

ULTIMA

USER'S GUIDE
For Patient and Clinician



*The Personal
Pain Relief System
That Breaks
The Pain Cycle*

ULTIMA

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For Patient and Clinician

PM PAIN
MANAGEMENT
TECHNOLOGIES
Professional Systems

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TECHNOLOGIES
Professional Systems

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TO THE CLINICIAN

These diagrams were produced from 1 second sweep duration of an oscilloscope illustrating the electrical impulses of each of the 5 modes of operation. Control settings for each mode are detailed on page 10.



CONVENTIONAL MODE



MODULATION MODE



BURST MODE



ACUPUNCTURE MODE



BRIEF INTENS MODE

WARNINGS & PRECAUTIONS

- CARDIAC PACEMAKERS** -
Do not use the ULTIMA T.E.N.S. unit with demand type Cardiac Pacemakers.
- THROAT (CARTILIO SINUS)** -
Do not use over the nerves, muscles or arteries of the throat or the larynx (voice box) - strong muscle contractions could close the airway.
- EYES** -
Do not use on the eyelids.
- HEAD** -
Do not place electrodes so electrical fields from one side of the head to the other.
- EKG MONITORS & ALARMS** -
Monitors and alarms for EKG units may not operate properly when the ULTIMA unit is in use.
- MYOCARDIAL DISEASE OR ARRHYTHMIAS** -
The ULTIMA T.E.N.S. unit should be used by patients with these conditions only under the direction and supervision of the prescribing physician.
- PREGNANCY** -
The safety of the ULTIMA T.E.N.S. unit during pregnancy or delivery has not been established.
- UNDIAGNOSED PAIN** -
Do not use the ULTIMA unit to treat undiagnosed pain syndromes.
- MACHINERY OPERATION** -
Do not adjust the control settings of the ULTIMA unit while operating vehicles, heavy equipment, machinery or tools.
- CHILDREN** -
Keep out of the reach of children.

CAUTION - United States Federal Law requires a physician's prescription for the purchase and use of the ULTIMA T.E.N.S. system. Ultima is approved by the Food & Drug Administration.

PATIENT INSTRUCTIONS

The ULTIMA T.E.N.S. system should be used only under the supervision of a physician or a qualified medical professional to whom you are referred by your physician. Use it only for the condition for which it is prescribed.

Understanding Pain

Pain is the body's warning system. It alerts us to injury or illness. And it is absolutely necessary for life and health.

Unfortunately, however, this vital warning system is not equipped with an "off" switch. So sometimes, long after we have gotten the "message" and responded to the problem pain signals keep on being sent to the brain.

Pain signals, in the form of electrical impulses, travel to the brain through the body's nervous system from the site of the injury or ailment. In the brain, the impulses are interpreted as pain.

If these impulses can be interfered with before the brain can receive and interpret them, the result is pain relief.

How ULTIMA Relieves Pain

ULTIMA is the advanced, pocket-sized, fully portable, Transcutaneous Electrical Nerve Stimulation (T.E.N.S.) system designed to relieve both acute and persistent pain without pills, drugs or narcotics. It sends gentle electrical impulses through the skin to the nerves to suppress pain by scrambling the pain signals before they reach the brain.

ULTIMA provides five different modes of operation for pain treatment versatility.

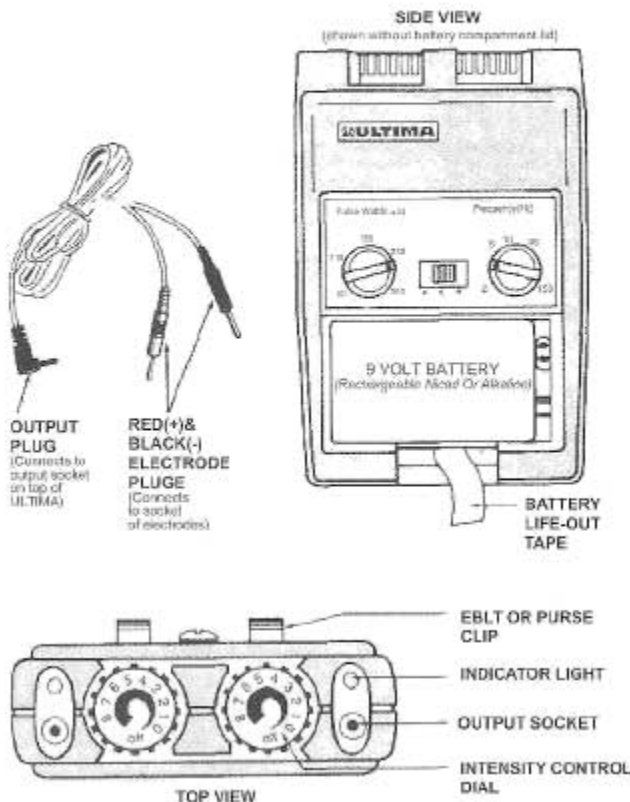
Because ULTIMA has two channels, it can be used to relieve pain at two body locations, simultaneously, or to provide extra relief at a single body location or over a large body area.

ULTIMA may not work for everybody who suffers from pain, but for many people, ULTIMA offers comforting relief, reducing and often even eliminating pain.

Because there are many different kinds of pain, and each individual is unique, ULTIMA pain relief varies from person to person. Some users experience relief only while the ULTIMA unit is turned on. For others, relief continues for a length of time even after the unit is turned off. Some users experience relief in one mode, some in others.

The ULTIMA system can help you return to normal activity. It is about the size of a pack of playing cards and battery powered, so you can wear it everywhere - at home, to work, in your car. And it is equipped with a convenient clip so you can wear it on your belt or even inside your clothing.

Introduction to The ULTIMA Unit

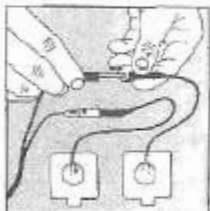




Attaching Electrodes

1. Make sure the ULTIMA unit is turned OFF.
2. Determine which channel-1, 2 or both - you wish to use.
3. Plug the "L" shaped lead wire output plug into the appropriate channel output socket of the ULTIMA unit.
4. Insert the red electrode plug into the socket of one electrode.
5. Insert the black electrode plug into the socket of other electrode.

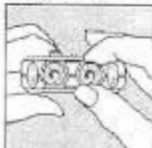
CAUTION: Always grip the plug connector when you plug in and unplug the lead wires. Pulling the wire can break it.



Applying Electrodes

1. Your physician or clinician will determine which type of electrode is best suited for your treatment.
2. Follow your physician's or clinician's directions as to proper electrode positioning for best results.
3. Prepare your skin where electrodes will be placed by washing, rinsing and thoroughly drying it, making sure all skin oils are removed.
4. Apply electrodes following application instructions included with the electrodes packaging.
5. Use ULTIMA electrodes for best results.

Adjusting Controls



1. Each time you use your ULTIMA unit, begin with the intensity controls for both channels 1 & 2 turned OFF.



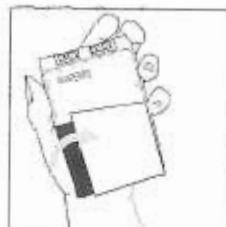
2. Adjust the sliding Mode Selector Switch to the "C" (Conventional), "M" (Modulated), or "B" (Burst) position as recommended by your clinician.



3. Adjust the Pulse Rate control the position as recommended by your clinician.



4. Adjust the Pulse Width control the position recommended by your clinician.



Personalizing Control Settings

Your clinician will work with you to achieve optimum control settings to custom tailor your ULTIMA unit to your own personal needs. Carefully follow his or her instructions regarding electrode placement, control settings and user adjustment procedures.

Changing Batteries

Your ULTIMA unit is designed to operate on a 9 Volt rechargeable battery like those included with it, or on the disposable alkaline type available in most stores.

1. The ULTIMA unit will shut off automatically when the battery needs recharging. Prior to shutting off, the indicator lights will dim and the unit may perform somewhat erratically.
2. Open the battery compartment by pressing up on the latch at the bottom of the compartment cover and lifting the cover off.



3. Remove the old battery by lifting up on the end of the lift-out tab, which should be beneath the battery.



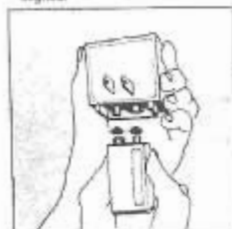
4. Insert the battery according to the diagram inside the battery compartment, making sure that the terminals are properly aligned. Make sure the lift-out tab is beneath the battery for easy removal next time.
5. If you are using the ULTIMA unit's rechargeable NiCad batteries, attach the discharged battery to the charger, following the "Charging NiCad Batteries" instructions below. If you are using alkaline batteries, safely dispose of the old battery.
6. Replace the battery compartment cover.

Charging Nicad Batteries

Included as part of your ULTIMA system are a pair of rechargeable NiCad batteries and a convenient, snap-on battery charger. This allows one battery to be in use while the other is recharging. NiCad batteries can be recharged and reused hundreds of times if proper procedures are followed.

1. For maximum NiCad battery life, always allow it to discharge completely, and the ULTIMA unit automatically turns itself off. Then remove the battery and recharge it immediately.
2. To recharge the battery, snap its terminals onto those of the battery charger. Pay special attention to the differences in positive (+) and negative (-) terminal configurations and make sure you have battery and charger terminals properly aligned.

WARNING: Do not attempt to use your battery charged to its charge any further after than rechargeable NiCad batteries like those included with your ULTIMA unit. Other types of rechargeable batteries are not safe to use. Do not recharge batteries if they may explode!



Battery charger and rechargeable battery are optional.

3. Plug the charger into a standard 110 Volt AC electrical outlet. For use outside the U.S., contact Pain Management Technology for the proper electrical adapter.
4. Allow the battery to charge for 14-16 hours.
5. After recharging, unplug the charger and remove the battery.
6. Although overcharging the battery will not damage it, repeated overcharging may decrease battery life. Avoid slowing battery to remain on charger more than 48 hours.
7. For maximum battery life, follow these simple procedures: after a battery has been fully discharged, recharge it immediately. Avoid recharging a partially discharged battery; allow it to discharge fully before recharging. Always store batteries in their fully charged state. NiCad batteries gradually lose their charge when not in use. If stored more than 45 days, recharge before use.
8. Battery charger and rechargeable battery are optional.

Skincare

To keep your skin healthy and avoid irritation, follow these simple recommendations:

1. Before applying electrodes and after removing them, wash the area of skin where electrodes are placed with mild soap and water. Rinse and dry thoroughly.
2. Skin oils can be removed by wiping the skin with rubbing alcohol.
3. Do not shave electrode area; hair may be trimmed short with scissors.
4. Always remove electrodes by pulling in the direction of hair growth.
5. Avoid skin stress that can be caused by electrodes or toe holding lead wires stretching or pulling the skin.

TROUBLESHOOTING

| THE "ON" INDICATOR LIGHTS UP BUT THE UNIT DOES NOT FUNCTION PROPERLY | THE "ON" INDICATOR IS DIM | THE "ON" INDICATOR DOES NOT LIGHT UP |
|---|--|---|
| Control settings may not be set to prescribed values. Electrodes may not be in proper position. Electrodes may be sweating out or drying out (A pricking sensation may accompany this problem). Electrodes may be defective. Lead wires may not be securely connected. Lead wires may be broken inside the insulation. | The battery is discharged; replace with a fresh one. | The battery is discharged; replace with a fresh one. The battery may be improperly positioned; follow diagram in battery compartment. The unit may be damaged; contact your supplier for service. |

CLINICIAN INFORMATION

Indications

The ULTIMA transcutaneous electrical nerve stimulation system is indicated as a first line treatment modality or as part of a multi-modality treatment strategy for symptomatic relief and management of acute, persistent and chronic pain.

ULTIMA provides proven effective pain relief for back pain, myofascial pain syndromes, post-operative surgical & scar pain, post-traumatic pain, knee & shoulder pain, arthritis, strains & sprains, TMJ neuropathies, neuritis, RSD causalgia pain, dysempfindes, tension headaches, carcinoma pain and any pain condition requiring medication.

References available upon request.

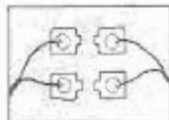
Contraindications

ULTIMA is contraindicated for use on patients using demand-type cardiac pacemakers.

IMPORTANT: See "Warnings & Precautions" section on page 3.

Recommended Electrode Placement

This chart shows typical electrode placement positions for treatment of typical pain conditions.



In-Line Placement is recommended for neck, sciatica and lower-back muscle pain.



Criss-Cross Placement is recommended for shoulder, knee and lower-back spine pain.



LOWER BACK



SCIATICA



NECK



NECK/LOWER BACK



SHOULDER OR KNEE



TMJ
(Bilateral Placement)

Modes of Operation

The dual-channel ULTIMA System is designed to operate in 5 different modes to provide maximum flexibility in pain treatment:

1. Conventional Mode
2. Modulation Mode
3. Burst Mode
4. Acupuncture Mode
5. Brief Intense Mode

Control Settings

Adjusting the ULTIMA unit for optimum pain relief is a process of custom-tailoring settings to the individual patient. Pulse Intensity, Rate and Width are interactive phenomena, and require fine tuning from nominal settings, based on the patient's reactions, to achieve optimal results.

The following procedures are recommended for determining the most effective settings for optimum patient treatment.

The Conventional Mode is recommended as the initial treatment mode for patients new to transcutaneous electrical nerve stimulation treatment.

Conventional Mode

The Conventional Mode provides nerve stimulation with pulse amplitude, width and rate fully adjustable.

PRESET CONTROLS TO:

- Intensity: OFF
- Mode Selector: "C"
- Pulse Width: 200 μ S (microseconds)
- Pulse Rate: 60 pps (pulses per second)

Modulation Mode

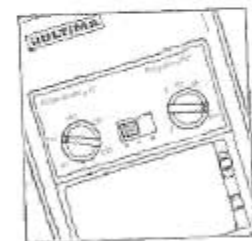
In the Modulation Mode, the pulse width decreases and increases in a cyclic pattern over a period of 5 seconds. Because treatment alternates between superficial and deep stimulation, we recommend this mode for situations where the patient has developed tolerance to the Conventional Mode.

PRESET CONTROLS TO:

- Intensity: OFF
- Mode Selector: "M"
- Pulse Width: 60 μ S
- Pulse Rate: 40 pps

Customizing Control Settings for Conventional & Modulation Modes

1. Preset controls as indicated.
2. Turn ON the intensity for the channel indicator light begins to blink.
3. Gradually increase intensity up until the patient notices a change in sensation in the electrode area.
4. Slowly increase the intensity until the patient experiences slight discomfort. Then immediately decrease intensity slightly to just below the pain threshold (the sensation, however, should still be detectable). This will allow maximum excitation of the large nerve fibers without stimulation of the smaller, pain-conducting fibers. (Gate Control Theory).
5. As the patient adapts to the sensations, typically after 5 to 10 minutes of stimulation, and perceives that the strength of stimulation has decreased, increase the intensity slightly to restore the desired perception.



6. After this preliminary period, slowly advance the Pulse Width control (no higher than 200 μ S) until the patient perceives a change. If the perception is only that the stimulation is growing stronger, but not expanding the area of pain relief, reduce the Pulse Width to the nominal setting. If the perception is that the stimulation is growing deeper, wider or spreading, sustain stimulation at the higher Pulse width setting.
7. Relief is usually evident within 10 to 30 minutes.
8. Conventional and Modulation Modes may be used as long as desired.

Burst Mode

Use the Burst Mode at low Intensity settings to treat acute superficial pain.

Use at higher Intensity settings - resulting in strong muscle contractions - to treat chronic, deep pain.

PRESET CONTROLS TO:

- Intensity: OFF
- Mode Selector: "B"
- Pulse Width: 200 μ S
- Pulse Rate: Automatically controlled by the ULTIMA unit in this mode. (8 pulses per Burst, 2 bursts per second)

Acupuncture Mode (High Width, Low Rate)

The high intensity Acupuncture Mode provides nerve stimulation with electrodes positioned on the traditional Chinese acupuncture points or on any painful trigger or tender points.

Stimulation is thought to cause signals to be transmitted to the brainstem, which uses descending pathways to block pain through the release of endogenous opiates such as endorphins, as well as other pain-modulating neurotransmitters such as serotonin.

This mode is very effective for deep aching chronic pain. It is also useful when previous nerve damage has occurred.

PRESET CONTROLS TO:

- Intensity: OFF
- Mode Selector: "A"
- Pulse Width: 200 μ S
- Pulse Rate: 2-4 pps

Brief Intense Mode (High Width, High Rate)

The high-intensity Brief Intense Mode is recommended for immediate relief of severe pain. It is especially useful during painful therapeutic procedures such as joint mobilization.

PRESET CONTROLS TO:

- Intensity: OFF
- Mode Selector: "I"
- Pulse Width: 240 μ S
- Pulse Rate: 120 pps

ADDENDUM

This Manual applies to the *Ultima 3* (three mode device without timer). If you have the *Ultima* or *Ultima 3t*, please read below:

The Ultima

is a single mode device. This manual will provide accurate instructions on using the modulation and burst modes.

The Ultima 3t

is a three mode device with a timer. This manual will provide accurate instructions on using the use of the timer.

Also note:

Throughout this manual the "n" is designated as the "conventional mode", however on most devices an "n" or "normal mode" will be found to have the same function.

LIFE TIME WARRANTY

This warranty is in lieu of any other warranty expressed or implied.

Pain Management Technologies provides a life-time warranty from the date of purchase on each new ULTIMA TENS stimulator against any defects in material and workmanship. If the new ULTIMA stimulator is found to be defective within the warranty period, it will be replaced or repaired free of charge if returned to your place of purchase.

This warranty applies to the ULTIMA unit only, and does not cover charger, batteries, electrodes, lead wires or other accessories. This warranty does not cover damage caused by misuse, negligence, accident, abuse, alteration or modification of the unit.