

# Profile TENS™

## 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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## Profile TENS Technical Data

### Equipment Type:

Dual channel digital TENS

**Output Intensity:** 0 -100 mA peak to peak adjustable in level 0 - 20 (measured across a 500 Ohm load)  
Level 0 is 0v and has no output (500 ohms load)

### Output Voltage:

0 - 50v peak to peak adjustable in levels  
0 - 20 (through a 500 Ohm load)

### Frequency:

50 selectable frequencies - adjustable up or down 1- 200Hz  
i.e.1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,22,24,26,28,30,35,40,45,50,55,60,65,70,75,80,85,90,95,100,105,110,120,130,140,150,160,170,180,190,200Hz

### Pulse Width:

10 selectable pulse width settings adjustable up or down 25,50,75,100,125,150,175,200,225,and 250 microseconds

### Output waveform:

Symmetrical bi- phasic rectangular

### Output Modes:

5 selectable modes

- (a): Constant
- (b): Burst 1 - Fixed 1 burst per 2 seconds. Each burst consists of 80 pulses. Pulse width is adjustable.
- (c): Fixed 2 bursts per second. Each burst consists of 7 pulses. Pulse width is adjustable.
- (d): Width Modulation - Pulse width modulates between 25-250 $\mu$ s, ramp up for 8 seconds and ramp down for 8 seconds. Frequency is adjustable.

- (e):** Rate Modulation - Frequency modulates decreasing from 100Hz to 20Hz in a period of 8 seconds. The frequency then increases from 20Hz to 100Hz in the next 8 seconds. This pattern is then repeated. Pulse width is adjustable.

**Timer:**

7 selectable settings

- (a) Continuous (b) 10 minutes  
(c) 15 minutes (d) 20 minutes  
(e) 30 minutes (f) 45 minutes  
(g) 60 minutes

**Output Jacks:**

CE touchproof

**Batteries:**

2 x 1.5 v AA batteries (type LR6)

**Functions**

**Memory:**

Saves last mode attempt in memory i.e. the next time the unit is used it will start again at the same setting as before. This memory is erased when batteries are changed.

**Mode Change:**

When the mode is changed, the intensity level will drop back to zero. It will then gradually increase to the level set by the user.

**Display:**

In both modulation modes, output changes are visible on the display.

**Timer:**

Timer counts down in minutes when timer is on.

### **Automatic shutdown:**

If intensity levels are 0 on both channels and if the unit has not been in use for five minutes it will shut down automatically.

### **Low battery indicator:**

A flashing symbol indicates low battery.

### **Load detector:**

If an electrode should accidentally detach itself from the body or the leadwire, the intensity will drop to zero.

## **Professional Functions**

### **Permanent time used memory:**

Memorises up to 99 hours used time. Display appears in hours and minutes.

### **Number of times used:**

Provided the unit is in use for five minutes with the intensity activated, the unit will memorise the number of times the unit is used.

### **Lock/unlock parameter facility:**

Option to lock and unlock device settings. When batteries are removed, parameters are retained provided the locking facility is activated

Specifications are nominal and subject to variation from listed values due to normal production tolerances of  $\pm 10\%$ .

## Classification

This unit is fully compliant with EEC Directive 93/42/EEC, classified as internally powered Equipment Type BF. It is intended for continuous operation.

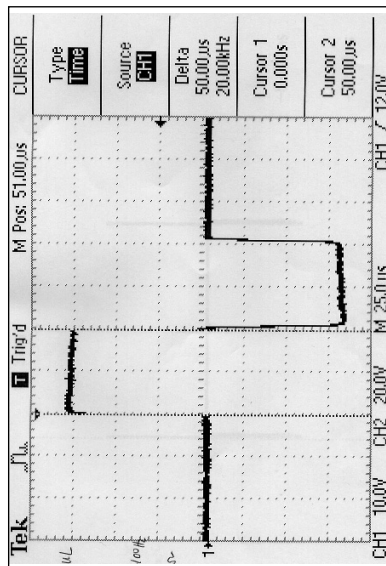


Equipment providing a particular degree of protection against electric shock particularly regarding allowable leakage currents having an F type (floating) applied part.



Warning - refer to these instructions and “Easy Guide to TENS Pain Relief”

## Output waveform



## **Introduction to Patient and Professional**

The Body Clock Profile TENS is 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.

### **What is TENS and how does it work?**

TENS stands for Transcutaneous Electrical Nerve Stimulation.

The treatment consists of passing mild electrical impulses through your skin into the nerve fibers that lie below. Contact is made with your skin via electrodes. TENS electrodes are placed around or over the painful area.

In 1965, researchers Melzack and Wall presented their concept of a “gate” theory for pain control. This theory says that a “T” cell transmits signals to the dorsal horn, and that the stimulation of large nerve fibers may result in the blocking of pain transmission. The TENS message is carried to the spinal chord faster than a pain message and closes a hypothetical gate, inhibiting the pain message to the brain. This applies when the pulse rate is set at a higher frequency of 60-80 pulses per second or more.

TENS can also work by stimulating the body to release endorphins, the body's own pain killing substances. This applies when the Pulse Rate is set below 4 pulses per second – usually at 2 pulses per second. This lower frequency treatment produces slight muscle twitching (tapping). Patients find this treatment takes longer, at least 20-30 minutes to be effective, but the resulting pain relief can last for a longer period.

### Accessories

The Profile TENS is a dual channel TENS unit, supplied with the following accessories:

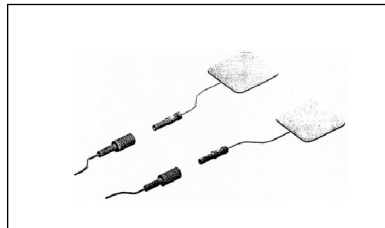
1. 1 pack of 4 50mm x 50mm self adhesive electrodes;
2. 4 x AA batteries;
3. 2 lead wires;

4. 1 manual; and
5. 1 carrying pouch.

### How to place electrodes

Body Clock TENS units are supplied with 2 x 2 (50mm x 50mm) self-adhesive rectangular electrodes. These are consumable items that can be re-ordered from Body Clock.

- Store electrodes in packaging provided in a cool dry place.
- A key to successful use of the



stimulator is finding the best placement for the electrodes. You may need to try several electrode locations before you find the best one to intercept your pain.

- Before placing the electrodes on your skin, wash the area with mild soap and water and then thoroughly rinse and dry.
- Trim excess body hair, which could interfere with smooth electrode contact with the skin, but do not shave it.
- Do not place electrodes on cut, broken or irritated skin.
- Moisturizing cream may be applied after treatment, but not before.
- Never place or remove the electrodes, test or wet them while the system is turned on and connected to the electrodes. Failure to comply can result in a sudden unpleasant sensation on your fingertips.

## Lead Wires

The lead wires are made of high quality shielded wiring. They are made from fine wire to be flexible and lightweight and if treated gently are designed for long life. The pin ends of the leadwires are inserted into the electrodes.

## How to Use the Body Clock Profile TENS

1. Slide battery cover off by gently pressing on the triangular ribbed area with your thumb and move downwards. Insert batteries, ensuring the positive and negative terminals are correct as marked inside the battery compartment. Ensure that the ribbon is left underneath the batteries as this will assist you when the batteries need to be removed. Replace battery cover.

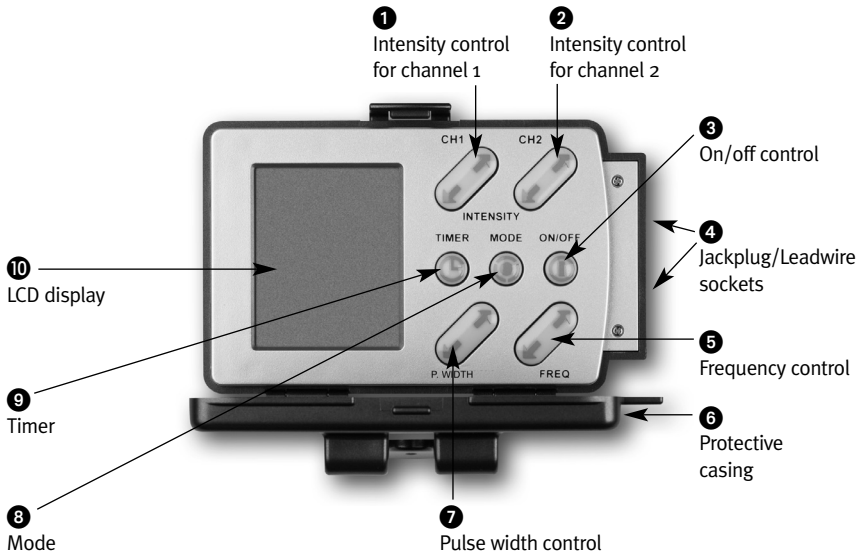
2. Insert the leadwire pins into the electrodes.
3. If using carbon rubber electrodes spread on a small amount of gel and affix with surgical tape (not supplied).
4. If using self-adhesive electrodes, read instructions provided with the electrodes and ensure your skin is free from oil, talc, etc.
5. Position electrodes in accordance with instructions provided with the electrodes or preferably with your medical advisor. NB It is a safety feature of the Profile TENS that the intensity controls will only work if the leadwires are connected with electrodes attached to the skin.
6. With the unit switched off, insert the leadwires into the sockets (see diagram on page 11). You are now ready to commence stimulation.
7. Turn on the unit by means of the ON/OFF button.
8. Set the pulse rate (frequency) control to the 2Hz
9. Pulse Width adjustment provides extra versatility. Increasing or decreasing the setting heightens or lessens the sensation at the site of the electrodes. Set initially to 100, then adjust as desired.
10. Slowly turn up the intensity using the intensity controls (see diagram on page 11).

11. By setting the pulse rate control to the upper end of the pulse rate range (80Hz or above) you feel a tingling sensation. This is based upon the Gate Control Theory.
12. Effective pain relief may also be achieved at the lower end of the pulse rate range - approx 2Hz, this will feel like a heart beat. This is based upon the Gate Control Theory.
13. With the mode button then select the mode you wish to use . There are five modes to choose from.- Constant: The pulses are steady and continuous; Burst 1 The pulses are off and on in regular cycles resembling massage; Burst 11 The pulses are off and on in regular cycles in a tapping rhythm. Width modulation; Pulse width modulates to create a gentle ebbing and flowing effect. Frequency modulation; Pulse rate quickens and then slows down creating a pleasant tingling sensation.
14. Varying the modes helps avoid or delay your body becoming used to any particular setting. Your medical adviser will be pleased to assist you with electrode positions and settings. Continue stimulating for as long as necessary but preferably for no less than 30 minutes unless you experience discomfort.
15. Some people achieve pain relief after a short period, while others may require to use their TENS for longer.
16. If you stimulate for a number of hours check there is sufficient gel on carbon rubber electrodes. If using self-adhesive electrodes check they have not dried out. If this happens,

dampen slightly. If electrodes dry out this can cause minor skin irritation.

17. The timer allows you to pre-set your Profile TENS to switch off automatically and the LCD display will keep you informed about the amount of time your treatment still has to run.
18. When you have finished stimulating, turn the machine off by pressing the On/Off button (see diagram on page 11).
19. Ensure that the unit is switched off before removing the leads. Do not pull the wires. Remove leads by holding the jack plug between the forefinger and thumb.

## Profile TENS Dials and Controls



## Profile TENS Key

### 1 and 2

Two way buttons to increase and decrease intensity for channels 1 and 2. Pressing the UP arrow increases intensity. Pressing the DOWN arrow decreases intensity. The selected level of intensity is indicated on the LCD screen by means of black bars on the left of the screen for Channel 1 and on the right for Channel 2.

### 3

This button switches the machine on and off. Press once to turn the unit on. There will be no feeling from either channel at this time because the intensity always starts at zero. Press this button again to switch the machine off.

### 4

Jack plug sockets.

### 5

Frequency (pulse rate) control. This two way button enables you to select the frequency you require between 1 - 200 Hz,

### 6

Protective cover closes over screen with belt clip on reverse for ease of use.

### 7

Pulse width control. This two way button enables you to adjust the pulse width upwards or downwards as desired between 25 - 250 microseconds.

### 8

Mode selector button.

**9**

Timer. This unit has 7 selectable settings

(i) continuous

When the unit is first used (or after removal of batteries unless you have activated the locking facility) it will be automatically in constant time.

This means that the unit will work continuously until it is switched off by the user. In this setting there is no time display on the screen.

(ii) If a specific time is selected, time will count down on the screen as the unit is used. You simply press the timer button to select the time in minutes which you require. The unit will shut down automatically after the timer has completed counting.

**10**

LCD display.

## Contraindications

1. Any electrode placement that applies current to the carotid sinus (neck) region.
2. Any use of TENS on patients who have a demand-type cardiac pacemaker.
3. Any electrode placement that causes current to flow transcranially (through the 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 (This includes headache).

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

## Adverse Reactions

Skin Irritation and electrode burns are potential adverse reactions.

## 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.

## Precautions

1. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.

### General Precautions:

- Do not yank or twist the leadwires – treat them gently for long life. They are made from fine wire to be flexible and lightweight.
- Do not immerse your TENS in water or any other liquid
- Do not place it close to any source of excess heat
- Do not operate your unit in the presence of flammable gases
- Do not attempt to open the TENS unit
- Do not use battery or power sources other than those specified
- Do not drop this unit onto a hard surface

### Checking system performance:

- If your unit does not appear to be operating properly, first change the battery. Replacing the battery can eliminate most operational problems.
- Ensure that the leadwire attachment is properly fixed to the unit.
- Check the electrodes are firmly attached to the pins of the leadwire.
- Make sure that the leadwire is not damaged or broken.

### 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](mailto:sales@bodyclock.net)

## For professional use only

In order to assist the professional a usage monitor facility is included. Holding down the following combinations will produce these additional functions. To avoid the patient being able to accidentally operate these facilities, it is necessary to hold down the buttons for a few seconds.

### 1) **Timer + CH1 Up/Lock**

This function allows you to lock the current parameter you are using. A "key" locked symbol will appear at the bottom of the screen.

### 2) **Timer + CH1 Down/Unlock**

This function will unlock the parameter that you have locked. The "key" locked symbol will disappear after you have pressed these buttons.

### 3) **Timer + CH2 Up/Total time used**

This function allows you to read the total usage time of the unit.

### 4) **Timer + Ch2 Down / Reset total time**

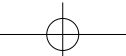
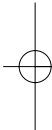
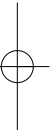
This function gives you an option to reset the usage time to zero.

### 5) **Timer + Pulse Rate Up / Number of times used**

This function allows you to read the total number of times you have used the unit. You must operate the unit correctly and for at least one minute. The counter will increase by one each time the unit is used.

### 6) **Time + Pulse Rate Down**

This function gives you an option to reset the number of times used to zero.



## ***Guarantee***

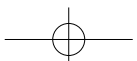
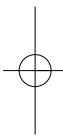
Your TENS machine is guaranteed for a period of 5 years against manufacturer's defects. Please record purchase details in the space provided below for your record purposes.

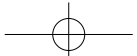
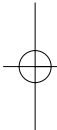
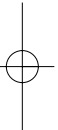
The guarantee does not include leads, electrodes or battery

Name of product: Profile TENS

Date of purchase: \_\_\_\_\_

Invoice number: \_\_\_\_\_







Medical Devices Directive 93/42/EEC Annex V

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