

STIMULATOR



ELECTRODES & CABLES



Channels

2 Independent Channels

Output voltage

max 60 mA $\pm$ 10% (1000 Ω) / max 60 V $\pm$ 10%

Frequency

1-120 Hz $\pm$ 10%

Pulse Width

50-400 μ s $\pm$ 5 μ s

Programs

- P1 = 100Hz
- P2 = 80 Hz
- P3 = 2Hz
- P4 = Mixed
- P5 = Sequential
- P6 = HAN Stimulation
- P7 = Burst 2Hz
- P8 = Frequency Modulation
- P9 = Muscle Stimulation
- P10 = Massage
- P11 = Rubbing
- P12 = Sensitive Area Treatment
- P13 = Nausea

INTENDED USE

Use of Transcutaneous Electrical Nerve and Electrical Muscle stimulation through the application of electrical current via cutaneous electrodes for the purpose of providing therapeutic nerve and muscle stimulation, and pain relief.

TREATMENT

Program duration:

- From 10 to 720 minutes, adjustable via the mobile app

20 Hour Battery Life

(100Hz, 2 channels, 15mA)

Li-Ion battery fully charged in 2 hours

INDICATIONS FOR USE

- symptomatic relief and management of chronic intractable pain
- post-operative and post-trauma pain relief
- temporary relief of pain associated with aching or sore muscles due to mild strain associated with activities of daily living
- relief of arthritis pain
- temporary relaxation of muscle spasms
- to prevent or retard muscle disuse atrophy
- to increase blood flow to the treatment area
- muscle re-education
- to maintain or increase range of motion
- to prevent development of venous thrombosis of the calf muscles immediately after surgery (program 9)

CONTRAINDICATIONS

- on patients with pacemakers, implantable cardioverter defibrillators, or other similar active implantable devices
- heart-risk patients
- patients with epilepsy
- patients with dermatological conditions in the area of the electrodes placement
- Allodynia
- Allergy to electrodes
- Pregnant women
- Children (under age 22)

PRODUCT INFO

Manufactured by SUBLIMED SAS.



FDA REGISTRATION

Product codes: GZJ, NYN; IPF, NGX

Class: II

Regulation #: 882.5890; 890.5850

510k #: K202159