# Product Configuration

## CASE

TENS Unit X 1

TENS Electrodes X 4

Leadwires X 2

9V Battery, type 6F22 X 1

Instruction Manual X 1

Carrying Case X 1


Bio Protech Inc.

Donghwa Medical Instrument Complex, 1654-7 Donghwa-ri Munmak-eup, Wonju si, Gangwon-do,Korea.

Tel : 82-33-735-7720, Fax : 82-33-735-7736

EC REP **DONGBANG AcuPrime**

Gater House, Gater Lane, Palace Gate, Exeter, EX1 1JL, U.K

Tel: +44 1392 273908 , Fax: +44 1392 273909



* Date. 02/17/2011 Rev.003


# INSTRUCTION MANUAL

for the

# MAXTENS 1000

## INDEX





## Chapter 1: INTRODUCTION

**INTENDED USE**

The MAXTENS 1000 is used for the symptomatic relief and management of chronic intractable pain and adjunctive treatment of post-surgical or post-traumatic acute pain. This is a prescription device and should be used under continued medical supervision.

**EXPLANATION OF TENS**

Transcutaneous Electrical Nerve Stimulation is non-invasive, drug-free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

## Chapter 2: PRESCRIBING INFORMATION

**1. FOREWORD**

Read this User manual carefully before you start using your TENS unit. Before use, please read the following cautions, warnings, contraindications, precaution and adverse reactions. If in doubt about the use or suitability of the TENS unit , consult your medical practitioner before use.

**2. PRECAUTIONS**

1) Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
2) TENS is not effective for pain of central origin. (This includes headache.)
3) TENS devices have no curative value.
4) Keep the device out of reach of children.
5) Long-term stimulation at the same electrode site may cause skin irritation.
6) Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

### 3. CONTRAINDICATIONS

1) If you have a demand-type cardiac pacemaker, do not use a TENS unit.
2) Do not use TENS on the carotid sinus (neck) region.
3) Do not use TENS for patients with known myocardial disease or arrhythmias without consultation and evaluation by a physician.
4) Do not apply TENS for undiagnosed pain syndromes until etiology is established.
5) Do not place electrodes on the site that may cause current to flow transcerebrally (through the head).

### 4. ADVERSE REACTIONS

Allergic reactions are rare. However an allergic reaction to the self-adhesive electrodes may occur in the form of skin irritation. Rarely, an electrode burn on the electrode site may occur. If skin irritation persists, discontinue use and consult a physician.

## Chapter 3 : WARNINGS

1. The safety of TENS devices for use during pregnancy or birth has not been established. Do not use TENS during pregnancy.
2. TENS is symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
3. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.
4. If you have epilepsy, myocardial disease or arrhythmias always consult your doctor before using TENS.
5. Don't attempt to use TENS or its accessories in any other way than described in this user's guide.
6. Care should be taken so that when operating potentially dangerous machinery the stimulator controls are not changed abruptly.
7. Do not place eletrode over the eyelids, in the mouth, or internally.



8. Simultaneous connection of a patient to a HF SURGICAL EQUIPMENT may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
9. Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
10. Remove batteries if unit is not used for a long period of time.
11. Never apply electrodes over irritated or broken skin.

## Chapter 4 : EMC WARNINGS

This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2002. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

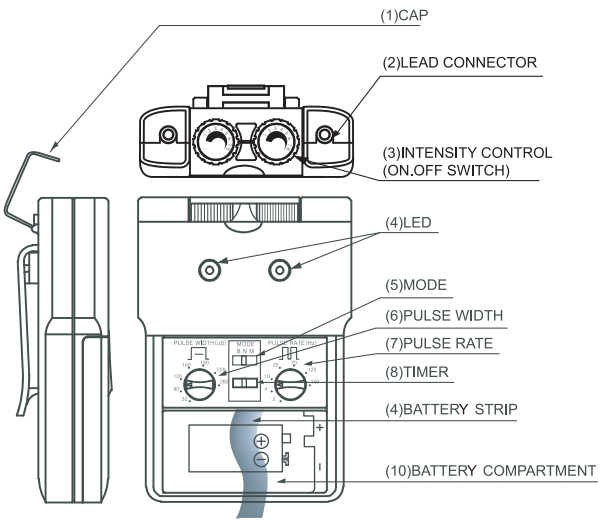
- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult the manufacturer or field service technician for help.

## Chapter 5: GENERAL DESCRIPTION

The MAXTENS 1000 is a battery operated pulse generator that sends electrical impulses to the body which 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 MAXTENS 1000 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 6: CONSTRUCTION





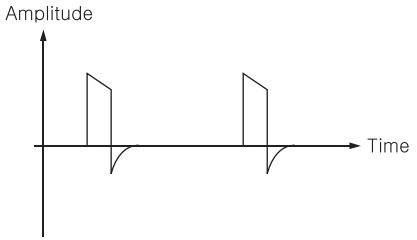

## Chapter 7: TECHNICAL SPECIFICTIONS

The technical specification details of MAXTENS 1000 are as follow.

| | MECHANISM | TECHNICAL DESCRIPTION |
|---|---|---|
| 1 | Channel | Dual, isolated between channels |
| 2 | Pulse Amplitude | Adjustable, 0–80 mA<br>Peak into 500 ohm load each channel |
| 3 | Pulse Rate | Adjustable, from 2 to 150 Hz |
| 4 | Pulse Width | Adjustable, from 30$\mu s$ to 260$\mu s$ |
| 5 | Burst Mode | Bursts occur twice every second.<br>Pulse width(adjustable), frequency = 100 Hz |
| 6 | Modulation Mode | Pulse rate is automatically varied in a cyclic pattern over an interval of nominally 10 seconds.(in max 150 Hz) Pulse rate decreases linearly over a period of 4 seconds from the control setting value to a value which is 40% less. The lower pulse rate will continue for 1 second. Then increase linearly over a 4 seconds period to its original value. The original pulse rate will continue for 1 second. The cycle is then repeated. |
| 7 | Wave Form | Asymmetrical biphasic pulse |
| 8 | Timer | 15, 30 minutes or Continue |
| 9 | Voltage | 0 to 40 V (Load : 500 ohm) |
| 10 | Power Supply | 9V Battery, type 6F22 |
| 11 | Battery Life | Approximately 50hours at normal settings. |
| 12 | Size | 105(H) x 70(W) x 24(T) mm |
| 13 | Weight | 127 grams(battery included) |

A. Waveform

Asymmetrical biphasic pulse




Pulse Width: adjustable, from 30 to 260us (load: 500ohm)
Pulse Rate: adjustable, from 2 to 150Hz (load: 500ohm)
Output Voltage: adjustable, from 0 to 40V (load: 500ohm)
Output Current: adjustable, from 0~80mA (load: 500ohm)
Power source: 9V Battery (type 6F22)

## Chapter 8: ACCESSORIES

| | | |
|---|---|---|
| 1. | 48 X 48 mm Adhesive Electrodes | 4 piece |
| 2. | Electrodes Leads | 2 pieces |
| 3. | 9V Battery, type 6F22 | 1 piece |
| 4. | Instruction manual | 1 piece |
| 5. | Carrying Case | 1 piece |



## Chapter 9 : GRAPHIC SYMBOLS

1. ⎓ Direct current
2. SN Serial number
3. Type BF applied part
4. Caution, consult accompanying documents

## 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 width 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 then 80 Hz 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 above settings, according to the nature of their condition.

**TREATMENT MODE**

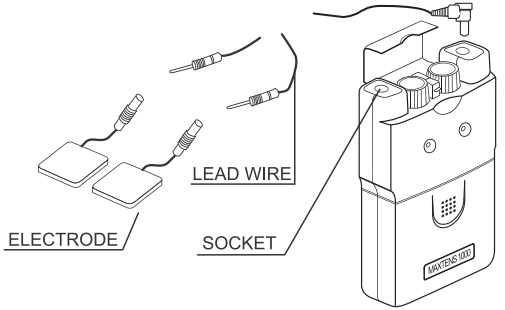
Normal or Conventional TENS offers the practitioners complete control over all the various treatment parameters of the instrument.
Burst Mode is analogous to the Low Rate TENS technique except the low frequency individual pulses are replaced by individual "bursts" of 7-10 individual pulse. It is thus 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 cycle , the patient should turn up the control very slowly , so that they will not feel a sudden increase in intensity.



## 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 by 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.

## 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 of legally marketed TENS electrode is recommended. The device is provided with standard carbon film adhesive electrodes in size 48 X 48 mm

## 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 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 very from the conventional settings suggested here. Contact your physician if the initial electrode placement results are not positive. Once an acceptable placement has been achieved, mark down the electrodes sites and the setting on the patient's reference sheet of this manual, so the patient can easily continue treatment at home.

### CONTIGUOUS PLACMENT

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. 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.

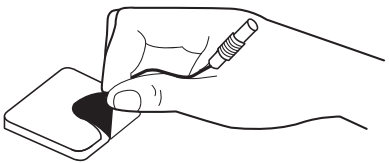
## Chapter 16: APPLICATION OF RE - USABLE SELF ADHESIVE ELECTRODES

**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 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 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.

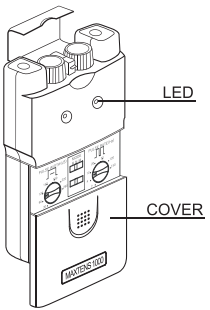


NOTE

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.

## Chapter17 : 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.



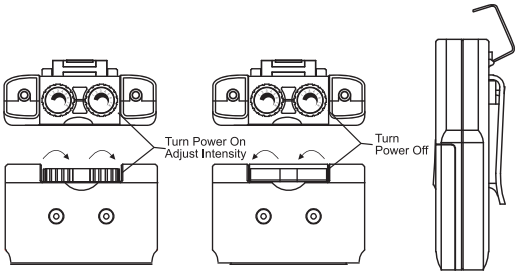

2. Display LED:
   Each of the leds illuminates whenever the electronics of the device create a current impulse. Due to the capacity of the human eye, the illumination of the lamp can only be recognized up to a frequency of approximately 30 Hz. At higher frequencies, the lamp will appear to be constantly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

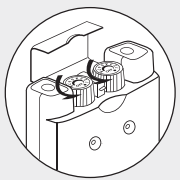
3. On/Off Switch and Intensity Control:
   If both controls are in the off-position the device is switched off.

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 counterclockwise to the required setting or off-position.



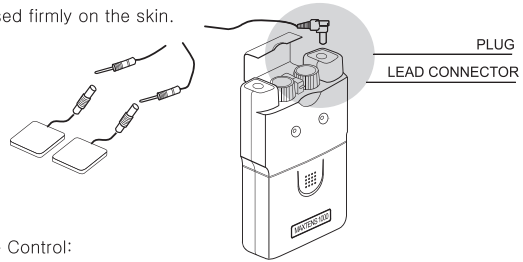



0FF Position

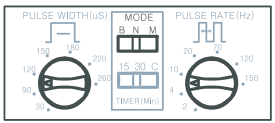
- Zero Start Function ( Shock Prevention )
  If both intensity adjusters are not in the off position while the battery is being connected ( first Installation or exchange of battery), MAXTENS1000 will not operate and thus not shock the end user.
  Please turn adjusters to the off position after installation of battery.
  Then turn on the adjusters to operate.



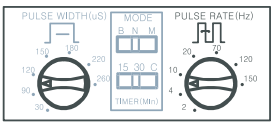
4. Lead Connector:
   Connection of the electrodes is made with two-lead connector. The device must be switched off before connecting the cables. Both intensity controls must be at the off position. Electrodes must be pressed firmly on the skin.




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

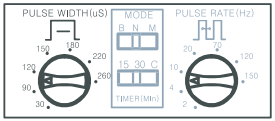



6. Pulse Rate Control:
   This dial determines how many electrical impulses are applied through the skin each second. By turning these controls, the number of current impulses per second(Hz) for both channels can be continually adjusted. Unless otherwise instructed, turn the pulse rate control to the 2-150 Hz range.



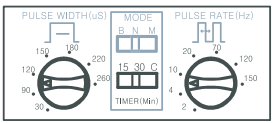
7. Pulse Width Control:

This dial adjusts the length of time each electrical signal is applied through the skin, which controls the strength and sensation of the stimulation.

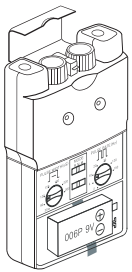



8. Timer Control:

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.
6. If the output adjust is not set to “0”while the battery is being connected, Prostim unit will not operate.



## Chapter 18: MAINTENANCE, TRANSPORTATION AND STORAGE OF TENS UNIT

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℃ ~ +60℃, relative humidity 20% ~ 95%, atmosphere pressure 500 hPa ~ 1060hPa.

## Chapter 19: SAFETY - TECHNICAL CONTROLS

For safety reasons, check your MAXTENS 1000 each week based on the following checklist.

1. Check the device for external damage.
   - deformation of the housing.
   - damaged or defective output sockets.

2. Check the device for defective operating elements.
   - legibility of inscriptions and labels.
   - make sure the inscriptions and labels are not distorted.
3. Check LED
   - LED must be illuminated when switched on.
4. Check the usability of accessories.
   - patient cable undamaged.
   - electrodes undamaged.

## Chapter 20: MALFUNCTIONS

Should any malfunctions occur while using the TENS, check

- Whether the switch/control is set to the appropriate form of therapy. Adjust the control correctly.
- Whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
- Whether the impulse display LED is illuminated. If necessary, insert a new battery.
- For possible damage to the cable. Change the cable if any damage is detected.

※ If there is any other problem, please return the device to your distributor. Do not try to repair a defective device.

## Chapter 21 : CONFORMITY TO SAFETY STANDARDS

The MAXTENS 1000 devices are in compliance with IEC60601-1:1998 IEC60601-2-10:1987+A1:2001



## Chapter 22: WARRANTY

All MAXTENS 1000 models carry a warranty of one year from the date of delivery. The warranty applies to the stimulator only and covers both parts and labor relating thereto.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alteration or disassembly by unauthorized personnel.