

Ultima Neuro

Advanced Neuropathy Stimulator



User's Manual

User Manual for Ultima Neuro

PRESCRIBING INFORMATION

FOREWORD



Read this manual carefully before using the Ultima Neuro 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 use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2. Do not use this device on patients whose pain syndromes are undiagnosed.

WARNINGS

1. Do not apply stimulation over the patient's neck or mouth because this could cause severe muscle spasms resulting in closure of the airway, difficulty in

- breathing, or adverse effects on heart rhythm or blood pressure;
2. Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be dangerous;
3. 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);
4. Do not apply stimulation over, or in proximity to, cancerous lesions;
5. 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;
6. Do not apply stimulation when the patient is in the bath or shower;
7. Do not apply stimulation while the patient is sleeping;
8. Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
9. Consult with the patient's physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals;
10. Apply stimulation only to normal, intact, clean, healthy skin.

PRECAUTIONS

1. TENS is not effective for pain of central origin, including headache or stomach ache;
2. TENS is not a substitute for 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 could 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. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head;
9. The safety of electrical stimulation during pregnancy has not been established;
10. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (spray);
11. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians;
12. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
13. Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture;

14. Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process;
15. Use caution if stimulation is applied over the menstruating or pregnant uterus;
16. Use caution if stimulation is applied over areas of skin that lack normal sensation.
17. Keep this device out of the reach of children;
18. Use this device only with the leads, electrodes, and accessories recommended by the manufacturer; and
19. Use this device only under the continued supervision of a licensed practitioner.

ADVERSE REACTIONS

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face; and
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device or redness on the skin that doesn't go away after treatment. Also, if you experience

GENERAL WARNINGS

1. Do not immerse the device in water.
2. Do not place the device close to excessive heat.
3. If you notice any adverse reactions or burning feeling, discontinue use immediately.
4. Use only the specified battery: 1x 3.7volt rechargeable lithium battery. The use of any other battery could damage the unit.
5. Remove battery if device is not used for a long period of time.
6. Do not use the device while asleep.
7. Keep the device 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.

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INTENDED USE

The Ultima Neuro is a portable device that is a combination of a pain relieving T.E.N.S. and a therapeutically driven Micro current unit. The technical attributes are geared towards treating Peripheral Neuropathy over a progressive therapy regime. The Neuro A and B modes are the main Neuropathy treatment modes (intended for the hands or feet treatments).

The Ultima Neuro was designed to treat Peripheral Neuropathy of the hands or feet through treatment wraps that cover the hands or feet with circumferential electrotherapy stimulation.

HOW DOES THE NEURO WORK

The Neuro works by stimulating your body's own natural defenses against pain.

The Neuro A and B modes comprise of technical specifications that are geared towards treating pain associated with neuropathy through the use of a low level monophasic (direct current) wave form. This wave form has been found effective in push fluids, and relieve the symptoms associated with pain intense neuropathy.

The unit produces a gentle stimulus through garment electrodes placed over the area of pain. This stimulus helps the body to produce natural pain relievers called endorphins. Some people feel immediate benefit; however some may only achieve benefit after repeated treatment sessions and over an extended period of time.

Treatment times should be 10-15 minute per program per treatment session. When you first try electrotherapy keep it to short term treatment sessions, and check your skin periodically. Since you may have circulatory conditions or other compromising ailments, it is best to be conservative in your treatment sessions and watchful of any adverse reactions or additional pains...

The most important thing is to spray your electrode garments (both the active garment electrode, and the grounding cuff).

Once you are comfortable with electrotherapy, you can try 15, 30 minute therapy sessions.

Important note: if you are using the Ultima Neuro to treat your hands and feet for neuropathy symptoms, utilize Neuro A and/or Neuro B for treatment sessions.

INSTRUCTIONS FOR USE

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

CONTENT IN THE PACK

Your Ultima Neuro pack should contain the following:

- 1 × Ultima Neuro Unit
- 2 × Leads
- 1 × Electrode garment (sock or glove)
- 1 × Electrode garment (grounding cuff)
- 1 × 3.7V Rechargeable Lithium Battery (BL-6F)
- 1 × Charger with an adaptor and a charging cradle
- 1 × Instruction Booklet (which you are reading)

*other electrode types can be ordered upon request.

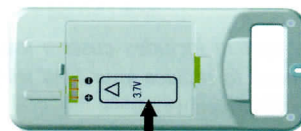
Having checked all the contents are correct please proceed to assemble the unit.

HOW TO ASSEMBLE YOUR UNIT

Assembly of the Ultima Neuro Unit is very simple and requires only five steps.

STEP 1 BATTERY

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



Insert the battery



Replace the battery cover

CAUTION

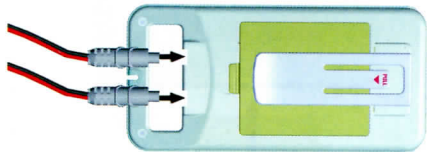
There is a risk of explosion if the battery is fitted incorrectly. Replace with the 3.7 volt lithium battery. Do not dispose of the battery in a fire and keep them out of reach of children. The battery must be removed from the unit if unit is not used for a long period of time.

STEP 2 LEADS

NOTE: *This system includes custom lead wires. When you need to replace your lead wires, only use manufacturer lead wires.*

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.



Insert the lead wires

STEP 3 Garment treatment Pads

Remove the garment electrodes from the bag and connect to the leads. Note the active red pin from the lead wires goes into the active garment treatment electrode (sock or glove). The black pin goes into the grounding cuff. And the grounding cuff goes on the same appendage as the active garment electrode. So, if the sock is on the left foot, the cuff should be on the left leg. Be sure to pull the cuff to about 6-8 inches away from the active garment sock.

Important note: be sure to spray about 3 strong sprays onto your treatment garment. Spray the inside of the sock or glove, and the cuff. Spray is a must, or the stimulation will be rough.

STEP 4

Read the section on "Operation of the Ultima Neuro Unit", and decide how you want to set your settings before you use the unit for the treatment.

When setting the technical specifications of the device, adjust the intensity only to the level of minimum sensation. The condition of skin and cutaneous nerve endings can be delicate, especially in seniors or those with compromising health conditions.

NOTE: AFTER USE

Always ensure that the unit is switched OFF before removing the pads. After use, air dry the garment electrodes. There is no need to separate the pads unit from the leads and pads.

CHARGING THE BATTERY

The Ultima Neuro is powered by a type BL-6F rechargeable Lithium battery. A separate Charging Cradle and Power Adaptor are included in the kit.

When the battery is running low, a low battery indicator will show on the screen (battery symbol). Although the display fades as the battery runs down, the strength of the output does not change until the warning is shown.

When the battery is fully charged, the indicator light on the cradle will change from red to green.

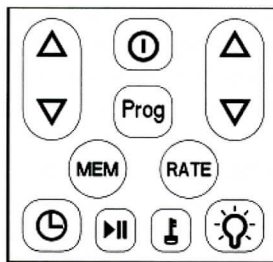
NOTE

1. Remove the battery from the Ultima Neuro if the unit is unlikely to be used for a long period.
2. When the battery is running low, it has to be removed from the unit and charged in the charging cradle.
3. Use only the power adaptor and charging cradle supplied.

USE OF OTHER CHAGERS COULD BE HAZARDOUS.

OPERATION OF THE ULTIMA NEURO UNIT

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




WHAT DOES EACH KEY DO


⏻ The ON/OFF key - It allows switching the unit ON and OFF. The LCD display 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 There are two main programs involve in Ultima Neuro (Neuro A and Neuro B). Press the "Prog" key to switch to each other. The symbol "Neuro A", "Neuro B", will display on the LCD accordingly.


To begin, insert the battery and switch on the unit, the


default program is Neuro A. There are 2 Neuro programs (Neuro A and Neuro B).


 The treatment time will be accumulative recorded when the output level is above zero, by pressing "MEM" key the treatment time accumulated in minute can be displayed, or return back to the previous normal display in toggle; by pressing "MEM" key for 5 seconds will clear the treatment time to zero.


 Press this key you can swith the pulse rate. In Neuro A you can switch between 94Hz and 8Hz (corresponding Neuro A/A1). In Neuro B you can switch between 94Hz and 40Hz (corresponding Neuro B/B1)

 Press this key you can select the treatment time. In Neuro A you can select 15mins(default), 30mins, 45mins. In Neuro B you can select 15mins(default), 30mins.

 These keys are use to adjust the intensity of channels. Left side is for the Ch1, right side is for the Ch2. When the intensity over zero, the corresponding LED light located at the top of the knob will light up.

 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 "▶ ||" 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 intensity and timer. By removing battery or pressing ON/OFF key cannot change the status of locked/unlocked.

 Press this key to enable or disable the backlight of the device. When the backlight is enabling, each time when a key is pressed, the backlight is lighted and last 8 seconds.

SPECIFICATION

Model:	Ultima Neuro
Channel:	Dual
Output:	Maximum 72 mA (peak value) Across 500 Ohm load
Pulse Width:	250µs, 2.1ms, 2.9ms, 5ms
Pulse rate:	8Hz, 40Hz, 94Hz
Waveform:	Asymmetrical Bi-phasic rectangular Monophasic rectangular
Treatment Timer:	15min, 30min, 45min, selectable
Mode:	2 modes

Neuro A/A1 – Neuro B/B1

Neuro A/A1	
Voltage	Pos 0-36V, Neg 0-36V
Peak Current to 500 Ω load, Pos or Neg	Pos 0-72mA Neg 0-72mA
Max Avg Current to 500 Ω load, Pos or Neg	Pos 1.692mA Neg 1.692mA
Pulse Width	250us/2.9ms(A/A1)
Frequency	94Hz/8Hz(A/A1)
Waveform	Symmetrical Bi-phasic rectangular;
Modulations	Burst 5sec on/off, Ramp 0.5sec on, 0.25sec off
%On Time Calculated – SG	Pos 2.35%(on) Neg 2.35%(on)

Peak charge per pulse to 500 Ω load	Pos 18.0 uC Neg 18.0 uC
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Neuro B/B1	
Voltage	Pos 0-12V
Peak Current to 1k Ω load, Pos or Neg	Pos 0-12mA
Max Avg Current to 1k Ω load, Pos or Neg	Pos 2.4mA
Pulse Width	2.1ms/5ms(B/B1)
Frequency	94Hz/40Hz(B/B1)
Waveform	Monophasic rectangular Positive Rectangular
Modulations	Constant
%On Time Calculated -	20%
Peak charge per pulse to 1k Ω load	Pos 25.5 uC

OTHER FEATURES

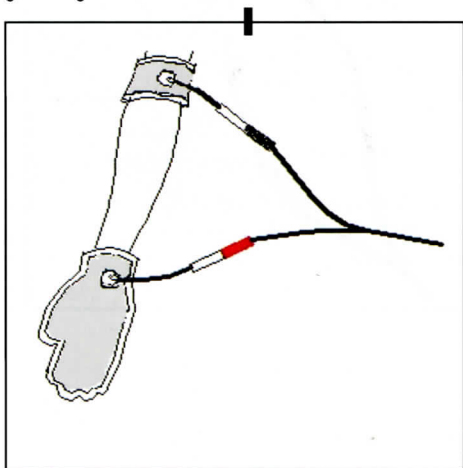
1. Labels "Neuro A" and "Neuro B". on the LCD display, will switch on according the program;
2. When programs change, the intensity will automatically go down to zero;
3. When the treatment timer is set, it will begin to count down one minute by one minute; Once it count down to zero, the unit will automatically shut off;
4. When the 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.
5. When the battery is running low, the symbol of battery is flashing in 2 Hz indicating that the battery should be recharged.
6. 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.

ELECTRODES PLACEMENT

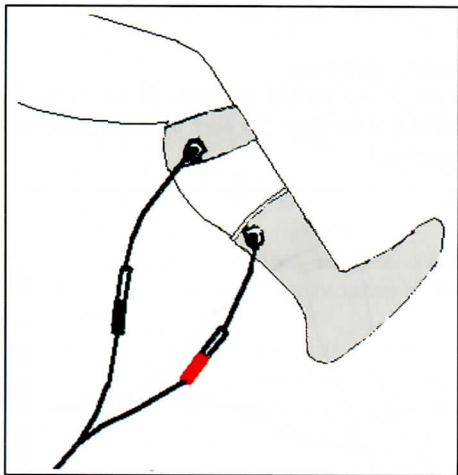
The following are electrode placement examples. Please note, the Gloves and Socks (red pin) are used in combination with a grounding cuff (black pin).

1. HANDS AND FEET

The red pin from the lead wires connects with the female pigtail plug of the glove. The black pin connects with the grounding cuff



The red pin from the lead wires connects with the female pigtail plug of the Sock. The black pin connects with the grounding cuff.



PADS

Treatment sessions should be accompanied by rests during and/or following treatment. Skin must be allowed to breathe, so the pads should be removed periodically. When not in use, the garments should be air dried.

The condition of the pads does affect the conductivity and, therefore, the performance of the unit. It is essential to use conductive spray when using conductive garments.

WARNINGS

- 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.

Ultima Neuro

Manufactured for:

