

Recommended Treatment Protocol

The Calmare Therapy Treatment for pain relief has been specifically designed and clinically tested to provide treatment of high-intensity neuropathic and oncologic pain, including pain resistant to morphine and other drugs. Patients selected for treatment typically have not responded satisfactorily to any previous treatment protocol performed in accordance with Multidrug Therapy (MDT), or surface electro-stimulation.

Treatment Protocol

- To guarantee the most effective and lasting pain relief, treatment should last 45 minutes, but it is possible to set up from 20 to 60 minutes.
- The treatment program should include individual treatment sessions, that can be repeated, made up of at least 10 to 12 treatments, to be carried out at a frequency of five times a week (one treatment per day).
- The electrodes are never applied directly on the pain area.
- Electrodes are applied on the dermatomes, which correspond to one/two superior metamer, and one/two inferior metamer at the widest extension in the pain affected area.
- The intensity of the electric stimulus used to modulate and transmit the system's non-pain information will vary from patient to patient.
- Patient adaptation to the intensity of the treatment should be achieved on the basis of the criterion of the maximum intensity individually bearable by the patient without any input of pain or discomfort.
- The patient should be treated only when the disappearance of the pain during the application is immediate and complete. This is a clear sign that the proper nerve pathway has (have) been correctly identified, or, even in the case of partial success no feeling of discomfort is reported by the patient.
- If the clinician is unable to identify patient's dermatometric pathways of use in a correct therapeutic approach a relapse of pain will probably occur during treatment of the symptoms.
- In the case of polyneuropathies any medium-term relapse may be effectively corrected by initiating another treatment cycle.

Exclusion Criteria

The following exclusion criteria are recommended when considering a patient for treatment:

- Pacemaker user
- Neurolithic blockage of celiac plexus
- Other Neurolesive pain control treatment
- Anticonvulsant drugs



TREATMENT PROTOCOLS

<u>NEUROPATHIC PAIN INDICATIONS</u>	<u>TREATMENT PROTOCOL</u>
Post-Surgical Neuropathic Pain (PSNP) Post-Herpetic Neuralgia (Sciatic and Lumbar Pain) Narrow Canal Syndrome SCS (Putative neuropathic pain) Failed Back Surgery Syndrome (FBSS) Pudendal Neuropathy Brachial Plexus Neuropathy Low Back Pain <u>Phantom Limb Pain Syndrome</u>	<ul style="list-style-type: none"> • Establish initial treatment program at 10 to 12 individual treatment sessions. • Treatment should be set at a frequency of one treatment per day. • Set treatment duration to 30 to 45 minutes. • Determine proper level of intensity to achieve maximum allowed without discomfort to patient. • Patient should be void of pain and discomfort during treatment. • Follow procedures in User Manual.

<u>ONCOLOGIC PAIN INDICATIONS</u>	<u>TREATMENT PROTOCOL</u>
Cancers: Pancreatic Colon Gastric Ovarian Cervical Lung Colorectal Bladder Prostate Kidney Rectal Liver Uterine Gall Bladder Laryngeal Esophageal	<ul style="list-style-type: none"> • Establish initial treatment program at 10 to 12 individual treatment sessions. • Frequency of treatment is dependent upon patient's need for analgesia. • Set treatment duration to 45 minutes. • Determine proper level of intensity to achieve maximum allowed without discomfort to patient. • Patient should be void of pain and discomfort during treatment. • Follow procedures in User Manual.