

Ultima 20



User's manual

PRESCRIBING INFORMATION

FOREWORD



Read this manual carefully before using your Ultima 20 T.E.N.S. unit.

The manufacturer strongly recommends carefully reading the "Warnings and Cautions", and subsequent chapters of this 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, including 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.

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.

CONTENTS

Prescribing Information.....	1
Contents	4
Operating Instruction for Physician.....	5
Instruction For Use.....	6
How to Assemble Your Unit.....	6
After Use	11
Operation of the T.E.N.S .Unit.....	12
Specification.....	13
Other Features.....	17
Electrodes Placement.....	20

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.

WHAT IS T.E.N.S. USED FOR

T.E.N.S. is commonly used to provide relief from pain associated with the following:

BACK ACHE, CERVICAL ARTHROSIS,
TORTICOLLIS, ARTHRITIS, SCIATICA,
SPORTS INJURIES, ANKLE SPRAINS,
MUSCULAR STRAINS, MYALGIA,
RHEUMATISM, NEURALGIA, LABOUR,
AFTER SURGERY, MIGRAINE, MENSES.

HOW DOES T.E.N.S. WORK

T.E.N.S. works 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 20 T.E.N.S. Pain Relief unit has been designed to be simple and easy to use.

CONTENT IN THE PACK

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

- 1 × T.E.N.S. Unit
- 2 × Leads
- 4 × Self Adhesive Pads with Connectors
(Size: 40mm × 40mm)
- 2 × Alkaline AA 1.5V (LR6) Batteries
- 1 × Instruction Booklet (which you are reading)

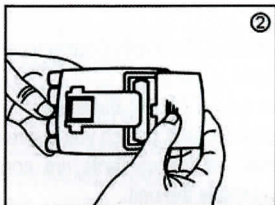
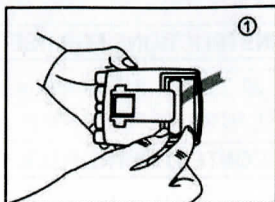
Having checked all the contents are correct please proceed to assemble the unit.

HOW TO ASSEMBLE YOUR UNIT

Assembly of the Ultima 20 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 ON/OFF key once and the LCD display will start up. Having made this check, press the ON/OFF key again to switch the unit off.

CAUTION

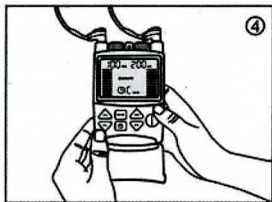
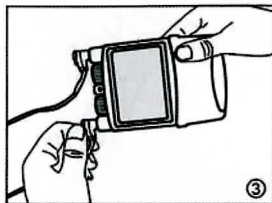
There is a risk of explosion if the batteries are fitted incorrectly. Replace with AA Alkaline 1.5 volt batteries (LR6). Do not mix old and new batteries. Do not dispose

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

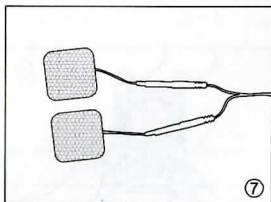
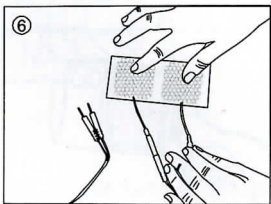
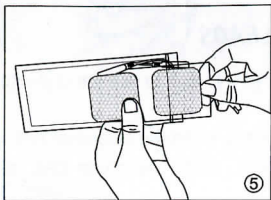
Decide whether you wish to use the unit with one lead or two.

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



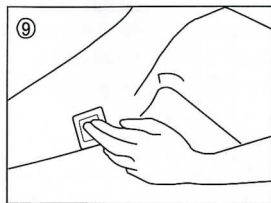
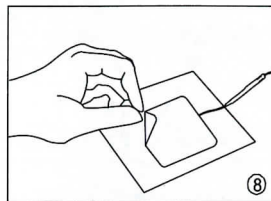
STEP 3 PADS

Remove pads from the bag and connect to the leads.



STEP 4 PLACEMENT OF PADS

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

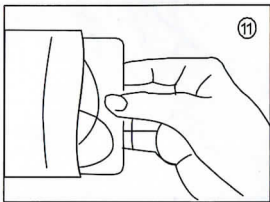
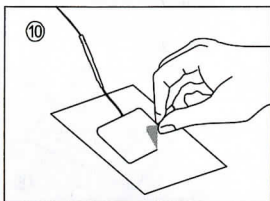


STEP 5 READING

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

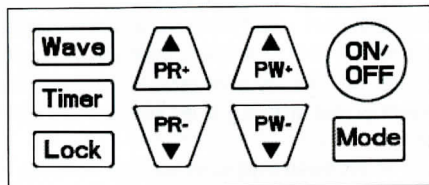
Always ensure that the unit is switched OFF before removing the pads. After use, return the pads to the clear plastic shields. There is no need to separate the pads unit from the leads and pads.



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



WHAT DOES EACH KEY DO

ON/OFF The ON/OFF key - It allows switching the unit ON and OFF. The LCD display, located at the front of the unit will light up, there will be no feeling from either leads at this point as the intensity always start at zero. Press this key again and the unit will switch OFF.

Mode Press this key to select mode, between 12 PRESET modes. They are identified on the display, by a small point or a small arrow, pointing to the specific pain area. Press and hold 5 seconds for switching to the MANUAL modes (P12-P19). Simply press again the MODE key to select one of them. Press and hold the MODE key 5 seconds for switching again to the PRESET modes.

Timer Press this key, before to set the stimulation

levels, to select the treatment time (for Manual Modes). If a preset mode is working, press the "timer" key to skip a phase (sub-programs A B C).



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



Press these keys to increase or decrease the frequency. (for Manual Modes)



Press these keys to increase or decrease the pulse width. (for Manual Modes)



Wave Press this key to change the form of the stimulation wave (for manual modes only) and the change is directly felt by the user.

Lock Press and hold this key for 3 seconds; the unit will be locked or unlocked in toggle. While the unit is locked, all parameters cannot be adjusted except timer and intensity. By removing batteries or pressing ON/OFF key cannot change the status of locked/unlocked.

SPECIFICATION

Model: Ultima 20
Channel: Dual

Output: Maximum 130 mA (peak value)
across 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: **12 PRESET programs**
They are identified, on the display, directly through the area to be treated on the body; they are:

- P0 - NECK pain
- P1 - TORTICOLLIS
- P2 - LOW BACK pain
- P3 - SCIATICA
- P4 - EPICONDYLITIS
- P5 - WRIST PAIN
- P6 - POST-SURGERY knee pain
- P7 - ANKLE sprain
- P8 - KNEE pain (gonalgia)
- P9 - HIP pain (coxalgia)
- P10 - MENSTRUAL pain
- P11 - NEURALGIA

The PRESET program apply a sequence of 3 sub-programs A B C, optimized to treat the specific pain situation. The characters A, B or C will flash, showing the phase in use or will be ON to show the completed phase.

8 MANUAL Modes Available

Mode Constant A – Both Pulse Rate and Pulse Width will be freely adjustable. Default values are PR=3Hz and PW=250 μ s characterized by a decontracturing effect. Use this program if you want relax the painful area. The stimulation level must be set to produce a gentle muscular contraction.

Mode Constant B – Both Pulse Rate and Pulse Width will be freely adjustable. Default values are PR=10Hz and PW=150 μ s characterized by an endorphins stimulating effect. Use this program if you want produce endorphins at the painful area. The stimulation level may reach the muscular contraction. If the Pulse Rate will be increased, the stimulation level must be set to avoid the muscular contraction.

Mode Constant C – Both Pulse Rate and Pulse Width will be freely adjustable. Default values are PR=70Hz and PW=50 μ s characterized by an endorphins stimulating effect, through the Gate-control mechanism. Use this program in case of ACUTE PAIN. The stimulation level must be set to avoid the muscular contraction.

Mode MODulation SW (B) — Pulse Rate SWEEP modulation. Pulse Rate is automatically modulated within F1=50Hz and F2=80Hz (adjustable); each frequency step will last 1 sec. F2 can be changed only if the intensity level of both channels are set to 0. The Pulse Width is 200 μ s (adjustable from 50 μ S to 250 μ S).

Mode MODULATION 2F (B) — Pulse Rate Dual Frequencies modulation. Pulse Rate is automatically changed, any 5 seconds, between F1=70Hz (adjustable) and F2=5Hz. F1 can be changed only if the intensity level of both channels are set to 0. The Pulse Width is 50 μ s (adjustable from 50 μ S to 250 μ S).

Mode Burst A - One train any 3 seconds, 1s on, 2s off. Both Pulse Rate and Pulse Width will be freely adjustable. Default values are PR=30Hz and PW=250 μ s. The stimulation level must be set to produce a gentle muscular contraction.

Mode Burst B - One train any 1.5 seconds, 0.5s on, 1s off. Both Pulse Rate and Pulse Width will be freely adjustable. Default values are PR=50Hz and PW=200 μ s. The stimulation level must be set to produce a gentle muscular contraction.

Mode Burst C - One train any 0.75 seconds, 0.25s on, 0.5s off. Both Pulse Rate and Pulse Width will be freely adjustable. Default values are PR=100Hz and PW=150 μ s. The stimulation level must be set to produce a gentle muscular contraction.

Treatment Timer: Continuous, 15min, 30min, 45min, 60min, 90min selectable

OTHER FEATURES

1. Labels MANUAL and PRESET on the LCD display, will switch on according the program;
2. Labels ACUTE and CHRONIC will switch on according to the Pulse Width (50 μ s = Gate Control, then most suitable to ACUTE pain – Above 50 μ s = Endorphins then most suitable to chronic pain), regardless the PW is manually or automatically adjusted.
3. Symbols (A) (B) (C) will show the occurring phase (if blinking) or the passed phase (if permanently ON) of the PRESET programs.
4. Labels CONT, MOD and BURST have not to be shown during the PRESET programs.
5. When mode changes, the intensity will automatically go down to zero;
6. When the unit is turned on, it will automatically enter the mode that the unit had worked in before the unit was turned off;
7. 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;
8. 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 increased or decreased 1 step per 1/4 second.

9. The treatment time will be accumulative recorded when the output level is above zero, by pressing "Timer" key and "PR-" key for 4 seconds the treatment time accumulated in minute can be displayed, or return back to the previous normal display in toggle; by pressing "Timer" key and "PW-" key for 4 seconds will clear the treatment time to zero.

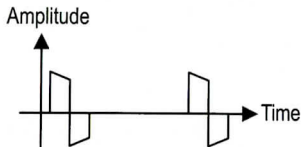
10. When the unit intensity levels are 0 on both channels, and it has not been in use for 5 minutes, the unit will be shut off automatically.

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

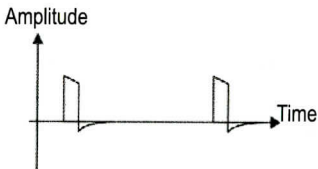
A. Waveform

There are 3 types of waveforms:

(1). Symmetrical Bi-Phasic rectangular waveform

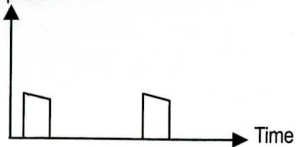


(2). Asymmetrical Bi-Phasic rectangular waveform



(3). Mono-Phasic waveform

Amplitude



B. Pulse duration

Except MANUAL Modes, which pulse duration can not be adjusted, by pressing PW+ or PW- key, the pulse width can be adjusted from $50\mu\text{S}$ to $250\mu\text{S}$ in step of $10\mu\text{S}$.

C. Pulse frequency

Except MANUAL Modes, with a pulse rate, by pressing PR+ or PR- key, the pulse width 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, 75, 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 500Ω load, the output voltage can be changed from 6V to 73V.

E. Peak pulse output current

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

ELECTRODES PLACEMENT

Please study the body maps in this guide, which show correct positioning of the electrodes depending on your symptoms.

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:

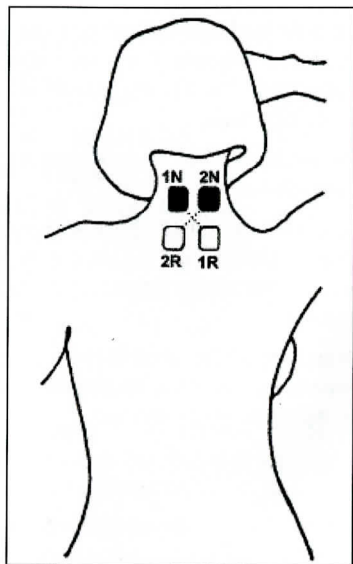
1. More sensation tends to come from the black adapter (Cathode).
2. Where applicable place the black adapter closer to the spinal column; e. g. if the arm is to be treated, place the black adaptor higher up the arm the red adaptor.

If you are applying a Symmetrical Bi-phasic rectangular or an Asymmetrical Bi-phasic rectangular wave, the above concept will be exactly reversed.

P0 - NECK PAIN

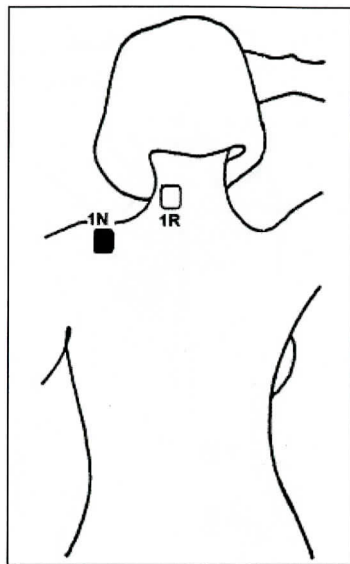
Using both leads, place the electrodes at the back of the neck and over the top of your shoulders.

Note: Do not place electrodes on the side or front of the neck.



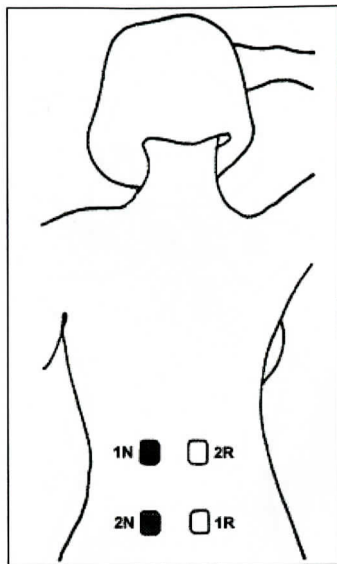
P1 - TORTICOLLIS

By using a single channel, place the couple of electrodes, over the area of maximum pain.



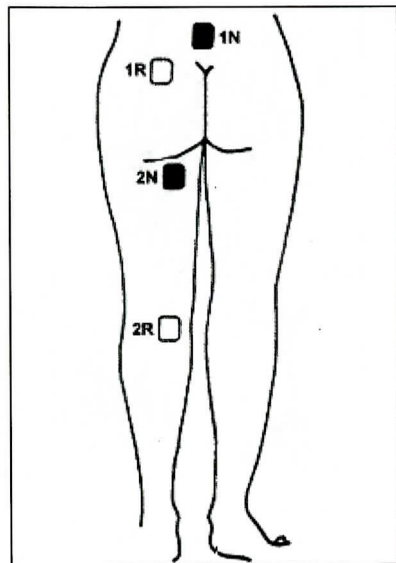
P2 – LOW BACK PAIN

Using both leads, place electrodes either side of the spine, crossing the channels, at the site of pain.



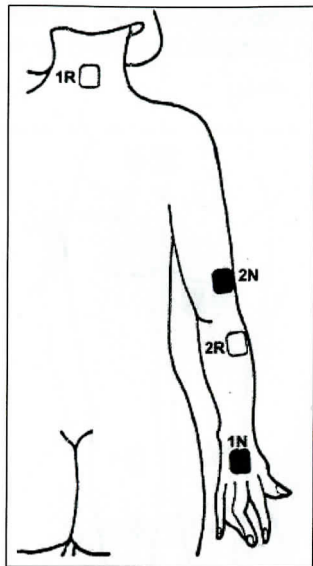
P3 – SCIATICA

Using both leads, take the first lead and place the electrode with the black adapter on your lower back one side of your spine and the second electrode with the red adapter at the top of the back of you leg. Repeat for the second lead, placing the second electrode lower down the leg.



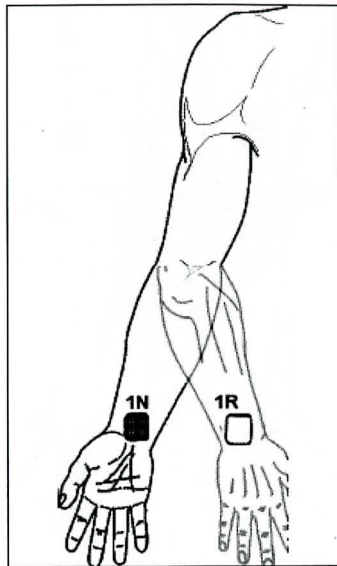
P4 – EPICONDYLITIS

Using both leads, place electrodes either side of the elbow.



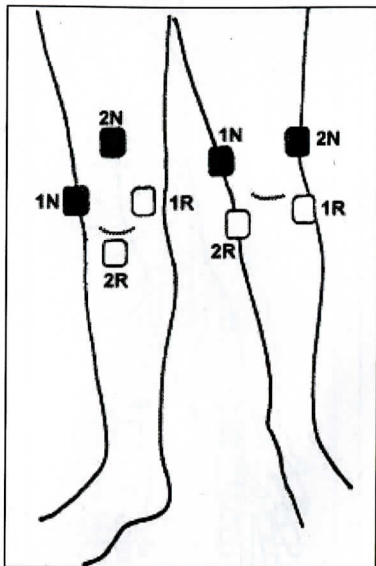
P5 – WRIST PAIN

By using a single channel, place the couple of electrodes over the area of maximum pain, involving both sides of the wrist.



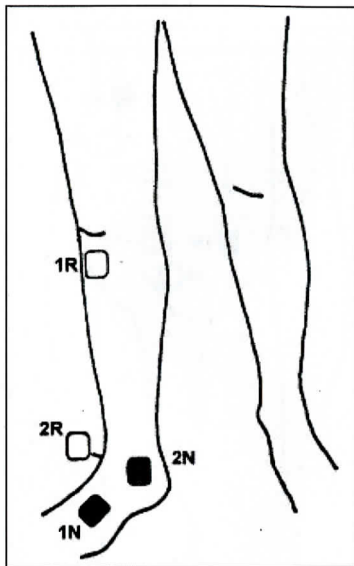
P6/P8 - KNEE PAIN (GONALGIA)

Using both leads, place electrodes over the top and base of the knee. Avoid to place directly on the kneecap.



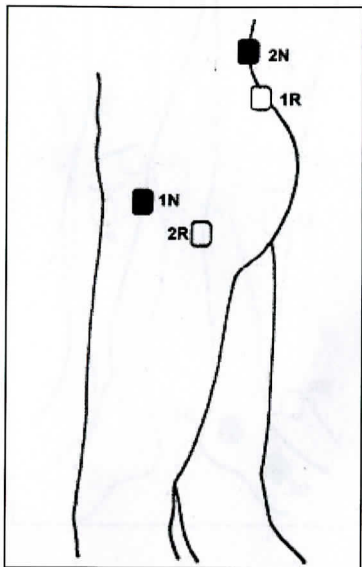
P7 - ANKLE SPRAIN

Using both leads, place the electrodes from one lead either side of the spine, on your ankle, the other couple will be placed along the involve nerve.



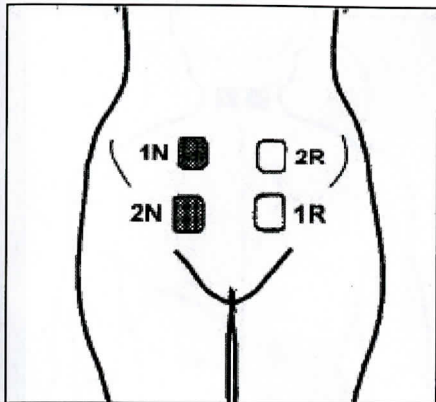
P9 – HIP PAIN (COXALGIA)

Using both leads, place one electrode from each lead a side of the spine, on your lower back. The remaining electrodes must be placed on the area of pain, on your hip.



P10 – MENSTRUAL PAIN

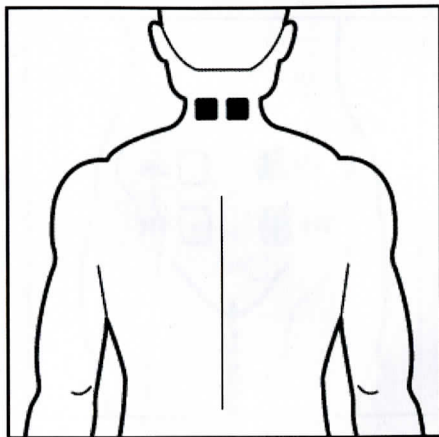
Using both leads, place electrodes over the tummy area.



P11- MIGRAINE

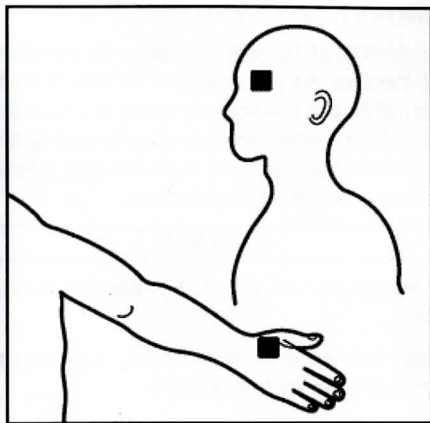
Using 2 pads only, place both pads on the back of the neck.

Note: Do not place pads on the side or front of the neck.



MIGRAINE (ADDITIONAL POSITION)

Using 2 pads only, place one pad on the left temple, and the other on the back of your right hand between your thumb and first finger.



Note: If only 2 pads being used, connect both pads to the 2-lead single-channel lead wire.

PADS

The pads that are supplied with your Ultima 20 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.

Manufactured for:

Pain Management Technologies