Manufactured for:
Pain Management Technologies

Manufacturer:
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Ultima Combo

User’s manual
User Manual for Ultima Combo Unit

PRESCRIBING INFORMATION

FOREWORD
Read this manual carefully before using your Ultima Combo 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:
Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

WARNINGS

1. If you are in the care of a physician, consult with your physician before using this device;

2. If you have had medical or physical treatment for your pain, consult with your physician before using this device;

3. If your pain does not improve, becomes more than mild, or
continues for more than five days, stop using the device and consult with your physician;
4. Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
5. Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal;
6. Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
7. Do not apply stimulation over, or in proximity to, cancerous lesions;
8. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
9. Do not apply stimulation when in the bath or shower;
10. Do not apply stimulation while sleeping;
11. Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury;
12. Do not use the device on children, if it has not been evaluated for pediatric use.
13. Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals;
14. Apply stimulation only to normal, intact, clean, healthy skin.
15. No modification of this equipment is allowed.

**PRECAUTIONS**

1. TENS is not effective for pain of central origin, including headache;
2. TENS is not a substitute for pain medications and other pain management therapies;
3. TENS devices have no curative value;
4. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
5. Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients
6. The long-term effects of electrical stimulation are unknown;
7. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head
8. The safety of electrical stimulation during pregnancy has not been established;
9. You may experience skin irritation or hypersensitivity due to
the electrical stimulation or electrical conductive medium (gel);

10. If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician;

11. If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.

12. Use caution if you have a tendency to bleed internally, such as following an injury or fracture;

13. Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;

14. Use caution if stimulation is applied over the menstruating or pregnant uterus;

15. Use caution if stimulation is applied over areas of skin that lack normal sensation.

16. Keep this device out of the reach of children;

17. Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

ADVERSE REACTIONS

1. You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;

2. You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face;

3. You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

GENERAL WARNINGS

1. Do not immerse Combo units in water.

2. Do not place the Combo unit close to excessive heat.

3. Do not use any pad which size is less than 50mm X 50mm.

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. Keep the unit away from sources of high magnetic fields such as TVs, microwave ovens and hi-fi speakers, as these may affect the LCD screen.

7. Environmental Condition:
   - Operating Temperature: +0°C to +40°C
   - Operating Humidity: 10%RH to 93%RH
   - Operating Atmospheric Pressure: 700 hPa to 1060 hPa
   - Storage/Transport Temperature: -25°C to +70°C
   - Storage/Transport Humidity: 8% to 93% R.H
INTENDED USE

This portable device is a combination of a pain relieving T.E.N.S. and a muscle recovering E.M.S. unit. Through electrode pads attached on skin of a patient, electric stimulation current performs treatment accordingly.

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.

E.M.S. stands for Electrical Muscle Stimulation. This E.M.S. is a safe and highly effective muscular training system, and a complementary way to perform a selective muscular training.

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.
**HOW DOES E.M.S. WORK**

Through a couple of self-adhering electrodes, stimulation pulses are applied over the muscle; as a result, the muscle will alternatively contract and relax, exactly as it happens during the physiological activity but with the advantage of avoiding the general sense of fatigue.

**INSTRUCTIONS FOR USE**

Your Ultima Combo unit has been designed to be simple and easy to use.

**CONTENT IN THE PACK**

Your Combo unit pack should contain the following:
- 1 x Ultima Combo Unit
- 2 x Leads
- 4 x Self Adhesive Pads with Connectors
  (Size: 50mm × 50mm)
- 2 x Alkaline AA 1.5V (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 Combo 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.

![Battery Installation](image)

**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 Combo Unit”, and decide how to use the 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 COMBO UNIT**

Ultima Combo Unit is easy to operate by pressing the key as following diagram.

![Diagram of control keys](image)

**WHAT DOES EACH KEY DO**

- **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.

- **PROG**: Press this key to select TENS programs. Press and hold 5 seconds for switching from TENS program to EMS programs. Simply press this key again to select one of them. Press and hold 5 seconds for switching again to the TENS programs. The symbol "TENS" / "EMS" and "PRESET" / "MANUAL" will display on the LCD accordingly. The PRESET modes are identified on the display, by a small point, pointing to the specific treatment area.

- **AEROBIC EXERCISE**: Force 1
- **TONING**: Force 2
- **HARDENING**: Fast Force
- **RESISTING FORCE**: Explosive Force
- **WARM-UP**: Progressive Recuperation

For TENS preset modes (Prog 0- Prog 11), if a preset mode is working, press this key to skip a phase (sub-programs A B C). For EMS preset modes (Prog 20- Prog 29), if a preset mode is working, press this key to choose the treatment status.

The treatment status symbols below will be displayed automatically base on the choice of the user:

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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 two keys you can go through and select the following parameters one by one (manually selectable only):
FREQUENCY (Hz),
PULSE WIDTH (µs),
WAVEFORM,
Treatment Time (min),
SYNCHRONOUS/ALTERNATING (EMS Mode only),
ACTION TIME (EMS Mode only) (sec),
REST TIME (EMS Mode only) (sec),
RISE TIME (EMS Mode only) (sec),
FALL TIME (EMS Mode only) (sec),

When one of the above parameters has been selected, the corresponding digits or letters or symbols on the LCD are flashing, then you can use “+” or “-” key to adjust that parameter value. If you will not change the value within 5 seconds, the unit will automatically save the value you last set as the treatment parameter. Or you can press the "MENU" keys to save value and skip to the other parameter setting.

When MENU (▲ / ▼ ) key is pressed, the output level goes immediately to zero.

By pressing “+” or “-” keys you can increase or decrease the value of the parameter which has been selected by “MENU” keys and is now being flashed. An auto-repeat function is available; when +/- key is held down over 1/4 second the value of the parameter will increase/decrease 1 step per 1/4 second until the key is released.

Press this key you can make the unit pause. To continue it, press and hold down this key again. When the unit is paused, the intensity level goes down to zero, and "II" is displayed in the LCD. Once the unit is released from paused, it starts from the point where it was broke to be paused.

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.

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**SPECIFICATION**

Model: Ultima Combo
Channel: Dual
Output: Maximum 130 mA (peak value) across 500 Ohm load
Pulse Width: From 50µS to 400µS adjustable
Pulse rate: From 1Hz to 150Hz Adjustable
Waveform: Symmetrical Bi-phasic rectangular

Asymmetrical Bi-phasic rectangular
Monophasic rectangular
Alternated bi-phasic rectangular
Mode: 20 T.E.N.S. modes and 15 E.M.S. modes
Ramp Time: 0-5s, in steps of 1s
On time: 1-60s, in steps of 1s
Off time: 0-60s, in steps of 1s
In T.E.N.S. mode (P0-P19):

1) 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.

2) 8 MANUAL Modes
Mode Constant A – Both Pulse Rate and Pulse Width will be freely adjustable. Default values are PR=3Hz and PW=250µs characterized by a decontracturating 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=150µs 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=50µs 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 SWeeep 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 200µs (adjustable from 50µS to 250µS).

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 50µs (adjustable from 50µS to 250µS).

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=250µs. 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=200μs. 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=150μs. The stimulation level must be set to produce a gentle muscular contraction.

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

In E.M.S. mode (P20-P33):

1) 11 PRESET programs
   P20 - Triceps;
   P21 - Latissimus dorsi;
   P22 - Spinalis;
   P23 - Gluteus;
   P24 - Hamstrings;
   P25 - Calves
   P26 - Breast;
   P27 - Abdomen;
   P28 - Abdomen + Waist;
   P29 - Thighs

2) 4 MANUAL Modes available: P30-P33
   Treatment Timer: Continuous, 10min, 20min, 30min, 45min, 60min, 90min selectable

OTHER 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, 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/decreased 1 step per 1/4 second.

5. The treatment time will be accumulative recorded when the output level is above zero, by pressing [key and “MENU ▼” 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 [ key and “-” key for 4 seconds will clear the treatment time to zero.

6. 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.

7. When the batteries are low, the symbol of battery is flashing in 2 Hz indicating that the batteries should be replaced.

8. Open circuit detection: 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.
Detail information regarding to the Waveform, Pulse width, Pulse frequency, Output voltage range, and Peak pulse output current:

A. Waveform

There are 4 types of waveforms:

1. Symmetrical Bi-Phasic rectangular waveform
   Amplitude

2. Asymmetrical Bi-Phasic rectangular waveform
   Amplitude

3. Mono-Phasic waveform
   Amplitude

B. Pulse width

Except PRESET Modes, which pulse width can not be adjusted, by pressing “+” or “-” keys when the pulse width has been selected by MENU (▲ / ▼) keys, the pulse width can be adjusted from 50μS to 250μS in step of 10μS in TENS modes and from 50μS to 400μS in step of 50μS in EMS modes.

C. Pulse frequency

Except PRESET Modes, by pressing “+” or “-” keys when the pulse frequency has been selected by MENU (▲ / ▼) keys, the pulse frequency can be adjusted to one of the following values (Hz):

For TENS Modes:
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.

For EMS Modes:
1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80, 90, 100, 110

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.

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**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.

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**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.

1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red
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 your leg. Repeat for the second lead, placing the second electrode lower down the leg.

1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red

P4 – EPICONDYLITIS
Using both leads, place electrodes either side of the elbow.

1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red
**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.

![Diagram of wrist pain placement](image1.png)

**Ch1 Ch2**

1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red

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**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.

![Diagram of knee pain placement](image2.png)

**Ch1 Ch2**

1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red
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.
P22 – SPINALIS

1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red

P23 – GLUTEUS

1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red
P24 - HAMSTRINGS

1R  2R
1B  2B

P25 - CALVES

2R  1R
2B  1B

Ch1  Ch2
1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red

P26 - BREAST

1R  1B  2B  2R

Ch1  Ch2
1B = Channel 1 black / 1R = Channel 1 red
2B = Channel 2 black / 2R = Channel 2 red
**P27 - ABDOMEN**

- 1B = Channel 1 black / 1R = Channel 1 red
- 2B = Channel 2 black / 2R = Channel 2 red

**P28 - ABDOMEN + WAIST**

- 1B = Channel 1 black / 1R = Channel 1 red
- 2B = Channel 2 black / 2R = Channel 2 red
P29 - THIGHS

PADS

The pads that are supplied with your Ultima Combo 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 50mm x 50mm.

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.

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