



Electroanalgesic Delivery System



...providing advancements in pain management

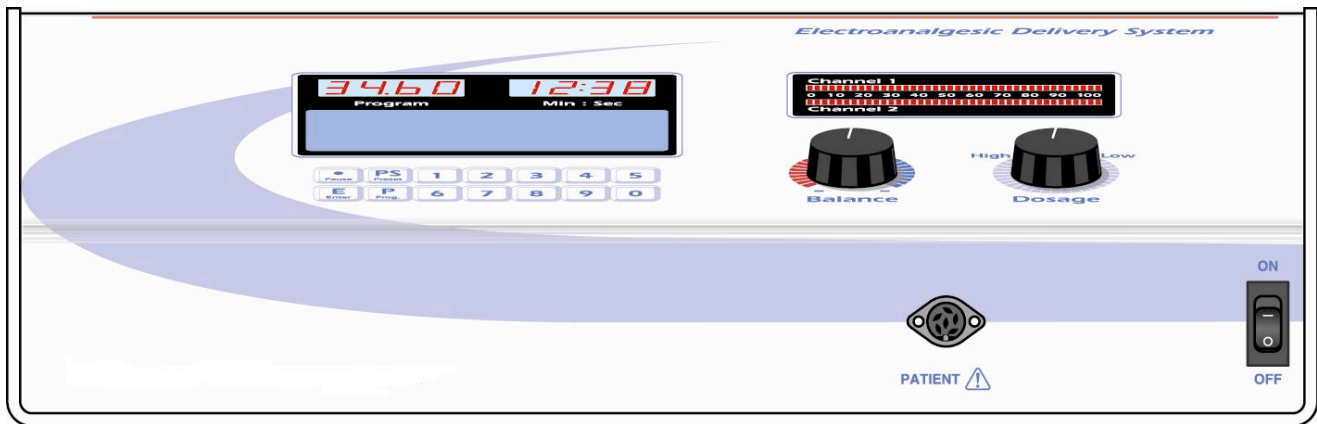
**FDA 510(k) Clearance
for the**

NeuroMed

Electroanalgesic Delivery System

"Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

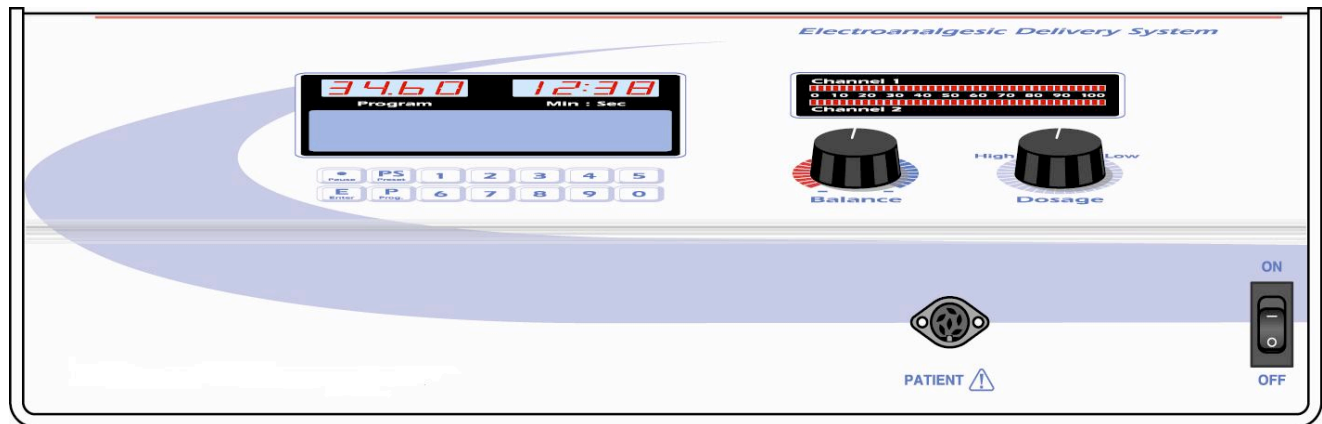
Electroanalgesic Delivery System



CLINICAL INDICATION FOR USE

- ❖ Stimulate peripheral nerves for the purpose of providing pain relief
- ❖ Management and symptomatic relief of chronic (Long-term) **INTRACTABLE PAIN**
- ❖ Adjunctive treatment of post-traumatic pain
- ❖ Adjunctive treatment in the management of post-surgical pain
- ❖ Increasing local blood circulation
- ❖ Maintaining or increasing range of motion
- ❖ Muscle Re-education
- ❖ Relaxation of muscle spasms
- ❖ Prevention or retardation of disuse atrophy
- ❖ Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Electroanalgesic Delivery System



CONTRAINDICATIONS

- Thrombophlebitis
- Manifest thrombosis
- Cardiac demand pacemaker
- Acute danger of haemorrhage
- Disturbances in cardiac rhythm. Do not stimulate over carotid sinus
- In tetany, caution should be exercised in dosing (intensity)
- Acute local inflammatory processes caused by bacterial or viral infections (for example: furuncle, phlegmon, herpes simplex, acute herpes zoster)
- Avoid direct high-dose stimulation over carotid sinus!
- Use adequate precautions in persons with suspected heart problems, epilepsy, or in trans-thoracic applications
- Use precaution following recent surgical procedures when muscle contractions may disrupt the healing process

WARNINGS AND PRECAUTIONS

1. Federal law restricts the sale, distribution, or use of this unit to, by, or on the lawful order a physician or other licensed practitioner.
2. The safety of interferential current units for use during pregnancy or delivery has not been established.
3. Keep the units out of reach of children.
4. In pain management, medical professionals using interferential current stimulators are accustomed to set intensity of the units above sensory and below motor threshold. In a few rare cases, the licensed practitioner might observe a motor contraction whereas the patient still will not report skin sensation. Therefore, in these cases the licensed practitioner should observe the contraction, and treat below motor threshold and be aware that in some cases reduced skin sensitivity might exist.
5. Avoid too strong pressure of the vacuum type electrode. Adjust the pressure at the minimum which is required to ensure a firm contact of the vacuum electrodes to the dermal region.
6. Transcutaneous electrical nerve stimulation is ineffective for pain of central origin.
7. Pay attention to contraindications, precautions and try to avoid adverse effects!
8. Transcutaneous electrical nerve stimulation is of no curative value.
9. Transcutaneous electrical nerve stimulation is a symptomatic treatment and as such it suppresses the sensation of pain.
10. Electronic monitoring equipment such as ECG monitors or ECG alarms will not operate properly when a transcutaneous electric nerve stimulatory is in use.
11. The long-term effects of electrical stimulation are unknown.
12. Adequate precautions should be taken in the case of persons with suspected heart problems.
13. Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
14. Caution should be used in the transthoracic application of EMS devices in that the introduction of electrical current into the heart may cause arrhythmias.
15. Precautions should be observed in the presence of the following:
 - a. Following recent surgical procedures when muscle contraction may disrupt the healing process.
 - b. Over the menstruating uterus.
16. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by use of an alternate conductive medium or alternate electrode placement. Skin irritation and electrode burns are potential adverse reactions. High dosage may cause dermal burns.
17. This device may only be used with electrodes and accessories offered by NeuroMed.
18. Repairs may only be carried out by NeuroMed technicians or by technicians authorized by NeuroMed.

It is recommended that this device be plugged into a surge protector.

ADVERSE EFFECTS

1. Patients with electro phobia, and patients who are uneasy, anxious, nervous, or jittery, often react extremely sensitive to electrical stimulation and feel uncomfortable even under very low intensity stimulation (in the range of sensory threshold). The physician or therapist should try to explain the safety of this form of electrical treatment. If the patients cannot be convinced, they are not suitable for transcutaneous electrical nerve stimulation.
2. Allergic skin reactions to cellulose sponges, textile, and disinfectants used for electrode materials can occur. In such cases, try changing the suspect materials or disinfecting fluid.
3. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
4. In some cases, petechiae can appear under the suction cups. They are" not dangerous, but they are avoidable by reducing the pressure of the vacuum during the treatment or by changing from suction cup to simple flat electrode treatments.
5. It has been reported on occasion, skin irritation and/or dermal burns beneath the electrodes, due to high dosage of current using small electrodes or adhesive electrodes. But they are avoidable by means of using larger electrodes or the reduction of the current dosage during the treatment or by changing from suction cup to simple flat electrode treatments.