SEP Stimulator User Guide

Compumedics Neuroscan
7850 Paseo Del Norte
El Paso, TX 79912
USA

Voice :915-845-5600
Fax: 915-845-2965
e-mail: sales@neuro.com
techsup@neuro.com
web site: www.neuro.com

Document number 7291, Rev A

Address:

Mailing:	7850 Paseo Del Norte El Paso, TX 79912
Web:	www.neuro.com

Technical Support:

Toll Free:	800.474.7875 (USA and Canada only)
Telephone:	915.845.5600
Fax:	915-845-2965
E-mail:	techsup@neuro.com

Sales:

Toll Free:	800.814.8890 (USA and Canada only)
Telephone:	915.845.5600
Fax:	915.845.0355
E-mail:	nsms@neuro.com

Text appearing in blue indicates a hyperlink. Click the text to go directly to that section.

TABLE OF CONTENTS

Document number 7291, Rev A

Introduction

The SEP Stimulator is the same high-quality device used with Comperio, our clinical EMG and EP system. The stimulator connects easily to your computer, and is controlled by the ACQUIRE software. The stimulator in this configuration is not intended to provide all of the functionality possible with the clinical system, but rather to provide the researcher with a device to acquire SEP data with ease.

The Somatosensory Stimulator is a hand held device that can deliver energy to the patient. The stimulator has built in buttons that allow the device to be controlled directly from the hand held unit. The intensity level, pulse action, polarity and response store actions can be controlled directly from the device. The stimulator also has additional functionality that can be controlled through the software. The device can function in constant current or constant voltage mode, can deliver a wide range of duration levels, can operate in single stimulus mode or at a user controlled frequency.

- Power Indicator- A yellow LED indicates that the somatosensory stimulator has power and is ready to pulse. Each time the device pulses the LED flashes green, then returns to yellow.
- The polarity button (+/-) is used to switch the cathode and anode. The lit LED indicates which side is the cathode, and the LED next to the anode will not be lit.
- The increase "+" button is used to increase the intensity level.
- The decrease "-" button is used to decrease the intensity level.
- The pulse button (yellow) is used to enable/disable the stimulator.
- The save (diskette) button is used to store a response.

Document number 7291, Rev A

Using this Manual

This manual is designed for researchers interested in recording SEP responses. It is assumed that you are already familiar with the various parameters used for SEP acquisition, and with the concommittent precautions you should employ. While it is beyond the scope of this manual to provide complete instruction in the acquisition of clinical quality SEPs, we will provide some realistic examples.

The following *symbols* are used to identify key information:

This symbol indicates a note of a special feature or something of special importance to the reader.

This symbol indicates a caution. A caution is a statement that advises the user of special cares necessary to ensure safe and effective use of the device and to prevent potential damage to the unit.

This symbol is used to indicate a warning. A warning is a statement that advises the user of potential injury, or death to the user or the patient.

It is very important that you read all Warnings and Cautions before using your SEP Stimulator. These warnings and cautions are provided to protect you and the subject from injury or death, and to protect the instrument from damage.

Cautions

Caution

The ACQUIRE program in SCAN is designed to operate as the only application running on the computer. It is recommended that you do not have any other applications running during data acquisition

Caution

Please read this manual in its entirety before using this device, to ensure safe operation.

Caution

Avoid accidental contact between connected but unapplied parts and other parts including those connected to protected earth.

Document number 7291, Rev A

Caution

The Power Supply is intended for use only with the SEP Stimulator only, and is the only power supply you should use with it. Use of any other equipment could result in damage to the power system or compromise patient isolation.

Caution

If you disconnect the Sep Stimulator cable(s), ensure that they are correctly reconnected to prevent damage to the system or its components.

Caution

The Biomedical Engineering Staff should check the SCAN acquisition system periodically for ground integrity, system leakage current, and leakage current on the amplifier. Contact **Neuroscan** for assistance if you do not have a Biomedical Engineering department.

Caution

Before cleaning the SEP Stimulator, ensure that it is disconnected from the computer. Prevent detergents or sterilization agents from seeping into the electronics of the instrument, and do not use abrasive cleaners.

Caution

Do not use the following chemicals: acetone, benzene, or toluene to clean the stimulator, as they will damage any plastic components.

Warnings

Warning

Do not use the SEP Stimulator in the presence of flammable anesthetics. The system is not explosion proof and could ignite a fire.

Document number 7291, Rev A

Warning

Do not turn the system on until you have ensured that all cable connections have been properly made. For assistance refer to the assembly instructions included with the system.

Warning

Inspect the power cord often for signs of wear or damage. Do not operate the system if any power cords or plugs are damaged. Touching a frayed or cut power cable can result in operator shock.

Warning

The SEP Stimulator and any other powered device that is connected to the system **must be** plugged into the SCAN Isolation Transformer provided. Excessive leakage current could occur if any of the above is plugged into a non-isolated outlet, resulting in patient shock.

Warning

The system and its components should be opened and serviced only by a qualified service technician. Shock will occur when high voltage components are touched.

Warning

Ensure that the power is OFF and the power cord is disconnected from the wall outlet, prior to removing the AC input from the Isolation Transformer to prevent the possibility of an injury from an electrical shock.

Warning

Do not eat or drink around the SCAN system, and do not place any liquid on the unit. Liquid spills into the system may result in personal injury (electrical shock) or could also cause damage to the system.

Warning

Transthoracic stimulation should be avoided (e.g., maintenance of anode and cathode stimulating sites in close proximity).

Document number 7291, Rev A

Warning

Patients with an implanted electronic device (e.g. cardiac pacemaker) should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained. Operation in close proximity (e.g., 1 meter) to a shortwave or microwave therapy equipment may produce instability in the electrical stimulator output.

Warning

This device can deliver electrical output of up to 400V constant voltage, and 100 mA constant current, for a period of 1ms at a rate of 50 Hz. Special care should be taken when stimulating with electrodes with high current densities such as needle electrodes. This device is intended for use by, or on the order of, a licensed medical practitioner.

Environmental Conditions That Affect Use

The instrument is designed to operate in standard hospital and clinic operating conditions. If the instrument has been exposed to freezing (< 0° C or 32° F) conditions for more than 2 hours, it should be defrosted *more than an hour at room temperature before being turned on.* This will allow any condensation that may form on the internal electronics of the system to evaporate.

Caution

The SEP Stimulator has not been tested in the presence of strong electromagnetic emissions. Care should be taken to place the instrument away from electromagnetic generators.

The instrument has been tested and found to comply with the limits and requirements for a Class B device per EN 60601-1-2 and EN55011. These limits and requirements are designed to provide reasonable protection under conditions of normal use from interference with and by other devices. There is, however, no guarantee that interference will not result from operating of this device in proximity or connected to some other device. This interference may contaminate the readings. If interference occurs, the operator is encouraged to try correcting the interference by one or more of the following measures: (1) Change the orientation of the two devices relative to one another; (2) Increase the separation between the two devices; (3) Check the power source and grounding for the two devices; and (4) Consult the dealer, **Neuroscan** Technical Support, or an experienced technician for help. Ensure that all 60 Hz generators are located away from the instrument. Any noise introduced into the system *prior to the amplifier* will interfere with the waveforms.

The safety and electromagnetic compatibility of this device has been tested. The user or operator is cautioned to ensure that when using accessories, parts, or associated devices other than those discussed in this manual, that the safety and electromagnetic compatibility of the system is maintained.

Document number 7291, Rev A

Parts that come into contact with the patient such as electrodes should only be supplied **by Neuroscan**. Please refer to Appendix A for a list of recommended electrodes and recommended cleaning and sterilization methods.

Caution

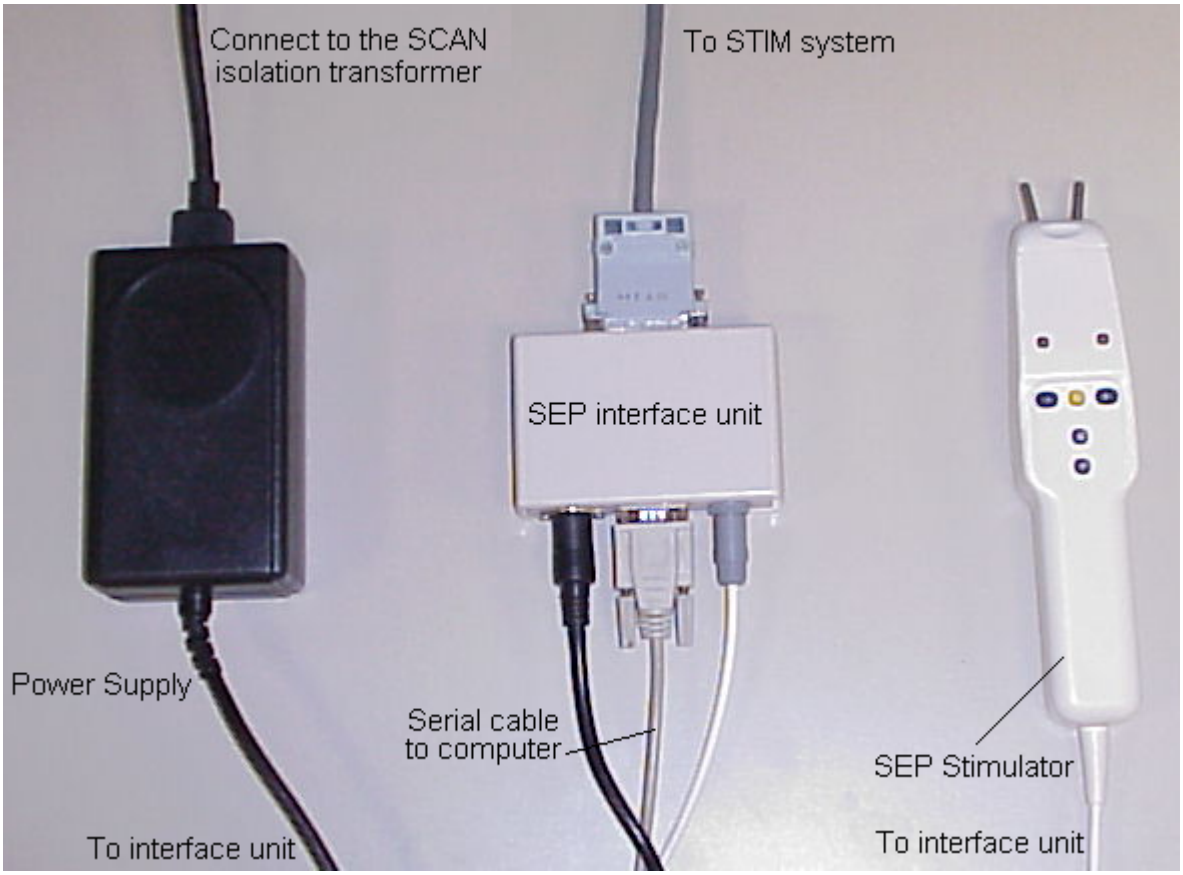
It is very important that Electrostatic Discharge (**ESD**) be minimized.
An effective ESD suppression program should be implemented, including:

- Touching a grounded object before touching the instrument to discharge any electrostatic buildup that you may have accumulated
- Ensure that the carpet in your lab (if any) is static repellent
- Maintain the humidity in the lab to reduce the incidence of ESD at greater than 30%. Failure to protect the system from ESD can result in severe damage to your System.

Document number 7291, Rev A

Installing the SEP Stimulator

Turn the SCAN computer off before connecting the SEP Stimulator to it. There are three components to install: the SEP Stimulator itself, an interface unit, and a DC power supply. The stimulator and the power supply connect to the interface unit. The STIM-to-SCAN cable (from the STIM Audio System Unit, or other stimulation device) connects to the opposite side of the interface unit. The serial cable connects the interface unit to the SCAN computer. After making these connections, *connect the power supply to the Isolation Transformer that came with your SCAN system*.



Turn the SCAN computer on. If you do not see the SEP Stimulator icon when you enter the ACQUIRE program, you need to complete the following steps.

1. Close the ACQUIRE (and EDIT) program,

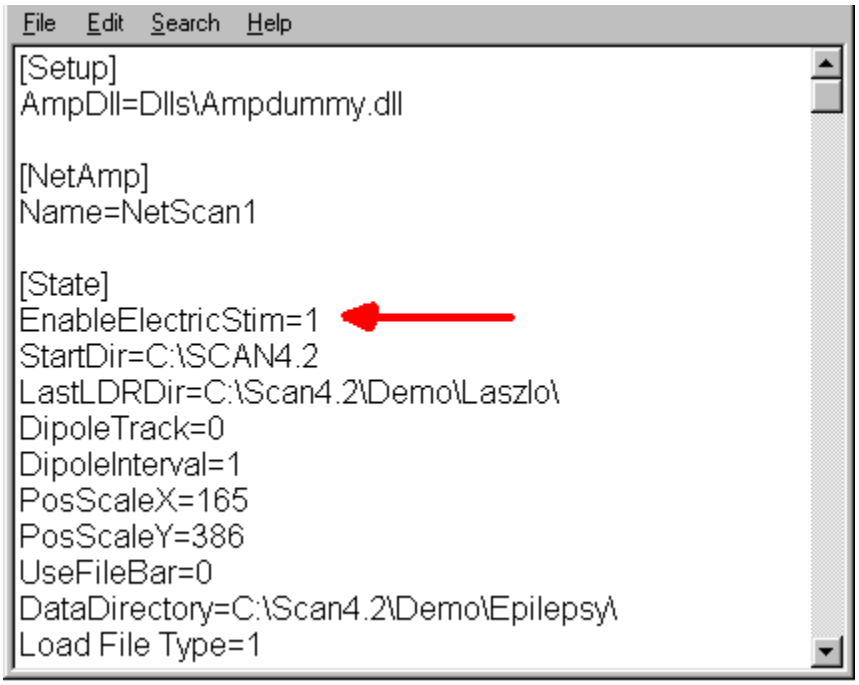
2. Using Notepad or Wordpad, open the *acquire43.ini* file in the c:\WINDOWS or c:\WINNT folder. If the file is not there, search the hard drive for it, and complete the modification wherever the file is stored.

Document number 7291, Rev A

3. In the [State] section, add the following line:

    EnableElectricStim=1

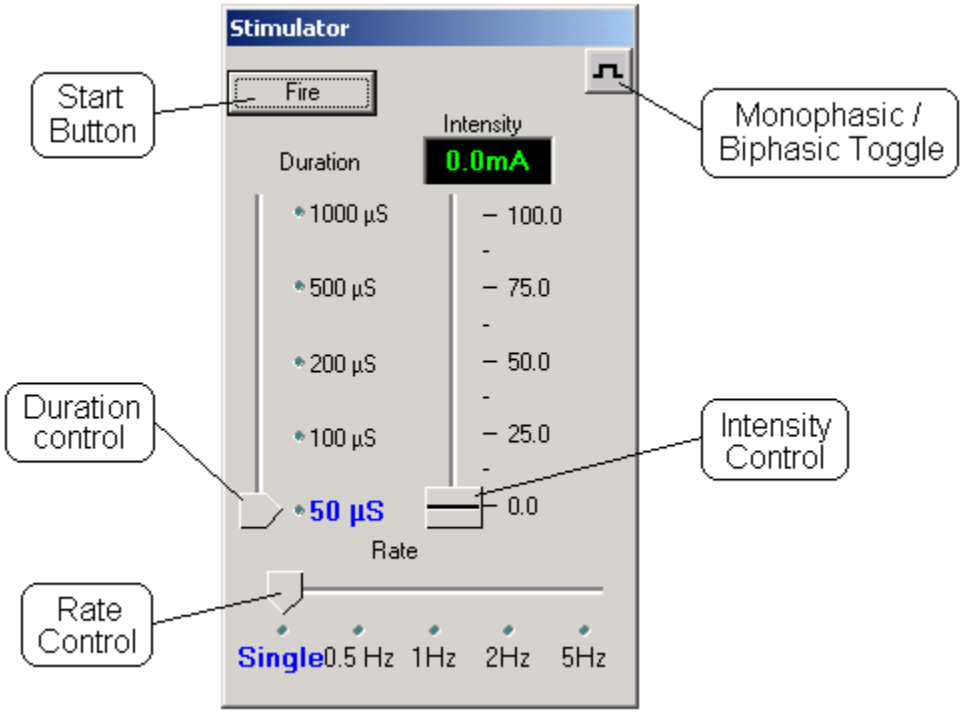
4. The lines in the acquire43.ini file should appear similar to the following



5. Save the file, and start the ACQUIRE program. You should now see the SEP Stimulator icon. (You must have the Stimulator connected to access the SEP control dialog screen).

Operating the SEP Stimulator with SCAN

In ACQUIRE, with the stimulator connected, click the  icon. (If you do not see the icon, or if you have not connected the stimulator, see the Installation steps above). You will see the following display.



Set the Duration, Intensity, and Rate levels as desired using the sliding buttons. The selections will be highlighted in blue, or shown in the Intensity display. Click the Monophasic / Biphasic toggle button, as desired. Then click the Fire button to start stimulation. Click the button again to disable the stimulator and close the display.

Stimulation parameters will vary. For example, if you are stimulating the left or right median nerve, the typical duration is 50uS, with an intensity of 20-30mA. The amperage will vary depending on the body fat of the subject, as well as how close to the nerve the placement is. The rate depends on your recording interval. For example, if you are recording -100 to 400ms sweeps, then your rate could be no faster then 2Hz. For scalp recorded SEPs, you probably will not use the Single pulse stimulation. Monophasic is conventional; biphasic is included if there is a need for it.

Recording SEPs

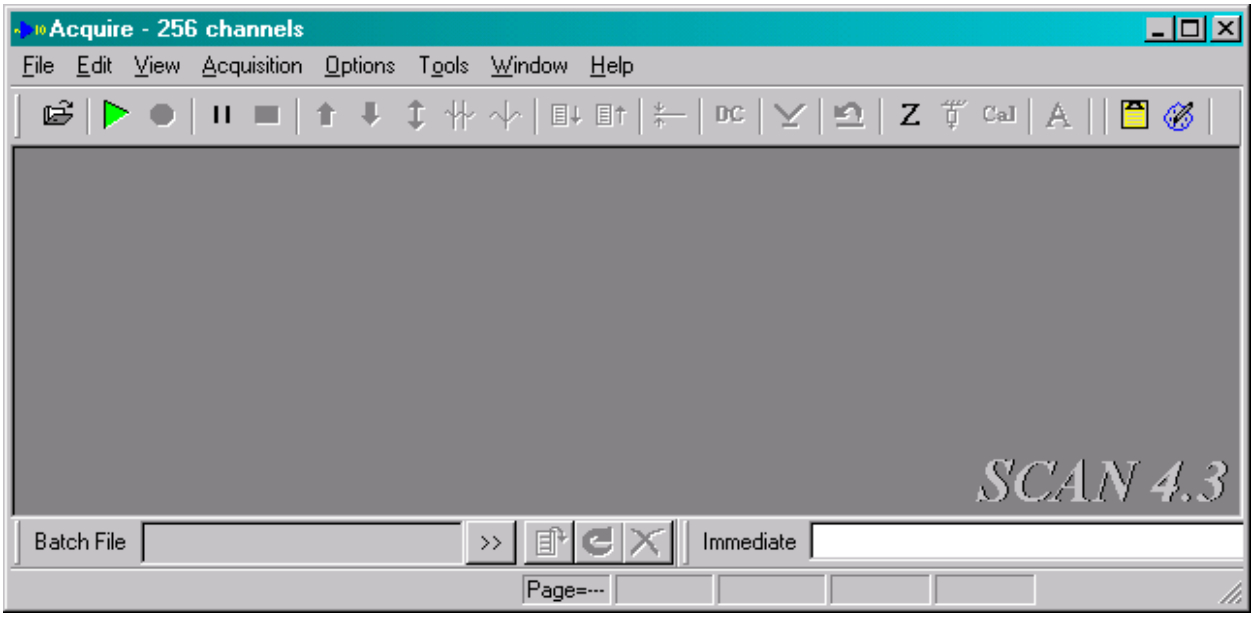
The SEP Stimulator is intended only for acquisition of cortical evoked responses to peripheral stimulation. There are no distance or temperature compensation routines in the software that would be needed for nerve conduction and related peripheral responses. Therefore, the setup files that you create will be very similar to those used for visual or auditory EP recordings. See, for example, the SEP Tutorial near the beginning of the ACQUIRE manual called "Single-sweep recording and an online average - SEP". That tutorial is repeated here, with modifications for use with the SEP Stimulator.

Single-sweep recording and an online average - SEP

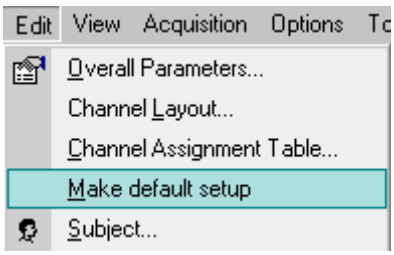
This section describes how to configure ACQUIRE for simultaneous online averaging and storage of single-sweep epochs to disk. This option is particularly useful for monitoring both the acquisition of the average and the reconstruction of the average offline with the EDIT module. Artifactual sweeps that may not have been removed in the online average can be removed or corrected offline to minimize their effects on the reconstructed average. A configuration for a somatosensory evoked potential to median nerve stimulation will be given to illustrate simultaneous average and epoch based acquisition.

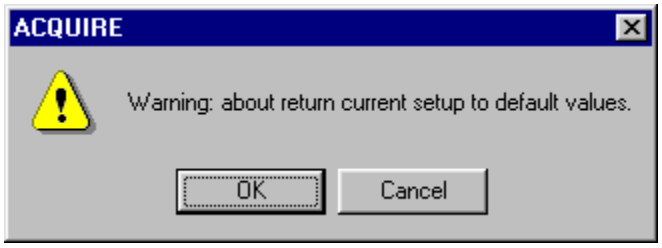
Follow these steps to configure the system for online SEP collection:

Step 1 - Start ACQUIRE (as described above), and you will see the ACQUIRE main screen.



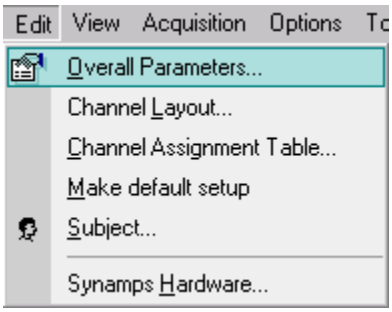
Step 2 - Since we will be using only a few channels for the SEP recording in this example, begin by selecting the Make Default Setup under *Edit*, and say OK to the Warning.



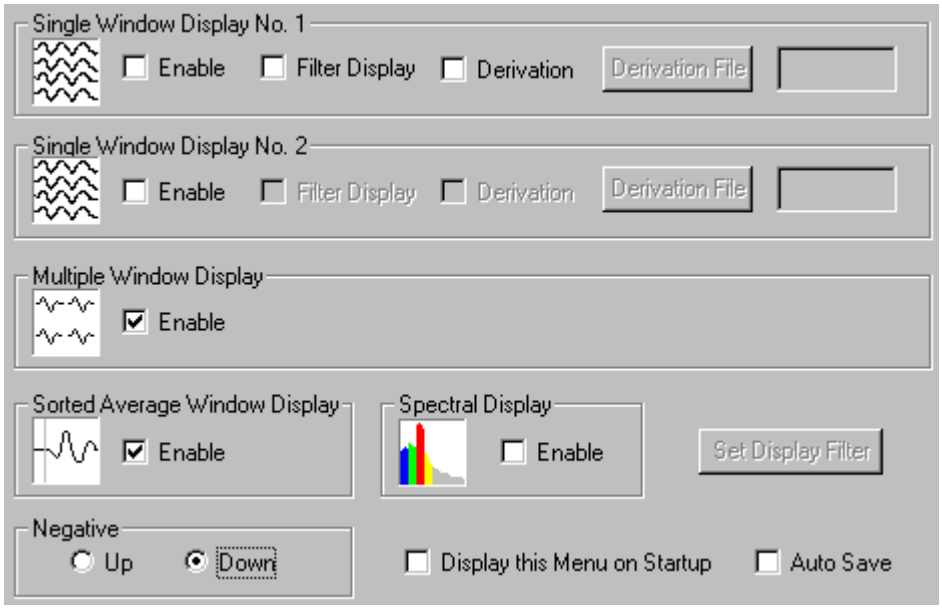


This restores all the default settings (if you have made any changes to an open setup file, be sure to Save these before using the Make Default Setup option).

Step 3 - Click *Edit* from the Main menu bar, then click *Overall Parameters*.



A multi-card window will appear, with the *Startup* "card" on top. For this recording, enable the Multiple

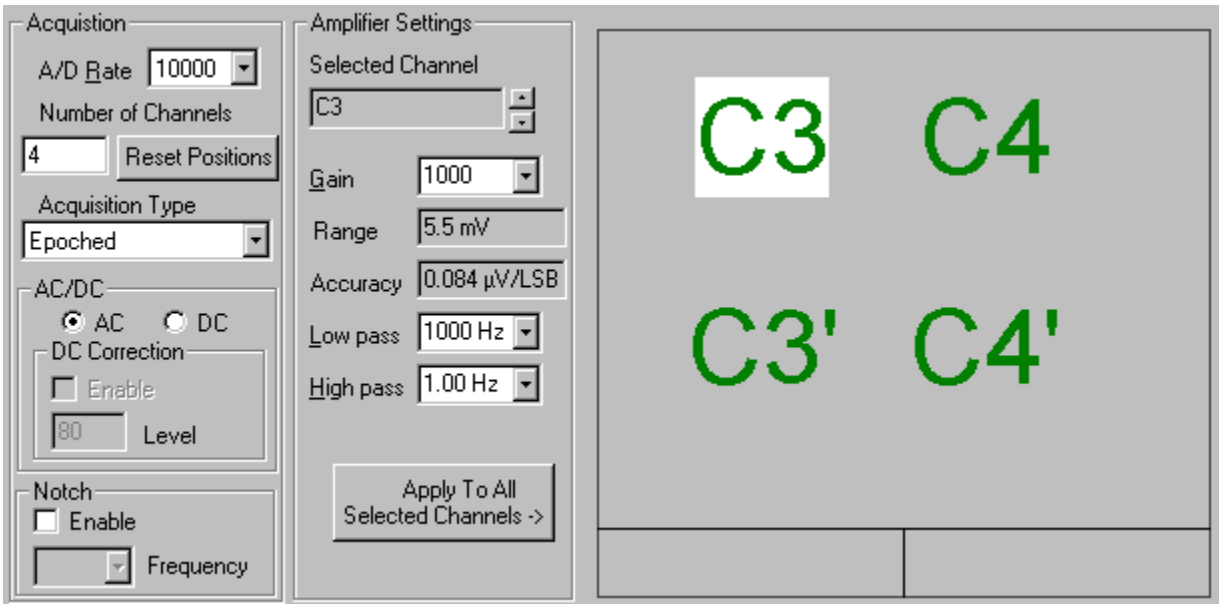


Window Display and Sorted Average Window Display (click on field so that check marks appear). Set the polarity as desired (Negative Up or Down). Make sure no other displays are enabled.

Step 4 - Now click the *Amplifiers* tab. Set the A/D rate to 10000Hz. Next, enter 4 for the number of channels, corresponding to electrode placements we will set for C3, C3', C4 and C4'. Click the Reset Positions button, and you will see 4 electrode displays, numbered 1-4. Don't worry about the labels or positions at this point; we will modify them shortly (these have already been renamed and repositioned in the figure below). For Acquisition type, select *Epoched* if you anticipate long time intervals between the stimuli (if you are acquiring single sweeps); select Continuous if you anticipate a fairly steady stimulation rate (as with regular averaged cortical SEPs). Under AC/DC, select AC mode.

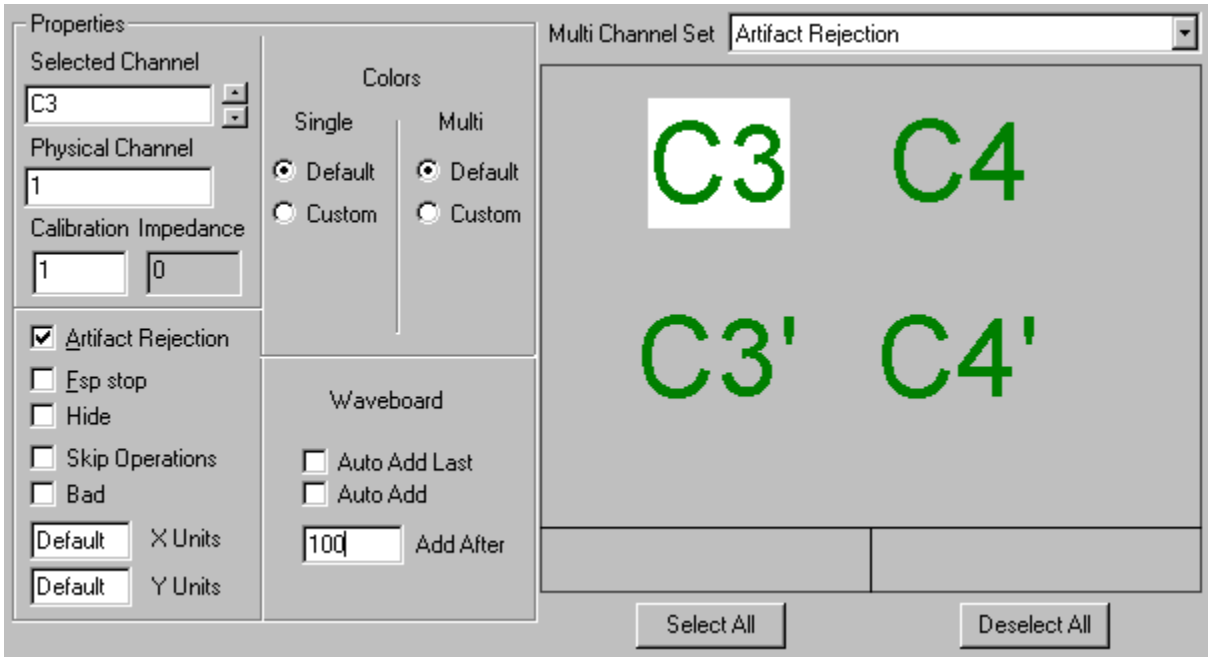
Document number 7291, Rev A

Under Amplifier Settings, set the gain to 1000x, the Low Pass filter to 1000Hz and the High Pass filter to 1Hz. Leave the Notch Filter OFF (no check mark in the box). Click the Select All button (all channels should be green), and then click the Apply To All Selected Channels -> button to apply the gain and filter settings to all channels. *(Note: It is not possible to use the SynAmps or SynAmps2 deblocking feature with the SEP Stimulator).*

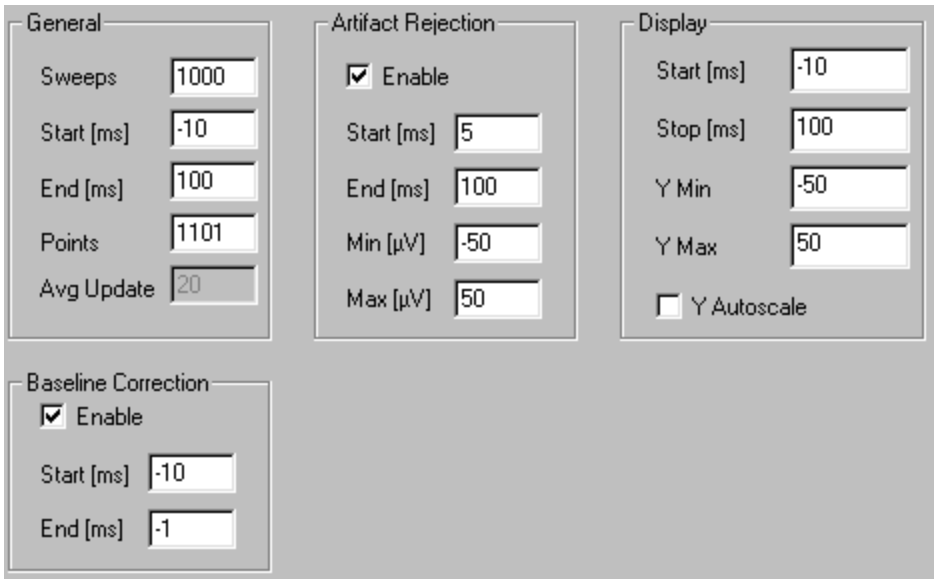


Step 5 - Now click the Channel Attributes tab. Since we started with the Make Default option, the channels appear with numbers instead of labels. To change these to labels, go to the Selected Channel region, and change the 1 to "C3" Selected Channel C3, then click the Select All button to transfer the new label to the display on the right side. Then click the Up Arrow button to go to the next channel. Change it to C3'. Continue to process until you have renamed the channels to C3, C3' C4 and C4'. We will reposition the displays shortly.

We can also set all the channels as Artifact Rejection channels. Make sure that "Artifact Rejection" is displayed in the Multi Channel Set field, then click the Select All button (the labels should turn green). You should also see a check mark by the Artifact Rejection field.



Step 7 - Click on the *Epochs* label of the display "card" to set parameters of the recording epoch. For



this example, assume that you want a 10ms pre-stimulus interval, a 100ms post-stimulus span, and the artifact rejection and automatic baseline correction features *enabled* during acquisition. In the area labeled "General", set the number of Sweeps to 1000. Set the Start time for -10 (pre-stimulus) and the end time for 100ms. The sample interval has now been set with a pre-stimulus interval of 10ms and a post-stimulus interval of 100ms. Click on the Points field, and enter 1101, if needed. The Avg. Update field is not accessible for this operation.

In this example a total sample interval of 111ms (10ms pre-stimulus, 100ms post-stimulus, and the zero point) has been selected. The stimulation protocol must therefore allow for at least this interval plus additional time for the processing overhead of the computer. A stimulation rate of about 5-6 per second is recommended in this example. If faster stimulation rates are desired you can decrease the sample interval as long as the post-stimulus interval is of sufficient duration to view the major response components.

The program is designed not to allow invalid settings for any of the fields. If you click on a field and get an error message saying to input a number within a certain range, click OK and see what field has been highlighted. It may not be the one you had clicked. Enter the appropriate number in the field that was highlighted, then return to the original field you had selected, and continue. Note the interaction between the A/D rate and the number of points - selecting the A/D rate in the Amplifier section will affect the sample duration and the number of points in the *Epochs* section.

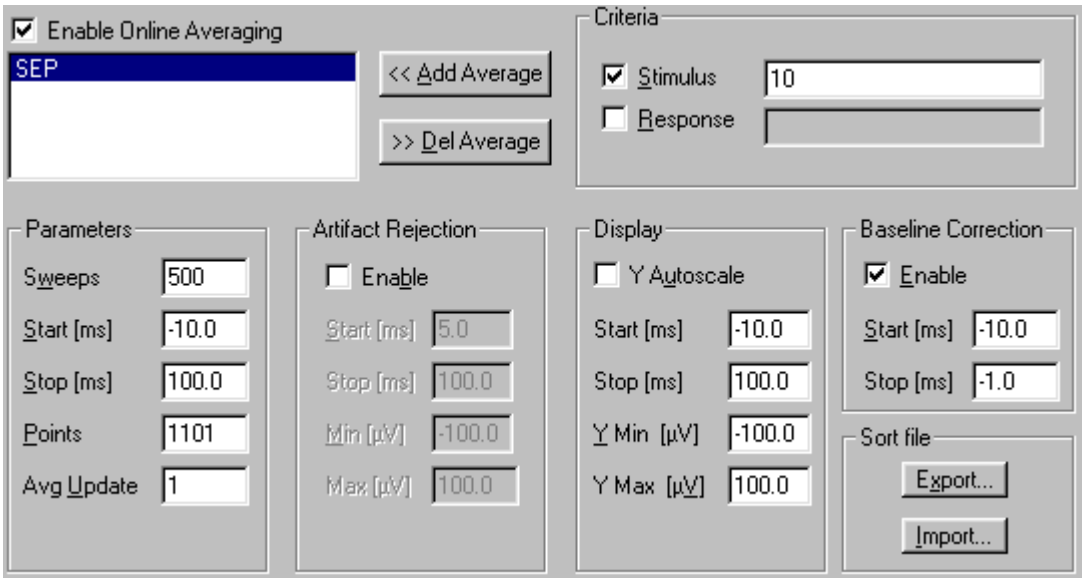
In the Baseline Correction area, click *Enable* and set the Start time to -10 and the End time to -1ms. The End point has been set prior to time zero to avoid potential stimulus artifact. Baseline correction will be performed online by computing the mean offset value from -10 to -1ms, and then by subtracting this value from the entire waveform.

In the Artifact Rejection area, click *Enable* and set the Start time to 5 and the End time to 100ms. The Start and End interval determines the range of the artifact scan. In this setup the scan begins after the stimulus artifact. Next, set the Minimum (-50uV) and Maximum (50uV) voltage threshold settings. Values in excess of +50uVs will result in rejection of the sweep.

Under Display, enter -10 and 100 for the Start and End time points, respectively, if these have not already been set. Enter -50 and 50 for the Min and Max microvolt settings, respectively. These settings affect the display of the averaged waveforms: the entire epoch will be displayed, and the amplitude will be scaled to +/-100uVs. Do not click on the Y Autoscale for these recordings.

Step 8 - To perform the online average, let's assume that the SEP stimulator is being controlled by the STIM system, and that STIM is sending a trigger type code of 1 via the STIM to SCAN cable to the SCAN system. While we are not actually sorting the stimuli, we can use the Sorting option to create an

Document number 7291, Rev A

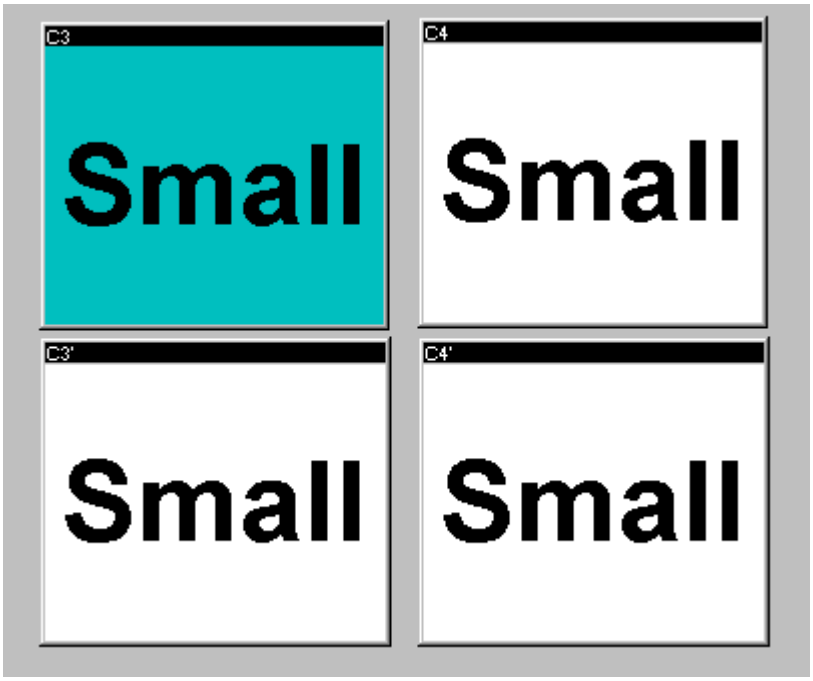


online SEP average. Click on the Sorting tab, and click the *Enable* field on, if needed (check mark will appear). Click on the *<<Add Average* button and a Windows Save file utility will appear. Enter a file name (such as SEP; the *.avg* extension is added automatically), and click *Save*. Next, enable the *Stimulus* field (check mark will apear) under *Criteria*, and enter 10 in the field. The online average will trigger when a trigger type code of 1 is received (i.e., all stimuli). Make any changes to the *Parameters, Artifact Rejection, Display* and *Baseline Correction* fields. Again, these settings are for the sorted average file only, and will not affect the EEG file that is being acquired (governed by the settings under *Epochs*). After you have entered the settings you wish, click on the *Export* button under *Sort file* and a Windows Save file utility will appear. Enter a file name (such as SEPsort; the *.srt* extension is added automatically) and click *Save*. To retrieve a saved file, click on the *Import* button, and select the file with the Open File utility. The current file will be shown in the lower field.

Step 9 - It would be a good idea at this point to save the settings that you have made thus far. Click on *Save As*... and label the Setup file SEPSET (the *.ast* extension will automatically be added). Click Save, then click on OK.

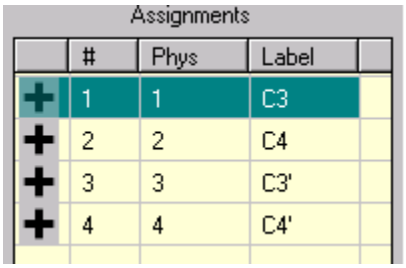
Step 10 - Click on *Edit* again at the Main Menu bar, and click on *Channel Layout*. You have 4 EEG channels in a line. Let's resize and reposition the displays. Select one of the displays and enlarge it using the standard Windows conventions (grab and drag a lower corner). Then click the Make Same Size button to change all the displays to that size. Drag the displays to the positions you wish, again using the standard Windows conventions. The result might appear similar to the figure below.

Document number 7291, Rev A



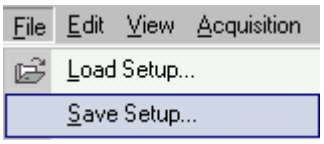
You can also use the Adjust Positions buttons to reposition the electrode windows automatically. The "Small" and "Large" designations allow you to set the displays to two sizes. The "Small" size is the one that appears as the default size. If you click inside the window to enlarge it to the mid-size (as opposed to double-clicking to get the full screen display), that intermediate size is the "Large" size, which you may also set as desired. Click OK to continue.

Step 11 - Now, go back to the *Edit* option on the Main Menu bar, and select *Channel Assignment Table*.



You will see the 4 channels, as previously entered. The order of the channels is contingent upon your actual cable connections and amplifiers (refer to your physical installation manual for more details, as well as the Channel Assignment table section in the *Operating* ACQUIRE section below). If you have not already relabeled the electrodes, you may relabel them here. When you are finished, click OK.

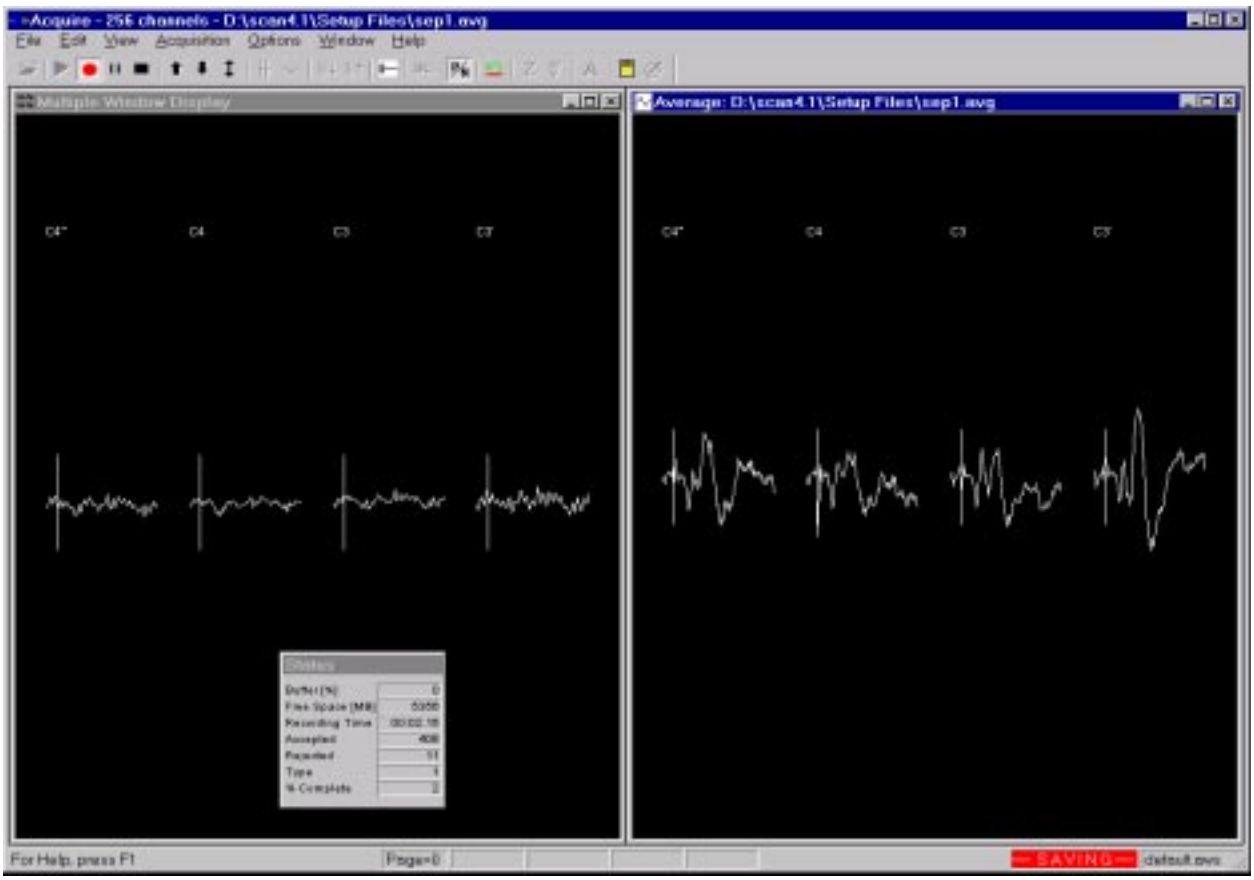
Step 12 - If you have made any changes since the prior Save step above, be sure to Save the setup file

again by clicking Save Setup... under the *File* option 

from the Main Menu bar (use SEPSET again to add the changes to the setup file).

Step 13 - Apply conductant to the stimulation area (e.g., over the left or right median nerve). Verify the stimulation parameters by clicking on the icon, making any adjustments as desired. Set the polarity on the Stimulator as desired, and *turn the intensity very low*. Gradually increase the intensity until you get the desired twitch response. Adjust the intensity level to generate a clean SEP, while maintaining a reasonable comfort level for the subject.

Step 14 - To begin recording, click *Acquisition* on the Main menu bar, followed by *Start Acquisition*, or, just click on the green triangle toward the left end of the Toolbar . You will see the Multiple



Window Display and, after initiating data storage, the sorted Average window display . When you are ready to begin recording, click on the *Record* icon (the red dot) on the Toolbar , and

Document number 7291, Rev A

enter a file name. The *.eeg* extension will be added automatically. Click on Save, and you will be returned to the Multiple Window Displays. The adjacent button with two vertical lines is the *Pause* button, and the button with the black rectangle is the *Stop* button.

In the averaged window display you will see the average waveform develop, with updates as specified in the Epoch section under *Edit/Overall Parameters*. Note that you will not see any data in the average display until the first trigger is received (or until you have reached the average update number of sweeps). Refer to the description of the *Options* section below in the *Operating* ACQUIRE part of the manual to see how to change display colors and to select different aspects of the window display. See the Tutorials at the beginning of the EDIT manual for general analysis guidelines.

Document number 7291, Rev A

Device Classification

The SEP Stimulator is a line-powered instrument designed to meet the applicable requirements of IEC601:1988. It should be used only according to the manufacturer's instructions. Replacement parts and accessories may be obtained from the manufacturer.

Manufacturer: Neuroscan
7850 Paseo Del Norte, Ste. 101
El Paso, TX, USA 79912
Phone: 915 845-5600
Fax: 915 845-2965
Internet: sales@neuro.com
techsup@neuro.com
Web: www.neuro.com

This equipment has been tested and found to comply with the limits and requirements for a Class II, Type BF device per EN60601-1-2 and EN55011. These limits and requirements are designed to provide reasonable protection under conditions of normal use from interference with and by other devices. There is, however, no guarantee that interference will not result from operation of this device in proximity or connected to some other device. If interference occurs, the user or operator is encouraged to try and correct the interference by one or more of the following measures:

(1) Change the orientation of the two devices relative to one another.
(2) Increase the separation between the two devices.
(3) Check the power source and grounding for the two devices.
(4) Ensure the system interconnect cables are not twisted together.
(5) Consult the dealer, NEUROSCAN Technical support, or an experienced technician for help.

The safety and electromagnetic compatibility of this system was tested with the following accessories, parts, and associated devices. The user or operator is cautioned to ensure that when using accessories, parts, or associated devices other than those listed, that the safety and electromagnetic compatibility of the system is maintained.

Portable System:
(1) NEUROSCAN Comperio amplifier, Model 6030
(2) NEUROSCAN somatosensory stimulator 1, Model 5856
(3) NEUROSCAN control module, Model 6053
(4) DELL® laptop computer, Model Inspiron™ 3800 (CE Marked) or other equivalent and CE Marked model. IBM® laptop computer, Model 390E can be used in place of the Dell Inspiron 3800 with IPSI 240VAC/13-17VDC medical grade power supply, Model PMP 130-13.
(5) International Power Sources Inc, medical grade power supply, Model PMP 130-13-1 (CE Marked)
(6) AULT 240VAC/12VDC medical grade power supply, Model SW152 (CE Marked)
(7) 2 medical grade power cords
(8) BROTHER® printer, Model MP-21C/CDX (CE Marked) or other equivalent and CE Marked model.

Stationary (Lab) system:
(1) NEUROSCAN Comperio amplifier, Model 6030
(2) NEUROSCAN somatosensory stimulator 1, Model 5856

Document number 7291, Rev A

(3) NEUROSCAN control module, Model 6053
(4) MICRON desktop computer, Model ClientPro® PIII650 (CE Marked) or other equivalent and CE Marked model
(5) Torid, Isolation Transformer Model: ISB-060W (CE Marked)
(6) Medical grade power cord
(7) Micron 17" SVGA Monitor (CE Marked) or other equivalent and CE marked model.
(8) HP Laser printer, Model LaserJet 2100 (CE Marked) or other equivalent and CE Marked laser printer.
(9) Ault 240VAC/12VDC medical grade power supply, Model SW152 (CE Marked)

Classification per IEC601-1:1988.

The device is ordinary equipment not protected against ingress of water and should not be used in the presence of any spilled liquids. It is not designed to be suitable for use in the presence of a flammable anesthetic mixture of air and oxygen or nitrous oxide. The device is capable of continuous operation. Class and degree of protection against electrical shock is Class B, Type BF.

Technical Description.

NEUROSCAN Somatosensory Stimulator, Model 5856:

Input:	12VDC (from AULT power supply or control module)
Fuses:	None
Weight:	~227 grams (0.5 lbs)
Dimensions:	51x241x38 mm (2.0x9.5x1.5 in)

Shipping and Storage Maximum Limits.

-20° C to +70° C, 10% to 100 Non-condensing RH, 500 hPa to 1060 hPa. After unpacking, allow devices to adjust to room temperature for at least two hours prior to interconnection and application of power.

Operational Maximum Limits.

+15° C to +30° C, 25% to 75% Non-condensing RH, 700 hPa to 1060 hPa.

Warnings and Precautions.

Instructions

Read instructions before operating the device.

⚠ **The Isolated Patient Ground is not any of the following: Protected earth ground, functional earth ground or a potential equalization terminal.**

The system contains no user serviceable parts and so is marked "CAUTION: Refer servicing to qualified personnel". This device is not equipped with appropriate alarms required for use in monitoring clinical parameters of a patient where it is necessary to alert the user of situations, which could lead to death or severe deterioration of the patient's state of health.The manufacturer has designed the trigger in/out port for connection only to NEUROSCAN approved accessories. Please contact NEUROSCAN before connecting a device to this port.

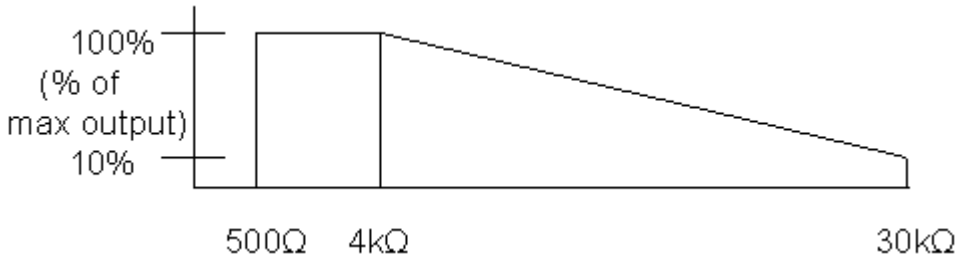
Impedance Limits for the Somatosensory Stimulator.

The range of acceptable impedance levels for the somatosensory stimulator is:

The stimulator output parameters are valid from 500Ohms to 30kOhms.

Document number 7291, Rev A

The following diagram explains how the impedance level of the stimulating electrode affects the output level of the device. The output level of the somatosensory stimulator is limited as the impedance level raises above 4kOhms.



Environment.

The system is designed for usage in a clinical environment. Extremes of humidity, temperature, or pressure should be avoided. The device should not be used in a location where contact with liquids is possible, and if liquids are spilled on or in the area of the device, it should not be used until it can be ensured that the fluid or its residue will not affect device operation. Questions should be directed to the manufacturer or its representatives.

Repair.

There are neither fuses nor user serviceable parts in the SEP Stimulator. Contact your dealer or NEUROSCAN Technical Support if you believe the stimulator is in need of repair.

Maintenance.

NEUROSCAN suggests that the earth and patient leakage currents be tested at least once per year to ensure continued safe use of the device. Also, visually inspect the device at least once per year, including the power cord. Replace any worn or frayed cable, and contact your dealer or NEUROSCAN Technical Support if you have concerns about what you see. This inspection interval may be shortened for devices that are moved often or experience unusually heavy use. No calibration of the device is required.

Installation Precaution.

Proper grounding is important for continued safe use of your stimulator. Ensure that the outlet supplying power to your system is grounded, and that the power cords supplied with your system are used. Other devices in the same patient area should be at the same ground potential, and should preferably use the same branch circuit. See the Hardware and Software Installation directions below for more details.

Power Source Characteristics.

The device is designed, produced, and tested to ensure reliable operation when connected to power systems having normal variability. If you believe that your power system may experience excessive noise or variability, NEUROSCAN recommends use of a power conditioner.

Interconnection with Other Devices.

Care should be taken when multiple devices are connected to a patient, or when devices are connected together. Leakage currents for individual devices may sum to values higher than expected for single devices. In particular, care should be taken when connecting Information Technology (IT) (e.g., computers) equipment to medical equipment. Allowable leakage current levels for IT equipment is higher than for medical equipment.

Document number 7291, Rev A

Use with HF Surgical Equipment.

This device does not contain protection against burning of the patient when used with high frequency (HF) surgical equipment. NEUROSCAN recommends that the device not be con nected to the patient during use of HF surgical equipment.

Document number 7291, Rev A

Appendix A

Cleaning and Maintenance

Cleaning

Warning

When cleaning your stimulator, ensure that all power is turned off and that the equipment is unplugged from the AC power outlet. This will eliminate the danger of electrical shock.

To clean the instrument, use a soft cloth and mild-cleaning agents.

Caution

Do not use the following chemicals: acetone, benzene, or toluene to clean your instrument, as they will damage any plastic components.

The stimulator should be cleaned periodically with a mild detergent and a soft, damp cloth (not wet) to remove any dust or salt residue from conductive gels and saline that may come in contact with the instrument.

Caution

Before cleaning, turn OFF the instrument. Prevent detergents or sterilization agents from seeping into the electronics of the instrument and do not use abrasive cleaners.

Maintenance

This section covers basic maintenance that you should perform on your stimulator on a regular basis.

Warning

Inspect the power cord often for signs of wear or damage. Do not operate the EMG/EP System if any power cords or plugs are damaged.

The stimulator cable should be regularly inspected for worn or broken insulation. The power cable should be regularly inspected for worn or broken insulation and to ensure that a proper and firm connection has been made to the power outlet.

If the system does not function properly, please contact **NEUROSCAN** immediately. Do not open the instrument to attempt to repair it yourself. If a system is not functioning properly, call **NEUROSCAN** technical support at (800) 474-7875 or (915) 845-5600, and we will be pleased to assist you in diagnosing the problem and arrange for appropriate service action. If you prefer to send us a fax or email, you may do so at our fax number: (915) 845-2965 or our email address: techsup@neuro.com.

Document number 7291, Rev A

Special Note

You have sole responsibility for any malfunction resulting from improper maintenance or repair by an unauthorized person.

Stimulators

Stimulus Output

User selectable:

Current	0-100 mA	+/- 2mA
Voltage	0-400 V	+/- 4V
Pulse Width	50µs-1ms	+/- 1µs

Measured Parameters

Signal Amplitude	DC-8V P-P	+/-2µV
Signal Latency	0-10 sec	+/-10%
Signal Area	0-500 mVms	+/-10%
Signal Duration	0-100 ms	+/-10%
Signal Conduction Velocity	0-100 m/s	+/-10%
Recording Impedance	0-100 kΩ	+/-10%
Temperature	20-40 °C	+/-10%