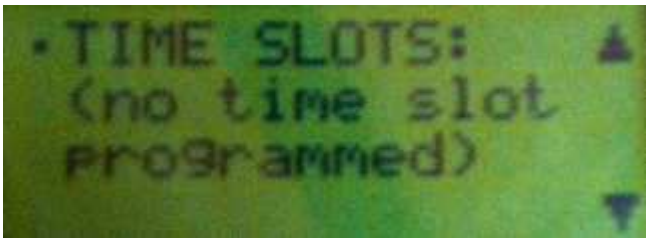


First of all, the number of stimulations programmed is shown in the top right hand corner – in this case 2.

The line below shows the stimulation waveform – in this case continuous – then, in the line below that, the parameters describing the waveform. In this case the duration of the rising ramp (1s) the constant level (60 s) and the the falling ramp (1s) – and lastly, in the line below, the intensity of stimulation – in this case -5 mA.

Press the up arrow to return to the previous page.

By pressing the down arrow again a new page will appear

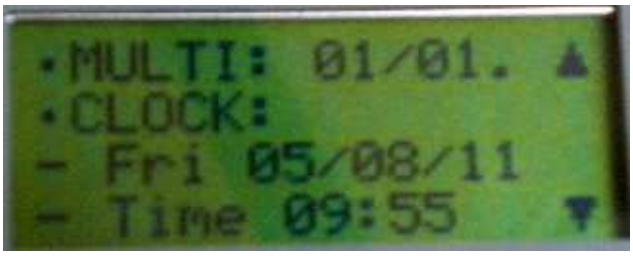


which lists, where present, the programmed time slots. The time slots may be one or two and are binding, so that the treatment must be carried out within the time slots defined. If no time slots have been defined, the treatment may be carried out at any time of day.

In the example given here, only one time slot has been programmed, between 10 a.m. and 12 noon. The second time slot is indicated, if present, in the line below – in this case it has not been chosen. The last line gives the current time.

Press the up arrow to return to the previous page.

By pressing the down arrow again the following page will appear



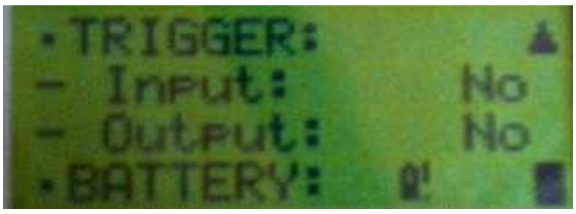
relating to the number of the stimulator (MULTI) – in this case 2 – with respect to the number of stimulators used at the same time, where applicable – in this case 3. Guidelines for using several stimulators at the same time and their possible synchronization will be given below.

The previous page also contains information on the system's clock, which indicates the current date and time.

Press the up arrow to return to the previous page.

By pressing the down arrow again the last page will appear

which describes the trigger status – input program, output program, both or neither – and the battery pack status. Do not start treatment unless the battery status is given as **OK**.

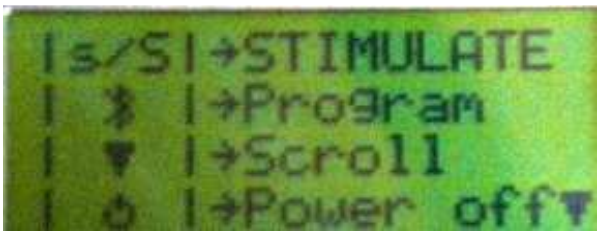


Should this not be the case, as in the page above, replace the battery pack or accumulators with a new one – if batteries – or charged – if accumulators.

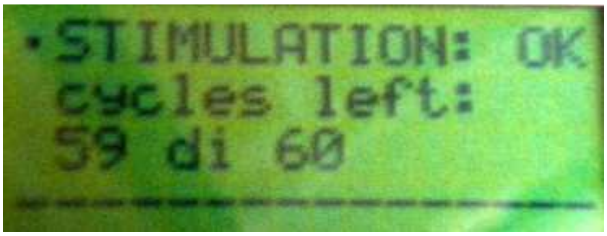
It is only possible to go back to previous pages from this mask.

3. Starting the stimulation

From the main page

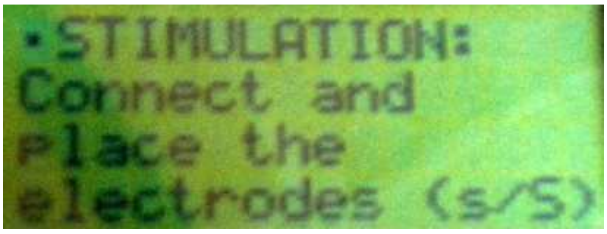


press the yellow **START/STOP** button to begin a treatment. The following page will appear

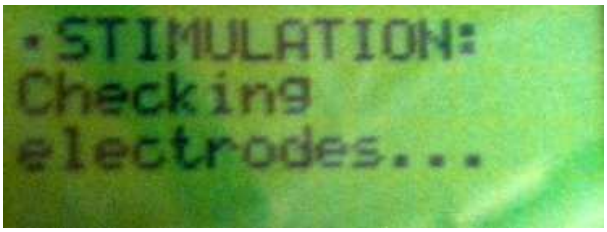


which indicates the number of stimulations that are still possible – in this case 59 of 60 stimulations.

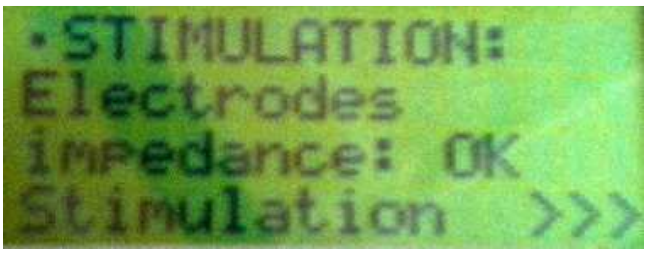
After a few seconds the following page will appear



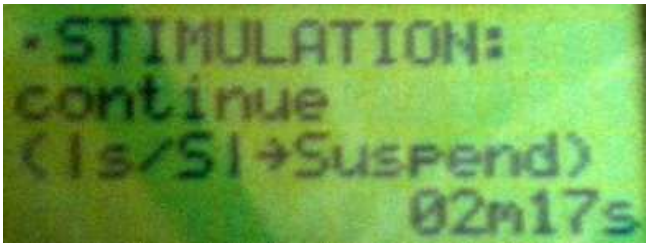
which asks you to position the stimulation electrodes as indicated by the physician. In particular, the conductive rubber electrodes must each be inserted into an electrode sleeve made of sponge which has been dampened with tap water beforehand. The two electrodes must then be connected to the appropriate cables. The red cable must then be connected to the red bush and the black cable to the black bush. When the electrodes are positioned on the skin and held in position with an elastic band, press the yellow **START/STOP** button again to start the stimulation. At this point the following page will appear



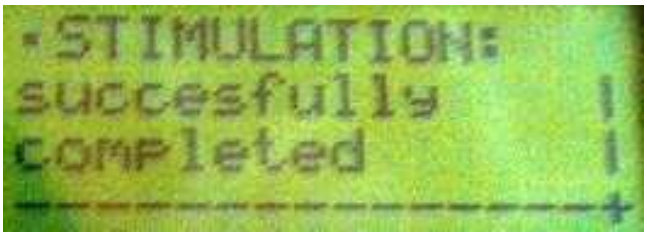
In this phase, the stimulator will measure the impedence of the electrodes by letting a continuous current of an intensity of 500µA flow for approximately 1s. At the end of the check, if the impedence of the electrodes is lower than approximately 5kΩ, a warning beep will sound and the stimulation will begin. The following page will also appear



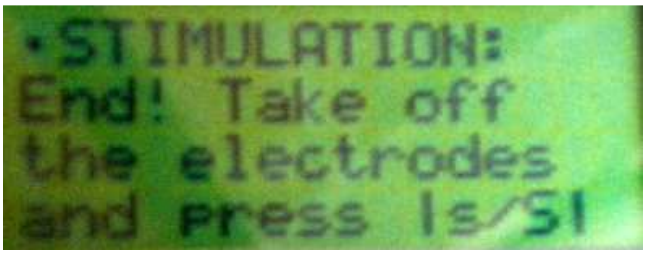
This page is followed by the one shown below which will remain active for the entire duration of the stimulation.



The above page indicates the activity (STIMULATION), the chosen waveform – in this case **continuous** – and the instruction to press the **START/STOP** button to interrupt the stimulation temporarily if needed. During the stimulation the yellow LED situated above the yellow **START/STOP** button is on. If the stimulation continues until the end without the operator stopping it and without the electrodes becoming detatched from the skin, the yellow LED will go off at the end of the stimulation and the following page will appear

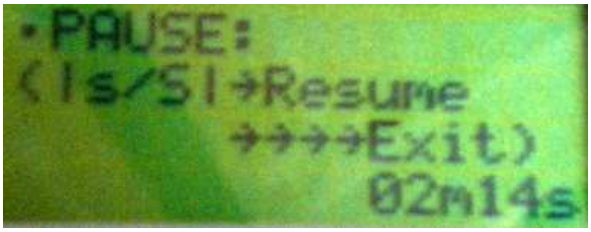


which will be replaced by the following page after 4 seconds:



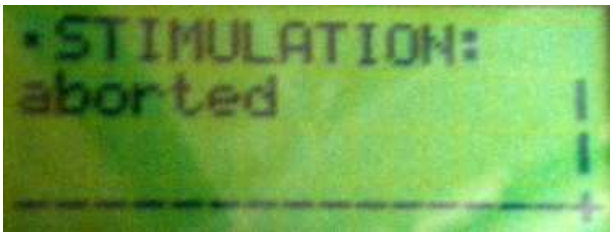
Now the operator can detach the electrodes from the stimulator, and press the **START/STOP** button and reach the main page.

If the yellow **START/STOP** button is pressed during the stimulation, the stimulation is temporarily interrupted, the yellow LED goes off and the following page appears

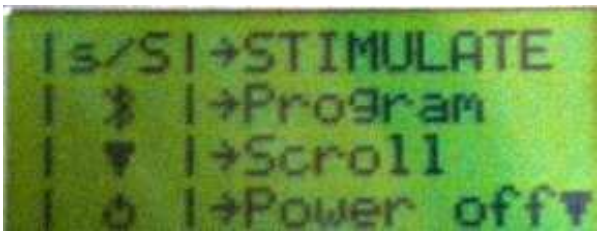


At this point, if the yellow **START/STOP** button is pressed again, the stimulation will continue, the yellow LED will go on again and the stimulation mask shown prior to the interruption will return. The stimulation will then continue until the end, unless it is interrupted again; in any case, the actual duration of the stimulation, if ended correctly, will be exactly as programmed, in the sense that any pause time during interruptions will not be counted.

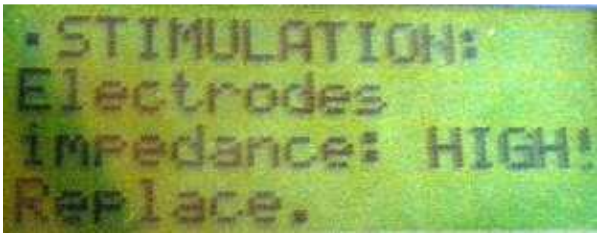
However, if the patient intends to finally stop the stimulation session, the yellow **START/STOP** button must be pressed for more than 4 seconds. When the button is released the stimulation session will end and the following page will appear



which will disappear automatically after approximately 4 seconds to be replaced by the main page

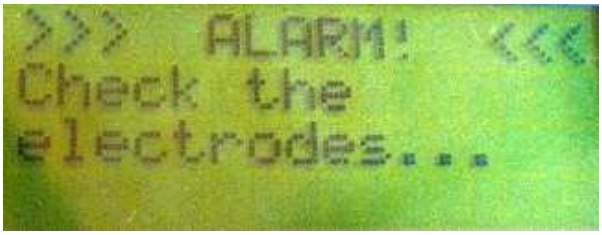


Should the impedence of the electrodes be found to be too high (greater than 5 kΩ) before starting the stimulation, the following page will appear



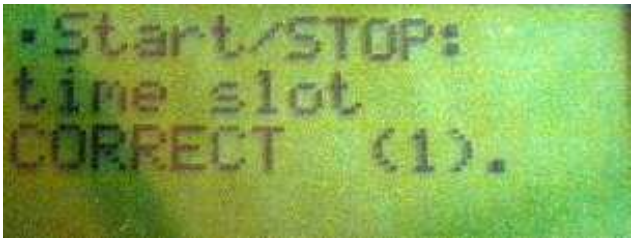
which requires verification of the positioning of the electrodes and the dampness of the electrode sleeve and the repeat of the verification.

Should the electrodes disconnect or become appreciably detatched from the skin during the stimulation, on reaching saturation in the final stage, the following page will appear

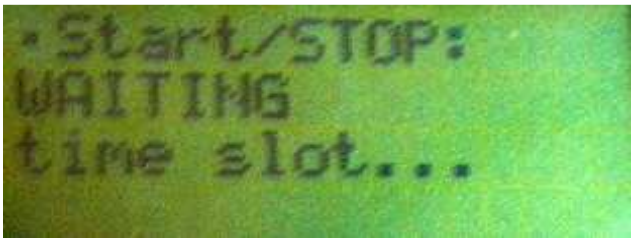


which requires verification that the electrodes are positioned correctly and allows the stimulation to continue by pressing the yellow **START/STOP** button briefly or to terminate the session by pressing the same yellow button for more than 4 seconds.

If time slots have been set, the time of stimulation will be checked before proceeding with the stimulation. At the end of the check, if correct, the following page will appear

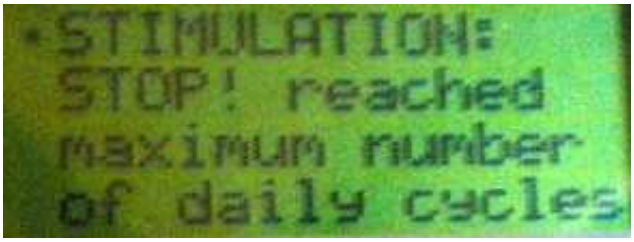


Otherwise it will not be possible to deliver the stimulation and the following message will appear



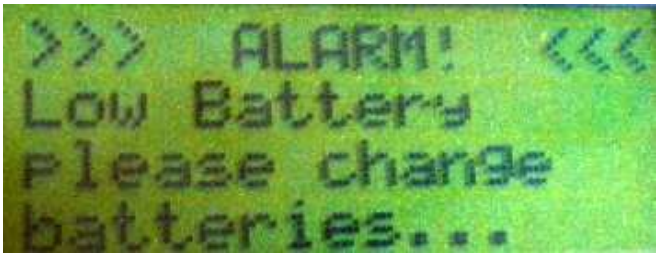
asking you to wait for the correct time.

At the end of the treatment cycle the following page will appear



And it will not be possible to deliver any more stimulation sessions.

If the following page appears, you must replace the battery pack or accumulators with a new one – if batteries – or charged – if accumulators.

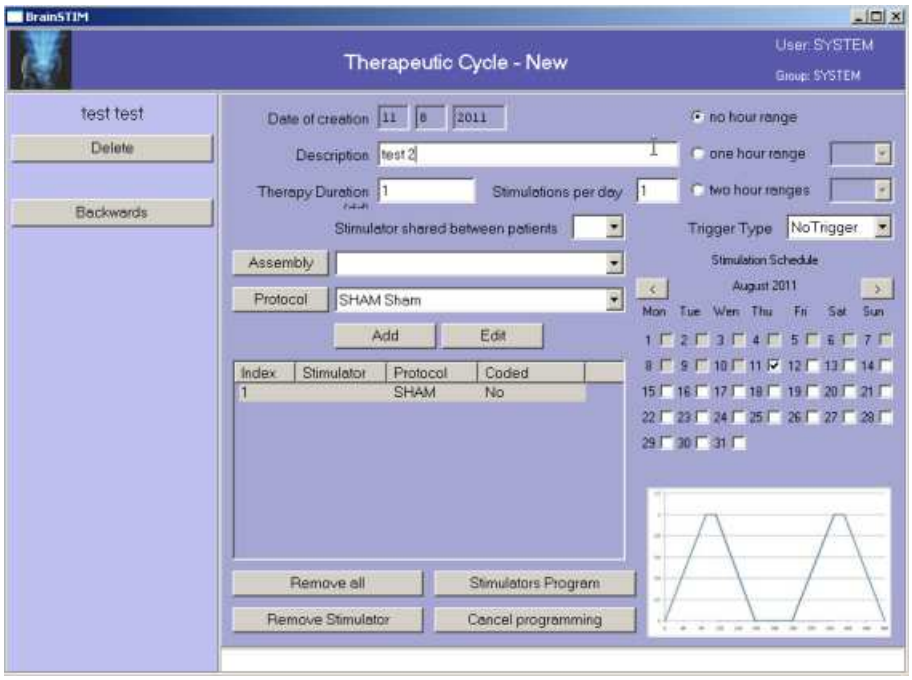


In order to switch off the stimulator, from any page, press the green on/off button for more than 4 seconds.

10. Synchronizing the stimulator

The functioning of a stimulator can synchronize other stimulators – in protocols which envisage the use of several stimulators at the same time – or may be synchronized by another stimulator, or in general another device. The stimulator must be provided with the BrianSTIM Trigger accessory and connection cables in order to perform synchronization operations.

If you wish to make use of the possibility of synchronization, you must activate the trigger input, output, or both directions, using the stimulator's programming software.



The trigger input and output levels from the BrainSTIM Trigger are compatible with the TTL standard. The BrainSTIM Trigger input and output must therefore be connected only to devices which have TTL-compatible inputs/outputs.

11. Technical characteristics

Current output	Unidirectional
Current output resolution	12 bit
Current intensity	Maximum intensity 5mA, starting from 100 µA in steps of 100 µA.
Maximum voltage output	24 V
Parts applied	BF type
Classification	Class IIa (according to Directive 93/42/EEC and subsequent amendments)
Stimulation waveforms:	
Continuous	composed of: rising ramp (1 – 180s), level (0 – 3600s), falling ramp (1 – 180s)
Pulse	composed of: impulse of a duration selectable from between 50ms and ISI – 50ms (in steps of 50ms); ISI from impulse duration + 50ms to 2.5s (steps of 50ms); number of cycles selectable from 1 to 500 (steps of 1)
Sinusoidal semicycle	Stimulation duration selectable from 10s to 3600s (in steps of 1s). Bi-directional, in either the positive or negative sense; maximum intensity ±5mA, adjustable in steps of 25µA.
A sinusoidal cycle	Stimulation duration selectable from 10ms to 100s (in steps of 10ms). bi-directional, in either the positive or negative sense; maximum intensity ±5mA, adjustable in steps of 25µA.
Sinusoid cycle with offset of Ip/2	Frequency selectable from 0.1Hz to 250 Hz (in steps of 0.1Hz up to 250Hz); The duration of rising and falling ramps is 0-100 cycles, in steps of 1 cycle; total number of cycles 1-50000 in steps of 1 cycle; Phase adjustable from 0 to 360 degrees, in steps of 5 degrees.
Colored noise	bidirectional, in the sense that at the signal (IMAX = 3mA in steps of 25 µA) a positive or negative offset can be superimposed of a maximum of ± 1mA in steps of 10µA. Duration from 5s to 3600s in steps of 5s. Duration of rising and falling ramps from 0 to 120s.
High frequency noise	bidirectional, in the sense that at the signal (IMAX = 3mA in steps of 25 µA) a positive or negative offset can be superimposed of a maximum of ± 1mA a passi di 10µA. Duration from 5s to 3600s in steps of 5s. Duration of rising and falling ramps from 0 to 120s. Band limited to the low frequencies of approximately 100Hz.
Low frequency noise	LF noise - bidirectional, in the sense that at the signal (IMAX = 3mA in steps of 25 µA) a positive or negative offset can be superimposed of a maximum of ± 1mA in steps of 10µA. Duration from 5s to 3600s in steps of 5s. Duration of rising and falling ramps from 0 to 120s. Band limited to the low frequencies of approximately 100Hz.
Sham	unidirectional (positive only), constituted by: a rising ramp (1-180s), a level (1-300s), an interval with zero stimulation current (1-

	3600s), un livello (1-300s), a falling ramp (1-180s). All the times are selectable in steps of 1s. Maximum intensity is ±5mA adjustable in steps of 25µA starting from the ramps from 0 (zero current).
Maximum current error	< 3% f.s. A/D converter.
Trigger in	TTL compatible
Trigger out	TTL compatible
Other functions:	
	Monitoring the impedence of the electrode before the start of stimulation.
	Monitoring the detachment of the electrode or the reaching of output saturation voltage during the course of stimulation.
Power supply	4 AA Ni-MH batteries at least 2 Ah rechargeable. With less autonomy, 4 x 1.5 V AA non rechargeable Ni-MH batteries
	Monitoring the battery voltage and warning beeper and through alphanumeric display in the case of low battery voltage; interruption of functioning and the storage of parameters should the minimum acceptable battery voltage be reached.
Programmability	The stimulator may be programmed through the Bluetooth interface by means of an appropriate program installed on a personal computer.
Operating and storage conditions	upper and lower storage temperature limits
10°C 45 °C	Upper and lower operating and storage temperature limits recommended by the manufacturer.
20% 80%	Upper and lower operating and storage humidity limits recommended by the manufacturer.
IP Degree	IP20
Warning	The stimulator must not be used in the presence of inflammable atmospheres, inflammable anesthetic gases or oxygen-enriched environments.
	Warning: The BrainSTIM should not be used near or placed on top of other equipment. If it is necessary use it near or placed on top of other equipment, monitor the device to check it is working normally in the configuration in which it is used.

Electromagnetic Compatibility (Tables in conformity with EN 60601-1-2 : 2007 standard)

Table 1

Electromagnetic Emissions		
The intended use of the BrainSTIM device falls within the electromagnetic environment as specified below. The client of user of the BrainSTIM should make sure that it is used in that context.		
Emissions test	Conformity	Electromagnetic environment
RF emissions - CISPR 11	Group 1	The BrainSTIM device uses RF energy only for its internal functioning. Its RF emissions are therefore very low and do not seem to cause any interference to nearby electronic devices.
RF emissions - CISPR 11	Class B	The BrainSTIM is suitable for use in all premises, including domestic premises and those directly connected to public low voltage power networks supplying buildings for domestic use.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Electromagnetic immunity			
The intended use of the BrainSTIM device falls within the electromagnetic environment as specified below. The client of user of the BrainSTIM should make sure that it is used in that context.			
Immunity test	IEC 60601 test level	Level of conformity	Electromagnetic environment - guide
Discharge >Electrostatic (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contatto ± 8kV aria	Flooring must be in wood, cement or ceramic. If the floors are covered in synthetic material, the relative humidity must be at least 30%.
Rapid electric passage/ Discharge IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable	-
Surge test IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable	-
Voltage drop, brief interruptions and variations in voltage in the power supply lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT	Not applicable	-

	(30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s		
Frequency of power supply (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	Not applicable	-
NOTE UT is the main alternating current voltage before the application of the level test.			

Table 4

Manufacturer's Guide and Declaration–electromagnetic immunity			
The intended use of the BrainSTIM device falls within the electromagnetic environment as specified below. The client of user of the BrainSTIM should make sure that it is used in that context.			
Immunity Test	IEC 60601 Level test	Conformity level	Electromagnetic environment - guide
RF conducted IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz	3 Vrms from 150 kHz to 80 MHz	RF portable and mobile communication devices should not be used near any part of the BrainSTIM, including the cables, at a lower separation distance than the one recommended, calculated on the basis of the equation applicable to the frequency of the transmitter. Recommended separation distance: d = (3.5/3) √ P
RF Irradiated IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	3 V/m from 80 MHz to 2.5 GHz	d = (3.5/3) √ P from 80MHz to 800 MHz d = (7/3) √ P from 800MHz to 2.5GHz, where P is the maximum output power of the

			transmitter in watts (W) in accordance with the transmitter manufacturer and is the separation distance in meters(m). The field intensity of the fixed RF transmitters, as determined by an electromagnetic survey on site, should be lower than the level of conformity in each frequency range. b Interference may occur near equipment marked with the following symbol:
NOTE 1 the higher frequency range is applied at 80 MHz and 800 MHz. NOTE 2 These guidelines might not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection of buildings, objects and people.			
a) The field force coming from fixed transmitters, such as radio telephone base stations (cell / cordless) and land radiomobiles, amateur radios AM and FM radio transmissions and TV transmissions cannot be theoretically predicted with precision. An electromagnetic survey of the site must be considered to assess the electromagnetic field generated by fixed RF transmitters. If the field force measured in the place in which the BrainSTIM is used exceeds the higher RF level of conformity, the BrainSTIM must be observed to check that it is functioning normally. If any abnormal performance is observed, further measures could be necessary, such as the re-orienting or re-positioning of the BrainSTIM. b) In the frequency range from 150 kHz to 80 MHz, the field intensity must be lower than 3 V / m			

Table 6

Recommended separation distance between portable and mobile RF communication devices and the BrainSTIM

The BrainSTIM is intended for use in an electromagnetic environment in which RF irradiated disturbances are controlled.

The BrainSTIM client or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters) and the BrainSTIM as advised below, based on the maximum output power of the communication device.

Percentage of maximum output power of the transmitter W	Separation distance based on the transmitter frequency m		
	from 150 kHz to 80 MHz d = (3.5/3) √ P	from 80 MHz to 800 MHz d = (3.5/3) √ P	from 800 MHz to 2.5 GHz d = (7/3) √ P
0.01	0.117	0.117	0.234
0.1	0.369	0.369	0.738
1	1.167	1.167	2.334
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters with a maximum output power not listed above, the separation distance advised d in meters (m) can be calculated by using the equation applicable to the transmitter frequency, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the maximum separation distance applies.
NOTE 2 These guidelines might not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection of buildings, objects and people.

Appendix

Advices for use

The position of the electode is to be valuated in accordance to the lesion. Usually anode (exciting) on injured area, cathode (depressing) against lateral cephalic or extra- cephalic.

Pathology	Type of current	Positive polarity	Negative polarity	Electrodes size	Intensity of stimulation	Stimulation length
Depression	Direct	F3	F4	7x5	1mA	20 minutes
Alzheimer	Direct	F3	T7	7x5	1mA	30 minutes
Aphasia	Direct	Broca's area /CP5	Right shoulder/F4	7x5	1mA	20 minutes
Chronic pain	Tdcs	against lateral cephalic	T3	7x5	5mA	30 minutes
Dystonia	Tdcs	T3	F4	7x5	1mA	10 /20 minutes
Parkinson	Direct	T3	F4	7x5	1mA	20 minutes
Epilepsy	Direct	F3 (According to EEG)	F4 (According to EEG)	7x5	1mA	20 minutes
Migraine	Direct	Oz	Cz	7x5	1mA	20 minutes
Hypertension	Direct	Fp1	Fp2	7x5	1mA	20 minutes
Stroke	Direct	injured area	Shoulder or against lateral cephalic	7x5	1mA	20 minutes
Ischaemia	Direct	F3	F2	7x5	1mA	20 minutes
Addictions	Direct	F2	F3	7x5	2mA	20 minutes
Memory disfunctions	Direct	Fp1	Fp2	7x5	1mA	20 minutes
Tinnitus	Direct	F4	F3	7x5	1.5mA	30 minutes

- Mode of recognition of the electrodes position according to EEG 10-20 convention
- Electrodes sizes in cm

How to reset the EEPROM memory of BrainSTIM stimulator.

The aim of this procedure is to reset the internal memory of the stimulator, in order to check that all parts of the device work properly (display, power output, keys). This procedure is also useful as diagnostics in case of problems with the Bluetooth connection to PC.

1. Turn on the device.
2. Press the **down arrow key** three times.
3. The display shows the clock of the system.
4. Press and hold the **two arrow keys and the yellow stimulation key** at the same time for a few seconds.
5. The “TEST MODE” screen appears, with a notice warning the user that the internal clock of the device will be reset.
6. Press the **down arrow key** in order to confirm the operation, otherwise it will be cancelled within a few seconds.
7. A series of automatic tests for display diagnostics will start (1).
8. In the screen related to the battery test (2), the system will show a right arrow symbol in the upper part of the display. Press the **down arrow key**.
9. In the screen of the Bluetooth channel test (3), press the **down arrow key** to continue.
10. Then, a test of the internal buzzer (4) is performed, and the system goes on to the following phase automatically. In the upper right part of the display, a clock symbol is shown.
11. In the screen of the trigger channel test (5), press the **down arrow key** to continue.
12. The following is the keyboard test screen (6), then the system goes on to the following phase automatically. It is possible to test the correct operation of the keys by pressing them and checking their state on the display.
13. The screen related to the stimulator firmware revision (7) appears, press the **down arrow key** once more to continue.
14. In the screen of the power output test (8), press the **yellow key** several times in order to test the available power values and perform an impedance check. Then, press the **down arrow key** to continue.
15. The following screen displays the stimulator serial number (9), press the **down arrow key** to continue.
16. In the screen related to the state of the EEPROM memory (10), press and hold the **yellow key (start/stop)** and **the blue key (Bluetooth)** for several seconds, in order to reset the stimulator EEPROM state and go back to the main screen.