FDA CLEARED for OVER THE COUNTER SALES (OTC) – NO PRESCRIPTION REQUIRED

HiDow Wireless Tens/EMS Systems

WIRELESS DEVICE

INSTRUCTION MANUAL

INTRODUCTION TO TENS

EXPLANATION OF PAIN

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies.

Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until coded message travels to the brain where it is decoded, analyzed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

EXPLANATION OF TENS

Transcutaneous Electrical Nerve Stimulation is a 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 cure any physiological problem; it only helps control the pain. 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.

HOW TENS WORKS

There is nothing "magic" about Transcutaneous Electrical Nerve Stimulation (TENS). TENS is intended to be used to relieve pain. The TENS unit sends comfortable impulses through the skin that 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 patient, 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.

EXPLANATION OF EMS

Electrical Muscle Stimulation is an internationally accepted and proven way of treating muscular injuries. It works by sending electronic pulses to the muscle needing treatment; this causes the muscle to exercise passively to promote healing.

It is a product derived from the square waveform, originally invented by John Faraday in 1831. Through the square wave pattern it is able to work directly on muscle motor neurons. EMS has low frequency and this in conjunction with the square wave pattern allows direct work on muscle groupings. This is being widely used in hospitals and sports clinics for the treatment of muscular injuries and for the re-education of paralyzed muscles, to prevent atrophy in affected muscles and improving muscle tone and blood circulation.

HOW EMS WORKS

EMS is intended to be used to increase blood circulation, loosen tight and knotted muscles, stimulate muscle growth and also reduces stiffness in muscle joints. The EMS units send comfortable impulses through the skin that stimulate the nerves in the treatment area. When the muscle receives this signal it contracts as if the brain has sent the signal itself. As the signal strength increases, the muscle flexes as in physical exercise. Then when the pulse ceases, the muscle relaxes and the cycle starts over again, in a cycle of Stimulation, Contraction and Relaxation.

THE WIRELESS TENS/EMS - GENERAL DESCRIPTION

The HiDow WIRELESS TENS/EMS System is a battery operated WIRELESS pulse generator that sends electrical impulses from a REMOTE control to RECEIVERS (round) with ELECTRODES attached to them that are placed on the body to stimulate the nerves causing pain. When this happens, the nerves "FEEL" gentle electrical sensations instead of the pain.

The System is provided with 1 REMOTE and 2 RECEIVERS called CHANNEL 1 and CHANNEL 2 with each having DUAL outputs, independent of one other.

THE WIRELESS REMOTE controls the ON/OFF of the system, the INTENSITY and the MODE functions of each RECEIVER. Each RECEIVER with the electrodes attached to it adheres easily and firmly to the skin.

Press buttons are very easy to use and the liquid crystal display LCD shows the exact modes and values of the TENS or EMS functions being used.

See the pictures in this Manual that show the different COMPONENTS and CONTROLS of the HiDow System and how to operate it properly to get the best PAIN RELIEF.

Because the HiDow system is WIRELESS - Needing No Lead Wires - you must use only HiDow SNAP PIN Electrodes. Lead wire electrodes will not work with this WIRELESS system.

QUICK START GUIDE to USE your HiDow WIRELESS TENS/EMS System

1. **Charge up both the RECEIVERS and the REMOTE with the AC power cord**
2. **TURN the RECEIVERS "On" and the REMOTE "ON" and see the lights on both lit**
3. **Snap ELECTRODES onto the RECEIVERS and place them in the pain area**
4. **CHOOSE RECEIVER - CHANNEL 1 or 2 by adjusting "C" on the REMOTE and seeing 1 or 2 in the LCD display**
5. **SET MODE of RECEIVER to MODE1, MODE2, MODE3, or MODE4 by adjusting "M" on REMOTE and seeing 1,2,3,4, in the LCD display**
6. **ADJUST INTENSITY of RECEIVER + or - until the sensation is felt as comfortable**

INSTRUCTIONS FOR USE

PAIN RELIEF MADE SIMPLE - THE REMOTE CONTROL

The REMOTE CONTROL is the sleek looking handset. It has an LCD display, INTENSITY UP and DOWN + and - , chooses RECEIVER CHANNELS 1 and Channels 2 and a MODE button to control the MODE FUNCTIONS of the RECEIVERS.

ON/OFF – IS THE BUTTON ON the SIDE of the REMOTE, to turn it "On" and "OFF". If the LCD is blank the unit is "OFF" or the REMOTE and RECEIVERS needs to be recharged.

INTENSITY

When you turn the unit "ON" the INTENSITY is down to its LOWEST POINT and returns there when you turn the unit "OFF".

OUTPUT INTENSITY is on the REMOTE just below the LCD Screen figured as

+

-

These are the INTENSITY outputs that operate the 2 RECEIVERS or CHANNELS 1 and 2. The more you push the + the HIGHER UP the output levels of the CHANNEL go. The more you push – the LOWER DOWN the output levels of the CHANNEL go.

The AMPLITUDE INTENSITY will appear in the LCD screen in numbers.

Round RECEIVERS - The CHANNELS

There are 2 RECEIVERS in each HiDow WIRELESS Tens/EMS system. One is programmed as CHANNEL 1 and the other as CHANNEL 2.

CHANNEL 1 or CHANNEL 2 are each independently controlled in INTENSITY and MODE FUNCTIONS by the REMOTE and:

By Pushing C on the remote you change from (Receiver) Channel 1 to (Receiver) Channel 2

You can use either CHANNEL 1 or CHANNEL 2 or use both CHANNEL 1 and CHANNEL 2 at the same time.

CHANNEL 1 or Channel 2 will appear in the LCD screen as 1 or 2.

CHANNEL or RECEIVER CONTROLS

The input receptacle for the recharger is on the side of the RECEIVER. The RECEIVER has to be charged to work.

There is an On/Off button on each RECEIVER. When you push it ON a light comes on, and when you push it OFF the light goes off.

MODES – Pre-Programmed MODE FUNCTIONS

M (MODES 1, 2, 3, 4)

The MODES are pre-programmed into the 2 RECEIVERS. So when you change from Channel 1 to CHANNEL 2 you can control each RECEIVER MODE FUNCTIONS independently.

Simply push the M button to change from MODE 1 Mode 2 Mode 3 or Mode 4.

The MODE FUNCTION being used will appear in the LCD screen as 1,2,3,4.

RECEIVER CHANNEL 1 and CHANNEL 2 - MODE FUNCTIONS - SUGGESTIONS FOR BEST PAIN RELIEF

SUGGESTED FOR PAIN RELIEF

1. **Legs, Arms, Hands, Feet -**
   Mode1 Mode3
2. **Arthritis, Knees -**
   Mode1 Mode3
3. **Low Back, Hip, Stomach,**
   Muscle Spasms -
   Mode1 Mode2 Mode3
4. **Shoulders, Upper Back -**
   Mode1 Mode2 Mode3
5. **Headaches, Migraines, Neck -**
   Mode1 Mode2
6. **Combination Wave Mode 4 is a mixture of Mode1, Mode2 and Mode3 and works well on all Pain Conditions**

These are ONLY suggestions for these types of MODE uses. Electrical stimulation is felt differently by different people and some MODES may work better for some of your conditions than others. Feel free to try the different MODES for your PAIN condition to see what works the best for you.

(See Patient Manual Cautions and Warnings)

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.

ATTACHMENT OF ELECTRODES

The electrodes have SNAP CONNECTORS that plug into the INPUT SOCKETS on the RECEIVERS.

You can use on or 1 or 2 electrodes on each RECEIVER, both for Channel 1 or 2.

If you use 1 electrode on 1 RECEIVER the system is a SINGLE CHANNEL UNIT.

If you use 2 electrodes on 1 RECEIVER the system is a DUAL CHANNEL UNIT.

If you use 2 RECEIVERS with 4 ELECTRODES the system is 2 TENS UNITS in ONE SYSTEM.

ELECTRODE OPTIONS

Your pharmacist or clinician can help 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 "ONLY" HiDow SNAP PIN electrodes with this WIRELESS system.

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.

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.

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 centre 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.**

APPLICATION OF RE-USABLE SELF ADHESIVE ELECTRODES - (USE ONLY HiDow SNAP PIN ELECTRODES with this SYSTEM

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.**

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.**

CAUTIONS

1. **Precautions: For Tens and EMS**
   Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
2. **Contradictions:**
   TENS devices can affect the operation of demand type cardiac pacemakers. TENS is not recommended for patients with known heart disease without physical evaluation of risk. Do not use TENS on the carotid sinus (neck) region. Do not apply TENS for undiagnosed pain syndromes until etiology is established. Do not stimulate on the site that may cause current to flow transcerebrally - (through the head).
3. **Adverse Reactions**
   Possible allergic to gel, skin irritation and electrode burn are potential adverse reactions.
4. **Read operation manual before use of TENS.**
5. **We emphasize that patient with an implanted electronic device (for example, a pacemaker) should not undergo TENS treatment without first consulting a doctor. The same applies to patients with any metallic implants.**
6. **If TENS therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is re-evaluated by the physician or therapist.**
7. **Avoid adjusting controls while operating machinery or vehicles.**
8. **Turn the TENS off before applying or removing electrodes.**
   Do not use it in the presence of explosive atmosphere and flammable mixture.

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. **Keep this device out of the reach of children.**
4. **TENS devices have no curative value.**
5. **TENS is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.**
6. **Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.**
7. **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.**
8. **Do not place electrodes on the front of the throat as spasm of the Laryngeal and Pharyngeal muscle may occur.**
9. **Care should be taken so that when operating potentially dangerous machinery the stimulator controls are not changed abruptly.**
6. **Electrodes should not be placed over the eyes, in the mouth, or internally in the body.**

OTHER WARNINGS

Do not attempt to charge any other types of batteries in your HiDow WIRELESS TENS, other than those supplied with the system.

BATTERY INFORMATION

RECHARGEABLE BATTERIES:

Prior to the use of a new unit, the rechargeable battery in the REMOTE and the RECEIVER should be charged.

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 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 manufacturer's instructions for charging time.

(3) After the battery recommended charging time has been completed, unplug the charger.

MALFUNCTIONS

Should any malfunctions occur while using the TENS check:

1. **Whether the parameters are set properly. Adjust the controls correctly**
2. **Whether the electrodes are set into the RECEIVERS properly**
3. **If the LCD reveals the menu. If necessary, insert a new battery**
4. **If there is any other problem, please contact your distributor. Do not try to repair a defective device.**

Conformity to Safety Standards

STATEMENT OF EMC

The HiDow TENS devices are in compliance with IEC 60601-1-2: 1993.

CONFORMITY TO MDD REQUIREMENTS

The HiDow TENS devices are in compliance with IEC 60601-1 safety standard.

WARRANTY

All HiDow TENS models carry a warranty of one year from the date of delivery. The warranty applies to the Tens/EMS stimulator REMOTE and RECEIVER only.

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

COMPONENTS OF SYSTEM

(1) REMOTE CONTROL
(2) RECEIVERS (2)
(3) LCD ON REMOTE
(4) BATTERY RECHARGER INPUT CABLE
(5) OPERATION MANUAL

REPLACABLE PARTS

The replaceable parts and accessories of DIGITAL TENS devices are as given below –
Except leads, electrodes and battery, battery case cover, please do not try to replace the other parts of a device.

	PARTS
01	REMOTE
02	RECEIVERS
03	ELECTRODES
04	RECHARGER CABLE
05	BATTERIES

FCC Warning Statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation.

Contact Information:

Customer Service
HiDow International
2071 Congressional Drive
St. Louis, MO 63146
Phone: 314-569-2888
Email:info@hidowinc.com
www.hidowinc.com