THE ORIGINAL
TENSUNITS.COM

# TU 7000™


## INSTRUCTION MANUAL

www.tensunits.com

## This manual is valid for the TU 7000

This instruction manual is published by TENSunits.com

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United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner

**Conformity to safety standards**

TENSunits.com declares that the device complies with following normative documents:

**IEC60601-1, IEC60601-1-2, I EC60601-2-10, IEC62366, IEC60601-1-11, ISO10993-5, ISO10993-10, ISO10993-1, ISO7010**





## Table of Contents

# 1. INTRODUCTION

## 1.1 General

TU 7000 stimulator is a portable electrotherapy device featuring Transcutaneous Electrical Nerve Stimulation (TENS) therapeutic device, which is used for pain relief. The stimulator sends gentle electrical current to underlying nerves via electrodes applied on the skin. The parameters of device are controlled by the buttons on the front panel. The intensity level is adjustable according to the needs of patients.

## 1.2 Medical background

**Explanation of pain**

Pain is an unpleasant sensation that can serve a useful purpose by alerting us to a possible injury or disease. When the body is functioning normally, pain serves as a warning system that something is not right. Without pain a person would not know when to avoid danger or seek medical help. Pain becomes a problem when it continues after treatment has started or long after an injury is healed.

There are two types of pain:

**Acute** — Limited in duration. Examples include but are not limited to:

- Sprains
- Incisional pain
- Muscle strain

**Chronic** — Long-lasting, persistent pain that ceases to serve as a warning system and becomes a problem. Examples include but are not limited to:

- Low back pain
- Pinched Nerves
- Bursitis
- Joint Pain

The TU 7000 was developed to help relieve some types of chronic and acute pain.





**How does TENS work?**

There is nothing “magic” about Transcutaneous Electrical Nerve Stimulation (TENS). TENS is intended to help relieve pain. The TENS unit sends comfortable impulses through the skin to stimulate the nerve (or nerves) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patients, mode selected for therapy, and the type of pain. In many patients, the reduction or elimination of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified while stimulation actually occurs. You may discuss this with your physician or therapist.

## 1.3 Indication for use

TU 7000 Stimulator may be used for the following conditions:

1) Symptomatic relief of chronic intractable pain.
2) Post traumatic pain.
3) Post surgical pain.

## 2. IMPORTANT SAFETY PRECAUTIONS AND WARNINGS

**It is important that you read all the warning and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.**

| SAFETY SYMBOLS USED IN THIS MANUAL | |
|---|---|
| ⚠ **DANGER** | Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. |
| ⚠ **WARNING** | Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage. |
| ⚠ **CAUTION** | Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property. |

**⚠ DANGER**

This stimulator must not be used in combination with the following medical devices:

- Internally transplanted electronic medical devices, such as a pacemaker.
- Electronic life support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.

Using this stimulator with other electronic medical devices may cause erroneous operation of those devices.





**⚠ WARNING**

### DO NOT USE THIS DEVICE UNDER THESE CONDITIONS

- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.
- If you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- Together with a life-supporting medical electronic device such as an artificial heart or lung or respirator.
- In the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- On open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
- Over areas of skin that lack normal sensation.
- On the opposite sides of your head since the effects of stimulation of the brain are unknown.

### DO NOT USE ON THESE INDIVIDUALS

- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
- Children or infants, because the device has not been evaluated for pediatric use.
- Persons incapable of expressing their thoughts or intentions.

### DO NOT USE THIS DEVICE DURING THESE ACTIVITIES

- When in the bath or shower
- While sleeping
- While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk for injury.

**⚠ WARNING (CONTINUED)**

## PAIN MANAGEMENT WARNINGS

- If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician.
- The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Stimulator.

## WARNINGS AND PRECAUTIONS REGARDING THE PADS

- Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
- If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

## NEVER APPLY THE PADS TO:

- The head or any area of the face.

- Any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.





**⚠ CAUTION**

## WARNINGS AND PRECAUTIONS REGARDING THE PADS

- United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner
- Do not bend or fold because the pad may not function properly. Place the pads onto the plastic film and then store into the sealed package when not in use.
- Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
- The pads are already pre-gelled and will adhere to your skin.
- To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic film provided.
- Place the pads at least 1 inch apart on your skin. The pads should never touch each other.
- Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

## DO NOT USE YOUR PADS THIS WAY

- Pads should not touch each other when placed onto your skin.
- Do not place on your spine or backbone.
- Pad should not touch any metal object, such as a belt buckle or necklace.
- Pads should not be placed simultaneously on the soles of both feet.
- Pads should not be placed simultaneously on the calves of both legs.
- Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
- Do not place or relocate the pads while the device is on.
- Always turn the power off before removing or changing the pad location.
- Do not leave pads attached to the skin after treatment.

**⚠CAUTION (CONTINUED)**

## CAUTION WHILE USING THE STIMULATOR

- If the stimulator is not functioning properly or you feel discomfort, immediately stop using the device.
- Do not use for any other purpose except for what it is intended for.
- Do not insert the electrode plug into any place other than the jack on the main unit.
- Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
- Do not pull on the electrode cord during treatment.
- Do not use the device while wearing electronic devices such as watches as this may damage the device.
- Do not use near a cell phone as this may cause the stimulator to malfunction.
- Do not bend or pull the end of the cord.
- When pulling out the cord from the device, hold the plug and pull.
- Replace the cord when broken or damaged.
- Do not throw the batteries into a fire. The batteries may explode.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
- The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
- Using pads that are too small or incorrectly applied, could result in discomfort or skin burns.





## GENERAL PRECAUTIONS

- The long-term effects of electrical stimulation are unknown.
- Apply stimulation to only normal, intact, clean, dry, and healthy skin.
- TENS is not effective in treating the original source or cause of the pain, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices do not cure disease or injuries.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep unit away from young children. The unit contains small pieces that may be swallowed. The electrode cord can cause strangulation. Immediately contact your physician should any of these things occur.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
- Keep unit out of the reach of young children.

**POSSIBLE ADVERSE REACTIONS**

- Do not use to treat one region for extended periods of time (more than 30 minutes a session, up to 2 times/day) or muscles in that region may become exhausted and sore.
- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.
- You should stop using the device and consult with your physician if you experience adverse reactions from the device.

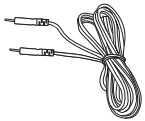
**Note:** Always use electrodes that are legally marked and sold in the United States under 510K guidelines.





## 3. PACKAGE CONTENTS

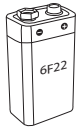
TU 7000 Unit



2 × Lead wires

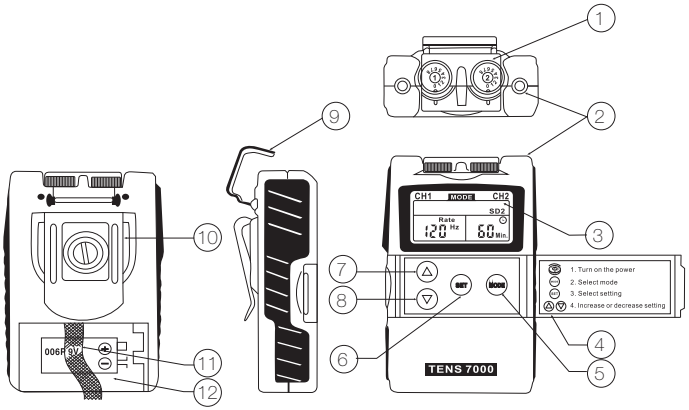
4 × Electrode pads (1.5" x 1.5")


1 x Instruction Manual




1 × 9-Volt Battery

### 3.1 Front and Top Panel




1. **Channel 1 & 2 Intensity Controls (On/Off Switches):** Increase or decrease the output intensity of channel 1 and/or 2.
2. **Output Sockets:** Lead wire output sockets
3. **LCD Display:** Displays current function of the device.
4. **Panel Cover:** Protects control Buttons from being changed.
5. **Mode:** B=Burst, N=Normal, M=Modulated, SD1 & SD2 (Strength Duration 1 & 2).
6. **Set:** To toggle through the available settings.
7. **Incremental Control:** The amount of Hertz or pulses per second.
8. **Decremental Control:** 15 min, 30 min, or continuous operation.
9. **Intensity Control Cap:** Protects controls from being changed.
10. Belt Clip
11. **Battery Ribbon:** Place under 9-volt battery to assist in removal
12. Battery Compartment.





## 4. SPECIFICATION

### 4.1 Technical Information

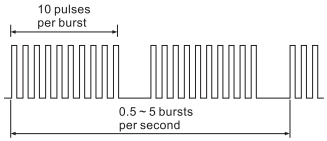
| | |
|---|---|
| Channel | Dual, isolated between channels |
| Power Supply | One 9 Volt Battery, Type 6F22 (alkaline). |
| Voltage | 0 to 50 V (Load: 500 ohm). |
| Burst Mode | Bursts occur twice every second. Pulse width (adjustable), frequency = 100Hz. |
| Normal | The pulse rate and pulse with are adjustable. It generates continuous stimulation based on the setting value. |
| 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 lineally over a period of 4 seconds from the control setting to a value which is 40% less. The lower pulse rate will continue for 1 second. Then increase linearly over a 4 second period to its original value. The original pule rate will continue for 1 second. The cycle is then repeated. |
| SD1 | The SD1 (Strength-Duration) mode consists of automatic modulation intensity and pulse width in 40% range. The intensity is always increasing while the pulse is decreasing and vice versa. The intensity is decreased by 40% while the pulse width is increased by 40% in 5 seconds. In the next 5 seconds, the intensity is increased by 40% while the pulse with is decreased by 40%. Total cycle time is 10 seconds. Pulse rate (2 ~ 150Hz) and pulse width (50 ~ 300μs) are fully adjustable. |
| SD2 | The SD1 (Strength-Duration) mode consists of automatic modulation intensity and pulse width in 70% range. The intensity is always increasing while the pulse is decreasing and vice versa. The intensity is decreased by 70% while the pulse width is increased by 70% in 5 seconds. In the next 5 seconds, the intensity is increased by 70% while the pulse with is decreased by 70%. Total cycle time is 10 seconds. Pulse rate (2 ~ 150Hz) and pulse width (50 ~ 300μs) are fully adjustable. |
| Dimensions | 10.1 × 6.1 × 2.45 cm (L*W*H) |
| Weight | 5.3 oz. (With battery) |

### 4.2 Technical Specifications

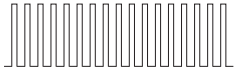
| | |
|---|---|
| Waveform | Asymmetrical Bi-Phasic Square Pulse |
| Pulse Amplitude | Adjustable, 0 to 80mA at 500 ohm Load each channel |
| Pulse Width | From 30 to 260us microseconds |
| Pulse Rate | From 2 to 150 Hz |
| Treatment Time | 15min, 30min or continuous operation |

### 4.3 Wave Form Information

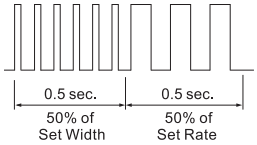
**Burst**



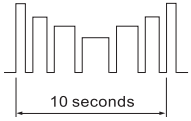

**Normal**



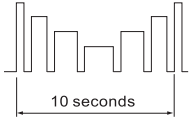
**Modulation**




**SD1 (Strength Duration)**




**SD2 (Strength Duration)**








## 5. PARAMETER CONTROLS

### 5.1 Pulse Width

Wider pulse width settings will deliver stronger stimulation for any given intensity setting. 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).

### 5.2 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.

## 5. PARAMETER CONTROLS (con't)

### 5.3 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 the lowest intensity of the modulation cycle time (i.e.: If pulse rate is set at 80Hz and decreases 40% down to 32Hz) the patient should turn up the intensity slowly, allowing 2 – 3 sec. between each intensity increase.

### 5.4 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 with in 30 minutes of the cessation of stimulation



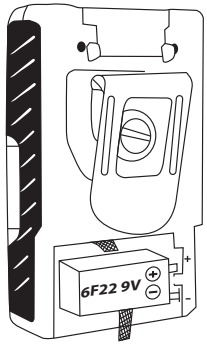


## 6. INSTRUCTION FOR USE

### 6.1 Battery

**Installation of Battery**

Turn the device around. Slide down the back battery cover. Remove and insert the battery as shown on the diagram.




**NOTE**: Make sure the battery ribbon is placed under the battery. This will be used to remove the battery later.

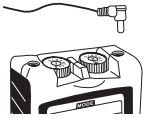
Replace the battery cover.

**⚠ CAUTION**

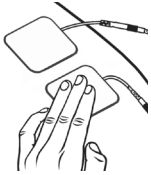
1) Keep the battery and the product out of the range of children.
2) **DO NOT** open the battery, thrown into fire or short-circuited.
3) Protect battery from excess heat; Remove the battery if the product is not going to be used for a long period of time.
4) Always replace with the same type of battery.

**Connecting Lead Wires and Electrodes**

Firmly insert the end of the lead wire pin into the electrode connectors. Make sure no bare metal of the pins are exposed.



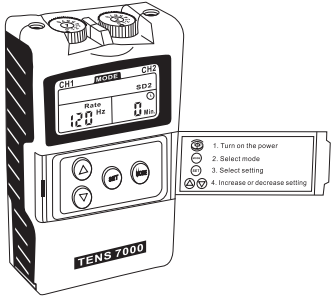
This unit operates with one or two sets of electrodes. When using one set, plug lead wire into Channel 1 on top of the unit. Use Channel 2 to operate a second set if directed by your healthcare provider.



Remove electrodes from protective backing. Keep backing to properly store electrodes after use. Apply electrodes to the exact site indicated by your doctor or therapist. Skin at the application site should be clean and dry. Check that electrodes are securely placed on the skin before activating device.

## 6.2 Adjusting Parameters

**PanelCover:**
A lid covers the controls for selecting mode and adjusting settings. Your medical professional may wish to set these controls for you and request that you leave the cover in place.



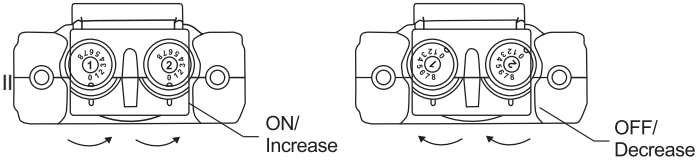





**Power On/Off Switch and Intensity Controls:**
If both controls are in the off-position, the device is switched off.

By turning the controls clockwise, the appropriate channel is switched on and CH1 and/or CH2 will blink on the LCD screen.

The intensity being transmitted to the electrodes will increase when the control is turned clockwise (1=Lowest Intensity 8=Highest Intensity).




To reduce the current strength or switch the device off, tum the control counter clockwise to the required setting or off-position, respectively. The controls are protected by a cap to avoid unintentionalchange

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### 6.4 Skin Care Tips

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.

### 6.5 Application Of Re-Usable Self Adhesive Electrodes

Application

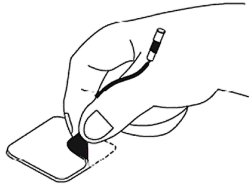
1. Clean and dry the skin at the prescribed area thoroughly with soap and water prior to application of electrodes.
2. Insert the lead wire into the pin connector on the pre-wired electrodes.
3. Remove the electrodes from the protective liner and apply the electrodes firmly to the treatment site.





**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.



## 7. CLEANING AND STORAGE

### 7.1 Cleaning the Unit

1) Turn unit off and disconnect the lead wires from the unit.
2) Clean the device after use with a soft, slightly moistened cloth and wipe gently.
   - Do not use chemicals (like thinner, benzene).
   - Do not let water get into the internal area.

**Note:** This device and accessories (including the electrodes) do not require sterilization.

### 7.2 Cleaning the Electrode Pads

1) Turn the power off and remove the lead wires from the electrodes.
2) Wash the electrodes when the adhesive surface becomes dirty and/or the electrodes are difficult to attach.
   - To “wash” the pads, place a small drop of water on your clean fingertip and rub the water across the entire gel part. Place the adhesive part face up and let it air dry until the water is absorbed and has been reconstituted. Do not wipe with a tissue paper or cloth. If the electrode still does not stick properly, replace them with new electrodes.

**⚠ CAUTION**

1. The life of electrodes may vary by the frequency of washing, skin condition, and storage state.
2. If the electrodes no longer stick to your skin or the electrodes are broken, you should replace new electrodes.
3. Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
4. Do not turn on the device when the electrodes are not positioned on the body.
5. Never remove the self-adhesive electrodes from the skin while the device is still turned on.
6. If replacement electrodes are necessary, use only electrodes that are the same size (2" x 2") as the electrodes provided with the TU 7000.
7. Use of electrodes that are larger may reduce the effect of the stimulation. Use of electrodes that are much smaller than the electrodes provided with the TU 7000 may increase the chance of skin irritation or electrode burns occurring under the electrodes.
8. Always use electrodes that have been cleared for marketing in the USA by the FDA.

### 7.3 Storing The Electrode Pads and Lead Wires

1) Turn the device off and remove the lead wires from the unit.
2) Remove the electrodes from your body and disconnect the lead wires from the electrodes.
3) Place the electrodes onto the plastic film and then store into the sealed package.
4) Wrap the lead wires and store into the sealed package.

### 7.4 Storing the Unit

1) Place the unit, electrodes, lead wires and manual back into the carrying case. Store the box in a cool, dry place, -10ºC ~ 55ºC; 10% ~ 90% relative humidity.
2) Do not keep in places that can be easily reached by children
3) When not in use for a long period, remove the battery before storage.





## 8. TROUBLESHOOTING

| Problem | Possible Causes | Possible Solution |
|---|---|---|
| The unit cannot power on | Are the batteries exhausted? | Charge or replace the batteries. |
| | Are the batteries installed correctly? | Insert the batteries observing polarity. |
| Stimulation weak or cannot feel any stimulation | Electrodes dried out or contaminated | Replace with new electrodes |
| | Electrodes are not securely attached to the skin. | Reconnect the electrodes |
| | Lead wires Old/worn/damaged | Replace with new lead wires |
| Stimulation is uncomfortable | Intensity is too high | Decrease intensity. |
| | Electrodes are too close together | Reposition the electrodes at least 1-1⁄2" apart. |
| | Electrode active area size is too small. | Replace electrodes with ones that have an active area no less than 25.0cm$^2$ (5cm*5cm). |
| | May not be operating the device according to the manual. | Please check the manual before use |
| Intermittent output | Lead wires | Verify connection is secure. |
| | | Turn down the intensity. |
| | | Rotate lead wires in socket 90°. If still intermittent, replace lead wire. |
| | | If still intermittent after replacing lead wire, a component may have failed. Call the repair department. |

| Problem | Possible Causes | Possible Solution |
|---|---|---|
| Stimulation is ineffective. | Improper electrode placement | Reposition the electrodes at least 1-1⁄2” apart. |
| | Unknown | Contact clinician. |
| The skin becomes red and/or you feel a stabbing pain | Using the electrodes on the same site every time. | Re-position the electrodes. If at any time you feel pain or discomfort stop use immediately. |
| | The electrodes aren’t stuck onto the skin properly | Ensure the electrodes are stuck securely on the skin. |
| | The electrodes are dirty. | Clean the electrodes according to description in this manual or replace with new electrodes. |
| | The surface of the electrode was scratched. | Replace with a new electrode. |
| Output current stops during therapy | The electrodes come off the skin. | Turn off the device and place the electrodes again. |
| | The lead wires are disconnected | Turn off the device and reconnect the lead wires. |
| | The power of the batteries has been exhausted. | Charge or replace the batteries. |
| Li rechargeable battery pack doesn’t last or life is short | Brand new or stored batteries | This is normal operation. Please charge and use in device. You must do this 3 – 5 times before full capacity is reached. |
| | Used Li rechargeable battery has reached end of life | Charge the battery. If this does not work, replace the battery. |





## 9. DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.

Please dispose of the device in accordance with the legal obligation.

## 10. GLOSSARY OF SYMBOLS

Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.

Type BF Applied Part

Please refer to instruction manual because of the higher levels of output.

# 11. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

**Information for accompanying documents in the scope of IEC60601-1-2:2007**

**Important information regarding Electro Magnetic Compatibility (EMC)**

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured for TENSunits.com conform to this EN60601-1-2:2007 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by TENSunits.com, with the exception of cables sold by TENSunits.com as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.





| **Guidance and manufacturer's declaration — electromagnetic emissions** | | |
|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic Environment — Guidance** |
| RF emissions CISPR 11 | Group 1 | The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR11 | Class B | The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Not applicable | |

| Guidance And Manufacturer's Declaration — Electromagnetic Immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment. | | | |
| **Immunity Test** | **EC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment — Guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/ burst IEC 61000-4-4 | Not applicable | Not applicable | Not applicable |
| Surge IEC 61000-4-5 | Not applicable | Not applicable | Not applicable |
| Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4- 11 | Not applicable | Not applicable | Not applicable |
| Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |





| Guidance And Manufacturer's Declaration — Electromagnetic Immunity (Continued) | | | |
|---|---|---|---|
| **Immunity Test** | **EC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment — Guidance** |
| Conducted RF IEC 61000-4-6 | Not applicable | | Portable and mobile RF communications equipment should be used no closer to any part of the Electrical Stimulator including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.<br><br>**Recommend separation distance**<br>d = 1.2 √P<br>d = 1.2 √P 80 MHz to 800 MHz<br>d = 2.3 √P 800 MHz to 2.5 GHz<br><br>Where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,<br>(a) should be less than the compliance level in each frequency range.<br>(b) Interference may occur in the vicinity of equipment marked with he following symbol:  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |

| Guidance And Manufacturer's Declaration — Electromagnetic Immunity (Continued) |
|---|
| Note1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. |
| a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Electrical Stimulator are used exceeds the applicable RF compliance level above, the Electrical Stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Electrical Stimulator.<br>b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m. |





**Recommended separation distance between portable and mobile RF communications equipment and the Electrical Stimulator**

The Electrical Stimulator are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of these Electrical Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Electrical Stimulator as recommended below, according to the maximum output power of the communications equipment.

| Output Power of Transmitter in Watt | Separation distance according to frequency of transmitter in meter | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.78 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note:** At 80MHz and 800MHz, the separation distance for the higher pole frequency range applies

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

**Note:** EMC tests conducted including attached electrode cord of 1.5 m length.

## 12. WARRANTY

**Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is. The following warranty terms apply:**

1) The warranty period for device is one years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2) Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
3) The following is excluded under the warranty:
   - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
   - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
   - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
   - Accessories which are subject to normal wear and tear.
4) Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

**Note:**

Shelf life is most influenced by several factors: exposure to light and heat, transmission of gases (including humidity), and mechanical stresses, this device and accessories does not require sterilization. The device is supplied to be used under non-sterile conditions, Material is not degraded phenomenon, also won't produce volatile phenomenon, this device has not restricted shelf-life.



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