

User Manual for Ultima 5 T.E.N.S. UNIT

PRESCRIBING INFORMATION

FOREWORD



Read this User Manual carefully before you start using your Ultima 5 T.E.N.S. unit.

The manufacturer strongly recommends carefully reading of the "Warnings and Cautions" and Chapters of this User Manual.

WARNINGS AND CAUTIONS

Prescription labeling:



Federal law restricts this device to sale or use by or on the order of a practitioner so licensed by the state.

Contraindications:

1. Do not place the pads on the carotid sinuses located at the two sides of the neck, (where a doctor feels for a pulse), or over the eyes.
2. Do not use this T.E.N.S. unit if you have a heart pacemaker or serious heart rhythm problem.
3. Any electrode placement that causes current to flow transcranially (through the head).

4. The use of T.E.N.S. whenever pain syndromes are undiagnosed, until etiology is established.

WARNINGS

1. Do not use this T.E.N.S. unit during the pregnancy or at anytime on the abdomen during pregnancy.
2. This T.E.N.S. unit is not effective for pain of central origin. (Include headache).
3. T.E.N.S. unit should be used only under the continued supervision of a physician.
4. T.E.N.S. unit has no curative value.
5. T.E.N.S. 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 the device out of the reach of children.
7. Electronic monitoring equipment may not operate properly when T.E.N.S. stimulation is in use.
8. Do not use T.E.N.S. unit if you are driving or operating machinery.
9. If you have epilepsy, consult your doctor

WARNINGS

Do not use any pad which size is less than 40mm X 40mm.

Allergic reactions to the self — adhesive pads can occur, even though they are hypoallergenic:

- Do not apply to broken skin.
- Do not apply pads to skin that do not have normal sensation. If the skin is numb, stimulation will not be felt and too great an intensity might then be used accidentally.

2. Where applicable place the black adapter closer to the spinal column; e. g. if the arm is to be treated, place the black adaptor higher up the arm than the red adaptor.

GENERAL INFORMATION

Statement: This T.E.N.S. Unit has been tested for EMC requirement according to EN 60601-1-2

PADS

The pads that are supplied with your Ultima 5 T.E.N.S. Pain Relief Unit are self-adhesive and can be used several times. Skin must be allowed to breathe, so the pads should be removed periodically. When not in use, the pads should be placed onto the clear plastic shield.

The condition of the pads does affect the conductivity and, therefore, the performance of the unit. When the pads initially lose their adhesive quality, it is possible to reactivate their adhesiveness by applying a fine spray of water. Once the pads have finally lost their adhesive quality, new pads should be purchased.

before using T.E.N.S.

PRECAUTIONS

1. Isolated cases of skin irritation may occur at the site of electrode 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 electrode burns are potential adverse reactions.

GENERAL WARNINGS

1. Do not immerse T.E.N.S. units in water.
2. Do not place the T.E.N.S. unit close to excessive heat.
3. Do not use any pad which size is less than 40mm X 40mm.
4. In the Ultima 5 model T.E.N.S unit, use either: two 1.5 volt AA Alkaline disposable (LR6) batteries or two 1.5 volt AA Ni-MH rechargeable batteries only. The use of any other battery could damage the unit and is not recommended.

5. When using a battery charger and rechargeable batteries with your unit, use only Ni-MH rechargeable batteries in your charger. Do not place non-rechargeable batteries (i.e. disposable alkaline batteries) in a battery charger - this may cause a battery leak or possible explosion.
6. Remove batteries if the unit is not used for three months.
7. Keep the unit away from sources of high magnetic fields such as TV ' S, microwave ovens and hi-fi speakers, as these may affect the LCD screen.
8. Temperature & R.H. of storage: -20°C --+80°C, 8%--80% R.H.
9. Temperature & R.H. of transportation:-20 °C--+80°C, 8%--80% R.H.

1,2,3,4,5,10,12,14,16,18,20,25,
30,35,40,45,50,60,70,80,90,
100,110,120,130,140,150.

D. Output voltage range

The output voltage of two channels can be adjusted individually in 20 steps. For 500-ohm load, the output voltage can be change from 6V to 73V in steps of 3.5V roughly.

E. Peak pulse output current

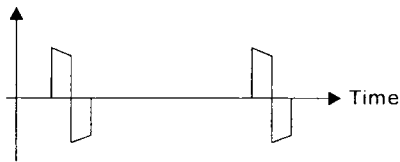
The peak pulse output current of two channels can be adjusted individually in 20 steps. For 500-ohm load, the output voltage can be change from 12mA to 150mA in steps of 7mA roughly.

RED& BLACK FASTENERS ON LEADS

At the end of the leads supplied with your unit, you will find red and black adapters. These are Cathode and Anode respectively. The following general points are made for your information:

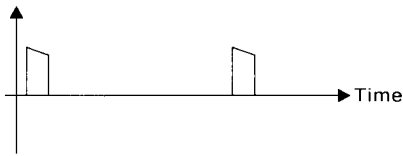
1. More sensation tends to come from the black adapter (Cathode).

Amplitude



(2). Mono-Phasic waveform

Amplitude



B. Pulse duration

Except Mode B, Mode D and Mode E, which pulse duration can not be adjusted, by pressing PW+ or PW- key, the pulse width can be adjusted from 50 μ S to 250 μ S in steps of 10 μ S.

C. Pulse frequency

Except Mode B and Mode E with a fixed pulse rate, by pressing PR+ or PR- key, the pulse rate can be adjusted to one of the following values (Hz):

20

CONTENTS

Prescribing Information	1
Contents	5
Operating Instruction for Physician	6
Instruction For Use	6
How to Assemble Your Unit	7
After Use	12
Operation of the T.E.N.S. Unit	13
Specification	17
Features.....	18
General Information	22

5

OPERATING INSTRUCTIONS FOR PHYSICIAN

INTENDED USE

T.E.N.S. Stands for (Transcutaneous Electrical Nerve Stimulation). This T.E.N.S. system is used to provide symptomatic pain relief for chronic, acute or post-operative pain.

HOW DOES T.E.N.S. WORK

T.E.N.S. is believed to work by stimulating your body's own natural defenses against pain.

The unit produces a gentle stimulus through pads normally placed over the area of pain. This stimulus helps the body to produce natural pain relievers called endorphins.

The correct positioning of the pads is important. Some people feel immediate benefit from T.E.N.S. However some may only achieve benefit after repeated treatment sessions and over an extended period of time.

INSTRUCTIONS FOR USE

Your Ultima 5 T.E.N.S. Pain Relief unit has been designed to be simple and easy to use.

counter-clockwise.

6. By pressing "PR-" key and "PW-" key simultaneously, the waveform can be changed in two types.
7. By pressing "timer key" for 2 seconds the unit will be locked or unlocked in toggle. While the unit is locked, all parameters can not be adjusted except timer and intensity. By pressing ON/OFF key can not change the status of locked/unlocked.
8. When the batteries are low, the symbol of battery is flashing in 2Hz indicating that the batteries should be replaced.
9. Automatic shut off: When the unit intensity levels are 0 on both channels, and it has not been in use for 5 minutes, the unit will be shut off automatically.

Detail information regarding to the Waveform, Pulse duration, Pulse frequency, Output voltage range, and Peak pulse output current:

A. Waveform

There are 2 types of waveforms:

- (1). Symmetrical Bi-Phasic rectangular waveform

and then back to 100 μ S in the next 6 seconds. Pulse rate is selectable.

Mode E--- Modul II, Pulse rate and Pulse width Modulation

Frequency increase from 50Hz to 100Hz while pulse width decrease from 200 μ S to 60 μ S within 5 seconds.

Treatment timer: Continuous, 15min, 30min, 45min, 60min, 90min selectable.

FEATURES

1. When mode changes, the intensity will automatically go down to zero;
2. When the unit is turned on, it will automatically enter the mode that the unit had worked in before the unit was turned off;
3. When the treatment timer is set, it will begin to count down one minute by one minute; Once it count down to zero, the unit will automatically shut off;
4. When the pulse rate or pulse width is being adjusted, the auto-repeat function is available, when "PR+" , "PR-" , "PW+" , or "PW-" key is held down over 1 second, it will automatically increased/ decreased 1 step per 1/4 second.
5. Two knobs on top of the unit adjust the intensity by turning in clockwise or

CONTENT IN THE PACK

Your T.E.N.S. pack should contain the following:

- 1 x T.E.N.S. Unit
- 2 x Leads
- 4 x Self Adhesive Pads with Connectors (size: 40mm X 40mm)
- 2 x Alkaline AA1.54V (LR6) Batteries
- 1 x Instruction Booklet (which you are reading)

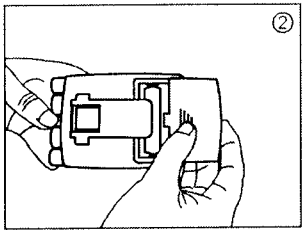
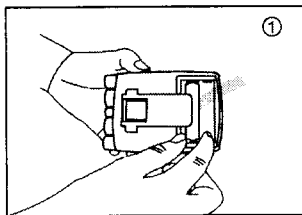
Having checked all the contents are correct please proceed to assemble the unit.

HOW TO ASSEMBLE YOUR UNIT

Assembly of the Ultima 5 T.E.N.S. Pain Relief unit is very simple and requires only five steps.

STEP 1 BATTERIES

Remove the battery cover and insert two batteries, as shown on the diagram inside the battery compartment. Replace the battery cover.



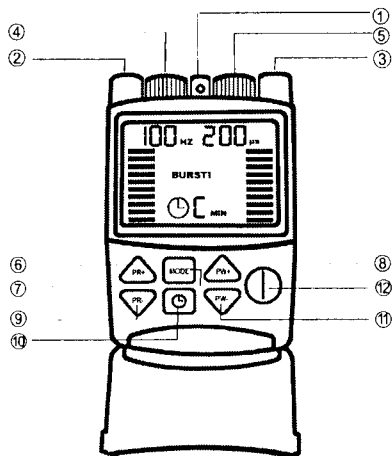
Note: Your unit will not function if the batteries are inserted incorrectly. To check, press the ① button once and the LCD display will start up. Having made this check press the ① button again to switch the unit off.

CAUTION

There is a risk of explosion if the batteries are fitted incorrectly. Replace with AA Alkaline 1.5 volt batteries (LR6). Do not mix old and new

SPECIFICATION

Model: Ultima 5
 Channel: Dual
 Output: Maximum 150mA (peak value) cross 500 Ohm load
 Pulse Width: From 50 μ S to 250 μ S adjustable
 Pulse rate: From 1Hz to 150Hz Adjustable
 Waveform: Symmetrical Bi-phasic rectangular
 Monophasic rectangular
 Mode: 5 Modes are available
 Mode A---Constant
 Mode B---Burst I
 Two train per second, 250ms on, 250ms off;
 25 pulses within one train, pulse width=200 μ S
 Mode C---Burst II
 Two train per second, 250ms on, 250ms off;
 Pulse width and Pulse rate are selectable.
 Mode D---Modul I, Pulse width modulation
 Pulse width modulated from 100 μ S to 250 μ S within 6 seconds



- | | |
|----------------------------|----------------------------------|
| ① LED light | ⑧ Pulse width up |
| ② Ch1 light | ⑨ Pulse Rate Down |
| ③ Ch2 light | ⑩ Timer for Treatment |
| ④ Intensity Up or down Ch1 | • Continuous |
| ⑤ Intensity Up or down Ch2 | • 15/30/45/60/90 min |
| ⑥ Pulse Rate Up | • Selectable |
| ⑦ Mode Select Switch | ⑪ Pulse Width Down |
| • Constant | ⑫ On/Off , intensity Lock/Unlock |
| • Burst I | ⑬+ ⑭ Waveform |
| • Burst II | |
| • Modul I | |
| • Modul II | |

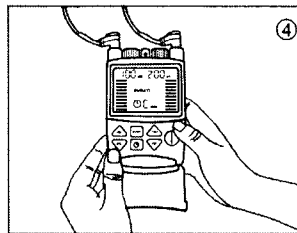
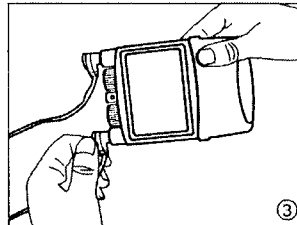
Please read the following detail specification carefully before using the T.E.N.S. Unit.

batteries. Do not dispose of the batteries in a fire and keep them out of reach of children. The batteries must be removed from the unit if unit is not used for a long period of time.

STEP 2 LEADS

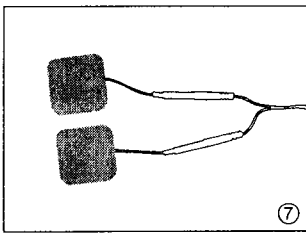
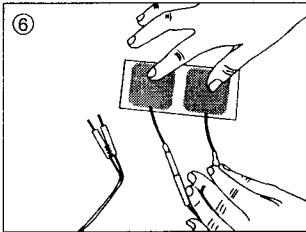
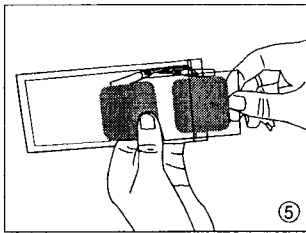
Decide whether you wish to use the unit with one lead or two.


If using two leads, insert the plugs into both jacks on the plugs of the unit. If only using one lead, insert into the **ch1** jack as marked on the unit.





STEP 3 PADS


Remove pads from the bag and connect to the leads.







 Turn in counter-clockwise decrease the intensity.




 Stands for Pulse Rate Up, press this key to increase the frequency.

 Stands for Pulse Rate Down, press this key to decrease the frequency.

 Stands for Pulse Width Up, press this key to increase the Pulse Width.


 Stands for Pulse Width Down, press this key to decrease the Pulse Width.


 Press the key  &  simultaneously to select the waveform. The following waveform symbols will be displayed for 3 seconds when you press the key.


- 
-  Symmetrical Bi-phasic rectangular
 -  Monophasic rectangular


NOTE

In a very small percentage of people, using T.E.N.S. in Monophasic Rectangular waveform can exacerbate the symptoms of pain. If this occurs, stop treatment in this waveform immediately.

 Press this key to select mode, total 5 modes are available. Constant, Burst I, Burst II, Modul I, Modul II.

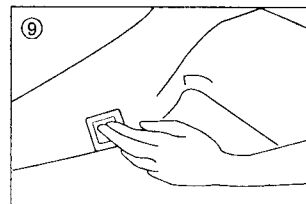
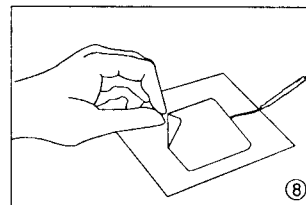
 Press this key to set the treatment time.

 These two knobs adjust the intensity of channels, left side is for the Ch1, right side is for Ch2. Turn the knob and the intensity over zero, the corresponding LED light located at the top of the knob will light up.

 Turn in clockwise increase the intensity.

STEP 4 PLACEMENT OF PADS

Ensure wherever you intend to place the pads, that the skin is clean and thoroughly dry. Remove the pads from the clear plastic shield and position on your body as required.



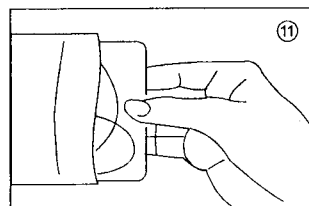
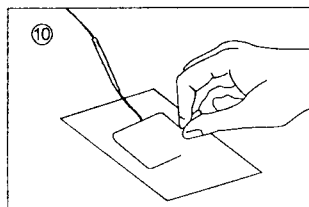
STEP 5 READING

Read section on "Operation of the T.E.N.S. Unit", and decide how to use the T.E.N.S. unit

for the treatment.

NOTE: AFTER USE

Always ensure that the unit is switched OFF before removing the pads. After use, return the pads to the clear plastic shields. There is no need to separate the pads unit from the leads and pads.

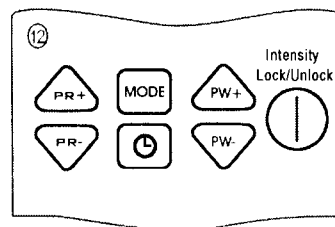


Life of the pads: When the pads initially lose their adhesive quality, it is possible to reactivate their adhesiveness by applying fine spray of water. Replace the pads when they lose their

adhesive quality in order not to affect the efficiency of the unit.

OPERATION THE T.E.N.S. UNIT

Ultima 5 T.E.N.S. Unit is easy to operate by pressing the key as following diagram.



WHAT DOES EACH KEY DO

① This key not only switches the unit on and off, but also has Lock/Unlock intensity function. By pressing this key for 3 seconds the unit is on, the LED light (green color) and the LCD display located at the front of the unit will light up, there will be no feeling from either lead at this time as the intensity always starts at zero. When the unit is on, and desirable intensity level is obtained, then, press this key once to lock the intensity. If you want to unlock the intensity, press this key once again.