

TENS 3000

8. Turn the TENS off before applying or removing electrodes.
9. TENS devices have no AP/APG protection.
Do not use it in the presence of explosive atmosphere and flammable mixture.

Chapter 3 : WARNINGS

1. Caution should be used in applying TENS to patients suspected of having heart disease. Further clinical data is needed to show there are no adverse results.
2. The safety of TENS devices for use during pregnancy or birth has not been established.
Do not use TENS during pregnancy.
3. TENS is not effective for pain of central origin. (This includes headache.)
4. TENS devices should be used only under the continued supervision of a physician.
5. TENS devices have no curative value.
6. TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
7. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.
8. There should be a prominently placed statement warning that stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.
9. Do not place electrodes on the front of the throat as spasm of the Laryngeal and Pharyngeal muscle may occur.
10. Care should be taken so that when operating potentially dangerous machinery the stimulator controls are not changed abruptly.
11. Electrodes should not be placed over the eyes, in the mouth, or internally.
12. Keep this device out of the reach of children.
13. Caution: Federal law restricts this device to sale by or no the order of a physician

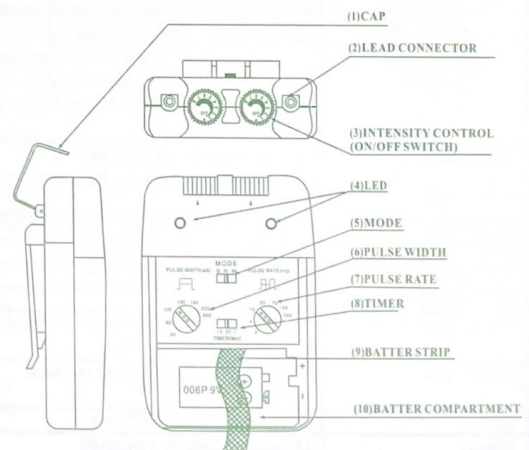
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Chapter 4 : GENERAL DESCRIPTION

The TENS 3000 is a battery operated pulse generator that sends electrical impulses electrodes to the body and reach the nerves causing pain. The device is provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel.






The electronics of the TENS 3000 create electrical impulses whose Intensity, duration, number per second and modulation may be altered with the controls or switches. Dial controls are very easy to use and the slide cover prevents accidental changes in the setting.

Chapter 5 : CONSTRUCTION



5

Chapter 9 : GRAPHIC SYMBOLS

1.  Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s.
2.  Type BF applied part
3.  Do not insert the plug into AC power supply socket.
4.  Direct Current (DC power source)
5.  Refer to Instruction Manual

Chapter 10 : PARAMETER CONTROLS

PULSE DURATION

Wider pulse duration settings will deliver stronger stimulation for any given intensity setting. As mentioned in the Controls section, by using a combination of intensity and pulse duration, it is felt that various pulse widths are capable of stimulating different groups of nerve fibers.

The choice of which pulse duration to use is partially dependent upon the Treatment Mode and Protocol selected (refer to the appropriate section).

PULSE RATE

The Pulse Rate (hertz or pulses per second) chosen depends greatly upon the type of electrode placement given to the patient.

When using contiguous and dermatome electrode placements (i.e. stimulating directly through the area of pain or localized enervation), a quick pulse rate (setting greater than 80Hz on the Pulse Rate Control) is desired. The patient should not perceive individual pulses but rather have the sensation of steady continuous stimulation.

Despite above recommendations, these individual patients may require slight variations of the above settings, according to the nature of their condition.

TREATMENT MODE

Normal or Conventional TENS offers the practitioners complete control over all the various treatment parameters of the instrument.

Burst Mode is analogous to the Low Rate TENS technique except the low frequency individual pulses are replaced by individual "bursts" of 7-10 individual pulses. It is thus a combination of Conventional TENS and Low Rate TENS. In Burst Mode, the treatment frequency is fixed by the instrument and is not adjustable with the Frequency Rate control.

Modulated Mode attempts to prevent nerve accommodation by continuously cycling the treatment intensity. When using Modulated Mode increase the intensity only when the unit is at the maximum intensity of the modulation cycle. If the intensity is increased during a low intensity period of the cycle, the patient may turn up the control very slowly, so that they may feel the intensity any higher.

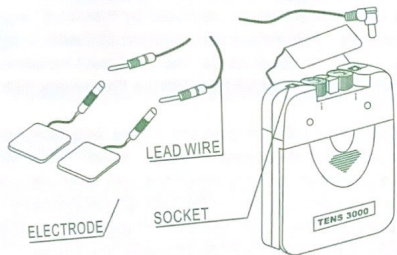
TIME DURATION

The onset of pain relief should occur shortly after the intensity setting has been determined. However, in some cases, pain relief may take as long as 30 minutes to achieve. TENS units are typically operated for long periods of time, with a minimum of 20 – 30 minutes and in some post-operation protocols, as long as 36 hours.

In general, pain relief will diminish within 30 minutes of the cessation of stimulation.

Chapter 11 : ATTACHMENT OF ELECTRODE LEAD WIRES

The wires provided with the system insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.



After connecting the wires to the stimulator, attach each wire to an electrode. Use care when you plug and unplug the wires. Jerking the wire instead of holding the insulated connector body may cause wire breakage.

CAUTION

Do not insert the plug of the patient lead wire into the AC power supply socket.

Chapter 12: LEAD WIRE MAINTENANCE

Clean the wires by wiping with a damp cloth. Coating them lightly with talcum powder will reduce tangling and prolong life.

10

Chapter 13 : ELECTRODE OPTIONS

Your clinician will decide which type of electrode is best for your condition. Follow application procedures outlined in electrode packing, to maintain stimulation and prevent skin irritation. Use the legally marketed TENS electrode is recommended. The device is completed with standard carbon film adhesive electrodes in size 4x4cm.

Chapter 14 : 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 settings 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 on the patient's reference sheet of this manual, so the patient can easily continue treatment at home.

CONTIGUOUS PLACEMENT

This is the most common placement technique. It involves placing the electrodes alongside the area of localized pain site, 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 pad on either side of the pain site if the pain is localized on a limb and deep within the tissue. Pad 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.

11

With a two channels 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.

Chapter 15 : TIPS FOR SKIN CARE

To avoid skin irritation, especially if you have sensitive skin, follow these suggestions:

1. Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.
2. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the "pulling stress" from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from center outward; avoid stretching over the skin.
5. To minimize "pulling stress", tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
6. When removing electrodes, always remove by pulling in the direction of hair growth.
7. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
8. Never apply electrodes over irritated or broken skin.

12

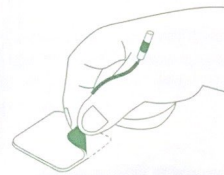
Chapter 16 APPLICATION OF RE-USABLE SELF ADHESIVE ELECTRODES

Application

1. Clean and dry the skin at the prescribed area thoroughly with soap and water prior to application of electrodes.
2. Insert the lead wire into the pin connector on the pre-wired electrodes.
3. Remove the electrodes from the protective liner and apply the electrodes firmly to the treatment site.

Removal

1. Lift at the edge of electrodes and peel; do not pull on the lead wires because it may damage the electrodes.
2. Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.



Care and Storage

1. Between uses, store the electrodes in the resealed bag in a cool dry place.
2. It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turn the surface up to air dry. Over Saturation with water will reduce the adhesive properties.

13

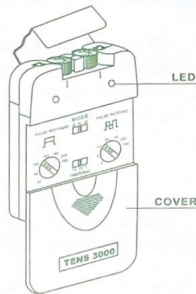
Important

1. Do not apply to broken skin.
2. The electrodes should be discarded when they are no longer adhering.
3. The electrodes are intended for single patient use only.
4. If irritation occurs, discontinue use and consult your clinician.
5. Read the instruction for use of self-adhesive electrodes before application.

Chapter 17 : ADJUSTING THE CONTROLS

1. Slide Cover:

A slide-on panel cover covers the controls for Pulse Width, Pulse Rate, Mode Selector and Modulation Selector. Your medical professional may wish to set these controls for you and request that you leave the cover in place.



2. Display Led

Each of the leds illuminates whenever the electronics of the device create a current impulse. Due to the capacity of the human eye, the illumination of the lamp can only be recognized up to a frequency of approximately 30 Hz. At higher frequencies, the lamp will appear to be constantly illuminated.

3. On/Off Switch and Intensity Control :

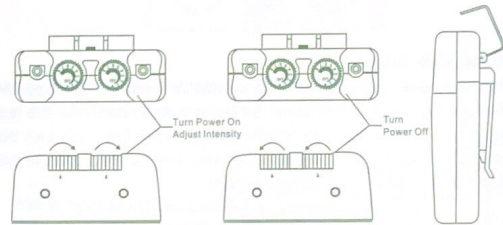
If both controls are in the off-position (white markings on the housing), the device is switched off.

14

By turning the controls clockwise, the appropriate channel is switched on and the impulse display led will illuminate and begin to pulse according to the frequency set.

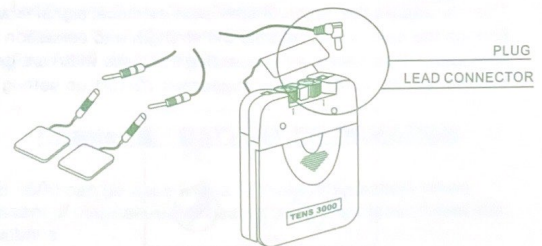
The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise.

To reduce the current strength or switch the device off, turn the controls counter clockwise to the required setting or off-position.



4. Lead Connector

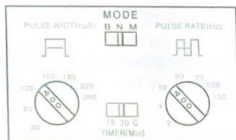
Connection of the electrodes is made with two-lead connector. The device must be switched off before connecting the cables. Both intensity controls must be at the Off position. Electrodes must be pressed firmly on the skin.



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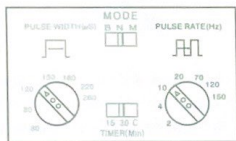
5. Mode Control

Expose the controls by sliding front cover down from top of unit. This switch has 3 positions: B for Burst stimulation, N for Constant stimulation, and M for modulation stimulation. Push the Mode Selector until engaged in position desired.



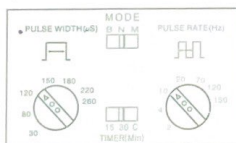
6. Pulse Rate Control:

This dial determines how many electrical impulses are applied through the skin each second. By turning these controls, the number of current impulses per second(Hz) for both channels can be continually adjusted. Unless otherwise instructed, turn the pulse rate control to the 70-120 Hz range.



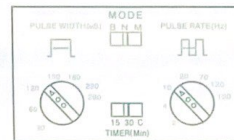
7. Pulse Width Control:

This dial adjusts the length of time each electrical signal is applied through the skin, which controls the strength and sensation of the stimulation. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 µs setting.



8. Timer Control

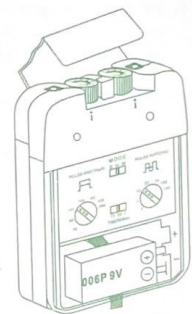
Treatment time of TENS can be preset with Timer Control. This switch has 3 positions, 15, 30 and C(Continue). Push the Timer Control until engaged in position desired.



9. Check/Replace the Battery:

Over time, in order to ensure the functional safety of TENS, changing the battery is necessary.

1. Make sure that both intensity controls are switched to off position.
2. Slide the battery compartment cover and remove.
3. Remove the battery from the compartment.
4. Insert the battery into the compartment. Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and slide to close



Chapter 18 : BATTERY INFORMATION

TENS 3000 can be used with a rechargeable battery when necessary. If you use rechargeable batteries, please follow the instructions.

RECHARGEABLE BATTERIES (NOT INCLUDED)

Prior to the use of a new unit, the rechargeable battery should be charged according to the battery manufacturer's instructions. Before using the battery charger, read all instructions and cautionary markings on the battery and in this instruction manual.

After being stored for 60 days or more, the batteries may lose their charge. After long periods of storage, batteries should be charged prior to use.

BATTERY CHARGING

- (1) Plug the charger into any working 110 or 220/240v mains electrical outlet. The use of any attachment not supplied with the charger may result in the risk of fire, electric shock, or injury to persons.
- (2) Follow the battery manufacturer's instructions for charging time.
- (3) After the battery manufacturer's recommended charging time has been completed, unplug the charger and remove the battery.
- (4) Batteries should always be stored in a fully charged state. To ensure optimum battery performance, follow these guidelines:
 - (a) Although overcharging the batteries for up to 24 hours will not damage them, repeated overcharging may decrease useful battery life.
 - (b) Always store batteries in their charged condition. After a battery has been discharged, recharge it as soon as possible. If the battery is stored more than 60 days, it may need to be recharged.
 - (c) Do not short the terminals of the battery. This will cause the battery to get hot and can cause permanent damage. Avoid storing the batteries in your pocket or purse where the terminals may accidentally come into contact with coins, keys or any metal objects.

(d) WARNINGS:

1. Do not attempt to charge any other types of batteries in your charger, other than the nickel-cadmium rechargeable batteries. Other types of batteries may leak or burst.
2. Do not incinerate the rechargeable battery as it may explode!

Chapter 19: MAINTENANCE, TRANSPORTATION AND STORAGE OF TENS DEVICE

1. Non-flammable cleaning solution is suitable for cleaning the device. Note: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Put the device and accessories in carrying box and keep it in cool dry place.
6. The packed TENS device should be stored and transported under the temperature range of $-20^{\circ}\text{C} \sim +60^{\circ}\text{C}$, relative humidity 20% - 95%, atmosphere pressure 500 hPa \sim 1060 hPa.