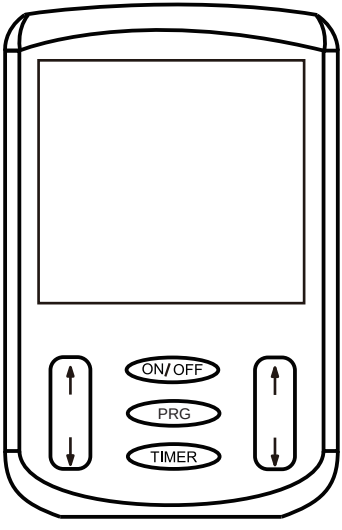
Instruction Manual

Model: OTC TENS
Item # : 21019



Please keep this instruction manual safe for future use.

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Chapter 1: INTRODUCTION TO TENS

(1) GENERAL DESCRIPTION

The device is a battery operated pulse generator that sends electrical impulses through electrodes to the body to reach nerves causing pain. Electrical impulses can be adjusted by changing the pulse width and rate. The strength is individually adjusted using the 2 channels. A slide button (button lock function) protects the device from accidental changes while in use.

(2) EXPLANATION OF PAIN

Pain is the body's natural warning mechanism and is intended to prevent additional injury. Pain is important, as without it, vital parts of our body might be injured or damaged without our knowledge. While ointments, drugs or even surgery can be used to treat chronic pain, these are all utilized with varying degrees of success, as each individual patient and condition is different. TENS offers a unique alternative method of pain relief with no potentially harmful side effects.

(3) WHAT IS TENS

TENS, Transcutaneous Electrical Nerve Stimulator, is a battery powered electrical unit which uses electrodes placed onto the skin over a painful area to deliver electrical impulses to the nerve fibers which lie underneath the skin surface. It provides pain relief by blocking pain signals to the brain via the spinal cord and peripheral nervous system. TENS also stimulates production of endorphins, the body's own "painkillers".

(4) COMMON APPLICATIONS FOR TENS

Although dependent on your specific pain problem, TENS devices have been used successfully to treat many conditions, including:

CHRONIC PAIN

Cervical (Neck) – Amputation – Phantom Limb – Headache – Lower Back – Lumbago – Leg Pain – Arthritis

ACUTE PAIN

Post Operative – Muscle and Joint – Tendonitis – Fractures – Tennis Elbow

Chapter 2: INDICATIONS / CONTRAINDICATIONS / WARNINGS

Read the operation manual in its entirely before using the device.

INDICATIONS:

This device may be used, with a physician/clinician's prescription, for the symptomatic relief and management of chronic (long term) pain and for the treatment of post-operative and post-traumatic pain.

CONTRAINDICATIONS

- **Heart Disease** – Use caution prior to using this device on patients suspected of having heart disease.
- **Cardiac pacemakers** – Do not use this device if you have a demand-type cardiac pacemaker or any implanted defibrillator.
- **Trans cerebral stimulation** – Do not apply electrical stimulation trans cerebrally (through the head).
- **Epilepsy** – Use caution for patients with suspected or diagnosed epilepsy when using this device.
- **Carotid sinus** – Do not apply electrical stimulation to carotid sinus region of the neck.
- **Unknown etiology** – Do not use this device if pain symptoms are undiagnosed. Use only after the origin / caused of pain has been determined by your doctor.
- **Hemorrhages** – Use caution when there is a tendency to hemorrhage, such as following acute trauma or fracture.
- **Post-surgical use** – Use caution following recent surgical procedures when muscle contraction may disrupt the healing process.
- **Uterus** – Do not use electrical stimulation during menstruation.
- **Sensory loss** – Do not use electrical stimulation where sensory nerve damage is present by a loss of normal skin sensation.
- **Skin irritation** – If patient experiences skin irritation due to electrical stimulation, stop using the device and consult the clinician. Irritation may be reduced by an alternative conductive medium or an alternative electrode placement. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.
- **Adverse reactions** – In addition to skin irritation, inflammation and burns beneath the electrodes are potential adverse reactions. Follow directions carefully.

WARNINGS

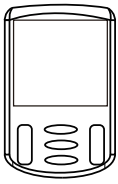
- **Pregnancy** – The safety of using electrical stimulation during pregnancy or birth has not been established.
- **Central origin pain** – This device is not effective for pain of central origin (including headaches).
- **Prescription** – Use electrical stimulation only in the prescribed manner and for the prescribed reason.
- **Symptomatic treatment** – This device is a symptomatic treatment and, as such, suppresses the sensation of pain which would otherwise serve as a protective or warning mechanism of your body.
- **Keep out of reach of children** – Do not store or use this device near children.
- **Electronic equipment** – Electronic monitoring equipment (such as ECG and EKG alarms) may not operate properly when electrical stimulation devices are in use.
- **Machinery operation** – Never operate potentially dangerous machinery such as power saws, automobiles, etc. while using this device.
- **Uncomfortable stimulation** – If the stimulation levels are uncomfortable or become uncomfortable, reduce the intensity (amplitude) to a comfortable level. Contact your physician / clinician if this does not resolve the problem or if the problem persists or re-occurs at your next prescribed treatments session.
- **Neck stimulation** –Do not place electrodes across the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur. This may be strong enough to close off the airway or cause breathing difficulty.
- **Long-term effects** – The long-term effects of chronic use of electrical stimulation are unknown.
- **Damage from liquids** – Do not immerse the stimulator unit in water or other liquids.
- **High frequency surgical devices** – Simultaneous connection of a patient to a high frequency surgical device while using this device may result in burns at the site of the electrodes and possible damage to the stimulator. Discontinue use before surgery.
- **Microwave or radio frequency sources** – Operation in close proximity to shortwave or microwave therapy equipment may shut the stimulator off.
- **Flammable** – Do not use the device in an environment where flammable or explosive fumes may exist.
- **External use** – This device is for external use only
- **Lead connection** – Do not connect the lead wires to an alternating current (AC) power source or other equipment not

▲Danger

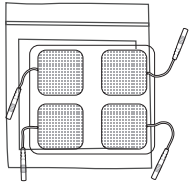
The device does not have AAP/APG protection.

Extreme hazard is possible if used in the presence of explosives, flammable materials or flammable anesthetics. Caution should be used when applying the device to patients suspected of having heart conditions. Further clinical data is needed to show if there are adverse side effects on those with coronary disease.

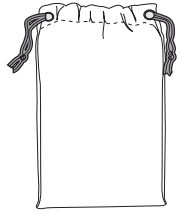
Chapter 3: CONTENTS



OTC unit



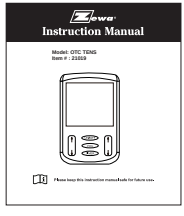
4 Electrodes



Storage bag

2 wires

3 AAA batteries



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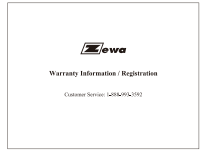
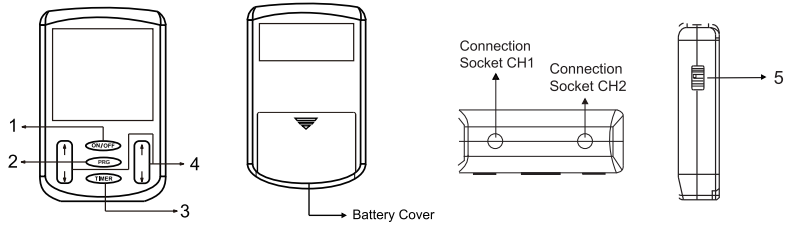


Warranty card

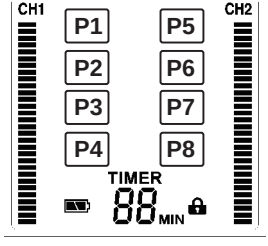
Chapter 4: DESCRIPTION OF DEVICE AND FUNCTIONAL BUTTONS



1. ON/OFF Button: Turns the power on and off.
2. PRG Button: Used to select a program.
3. TIMER Button: Used to program timer, 5 – 95 minutes or continuous (5 minute increments).
4. ↑ ↓ Buttons: Used to increase / decrease intensity level for CH 1 and CH 2.
5. Sliding Switch: Lock / unlock buttons

The LCD Display:

1. Intensity level for Ch1 & Ch2 (30 levels)
2. Program Number
3. Timer (5-95 min. and continuous)
4. Symbol of button lock function
5. Low battery indicator



Chapter 5: PROGRAM DETAILS

Program	Pulse intensity max.	Pulse width	Frequency	Mode
P1	100 mA	260µs	15 Hz	Constant (C)
P2	100 mA	260µs	100 Hz	Burst(B)
P3	100 mA	260µs	120 Hz	Constant (C)
P4	100 mA	260µs ~150µs	2 Hz ~100 Hz	Modulated Rate and Width
P5	100 mA	260µs ~150µs	100 Hz	Modulation Width (MW)
P6	100 mA	260µs	7 Hz ~80 Hz	Strength-Duration and Rate
P7	100 mA	260µs ~150µs	120 Hz	Strength-Duration and Width
P8	100 mA	P1 – P7		Sequential

Chapter 6: PREPARATION FOR USE

Insert batteries:

Your device operates with 3 AAA batteries. Please install batteries with polarities as indicated. Make sure the battery strip is placed below the batteries.

CAUTION: Never force a battery into the battery compartment. A battery that does not fit can damage the stimulator. This device requires 3 AAA batteries, never attempt to use any other battery type.

Preparing the Skin for a Therapy Session:

Proper preparation of the skin is essential to prolong electrode life and reduce the risk of skin irritation.

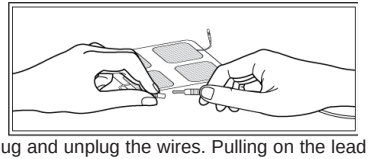
To prepare your skin at the electrode placement sites:

1. Determine the placement sites for the electrodes. Follow your clinician's instructions.
   NOTE: Your clinician generally has you place the electrodes above and below (or surrounding) the area of pain or along the "pain path" of your arm or leg.
2. Wash the area with mild soap and water (do not use alcohol). Rinse and dry thoroughly.
3. Trim excess body hair from the area with scissors (do not shave).
4. Optionally, apply skin prep to the area to form a protective barrier on your skin.
5. When removing electrodes, always remove by pulling in the direction of hair growth. Do NOT pull on the wire.
6. It may be helpful to apply skin lotion on electrode placement area when not wearing electrodes.

Connecting the electrodes to the device:

Hold the insulated portion of the electrode connector and push the plug end of the lead wire into the electrode connector. Repeat for all 4 electrodes. After connecting each electrode, plug the other end of the lead wire into the TENS device.

Caution: The device should be OFF before connecting the lead wire to the TENS device.



Note: Use care when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

Caution: Never insert the plug of the lead wire into an AC power supply or other equipment not specified as safe for the lead wires.

Chapter 7: ELECTRODES AND ELECTRODE PLACEMENT

General electrode information:

Electrodes should be routinely replaced when they start to lose their adhesive nature. If you are unsure of your electrode adhesive properties, order replacement electrodes. Replacement electrodes should be re-ordered through your local dealer or call Zewa customer service. Follow application procedures outlined on electrode packaging to maintain optimal stimulation and to prevent skin irritation.

Electrode Placement:

The placement of electrodes can be one of the most important parameters in achieving success with TENS therapy. Of utmost importance is the willingness of the clinician to try the various styles of electrode placement to find which method best fits the needs of the individual patient. Every patient responds to electrical stimulation differently and their needs may vary from the conventional setting suggested here. If the initial results are not positive, feel free to experiment. Once an acceptable placement has been achieved, mark down the electrodes sites and the settings, so that the patient can easily continue treatment at home.

Contiguous Electrode Placement:

This is the most common placement technique. It involves pacing the electrodes alongside the area of localized pain sites, in such a way as to direct the flow of current through or around the area of pain. In a single channel application, this would involve placing each electrode on either side of the pain site if the pain is localized on the limb and deep within the tissue. Electrode placement on the posterior and anterior aspects of the affected limb will allow the current to flow completely through the limb and thus through the endogenous pain site. With a 2 channel application, the clinician may either direct the current flow to cross through the pain site or in what is called the “bracket” method allowing the current flow on either side of the painful area, generally through the nerve branches that feed into the pain site.

Note: Electrodes should be placed between 0.5” – 2” apart from each other.

Caution: The device should be in the OFF position before placing the electrodes on your skin.

Chapter 8: USING THE DEVICE

1. Connect the electrodes to the TENS control unit.
2. Place electrodes on your skin.
3. Turn the Device ON by pressing the “ON/OFF” button.
4. To change to another program press the “PRG” button.
5. To change the timer, press the “TIMER” button.
6. The device will turn off automatically if the timer was set (count down minutes are shown on the display). If it was set to C (continuous) the device has to be turned OFF manually.
7. To turn the device OFF manually, press the “ON/OFF” button for 3 seconds.

Note 1:
When the device is in use and the “PRG” button is pushed, the intensity levels will change to “0” and the last selected program starts flashing.
Note 2:
If no button is pushed for 10 seconds while in programming mode, the device will stop flashing. To return into programming mode follow steps above by pressing the “PRG” button.
Note 3:
If the device is in programming mode (intensity bars are at “0”), the device will automatically turn OFF after 60 seconds if no button is pushed.

Chapter 9: ENDING YOUR TREATMENT SESSION

After the device shuts off, use the following steps as a quick reference for ending your session:

- Disconnect the lead wire(s) from the control unit.
- Remove electrodes from skin and place them back on the transparent liner. When removing electrodes, always pull in the direction of hair growth. DO NOT REMOVE ELECTRODES WHILE THEY ARE CONNECTED TO THE UNIT TO AVOID ANY ELECTRIC DISCHARGE. Do NOT pull on the wires, but peel off on the corner of the electrode.
- Disconnect the lead wire(s) from the electrodes.
- Store the components in the storage bag.

Chapter 10: SPECIAL FEATURES

Button Lock Function:
Slide the sliding switch to lock or unlock. The lock feature will lock all buttons so that no accidental changes can be made during a treatment.

Automatic Shutoff
- The device turns off automatically when not in use and no button is pressed for 60 seconds.
- The device will turn off automatically when the timer reaches “0” minutes.

Intensity Level Reset
1. For your safety and comfort, the intensity level will reset to 0 each time the device is turned off, including after a therapy session.
2. For your safety and comfort, the intensity level will reset to 0 in case the device is changed into programming mode (pressing the “MODE” button 2 times).

Low Battery Indicator
The low battery indicator is displayed whenever the battery is low. The battery needs to be changed.

Programming Recall
The last treatment and timer setting is automatically saved and will appear on the display when the device is turned on for the next treatment.

Chapter 11: CARING FOR YOUR DEVICE

The device may be cleaned by gently wiping it with a damp cloth moistened with mild soap and water. **Never immerse the device in water or other liquids.**
Wipe lead wires with a damp cloth as described above if they become soiled.
To properly store the device for an extended period of time, remove the battery from the device. Put the device and accessories in the storage bag and store in a cool dry location.

Chapter 12: CHANGING THE BATTERY

- When the low battery symbol is displayed, the battery is too weak to power the device and it is time to change it. At this point, the device will shut off until a fresh battery is inserted. If you decide to install a new battery before the device has shut itself off, be sure to turn the power off before you undertake to change the battery.
- To change the battery, open the battery compartment as you did when you first installed it. Pull out the old batteries and insert new ones according to directions.

CAUTIONS:

1. **Do not connect the stimulator to any electrical outlet.**
2. **Remove batteries from the device during storage to prevent battery leakage. Failure to do so may damage the device.**
3. **Replace battery if device was immersed in water or liquid.**
4. **Never recharge alkaline batteries. An explosion may result.**
5. **Dispose of all batteries according to current federal, state, and local regulations.**

Chapter 13: TROUBLESHOOTING

If your device does not function properly:

Problem	Possible Cause	Solution
Stimulation is weak	1. Low Batteries 2. Poor electrode contact 3. Worn electrodes	1. Change Batteries 1. Reapply electrodes, secure firmly 2. Replace electrodes
Stimulation stops	1. Low Batteries 2. Poor electrode contact 3. Damaged or worn lead wires and/or electrodes 4. Therapy time complete	1. Change Batteries 2. Reapply electrodes, secure firmly 3. Replace lead wires and/or electrodes 4. Restart device
Stimulation weakens with minutes after start	Normal “adaptation” response	Increase intensity
Unintentional muscle contractions	Intensity too high	Decrease intensity
Stimulation uncomfortable	1. Intensity too high 2. Improper electrode placement 3. Poor electrode contact	1. Decrease intensity 2. Reposition electrodes 3. Reapply electrodes, secure firmly
Stimulation ineffective	Improper electrode placement	Reposition electrodes

Note: If there is any other problem, please call Zewa customer service at 1-888-993-3592.

Chapter 14: TECHNICAL SPECIFICATIONS

Wave form	Asymmetrical Bi-Phasic square pulse
Channel	Dual, isolated between channels
Modes	8 modes
Pulse rate Range	2~120Hz(pk)
Pulse width Range	150~260uS(pk)
Pulse Intensity	Adjustable 0-100mA peak into 500 ohm load each channel
Timer	5~95 min and Continuous
Power supply	3 x AAA Batteries (4.5V)

※All electrical specification ±20%。

Model: OTC TENS

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