

Stimplus™ and Stimplus Pro™

Instructions for use

Caution: Federal Law restricts this device to sale or use by or on the order of a practitioner so licensed by the State.



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Introduction to Patient and Professional

The Body Clock Stimplus and Stimplus Pro units are designed for the treatment of symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

The instructions in this manual are designed to cover most operational issues. However if you have any questions about your particular condition or if problems arise, please seek advice from your physician or therapist.

Unique Features

- Audio and visual (LED) intensity indicator.
- 6 intensity levels indicated by 6 LED's.
- 3 choices of stimulation rhythm.
- Timer to adjust treatment duration.
- Stimulates through micro current therapy.
- Ear-phone jack to stimulate in silence.
- Free precision extension tip (with the Stimplus Pro only)
- Ergonomic design
- Compact, light and user friendly.

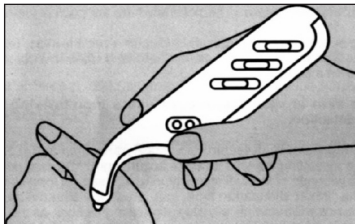
How to Use the Body Clock Stimplus

1. Activate the Body Clock Stimplus by turning the power switch on.
2. PLEASE NOTE that the device must be held by the person being treated, as the passive contact plate acts as one end of a circuit, the other being the tip of the device, which is applied to the desired point. When treating another party, the operator should hold the device onto the points to be treated, and ensure that physical contact is maintained between the operator and the other party in order to complete a circuit. (below). Alternatively, a wrist strap (which is not included with this unit and may



be purchased separately) may be used to the same effect. The wrist strap consists of a lead with the wrist strap at one end and a jack plug at the other end. If the strap is used, the jack plug should be inserted into the jack on the underside of the device. The wrist strap should then be worn by the other party. There is then no need for physical contact to be maintained between the operator and the other party. Stimulation may then be commenced.

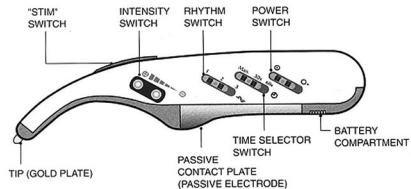
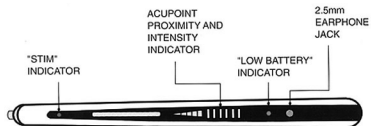
3. Begin stimulation by selecting the desired stimulation time by setting the time selector switch. A preset time of 30 or 60 seconds may be selected or alternatively manual stimulation, which lasts as long as you choose.
4. If a preset stimulation time is chosen, just press the stimulation button briefly and release. The



- device will automatically stop stimulating when the preset time is over. If manual stimulation is selected, the device will stimulate for as long as you press the stimulation button.
5. When the unit is switched off, the intensity level will automatically be reset to minimum. You can see the previous intensity setting by pressing the intensity button, after which, the previous intensity will appear for 5 seconds in the 6 LED bar scale. You can then increase or decrease that

- preset intensity level before beginning stimulation.
6. You may select one of three rhythm options during stimulation: continuous, 1Hz or 4Hz. You can select the rhythm that provides the best level of comfort.
 7. When you begin the stimulation, the beeper sound will stop and the green light will flash, indicating that stimulation has begun.
 8. Using the intensity control switch you can adjust the intensity to a comfortable level pressing the "+" or "-" keys to either increase or decrease intensity. The intensity level will be indicated by the LED scale. If the LED nearest to the tip is flashing, the unit is set at minimum intensity. If the LED furthest from the tip is flashing, the unit is set at maximum intensity.
 9. Once stimulation is over, the device switches back to search mode and the beeper sound will be audible again.
 10. During stimulation you may feel the electric current at the stimulation site.
 11. The ear piece included with this unit may be used to mute the beeper sound enabling the user solely to hear this sound. This piece consists of a lead with a jack plug at one end and the ear piece at the other end. To activate the ear piece, insert the jack plug into the earphone jack. The ear piece is now ready for use.

Stimulus Controls and indicators



Stimplus Technical Data

	MIN	TYP	MAX
Operating Voltage	4.5V	6.0V	6.5V
Output Intensity (500 ohms)	0mA	-	1.2mA
Output Waveform	Asymmetrical Biphasic rectangular		
Stimulation Pulse Rate	13 Hz	16 Hz	19Hz
Pulse Width	-	0.15ms	-
Low Battery Indication	4.1V	-	4.9V
Battery Life (30 sec/cycle)	3800 cycles	-	-
Power Source	Powered by 2 Lithium 3 volt batteries (included)		
Weight (grams)	43.5g		
Dimensions	16.5cm x 3.7cm x 1.3cm (6 1/2" x 1 7/16" x 9/16")		
Classification	This unit is fully compliant with EEC Directive 93/42/EEC, and is classified as internally powered equipment, Type BF. It is intended for continuous operation.		

Explanation of Symbols



BF Isolated applied part



Warning – refer to accompanying documents (i.e. this user manual)

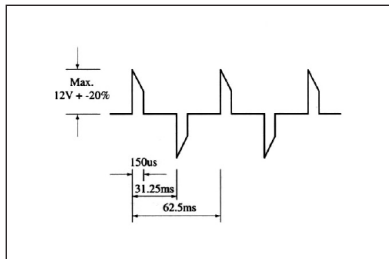
Storage Temperature Range

-5°C – 65°C

Storage Relative Humidity

Up to 80%

The radio shielding of the device has been ascertained according to VFG 243/1991 (interference suppression of ISM devices).



Shapes of output curves under a 500 ohm load

How to Use the Body Clock Stimplus Pro

1. Activate the Body Clock Stimplus Pro by turning the power switch on.
2. PLEASE NOTE that the device must be held by the person being treated, as the passive contact plate acts as one end of a circuit, the other being the tip of the device, which is applied to the desired point. When treating another party, the operator should hold the device onto the points to be treated, and ensure that physical contact is maintained between the operator and the other party in order to complete a circuit. (See right). Alternatively, the wrist strap included with this unit may be used to the same effect. The wrist strap consists of a lead with the wrist strap at one end and a jack plug at the other end. If the strap is

used, the jack plug should be inserted into the jack on the underside of the device. The wrist strap should then be worn by the other party. There is then no need for physical contact to be maintained between the operator and the other party. Stimulation may then be commenced.

3. Begin stimulation by selecting the desired stimulation time by setting the time selector switch. A preset time of 15 or 30 seconds may be selected or alternatively manual stimulation, which lasts as long as



you choose.

4. If a preset stimulation time is chosen, just press the stimulation button briefly and release. The device will automatically stop stimulating when the preset time is over. If manual stimulation is selected, the device will stimulate for as long as you press the stimulation button.
5. When the unit is switched off, the intensity level will automatically be reset to minimum. You can see the previous intensity setting by pressing the intensity button, after which, the previous intensity will appear for 5 seconds in the 6 LED bar scale. You can then increase or decrease that preset intensity level before beginning stimulation.
6. You may select one of three frequencies during stimulation: 5Hz, 10Hz or 20Hz. You can select the

frequency that provides the best level of comfort.

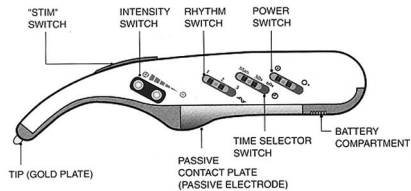
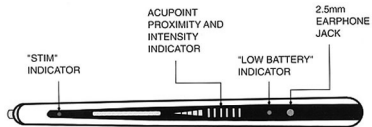
7. When you begin the stimulation, the beeper sound will stop and the green light will flash, indicating that stimulation has begun.
8. Using the intensity control switch you can adjust the intensity to a comfortable level pressing the "+" or "-" keys to either increase or decrease intensity. The intensity level will be indicated by the LED scale. If the LED nearest to the tip is flashing, the unit is set at minimum intensity. If the LED furthest from the tip is flashing, the unit is set at maximum intensity.
9. Once stimulation is over, the device switches back to search mode and the beeper sound will be audible again.
10. During stimulation you may feel the electric current at the stimulation site.
11. The ear piece included with this unit

may be used to mute the beeper sound enabling the user solely to hear this sound. This piece consists of a lead with a jack plug at one end and the ear piece at the other end. To activate the ear piece, insert the jack plug into the earphone jack. The ear piece is now ready for use.



12. A precision extension tip is also provided, which can extend the tip (+) to assist you where an acupoint is difficult to reach. This is simply placed over the tip and is then ready for use.



Stimplus Pro Controls and indicators

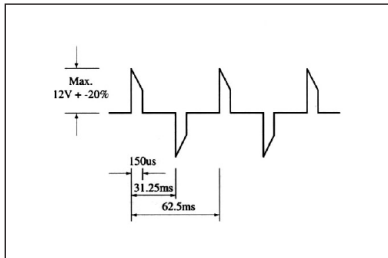


Stimplus Pro Technical Data

	MIN	TYP	MAX
Operating Voltage	4.5V	6.0V	6.5V
Output Intensity (500 ohms)	190uA	-	1.15mA
Output Waveform	Asymmetrical Biphasic rectangular		
Stimulation Pulse Rate	5 Hz	10 Hz	20Hz
Pulse Width	-	0.15ms	-
Low Battery Indication	4.1V	4.5V	4.9V
Battery Life (30 sec/cycle)	-	8800 cycles	- -
Power Source	Powered by 2 Lithium 3 volt batteries (included)		
Weight (grams)	43.5g		
Dimensions	16.5cm x 3.7cm x 1.3cm (6 1/2" x 1 7/16" x 9/16")		
Classification	This unit is fully compliant with EEC Directive 93/42/EEC, and is classified as internally powered equipment, Type BF. It is intended for continuous operation.		
Explanation of Symbols		BF Isolated applied part	
		Warning – refer to accompanying documents (i.e. this user manual)	
Storage Temperature Range	-5°C – 65°C		
Storage Relative Humidity	Up to 80%		

The radio shielding of the device has been ascertained according to VFG 243/1991 (interference suppression of ISM devices).

Shapes of output curves under a 500 ohm load



Contraindications

1. This device should not be used around the Carotid sinus (neck) region or the orbits of the eyes.
2. Any use of this device on patients who have a demand-type cardiac pacemaker.
3. Do not use this device transcranially (i.e. when treating another individual, do not make a circuit by placing the device and your spare hand on their head).
4. The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

Warnings

1. The safety of TENS devices for use during pregnancy or birth has not been established.
2. TENS is not effective for pain of

- central origin.
3. TENS devices should be used only under the continued supervision of a physician.
 4. TENS devices have no curative value.
 5. TENS is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
 6. The user must keep this device out of the reach of children.
 7. Electronic monitoring equipment (such as ECG monitors and ECG alarms may not operate properly when TENS stimulation is in use.

Precautions

1. Isolated cases of skin irritation may occur at the site of electrode (gold-tip) placement following long term application.

2. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

Adverse Reactions

Skin Irritation and contact burns can occur if the device is used in a constant and continuing stimulation pattern. Therefore be very careful as to the condition of the skin beneath the main contact point.

Skin Preparation

Prepare the skin before using the Body Clock Stimplus or Stimplus Pro by thoroughly washing the skin with a mild soap and water solution where contact will be made. This will remove non-conducting skin oils. Then rinse the area with warm water and dry thoroughly.

Electrode Placement (Gold tip)

For reducing the pain, place the gold tip on or above the point of pain.

Maintenance and Care

Guidelines for optimum performance:

- Change the battery regularly.
- The unit must be switched off when changing the battery.
- The unit should be wiped clean periodically using a very slightly dampened cloth. A mild soap may be used but DO NOT apply solvents.

General Precautions:

- Do not immerse your Body Clock Stimplus or Stimplus Pro in water or any other liquid
- Do not place the device close to any source of excess heat
- Do not operate the device in the presence of flammable gases
- Do not attempt to open the Body Clock Stimplus or Stimplus Pro unit
- Do not use battery or power sources other than those specified
- Do not drop this unit onto a hard surface

Checking system performance and trouble shooting

- If the “red” LED lamp illuminates when the power switch is turned on, turn the device off. Then replace the two three (3) volt batteries and turn the device on again. If it still does not function, return the device for repair.

- If your unit does not appear to be operating properly, first change the battery. Replacing the battery can eliminate most operational problems. If the device still does not appear to function properly, return the device for repair.
- If the “green” LED lamp does not illuminate when the stimulation switch is pressed, return the device for repair.

Battery Replacement

When replacing the batteries, ensure that the power switch is turned off. Then remove the battery compartment cover, and take out the two lithium three (3) volt batteries and replace them with two new two lithium three (3) volt batteries. Then replace the battery compartment cover.

Device failures

- Please do not attempt to repair damaged devices yourself.
- In case of further inquiries, always state the model of your device (as indicated on the back of the unit).
- Body Clock TENS should be repaired by qualified technical personnel.
- Body Clock TENS units are guaranteed for a period of 5 years against manufacturer’s defects.
- Note: the guarantee is null and void if any attempt is made to open the unit by unauthorized personnel.
- In the event of a fault please contact the supplier (address found on the invoice or delivery note) or Body Clock, 108 George Lane, South Woodford, E18 1AD.
Tel: +44 20 8532 9595
Fax: +44 20 8532 9551
email: sales@bodyclock.net

Guarantee

Your TENS machine is guaranteed for a period of 5 years against manufacturer's defects. Please record purchase details in the space provided below for your record purposes.

The guarantee does not include leads, electrodes or battery

Name of product: Stimplus / Stimplus Pro

Date of purchase: _____

Invoice number: _____



ISO 9001:2008 ISO 13485:2003
EC DIRECTIVE 93/42/EEC Annex V

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This manual is recyclable

