ZYNEX MEDICAL

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E-Wave

Muscle Stimulation

Users Manual

Technical Specifications

Amplitude:	0-100 mA
Frequency:	4-100 Hz Factory setting is 30 Hz.
Pulse width:	50-300 µsec. Factory setting is 200 µsec.
On-Time:	0.5 to 30 seconds Factory setting is 6 seconds.
Off-Time:	0.1 to 60 seconds Factory setting is 6 seconds.
Ramp Up:	0.1 to 6 seconds Factory setting is 1 second.
Ramp Down:	0.1 to 6 seconds Factory setting is 1 second.
Waveforms:	Symmetrical biphasic or monophasic selectable.
Treatment timer:	Continuous, 10-100 minutes, in 10 minutes steps. Factory setting is continuous.
Compliance meter:	Records total usage time in minutes and number of times used. Can be reset.
Dimensions:	2.5 x 5.5 x 1.0 in.
Weight:	8 oz. incl. Battery.
Warranty:	3 Years manufacturers warranty on materials and workmanship. Accessories excluded.

Precautions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
    1. When there is a tendency to hemorrhage following acute trauma or fracture;
    2. Following recent surgical procedures when muscle contraction may disrupt the healing process:
    3. Over the menstruating or pregnant uterus; and
    4. Over the areas of the skin which lack normal sensation.

- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of reach of children.
- This device should be used only with the leads and electrodes recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which voluntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions:

Skin irritation and burns beneath the electrodes are potential adverse reactions.

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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.

Get Started with the E-Wave

Make sure the electrodes are placed properly on the skin (see "Electrodes and Skin Care" for details) and that the lead wires are properly connected.

Turn on the unit by pressing ON for more than 1 second. A LED light will come on to indicate that the unit is functioning properly.

Keep pressing ↑ on either channel until a comfortable level is reached, as indicated by your physician or therapist.

To stop treatment, keep pressing ↓ on the channel used until display and light goes out after 1 additional second (mA will go to zero first). Thereafter remove the electrodes and place them on the plastic pad.

Stimulation will run continuously until the treatment timer is changed or the unit is turned off.

During treatment the display will show Remaining Time left on upper line and Stimulation Level on lower line.

Controls and features.

Turn unit ON and OFF: Press ON for 1 second to turn the unit on. The display will light up and the right LED will be constant green. Keep pressing OFF to turn the unit off. It takes one additional second after reaching 0 mA to turn it off. If no controls have been touched for 60 seconds with level at 0 mA or 60 seconds after timeout, the E-Wave will automatically turn off.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

Stimulation should not be applied over, or in proximity to, cancerous lesions.

Indications, contraindications, precautions, safety and warnings.

Safety References
Zynex Medical (Zynex) is only responsible for the safety, reliability and function of the device when repairs, adjustments and changes have been carried out by persons authorized by Zynex for such work and the device is used according to the user manual. Repairs and technical safety tests shall only be carried out by trained personnel.

Indications
This Zynex device has been designed for muscle re-education, prevention of retardation of disuse atrophy, increase local blood circulation, maintain or increase range of motion, relaxation of muscle spasms, and edema reduction.

Relaxation of muscle spasms.
Prevention or retardation of disuse atrophy.
Increasing local blood circulation.
Muscle re-education.
Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
Maintaining or increasing range of motion

This stimulator should only be used under supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Contraindications
- The device must not be used on patients with cardiac pacemaker.
- The device must not be used with stimulation over carotid sinus nerves.
- The stimulation must not be applied transcerebrally.
- The device must not be applied with undiagnosed pain syndromes until etiology is established.
- This stimulator should not be used on patients with cardiac demand pacemakers.

Electrodes should not be placed so that current will be applied to the carotid sinus (neck) region or transcerebrally (through the head).

Setting Stimulation Level: Use the ↑ and ↓ controls to increase or decrease the intensity. Do not use the PRG button. After 20 seconds the stimulation level is electronically locked as a safety feature to prevent the patient from unintentional increase in stimulation. To increase, just press ↓ to reduce it by at least 1 mA, which will unlock the safety feature. Thereafter you have 20 seconds to increase to desired level, before the lock is activated again. Any change in level or mode will unlock this safety feature.

Setting Frequency: Press PRG once and use ↑ or ↓ to increase or decrease the frequency.

SettingPulse Width: Press PRG twice and use ↑ or ↓ to increase or decrease the pulse width.

Setting the Treatment Time: Press PRG three times and use ↑ or ↓ to select the desired Treatment Time. Keep pressing ↓ to set a Continuous Treatment Time.

Setting the ON-Time: Press PRG four and use ↑ or ↓ to increase or decrease the ON-Time.

Setting the OFF-Time: Press PRG five and use ↑ or ↓ to increase or decrease the OFF-Time.

Setting the Ramp-Up: Press PRG six and use ↑ or ↓ to increase or decrease the Ramp-Up.

Setting the Ramp-Down: Press PRG seven and use ↑ or ↓ to increase or decrease the Ramp Down.

Setting Mode: Press PRG eight times and use ↑ or ↓ to toggle between Simultaneous stimulation or Alternating stimulation between the two channels.

Setting Waveform: Press PRG nine times and use ↑ or ↓ to toggle between Biphasic or monophasic waveforms (AC or DC).

Compliance data: Press PRG ten times and use ↓ to display the usage time in minutes and number of times used, when prompted by text in display. Only stimulation levels above 5 mA are recorded as usage time. The compliance meter can be reset by pressing ↑ to show prompt in display and thereafter press ↓ twice to reset both parameters to zero.

Return to factory settings: Press PRG eleven times and the display will prompt the choice to reset all parameters to factory settings. This is particularly useful if the user is unsure if the settings are correct and is a good starting point for variations.

Factory settings are:

Frequency:	30Hz
Pulse width:	200 µsec.
On-Time:	6 seconds
Off-Time:	6 second
Ramp Up:	1 second
Ramp Down:	1 second
Timer:	Continuous

Using the External Trigger Input: A standard external trigger, such as a heel-switch, can be connected through the connector on the left side of the unit. The Off-time is now disabled and a stimulation cycle will only begin when the switch is activated. The On-time will be continuous while the switch is triggered, and the Ramp Up and Ramp Down times will become zero. This functionality is enabled as soon as the connector is inserted into the E-Wave.

Electrodes and Skin Care

Proper skin care will help make the use of this device more comfortable and trouble-free. Prior to treatment, wash the areas where the electrodes will be placed with mild soap and water, rinse and dry the skin thoroughly. If necessary, remove excess body hair.

The E-Wave is intended to be used with re-usable, self-adhesive electrodes. Extended number of uses can be obtained by adding water to the adhesive surface immediately after each use and placing them on the plastic pad. They will regain their conductivity and adhesiveness as compared to leaving them dry.

Sterile electrodes may be required for some post-op applications.

Batteries

One 9 volt Alkaline battery is used. The battery compartment on the back of the device opens by sliding the cover downwards. Please ensure to dispose the used batteries properly.
Rechargeable batteries are not recommended as they only have a short usage time and are not charged while in the device.