

# TruWave

Tens Unit



# Users Manual

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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.*

## **Zynex Medical Contact Information**

### **CUSTOMER SERVICE**

**(866) 940-7030**

- Supplies:** To order more electrodes or other accessories
- Technical Support:** Questions or problems with using your device
- Device Return:** Order a postage paid return envelope to return your device at no charge

### **MAIN OFFICE**

**(800) 495-6670**

- Billing Questions:** Questions regarding insurance benefits and covered benefits for durable medical equipment or questions about an Explanation of Benefits form you received in the mail

### **FAX NUMBER**

**(800) 495-6695**

### **MAILING ADDRESS**

Zynex Medical  
9990 Park Meadows Drive  
Lone Tree, CO 80124

### **EMAIL**

**info@zynexmed.com**

### **WEBSITE**

**zynexmed.com**

### **Get Started with the TruWave**

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. The right LED will illuminate, indicating that the leads and electrodes are properly connected and that the unit functions 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.

### **Controls and features.**

The arrows on each side of the device will control only the intensity, unless the Program button is pressed and the display will indicate which parameter is being programmed.

These same arrows on the right side also serve as On or Off buttons. To turn the device On, press the Arrow-button marked “On” for more than one second. To turn off the device, press the Arrow-button marked Off for more than three seconds and it will turn off.

Programming is done as described below by pressing the middle button, “Program”, which is used to scroll through a number of options.

## **Directions for Use.**

**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 illuminate. 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 five minutes with level at 0 mA or five minutes after timeout, the TruWave will automatically turn off.

**Setting Stimulation Level:** Use ↑ and ↓ controls to increase or decrease level. 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 the level.

**Setting Mode:** Press PRG once and use ↑ or ↓ to scroll between Normal, Burst, Modulated and Strength Duration (SD) Modes.

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

**Setting Frequency:** Press PRG twice and use ↑ or ↓ to increase or decrease the frequency of the Normal, Burst or Modulated modes. In SD mode the frequency is always fixed at 100 Hz, so this is not programmable.

**Setting Pulse Width:** Press PRG three times and use ↑ or ↓ to increase or decrease the pulse width in Normal, Burst, or Modulated modes. In SD mode the pulse width is fixed at 225 μsec.

**Compliance data:** Press PRG five 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 six times and 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:**

	<b>Normal</b>	<b>Burst</b>	<b>Modulated</b>	<b>Strength Duration</b>
<b>Frequency</b>	70 Hz	2 Hz	66-100 Hz	100 Hz
<b>Pulse Width</b>	200 $\mu$ sec.	200 $\mu$ sec.	200 $\mu$ sec.	200 $\mu$ sec.
<b>Span</b>			50%	
<b>Cycle Time</b>			6 sec.	6 sec.
<b>Treatment Timer</b>	60 min	60 min	60 min	60 min

## **User Parameters:**

### ***Normal Mode:***

The default frequency is 70Hz, but as described in the section “Directions for Use” can be set with intervals of 5Hz between 21Hz and 160 Hz and with intervals of 1Hz between 2 and 20 Hz. The stimulation frequency is an indication of how often each stimulation pulse occurs, i.e. 70Hz means 70 stimulation pulses per second.

The default Pulse Width is 300  $\mu$ sec, but as described in the section “Directions for Use” can be set with intervals of 5 $\mu$ sec. between 50 and 400  $\mu$ sec. The stimulation Pulse Width is an indication of how long the stimulation lasts during each stimulation pulse, i.e an indication of the “strength” of the stimulation. An increase of Pulse Width will therefore be felt similar to an increase in intensity.

The treatment timer is set default to 20 minutes, but as described in the section “Directions for Use” can be set with intervals of 10 minutes between Continuous and up to 90 minutes. The treatment timer will count down as shown in the display and stimulation will drop to zero after time is out. The user can commence a new treatment session by increasing the level as desired.

The User can program the following parameters: Frequency, Pulse Width and Treatment Time.

***Burst Mode:***

The default frequency is 2 Hz, but as described in the section “Directions for Use” can be set with intervals of 0.5 Hz between 0.5 Hz and 4 Hz. The Burst Frequency is an indication of how often each train of pulses (eight pulses) occurs. Each of the eight pulses in the pulse train consists of 50-400µsec wide pulses each 10 millisecond (100 Hz). Burst stimulation is best applied when the intensity is set to a level where visible, yet comfortable contractions at the rate of the burst frequency are present. The effect is usually felt after 15 minutes or more of burst stimulation.

The treatment timer is set default to 20 minutes, but as described in the section “Directions for Use” can be set with intervals of 10 minutes between Continuous, 10 minutes and up to 90 minutes. The treatment timer will count down as shown in the display and stimulation will drop to zero after time is out. The user can commence a new treatment session by increasing the level as desired.

The User can program the following parameters: Burst Frequency, Pulse Width and Treatment Time.

***Modulated Mode:***

The frequency will shift (modulate) between 66 and 100 Hz with a preset interval of 6 seconds between each end frequency. The Pulse Width will also shift (modulate) during the 6 seconds interval from 50µsec. to 400 µsec. around the set Pulse Width. The Cycle Rate can be programmed between 5 and 12 seconds, but is preset at 6 seconds at default. The default Pulse Width is 225µsec. and when the frequency is at it’s minimum, the Pulse Width is at it’s maximum and visa versa.

The treatment timer is set default to 20 minutes, but as described in the section “Directions for Use” can be set with intervals of 10 minutes between Continuous and up to 90 minutes. The treatment timer will count down as shown in the display and stimulation will drop to zero after time is out. The user can commence a new treatment session by increasing the level as desired.

The User can program the following parameters: Pulse Width, Cycle Rate and Treatment Time.



***SD Mode:***

Strength Duration (SD). The Frequency is fixed at 100Hz in this mode. The Pulse Width as well as the intensity will vary in opposite ways during an interval of 6 seconds. The Span is preset to 50%, so the pulse width decreases to 50% of the set pulse width and up to 50% above. Simultaneously, the Intensity increases to 50% of the set value and decreases to 50% above. The pulse width is set at 225 $\mu$ sec. and can not be changed. The energy delivered through the electrodes therefore remains constant, due to the increase of the intensity while the pulse width decreases and visa versa.

The treatment timer is set default to 20 minutes, but as described in the section "Directions for Use" can be set with intervals of 10 minutes between Continuous and up to 90 minutes. The treatment timer will count down as shown in the display and stimulation will drop to zero after time is out. The user can commence a new treatment session by increasing the level as desired.

The User can program the following parameters: Span, Cycle Rate and Treatment Timer.

### **Electrodes and Skin Care**

The TruWave comes with 4 self-adhesive electrodes, 2" x 2" square. These electrodes are for multiple use, pre-wired and fit directly into the lead wires. The lead wires attach to the connectors at the top of the device, while the other end of the lead wires, consisting of two pins, will attach directly to the electrodes. For each channel used there must always be two electrodes connected and placed on the skin to complete the circuit for the electrical current to flow.

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 TruWave 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.

The display will indicate “Batt Low” when the voltage of the batteries drops below the level for satisfactory function. A red flashing LED will also lead the attention to replacing the battery. Please replace the battery with a new Alkaline battery in this event.

***The TruWave accommodates a 9 Volt battery even if it is inserted with reverse polarity and the TruWave circuitry will ensure full functionality with reverse polarity.***

### **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 pain relief and 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 stimulation must not be applied transcranially.
- The device must not be applied with undiagnosed pain syndromes until etiology is established.
- Electrodes should not be placed so that current will be applied to the carotid sinus (neck) region or transcranially (through the head).

**Warnings**

- This device is not effective for pain of central origin (This includes headache).
- The safety of tens devices for use during pregnancy or birth has not been established.
- This device should only be used under the continued supervision of a physician.
- This device does not have curative value.
- This device offers symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- The user must keep the device out of reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when this device is in use.

Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

**Precautions**

- 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.
- If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if problems persist.

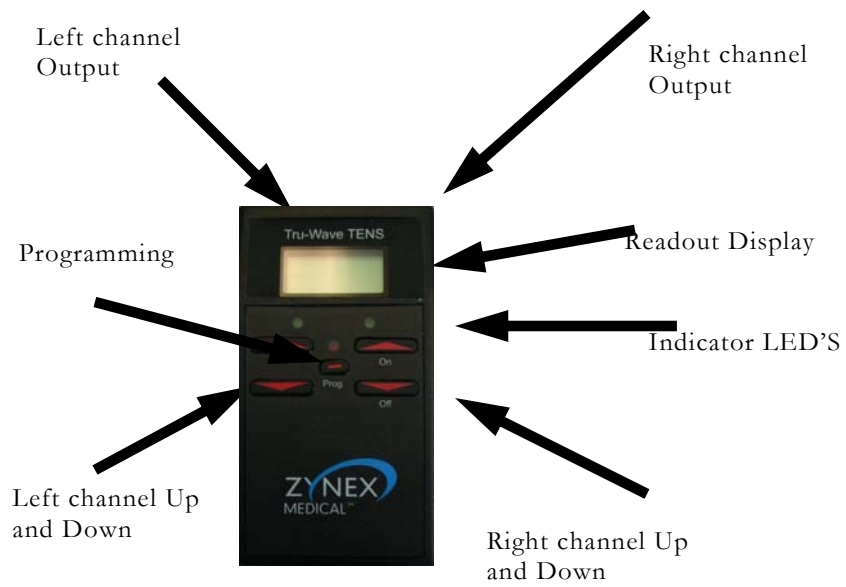
Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

**Adverse Reactions:**

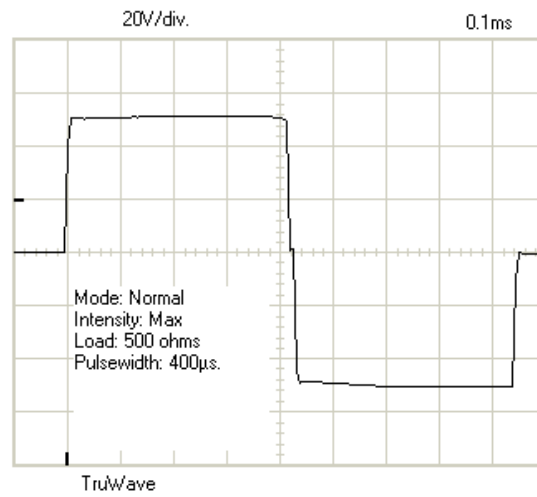
Skin irritation and burns beneath the electrodes are potential adverse reactions.

**Specifications.**

Dimensions: 2.5 x 5.5 x 1.0 in.  
Weight: 8 oz. incl. Battery.  
Accessories: 2 lead wires, one 9 Volt battery,  
carrying case, users manual and  
one pack of electrodes.  
Warranty: 3 Years manufacturers warranty on  
materials and workmanship.  
Accessories excluded.



Waveform:





9990 Park Meadows Drive, Lone Tree, CO 80124  
1-800-495-6670  
[www.zynexmed.com](http://www.zynexmed.com)

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