

Manufactured for:

Pain Management Technologies

Ultima 11



Instruction Guide

PADS

The pads that are supplied with your Ultima 11 T.E.N.S. 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.

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.

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).
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

User Manual for Ultima 11 T.E.N.S. UNIT

PRESCRIBING INFORMATION

FOREWORD



Read this User Manual carefully before you start using your Ultima 11 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:

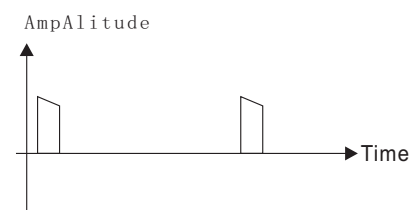
1. Do not place the pads on the carotid sinuses located at the two sides of the neck, (where a doctor feels for a pulse), or over the eyes.
2. Do not use this T.E.N.S. unit if you have a heart pacemaker or serious heart rhythm problem.
3. Any electrode placement that causes current to flow transcranially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

(3). Mono-Phasic rectangular waveform



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):

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 changed from 6V

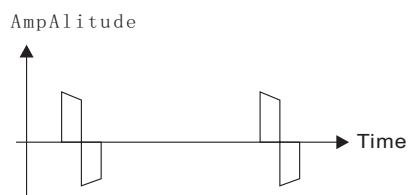
16. When the unit intensity levels are 0 on both channels, and it has not been in use for 5 minutes, the unit will be shut off automatically.

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

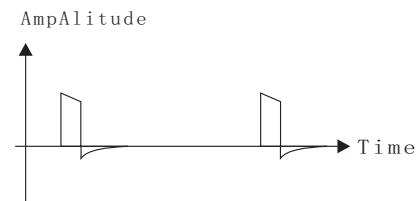
A. Waveform

There are 3 types of waveforms:

- (1). Symmetrical Bi-Phasic rectangular waveform



- (2). Asymmetrical Bi-Phasic rectangular waveform



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. Use only the specified batteries: 2x 1.5volt AA Alkaline (LR6). The use of any other battery could damage the unit.
5. Remove batteries if unit is not used for a long period of time.

6. Do not use the unit while asleep.
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.

the polarity of the symmetrical bi-phasic rectangular and mono-phasic rectangular waveform is reversed, and the corresponding symbol is flashed.

12. 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.
13. When the pulse rate, pulse width or intensity is being adjusted, the auto-repeat function is available, when the key is held down over 1 second, it will automatically increase/decrease 1 step per 1/4 second.
14. By pressing "waveform key" and "Ch2 down" key simultaneously for 2 seconds, the unit will be "Doctor-locked" or "Doctor-unlocked" in toggle. While the unit is "Doctor-locked", all parameters cannot be adjusted except timer and intensity but also the mode cannot be changed. By removing batteries or pressing ON/OFF key cannot change the status of Doctor-locked/Doctor-unlocked.
15. When one or both of the electrodes does not touch the skin or it is opened, the output level of the corresponding channel will go immediately down to zero (this feature is limited to the model Ultima 11).

can not change the status of locked/unlocked.

6. The treatment time will be accumulative recorded when the output level is above zero, by pressing “ch2 down” key and “timer” key for 2 seconds the treatment time accumulated in minute can be displayed, or return back to the previous normal display in toggle; by pressing “mode”key & “timer”key for 2 seconds will clear the treatment time to zero.
7. When the batteries are low, the symbol of battery is flashing in 2 Hz indicating that the batteries should be replaced.
8. Symbols (A)-(B)-(C) will show the passed phase (if permanently ON) of the programs Acute Pain and Chronic Pain.
9. Symbols Hz or/and μ S will flash when the respective shown value is different from the Default. Whenever the M key is pressed for 2 seconds, the default parameters of the current mode can be recovered; when the unit is in locked mode, the Default value will not be restored.
10. By pressing the waveform key, the form of the stimulation wave is changed and the change is directly felt by the user.
11. By pressing the waveform key for 2 seconds

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

the completed phase.

Acute Pain (Preset) —Both Pulse-Rate and Pulse-Width are preset to apply a sequence of 3 programs (A, B, C), optimized to treat the Acute pain.

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. Symbols MANUAL and PRESET, on the LCD display, will switch-on according the program.
4. Symbols Gate Control and Endorphins will show automatically if Gate Control or Endorphins techniques are applied.
5. By pressing “waveform” key and “Ch1 down” key simultaneously 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 removing batteries or pressing ON/OFF key

1s on, 2s off. Both Pulse Rate and Pulse Width will be freely adjustable.

Burst 2 — One train any 1.5 seconds, 0.5s on, 1s off. Both Pulse Rate and Pulse Width will be freely adjustable.

Burst 3 — One train any 0.75 seconds, 0.25s on, 0.5s off. Both Pulse Rate and pulse Width will be freely adjustable.

Modulation SW — Pulse Rate Sweep Modulation. Pulse Rate is automatically modulated within a basic frequency F1=5Hz and F2=20Hz (adjustable from 1 to 150Hz).

Modulation 2F — Pulse Rate Dual Frequencies Modulation. Pulse Rate is automatically changed, any 5 seconds, between F1=70Hz (adjustable) and F2=5Hz.

Modulation SW (Preset) — Frequency & Pulse Rate Sweep Modulation. Frequency increases from 50Hz to 100Hz while pulse width decrease from 200µ S to 50µ S, within 5 seconds.

Chronic Pain (Preset) — Both Pulse - Rate and Pulse - Width are preset to apply a sequence of 3 programs (A, B, C), optimized to treat the chronic pain.

The symbols A, B or C will flash, showing the phase in use of will be ON to show the completed phase.

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 AA1.5V (LR6) Batteries
- 1 x Instruction Booklet (which you are reading)

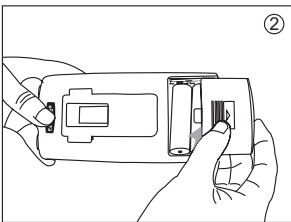
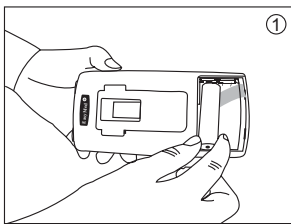
Having checked all the contents are correct please proceed to assemble the unit.



HOW TO ASSEMBLE YOUR UNIT

Assembly of the Ultima 11 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.



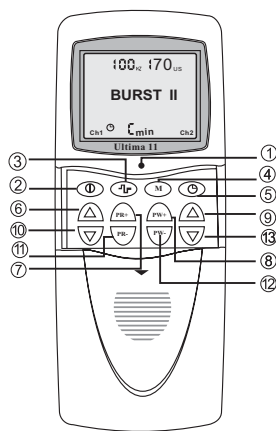
Note: Your unit will not function if the batteries are inserted incorrectly. To check, press the  button once and the LCD display will start up. Having made this check press the  button again to switch the unit off.

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 11
Channel:	Dual
Output:	Maximum 130mA (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 Asymmetrical Bi-phasic rectangular Monophasic rectangular
Mode:	11 Modes are available Constant 1 — Both Pulse Rate and pulse Width will be freely adjustable. Default values are PR=3Hz and PW=250 μ S. Constant 2 — Both Pulse Rate and pulse Width will be freely adjustable. Default values are PR=20Hz and PW=150 μ S. Constant 3 — Both Pulse Rate and pulse Width will be freely adjustable. Default values are PR=70Hz and PW=50 μ S. Burst 1 — One train any 3 seconds,



- | | |
|--|----------------------|
| ① LED light | ⑥ Intensity Up Ch1 |
| ② On/Off | ⑦ Pulse Rate Up |
| ③ Waveform | ⑧ Pulse Width Up |
| ④ 11 modes are available for selection | ⑨ Intensity Up Ch2 |
| ⑤ Timer for Treatment | ⑩ Intensity Down Ch1 |
| • Continuous | ⑪ Pulse Rate Down |
| • 15/30/45/60/90 min | ⑫ Pulse Width Down |
| • Selectable | ⑬ Intensity Down Ch2 |

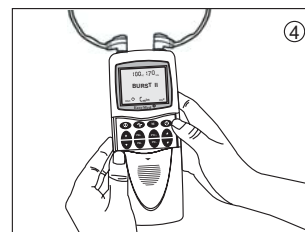
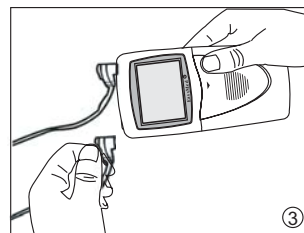
Please read the following detail specification carefully before using the T.E.N.S. Unit.

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

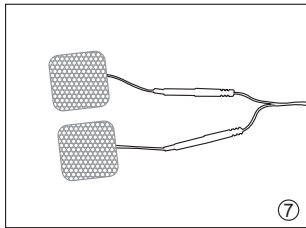
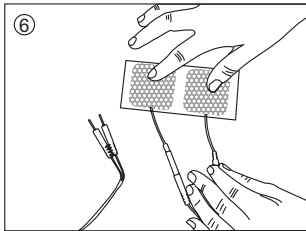
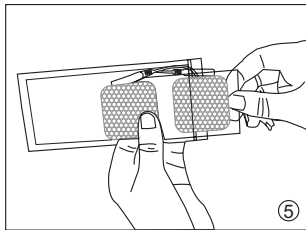
Decide whether you wish to use the unit with one lead or two.

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.



- ⊖ Press this key to set the treatment time.
- ⬆ / ⬇ Press this key to adjust the intensity of every channel, left side is for the ch1, right side is for ch2—⬆ increase the intensity.—⬇ decrease the intensity.
- PR+ Stands for Pulse Rate Up, press this key to increase the frequency.
- PR- Stands for Pulse Rate Down, press this key to decrease the frequency.
- PW+ Stands for Pulse Width Up, press this key to increase the Pulse Width.
- PW- Stands for Pulse Width Down, press this key to decrease the Pulse Width.

(L) Press the key respectively to select the waveform. The following waveform symbols will be displayed for 2 seconds when you press the key.

-  Symmetrical Bi-phasic rectangular
-  Asymmetrical Bi-phasic rectangular
-  Monophasic rectangular

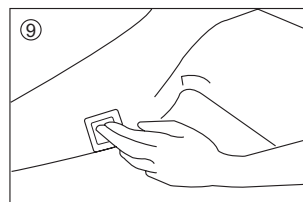
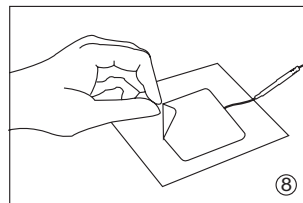
NOTE

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.

- (M)** Press this key to select mode, total 11 modes are available:
- Constant 1
 - Constant 2
 - Constant 3
 - Burst 1
 - Burst 2
 - Burst 3
 - Modulation SW
 - Modulation 2F
 - Modulation SW
 - Chronic Pain
 - Acute Pain

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.



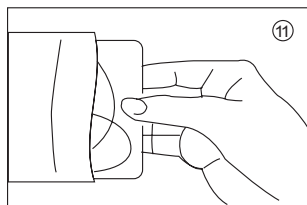
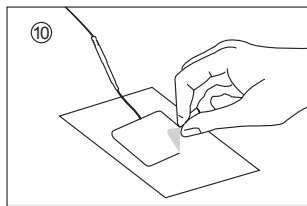
STEP 5 READING

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.

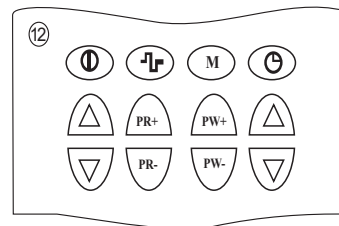


Life of the pads: When the pads initially lose their adhesive quality, it is possible to reactivate their adhesiveness by applying fine spray of water. Replace the pads when they lose their

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

OPERATION OF THE T.E.N.S. UNIT

Ultima 11 T.E.N.S. Unit is easy to operate by pressing the key as following diagram.



WHAT DOES EACH KEY DO

- ⓐ This key switches the unit on and off. Press once and 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 point as the intensity always starts at zero. Press this key again and the unit will switch off.