SpectraSTIM E3

Programmable Neuromuscular Stimulation

Therapeutic Alliances Inc.
333 North Broad Street
Fairborn, Ohio 45324 USA
(937) 879-0734 • (937) 879-5211 (fax) • www.ERGYS.com • info@ERGYS.com

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Catalog Number: 23-3500-2

Address comments, questions, or requests pertaining to this manual to:

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The SpectraSTIM E3 is an FDA registered medical device* for use in hospitals and clinics under the supervision of a qualified medical practitioner. The SpectraSTIM may be used at home under the prescription of a physician.

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Product design and specifications may be changed without notice.

*SpectraSTIM FDA Device Listing: D030291, Premarket Submission Number: K900029, Product Code: IPF, Device Type: Powered Muscle Stimulator

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SpectraSTIM E3

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1.0 Introduction

The Therapeutic Alliances SpectraSTIM E3 (the SE3) is a stand-alone neuromuscular stimulator designed for clinical and home applications in rehabilitation and sports medicine. It features four channels of programmable stimulus, operator controls and indicators, and user-programmable protocols.

One to four muscle groups may be treated with the SE3 in an isotonic or isometric fashion. Contractions are elicited by conduction of a low-level electrical stimulus through a set of surface electrodes placed over muscle motor points.

All components of stimulus--amplitude, frequency, pulse duration, and waveshape--are selectable.

Programmable profile times allow a broad range of treatment applications such as range of motion maintenance, muscle re-education, relaxation of spastic muscles, and prevention or retardation of tissue atrophy. Protocols of Alternating, Synchronous, Independent, and Reciprocal stimulus profiles are easily programmed through touchscreen menus and displays. Default protocols with preset profile times are available for common treatment modalities.

The SE3 has a simple user interface. Effective treatment requires mastery of just a touchscreen display, an illuminated STOP button, and a Patient Leads Cable for connection to one to four muscle sites.

Built in safety features include a self test when the unit is turned on, continuous system checks, and electrode and stimulus integrity checks during a session.

2.0 Indications/Contraindications

INDICATIONS FOR USE

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

CONTRAINDICATIONS

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

WARNINGS

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

PRECAUTIONS

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
    a. When there is a tendency to hemorrhage following acute trauma or fracture;
    b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
    c. Over the menstruating or pregnant uterus; and
    d. Over areas of the skin which lack normal sensation.
5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

ADVERSE REACTIONS

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

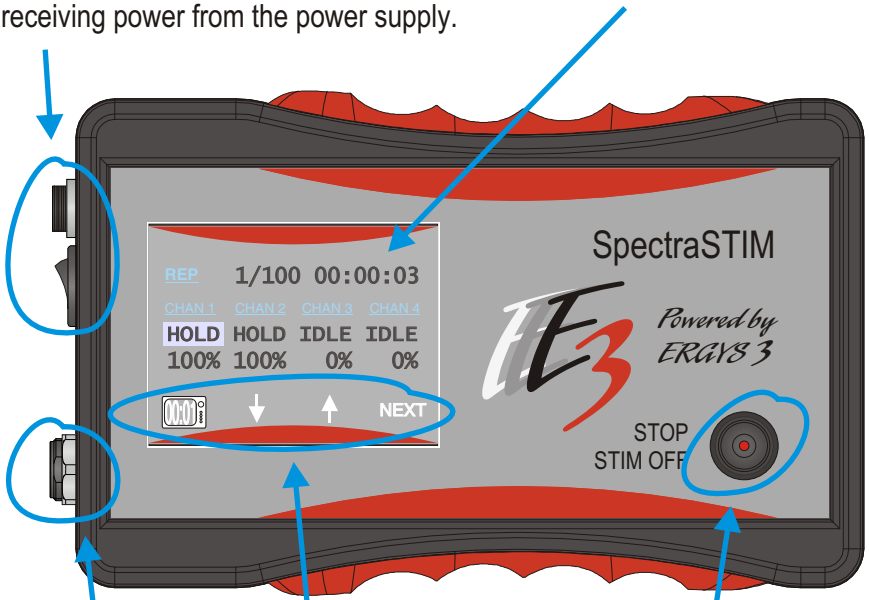
3.1 SPECIFICATIONS

Output Waveform:	Selectable biphasic balanced-charge waveshapes
Intensity:	140 mA (peak) +/- 5% constant current
Average Current: (into 500 Ohm load)	32.48 mA +/- 5%
Maximum Charge: (into 500 Ohm load)	50 microcoulombs per pulse
Power Density:	39.24 milliwatts/cm^2
Impedance Range:	50 to 1500 Ohms
Phase Duration:	Selectable 200, 300, 400, 500 microseconds
Pulses per Second:	Selectable 30, 40, 50, 60
Profile Time:	Selectable Idle 0 - 100 seconds Ramp Up 0 - 10 " Hold 1 - 100 " Ramp Down 0 - 10 " Rest 0 - 100 "
Repetitions	1 - 100
Channels:	Four isolated channels, independently adjustable stimulus amplitudes and profile times
Safety Testing:	System to ground - 100 microamps (max) Patient leads - 10 microamps (max)
Dimensions:	8.0" length x 5.0" width x 2.0" height
Weight:	1 lb, 5 ozs
Power Requirements:	INPUT: 100-240 AC volts, 50-60 Hz OUTPUT: 12 VDC, 2.0A, 24W

3.2 Features

Touchscreen
The touchscreen and an audio indicator provide prompting and instructions for set-up and administration of a session.

Power Inlet & Power Switch
This is the power inlet for the included medical-grade power supply. The green power light will glow when the unit is receiving power from the power supply.



Touchscreen Buttons
Under most circumstances, 1 - 4 buttons will appear on the bottom of the display to guide the session.

Patient Cable Connector
Either a lead wire cable or a garment cable plugs into this connector to provide the connection between the muscle sites and the stimulator.

Stop Switch & Stimulus Indicator
Pressing this button always shuts off stimulus. The red light on the top of the button will glow when stimulus is active.

3.3. Accessories

* 1 Stimulator, 8.0" length x 5.0" width x 2.0" height

* 1 Power supply, IN: 100-240 VAC, 50-60 Hz; OUT: 12 VDC, 2.0A, 24W

* 1 AC power cord

* 1 4-channel patient cable

and/or

* 1 4-channel garment cable

* 4 large self-adhering 3" x 4" electrodes (varies with configuration)

* 4 medium self-adhering 2" x 4" electrodes (varies with configuration)

* Operator's Manual

* Carrying Case (optional)

4.0 Operation

4.1 Overview

A session with the SpectraSTIM E3 can begin once installation is complete. Start by defining a treatment protocol: How many channels are required for the therapy? What are the best selections for pulse shape, duration, and frequency? How many repetitions are required? Is there a pre-programmed protocol available for this therapy or will it be necessary to set the profile times? What amount of rest is required?

It is important that a trained clinician answer these therapy questions and program the SpectraSTIM E3 in advance of the first patient session.

Careful selection of a treatment protocol along with a thorough study of sections 4.2 through 4.3 will greatly enhance the effectiveness and utility of the therapy session with SpectraSTIM E3.

An outline of the SpectraSTIM E3's "user-interface" is provided in section 4.2. Section 4.3 provides step-by-step instructions for a patient therapy session, while section 4.4 offers the clinician detailed instructions for programming the stimulator.

4.2 User Interface

The user interface has two major components: the Touchscreen and the Stop Button. These user inputs provide complete control of the stimulator, allowing menu selection, protocol setup, stimulus adjustment, suspension of a session, and so on.

4.3 Typical Patient Session

Install the SpectraSTIM as outlined in section 3.0. Switch on the rear-panel power switch. The green "Power" light should illuminate.

CAUTION: The patient should not be connected to the SpectraSTIM when it is first turned on.

At power-up, the SpectraSTIM will perform a self-test and then advance to the Startup display.

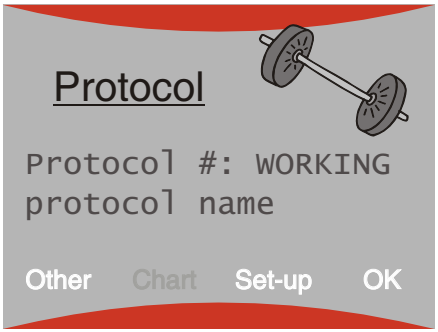
Startup Display

Copyright Display

1. Software version of main computer
2. Unit serial number
3. Software versions of Stimulus Modules
4. Unique identifier set in factory or by Advanced PIN

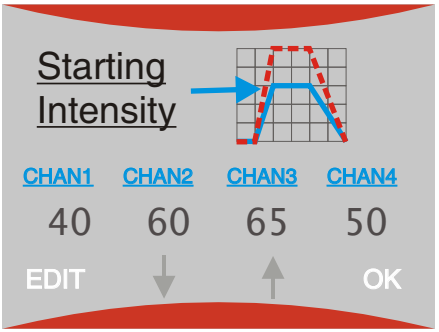
NOTE: A repeating flashing red light on the Stop Button or a repeating series of beeps indicates that the SpectraSTIM has failed its self-test. If the failure repeats after turning the SpectraSTIM off then on, consult the appendix of this manual for customer service information.

A number of preprogrammed protocols can be chosen from the *Select Protocol* display. Press *Other* to choose a different protocol. Press *Next* from this menu when the desired protocol appears.



Select Protocol Display

After selecting a preprogrammed protocol, parameters for that protocol such as stimulus waveshape, pulse duration, and frequency are automatically changed. These parameters can be edited by the clinician with the entry of a PIN after selecting the *Set-up* choice from the *Select Protocol* menu.

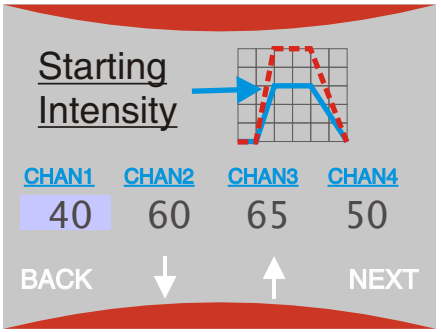


Stimulus Intensity Display

The Stimulus Intensity sets the level that each channel will ramp up to during a session. Typically, the higher the Intensity setting, the stronger the contraction. The Intensity should never be set to a point that is uncomfortable for the patient.

Press *EDIT* to change one or more of the Stimulus Intensity settings. Set the intensity of a channel by pointing to the channel using the *NEXT* and *BACK* keys then pressing the UP key to increase stimulus or the *DOWN* key to decrease stimulus. At the first press of an arrow key, the red "STIM" light will illuminate as a reminder that stimulus is active.

NOTE:
For safety, stimulus is never activated upon entry to the Stimulus Intensity display. This allows for review of the Intensity settings without having to activate the stimulus.



Edit Stimulus Intensity Display

The patient must be prepped before determining or changing the Stimulus Intensity. Affix the electrodes or don the electrode garment as directed by the clinician.

The SpectraSTIM will be equipped with either a Patient Lead Wire Cable with individual pins that connect to the electrodes or with a Garment Cable that will connect to a specially designed garment or sleeve with built-in electrodes.

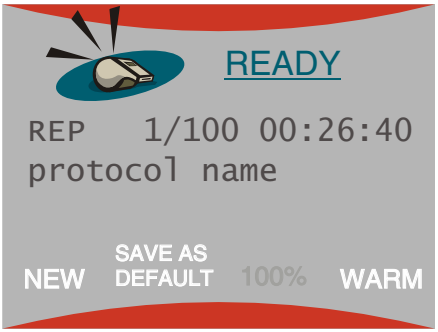
CAUTION:
To avoid electric shock, the electrode pins should not be touched by the operator or the patient when stimulus is active.

The first touchpress of the UP or DOWN key at a channel will always set the associated intensity back to 0. Subsequent keypresses of the UP and DOWN keys will increment and decrement the Intensity of the selected channel in steps of 1 milliamp.

NOTE:
The SpectraSTIM will begin testing electrode impedance at a low stimulus level. If the electrode interface is not in place, an impedance/open lead error will be signaled.

NOTE:
Treatment can be terminated immediately by pressing the STOP key. The stimulus light will turn off, indicating it is safe to disconnect the electrodes and electrode lead wires.

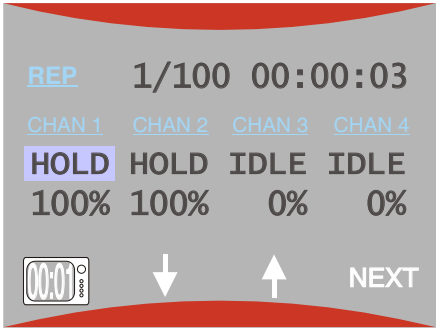
Once the Intensity is set for all channels, press *OK* to move to the *Ready* display. The intensity for any unused channel should be set to 0.



Ready Display

NEW	Return to Protocol Selection Display to choose new protocol or edit current one.
SAVE AS DEFAULT - or - *SAVE*	Tag this protocol as the one that will be loaded on power up of the SpectraSTIM. Save this modified protocol. This option appears if any part of the protocol was edited.
100%	Resume session with 100% of the Target Stimulus Intensity. This choice is grayed-out if the Warm-up Reps for this session have not been completed.
WARM	Start or re-start session beginning with the Warm-up level of stimulus.

The Session Display tracks the progress of a session and allows for gradual operator changes in the stimulus Intensity levels.



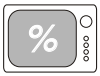
Session Display

The operation of the buttons is straightforward. *STOP* turns off stimulus and suspends the session. *NEXT* moves the highlight pointer from one channel to the next. The *UP* and *DOWN* keys increase and decrease the stimulus Intensity of the selected channel.

NOTE:
An Intensity setting for a channel is adjustable only during the Hold *phase of a profile.*

A session will continue until the programmed number of repetitions is reached. Session time counts up the hours, minutes, and seconds of the session. The bottom two lines of the display show the stimulus Intensity and profile phase of the channels.

The  button at the left bottom of the touchscreen allows the display mode to be changed:



Switch to *Percent of Target Intensity* display.

Switch to a Milliamp display of stimulus intensity.

Switch to Impedance Reading display.

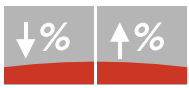
Switch to a large-numeral countdown of time remaining in session.

A session always begins with a Warm Up, starting with rep #1 or with the first rep after pausing the SpectraSTIM. The method and duration of the increase of stimulus during the Warm Up is predefined by one of two modes.

In the *Manual Warm Up* mode, stimulus can be increased and decreased by 20% for each repetition.

In the *Automatic Warm Up* mode, stimulus will increase uniformly from 0 up to the Target Intensity over the number of Warm Up Reps predefined in the protocol.

During the Warm Up, the INCREASE and DECREASE buttons are paired with a percent sign to indicate this mode. These buttons are grayed-out and inactive when in the Automatic Warm Up mode.



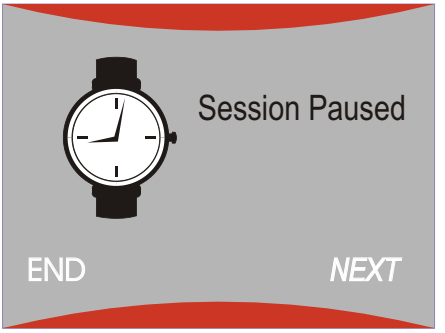
There are five phases in a Profile. These phases define the onset and offset of stimulus for each channel.

IDLE	Stimulus is off and waiting for the beginning of the next Ramp Up on the channel.
UP	Stimulus is ramping up to the current stimulus Intensity level.
HOLD	Stimulus is "holding" at the current stimulus Intensity level.
DOWN	Stimulus is ramping down to 0 from the current stimulus Intensity level.
REST	Stimulus is off and the channel has finished its Ramp Down and is waiting for the next REP to begin (i.e., for the other channels to finish their IDLE-UP-HOLD-DOWN-REST sequence).

Once the protocol is complete, i.e., the programmed number of REPS are finished, the *Session Complete* display will appear. From here, the session can be ended by turning off the SpectraSTIM or a new session can be started by touching *NEW*.

Session Complete Display

At any time, the *Stop Button* can be pressed to turn off stimulus and pause the session. Press *END* to move to the *Session Ended* display. Press *NEXT* to return control to the *Protocol Selection* display or, if in an active session, to the *Ready* display.



Session Paused Display

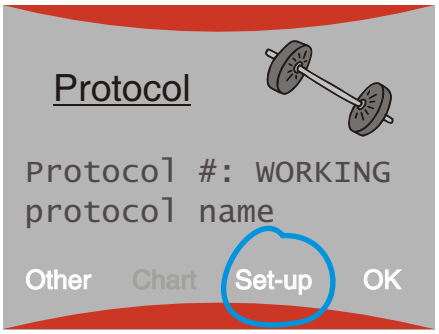
The SpectraSTIM E3 continuously performs system checks to ensure that the stimulator is working properly. When an error occurs, the SE3 will signal the error and end the current session.

Refer to the back of this manual for instructions for contacting Therapeutic Alliances in the event of an error.

System Error Display

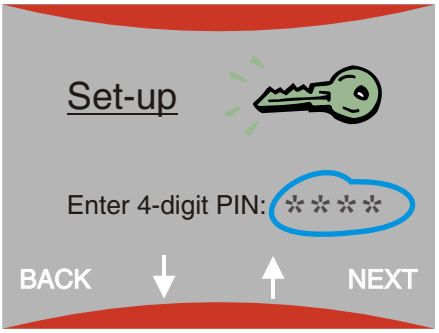
4.4 Programming the Stimulator

A complete set of protocol parameters can be modified by the clinician. Access to this section is made by choosing *Set-up* from the *Select Protocol* display.



Select Protocol Display

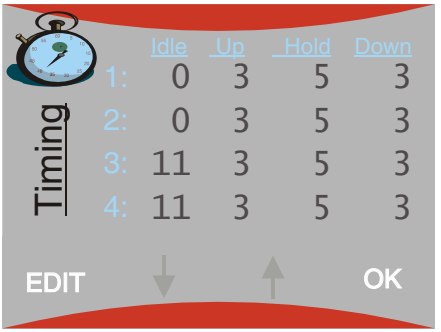
A 4-digit password is required to access the protocol parameters. Contact Therapeutic Alliances for a PIN assignment.



Enter Set-up PIN Display

4.4.1 Setting the protocol timing

The timing settings control the onset and offset of stimulus on all four channels. Any relationship among channels may be set by selecting an appropriate IDLE duration for each channel.



Protocol Timing Display

Choose *EDIT* to set the timing components of each channel. These components, Idle, Ramp Up, Hold, and Ramp Down, are entered independently for all channels. To better understand the components of a profile, they are presented in both table and graph form.

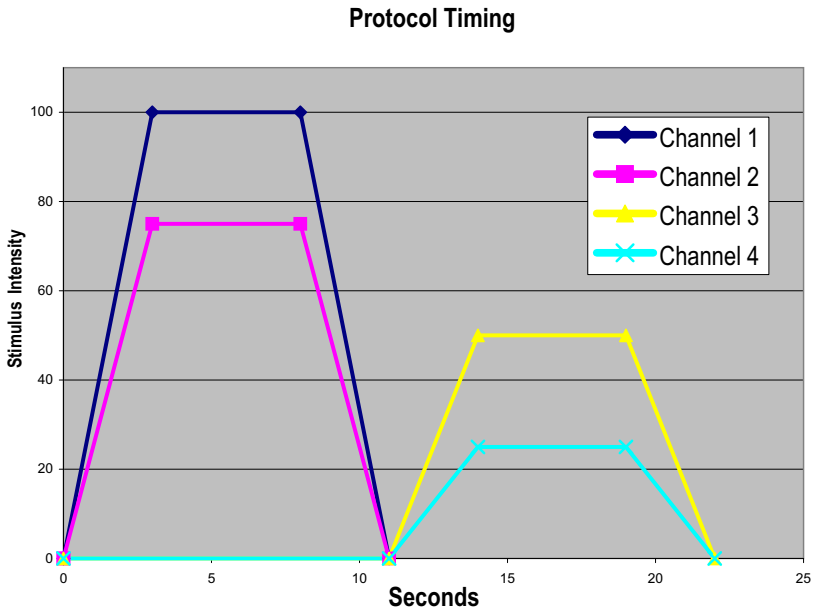
A profile time for any channel is the sum of its idle, ramp up, hold, and ramp down times. The time it takes to complete one repetition is computed by adding the rest time to the time it takes to complete the longest profile. In our example, channels 3 & 4 have the longest profile time, 22 seconds. So we add the 5 second rest to the 22 second profile, yielding a time per rep of 27 seconds.

```
profile_time = idle + ramp_up + hold + ramp_down

          CH1:     0   +     3     +    5   +       3       =   11 seconds
          CH2:     0   +     3     +    5   +       3       =   11
          CH3:    11   +     3     +    5   +       3       =   22
          CH4:    11   +     3     +    5   +       3       =   22
```

time/rep = max_profile_time + rest = 22 + 5 = 27 seconds

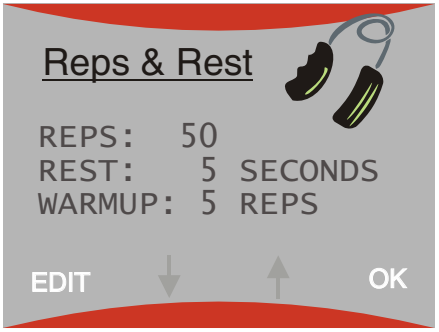
session_time = #reps x time/rep = 10 x 27 = 270 seconds = 00:04:30



For clarity in this example, the stimulus Intensities are set at different levels to separate the channel graphs on the y-axis.

4.4.2 Setting the reps/rest

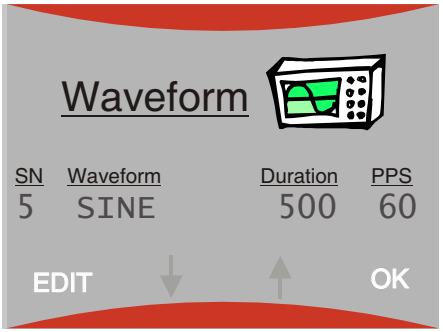
Session time is computed by multiplying time/rep by the number of reps. This yields the total time it will take to complete the session, less any paused time.



Reps/Rest Display

4.4.3 Setting the waveform

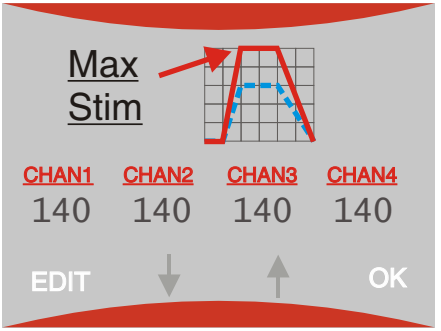
Four components of the waveform are programmable: waveshape, pulse duration, frequency, and amplitude. The first three of these stimulus parameters are accessed through the Set Waveform display.



Waveform Settings Display

4.4.4 Setting the Maximum Stimulus

The Maximum Stimulus along with the Stimulus Intensity are the most important of all of the parameters. Proper stimulus settings will help to ensure that the patient does not receive stimulus that is uncomfortable or a contraction that is too powerful for the selected therapy.



Maximum Stimulus Display

Press *EDIT* to change the Max Stim on any channel. Use the *NEXT* and *BACK* keys to move from one channel to the next. The *UP* and *DOWN* keys will increment and decrement the Max Stim setting by 10 milliamps at a time.

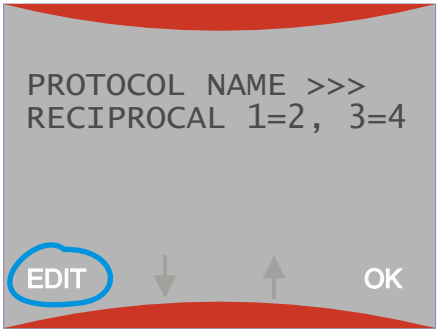
Note: Stimulus is not active when editing the Max Stims.

Note: Choosing to Edit the Max Stims will cause the Stimulus Intensity settings to be zeroed for all channels.

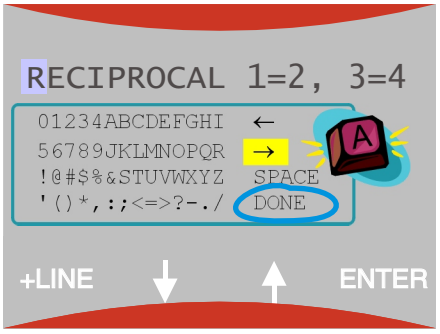
4.5 Saving Protocols

Once a protocol has been modified, it can be saved in its old position in memory or it can be assigned a new name and assigned a different slot.

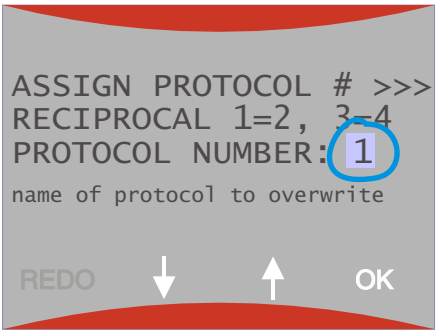
Save Protocol? Display



Edit Protocol Name? Display



Edit Protocol Name Display



Assign Protocol Number

Once the protocol name is entered/edited, highlight *DONE* and press the *ENTER* touch button. An entry for the protocol number will appear. The name of the protocol currently occupying the slot for that protocol number will appear on the line below. Select a different protocol slot by using the *UP* and *DOWN* keys. Press *NEXT* to replace this protocol with the newly-modified one.

Any protocol can be assigned as the default protocol. The SpectraSTIM will load the default protocol when the unit is first powered on. For this reason, it is convenient to assign the most often used protocol as the default.

5.1 Customer Service

To obtain service, please call the Therapeutic Alliances Customer Service Department at (937) 879-0734 for information and instructions. When calling, please have the following information:

* Name and address of original purchaser.
* Date of purchase.
* Serial number of the SpectraSTIM E3 stimulator (printed on the back of the unit).
* Error number, if applicable.

5.2 Limited Warranty

Therapeutic Alliances Inc. (TAI) will repair or replace any defective or out of specification SpectraSTIM E3 part at no charge to the purchaser for a period of one year from the date of shipment. This warranty is subject to the following conditions:

1. This warranty applies only to the original purchaser and is not transferable.
2. This warranty does not apply to defects or damage caused by misuse or abuse in storage, handling, transportation, or unauthorized repairs or alterations.
3. TAI shall have the opportunity to inspect all returned parts. The customer shall be liable for the cost of the repair if TAI determines that the part is not covered by this warranty.
4. The customer will be responsible for the shipping charges when returning any questionable part to TAI. Contact the TAI Customer Service Department for packing and shipping instructions.
5. This warranty does not cover disposable or consumable parts or accessories such as electrodes, wire assemblies, or supplies.

TAI makes no other warranty of any kind, implied or expressed, with regard to this product or documentation. No oral or written information or advice given by TAI, its dealers, distributors, agents, or employees shall create a warranty or in any way increase the scope of this warranty. This warranty sets forth specific legal rights. Other rights vary from state to state.

Neither TAI nor anyone else who has been involved in the creation, production, or delivery of this product shall be liable for errors contained herein or for any direct, indirect, incidental, or consequential damages arising out of the use of or inability to use this product. Because some states do not allow the exclusion or limitation of liability for consequential or incidental damages, the above limitation may not apply.

This Warranty is governed by the laws of the State of Ohio.

THERAPEUTIC ALLIANCES INC.

YOU ARE THE MOVING PART

Therapeutic Alliances Inc.
333 North Broad Street
Fairborn, Ohio 45324 USA

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