Twin Stim

INSTRUCTION MANUAL

Richmar®

This manual is valid for the

Twin Stim® TENS/EMS Stimulator

This user manual is published by Compass Health Brands Corp. (Compass Health).

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

Conformity to safety standards

Compass Health declares that the device complies with following normative documents:
IEC60601-1, IEC60601-1-2, IEC60601-2- 10, IEC60601-1-4, ISO10993-5, ISO10993-10, ISO10993-1

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1. GENERAL INFORMATION

1.1 General Description

The Twin Stim® is a battery operated pulse generator that sends electrical impulses electrodes to the body and reach the nerves and underlying muscle group. This unit is a combination stimulator of TENS and EMS which can be used for muscle stimulation and pain relief. 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 intensity controls are protected by a cap to avoid accidental touch. The settings are controlled by press buttons.

1.2 Medical Background

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 the 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 (TENS) 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 Stimulations (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 wish to discuss this method of pain management treatment with your physician or therapist.

EXPLANATION OF EMS

Electrical Muscle Stimulation (EMS) 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. 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. This device has low frequency and in conjunction with the square wave pattern allows direct work on muscle groupings. This is widely used in hospitals and sports clinics for the treatment of muscular injuries and for the reeducation of paralyzed muscles, to prevent atrophy in affected muscles and improving muscle tone and blood circulation.

HOW EMS WORKS

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. When the pulse ceases, the muscle relaxes and then this cycle is repeated until therapy is completed.

The goal of electrical muscle stimulation is to achieve contractions or vibrations in the muscles. Normal muscular activity is controlled by the central and peripheral nervous systems, which transmit electrical signals to the muscles. EMS works similarly but uses an external source (the stimulator) with electrodes attached to the skin for transmitting electrical impulses into the body. The impulses stimulate the nerves to send signals to a specifically targeted muscle, which reacts by contracting, just as it does with normal muscular activity.

Safety-Technical Controls

For safety reasons, review the following checklist before using your Twin Stim®.

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 the usability of accessories:
   - Patient cable undamaged
   - Electrodes undamaged
   - Battery is not corroded

Please consult your distributor if there are any problems with device and accessories.

1.3 Indication For Use

Twin Stim® Stimulator may be used for the following conditions:

TENS:

1. Symptomatic relief of chronic intractable pain.
2. Acute post-traumatic pain.
3. Acute post-surgical pain.

EMS:

1. Relaxation of muscle spasm.
2. Increase of blood flow circulation.
3. Prevention of disuse atrophy.
4. Muscle re-education.
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of lower leg muscles to prevent venous thrombosis.

2. SAFETY INFORMATION

Read instruction manual before operating. Be sure to comply with all "Contraindications", Warnings", "Cautions" and "Adverse reactions" in the manual. Failure to follow instructions may cause harm to user or device.

Safety Symbols Used in this Manual	
⚠ 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.

2.1 Contraindications

1. This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
2. This device should not be used when cancerous lesions are present in the treatment area.
3. Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).
4. Electrodes must not be applied to sites that might cause current/stimulation to flow through the carotid sinus region (anterior neck) or trans-cerebrally (through the head).
5. **DO NOT** use this device if the patient has a demand-type cardiac pacemaker or any implanted defibrillator.
6. This device should not be used over poorly enervated areas.
7. This device should not be used on patients with epilepsy.
8. This device should not be used on patients with serious arterial circulatory problems in the lower limbs.
9. This device should not be used on patients with abdominal or inguinal hernia.
10. **DO NOT** use this device if you have heart disease without consulting your physician.

2.2 Warnings, Cautions and Adverse Reactions

⚠ WARNINGS:

1. This device should be used only under the continued supervision of a licensed physician or practitioner.
2. The long-term effects of chronic electrical stimulation are unknown. Electrical stimulation devices **DO NOT** have any curative value.
3. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
4. Safety has not been established for the use of therapeutic electrical stimulation during pregnancy. **DO NOT** use during pregnancy unless directed by your physician.
5. Electrical stimulation is not effective for pain of central origin, such as a headache.
6. Electrical monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.
7. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
8. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contraction may be strong enough to close the airway or cause difficulty in breathing.
9. Stimulation should not be applied transthoracically. Introduction of electrical current into the heart may cause cardiac arrhythmias.
10. Stimulation should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
11. **DO NOT** use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
12. **NEVER** use in environments with high humidity such as in the bathroom or when having a bath or shower.
13. Caution should be used in applying electrical stimulation to patients suspected of having heart disease. Further clinical data is needed to show there are no adverse results.
14. **NEVER** use near the heart. Stimulation electrodes should **NEVER** be placed anywhere on the front of the thorax (marked by ribs and breastbone), take extreme caution not to place near or on the two large pectoral muscles. Here it can increase the risk of ventricular fibrillation and lead to cardiac arrest.

15. Electrodes should not be placed over the eyes, in the mouth, near the genitals or internally.
16. **NEVER** use on the areas of the skin which lack normal sensation.
17. Apply the electrodes to clean, dry, and unbroken skin only.
18. Keep electrodes separate during treatment, electrodes in contact with each other could result in improper stimulation or skin burns.
19. Keep the stimulator out of reach of children.
20. Consult your doctor if you have any questions or concerns before using this device.

⚠ CAUTIONS:

1. Federal law (USA) restricts this device to sale by or on the order of a physician.
2. This device is for single patient use only.
3. Keep yourself informed of the contraindications.
4. This device is not intended for use on an unattended patient who is non-compliant, emotionally disturbed, has dementia, or low IQ.
5. Read, understand, and practice the warnings, cautions and operating instructions. Know the limitations and hazards associated with using this device. Observe the cautionary and operational decals placed on the unit. Always follow the operating instructions prescribed by your healthcare practitioner.
6. The instruction of use was listed; any improper use may be dangerous.
7. Do no use this device for undiagnosed pain syndromes until consulting a physician.
8. Patients with an implanted electronic device, such as a cardiac pacemaker, implanted defibrillator, or any other metallic or electronic device should not use this device without first consulting a doctor.
9. Stimulation delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax or across the chest because it may cause cardiac arrhythmia.
10. **DO NOT** place electrodes on the front of the throat as spasm of the Laryngeal and Pharyngeal muscle may occur. Stimulation over the carotid sinus (neck region) may close the airways, make breathing difficult, and may have adverse effects on the heart rhythm or blood pressure.
11. **DO NOT** place electrodes on your head or at any sites that may cause the electrical current to flow trans-cerebrally (through the head).
12. Patients with heart disease, epilepsy, cancer or any other health condition should not use this device without first consulting a physician.

13. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or silicone rubber. If rash develops or pain persists, discontinue use and consult a doctor.
14. Electrode placement and stimulation settings should be based on the guidance of prescribing practitioner.
15. Effectiveness is highly dependent upon the patient and the selection of therapy by a person qualified in the management of pain.
16. Isolated cases of skin irritation have occurred at the site of the electrode placement following long-term application. If this occurs, discontinue use and consult your physician.
17. The electrodes are only to be placed on healthy skin. Avoid skin irritation by ensuring that good contact is achieved between electrodes and skin.
18. If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.
19. This device should not be used while driving, operating machinery, close to water or during any activity in which involuntary muscle contractions may put the user at undue risk for injury.
20. **NEVER** use the device in rooms where aerosols (sprays) are used or pure oxygen is being administered.
21. **DO NOT** use it near any highly flammable substances, gases or explosives.
22. **DO NOT** use this device at the same time as other equipment which sends electrical pulses to your body.
23. **DO NOT** confuse the electrode cables and contacts with your headphones or other devices, and **DO NOT** connect the electrodes to other devices.
24. **DO NOT** use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.
25. Inspect applicator cables and associated connectors before each use.
26. Turn the device off before applying or removing the electrodes.
27. Electrical stimulator should be used only with the leads and electrodes recommended for use by the manufacturer.
28. This device has no AP/APG protection. **DO NOT** use it in the presence of explosive atmosphere of flammable mixture.

ADVERSE REACTIONS:

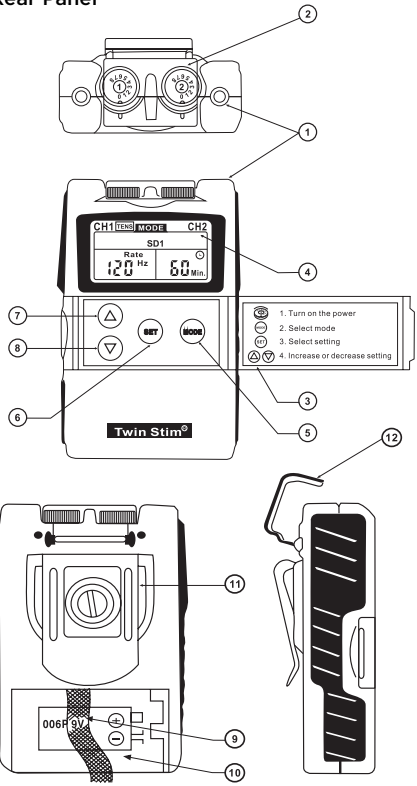
1. Skin irritation from the electrode gel and electrode burns are potential adverse reactions. If skin irritation occurs, discontinue use and consult your physician.

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

2. If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if any problems persist.

3. PRESENTATION

3.1 Front and Rear Panel



1. Lead Connector
2. Intensity Controls & Power On/Off Dial
3. Panel Cover
4. Liquid Crystal Display (LCD)
5. Mode Button
6. Set Button
7. Increase Parameter Button
8. Decrease Parameter Button
9. Battery Strip
10. Battery Cover
11. Belt Clip
12. Protective Cover

4. SPECIFICATIONS

4.1 Accessories

NO	DESCRIPTION	QTY
1	TENS/EMS Device (Item: DS2202)	1 each
2	Pair of Lead wires (Item: WW3005)	2/pk
3	2" x 2" Self-Adhesive electrodes (Item: EP2020WC2-INTM)	4/pk
4	9V TENScell alkaline battery (Item: TA5013-I)	1 each
5	Instruction manual	1 each
6	Carrying case (Item: CC5082)	1 each
7	Wall (AC) adapter (Item: DI1009X)	1 each

4.2 Technical Information

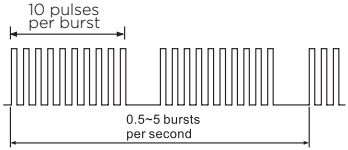
Channel	Dual, isolated between channels
Pulse Amplitude	Adjustable, 0 ~ 80mA at 500 ohm Load each channel, 1mA/Step.
Waveform	Asymmetrical Bi-phase square pulse wave
Voltage	0 to 40V (Load:500ohm)
Power Source	One 9.0 V Alkaline battery
Size	10.1cm × 6.1cm × 2.45cm (L*W*H)
Weight	150 grams with battery.
Pulse Rate	Adjustable from 2 to 150 Hz, 1 Hz/step
Pulse Width	Adjustable, from 50 to 300μs, 10μs/step
On Time	Adjustable, 2~90 seconds, 1 Sec./Step
Off Time	Adjustable, 0~90 seconds, 1 Sec./Step
Ramp Time	Adjustable, 1~8 seconds, 1 Sec./Step. The "On" time will increase and decrease in the setting value.
Mode	Five TENS Modes: B(Burst), N(Normal), M(Modulation), SD1 (Strength Duration), SD2 Two EMS Modes: S(Synchronous), A(Alternate)

Burst Mode	Burst rate: Adjustable, 0.5 - 5Hz Pulse width adjustable, 50-300μs Frequency fixed = 100 Hz
Normal Mode	The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value.
Modulation Mode	Modulation mode is a combination of pulse rate and pulse width modulation. The pulse rate and width are automatically varied in a cycle pattern. The pulse width is decreased by 50% from its original setting in 0.5 second, then the pulse rate is decreased by 50% from its original setting in 0.5 second. Total cycle time is 1 second. In this mode, pulse rate (2-150Hz) and pulse width (50-300 μs) are fully adjustable.
SD1 Mode	The SD1(Strength-Duration) mode consists of automatic modulation intensity and pulse width in 40% range. The intensity is always increasing while the pulse width 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 width is decreased by 40%. Total cycle time is 10 seconds. Pulse rate (2-150Hz) and pulse width (50-300μs) are fully adjustable.
SD2 Mode	The SD2(Strength-Duration) mode consists of automatic modulation intensity and pulse width in 70% range. The intensity is always increasing while the pulse width 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 width is decreased by 70%. Total cycle time is 10 seconds. Pulse rate (2-150Hz) and pulse width (50-300μs) are fully adjustable.
Synchronous Mode	Stimulation of both channels occurs synchronously. The “ON” time including “Ramp Up” and “Ramp Down” time. Therefore, the setting of ON Time should be no less than two times of the“Ramp” time in this mode.

Alternate Mode	ON TIME ≥ Ramp up + Ramp down The stimulation of the CH2 will occur after the 1st contraction of CH1 is completed. In this mode, the setting of ON Time should be no less than two times of the “Ramp” time. The OFF Time should be equal or more than the ON Time. ON TIME ≥Ramp up + Ramp down OFF TIME≥ON TIME
Timer	Adjustable, from 1 to 60 minutes or Continuous. Adjustable in 1 minutes each step. from 1 to 15 minutes, and 5 minutes each step from 15 to 60 minutes. Treatment time countdown automatically.
Patient Compliance Meter	This unit can store 60 sets of operation records. Total recorded time is 999 hours.
Low Battery Indicator	A low battery indicator will show up when the battery is low.
Operating Condition	Temperature:0°C~40°C Relative Humidity: 30%~75% Atmosphere Pressure : 700hPa~1060hPa
Remark	There may be up to a +/-5% tolerance of all parameters and +/-20% tolerance of amplitude & voltage.

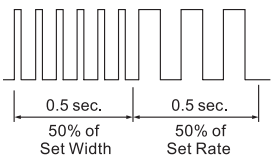
4.3 TENS and EMS Waveforms

Burst

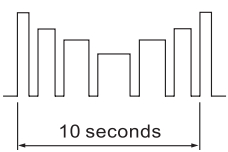


Normal

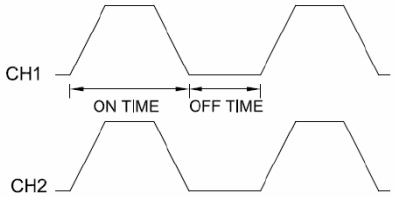
Modulation



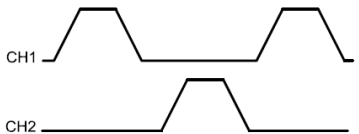
SD1 & SD2 (Strength-Duration)



Synchronous (S)



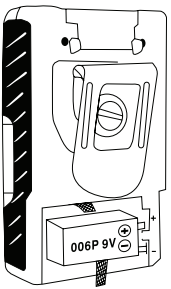
Alternate (A)



5. INSTRUCTIONS FOR USE

5.1 Battery

5.1.1 Check/Replace the Battery



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

1. Make sure that both intensity controls are switch to off position.
2. Slide the battery compartment cover and open.
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 press to close.

5.1.2 Disposal of Battery

Dispose of used batteries according to the current federal, state and local regulations. As a consumer, you are obligated by law to discard depleted batteries appropriately.

⚠ CAUTION FOR BATTERIES:

1. Swallowing a battery may be fatal. Keep the battery and the device out of the reach of children. If a battery is swallowed, consult a physician immediately.
2. If a battery has leaked, avoid contact with skin, eyes and mucus membranes. Rinse the affected areas with clear water immediately and contact a physician immediately.
3. Battery should not be charged, dismantled, thrown into fire or short-circuited.
4. Protect battery from excess heat.
5. Remove batteries from the unit if they are depleted or if you are not using the unit for prolonged periods of time. This prevents damage caused by leaking battery.
6. Always replace with the same type battery.

5.2 Connect Electrode to Lead Wires

Insert the lead wire connector into electrode connector (standard 0.08 inch female connection) (Figure 1). Make sure the connectors are completely pushed together showing no exposed metal of the pins.

⚠ CAUTION:

Always use the electrodes with CE mark, or which are legally marketed in the U.S. under 510(K) procedure.

5.3 Connect Lead Wires to Device

1. Before proceeding to this step, be sure the device is completely turned OFF.
2. Insert the wires provided with the system into the jack sockets located on top of the device (Figure 1).
3. 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.
4. This device has two output receptacles controlled by Channel 1 and Channel 2 at the top of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires. Using both channels gives the user the advantage of stimulating two different areas at the same time.

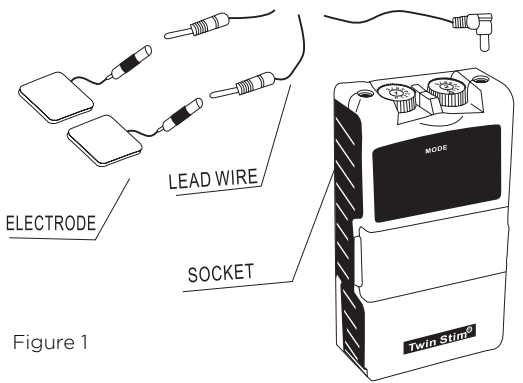


Figure 1

⚠ CAUTION:

DO NOT insert the plug of the patient lead wire into any AC power supply socket.

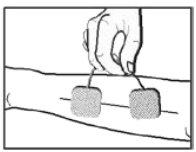
5.4 Electrode

5.4.1 Electrode Options

The electrodes are disposable and should be routinely replaced before they start to lose their adhesive nature. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality. Follow application procedures outlined in electrode package to maintain optimal stimulation and to prevent skin irritation.

5.4.2 Place Electrode on Skin

Apply electrodes to the exact site indicated by your physician or therapist. Before applying electrodes, be sure the skin surface over which electrodes are placed is thoroughly cleaned and dry.



Make sure the electrodes are pressed firmly to the skin and make good contact between the skin and the electrodes. Place the electrodes over the skin; attach them properly, firmly and evenly. Electrodes should be placed at least 2” but no more than 6” apart, per channel.

⚠ CAUTION:

1. Before applying the self-adhesive electrodes, it is recommended that you wash, degrease and dry the skin first.
2. **DO NOT** turn on the device when the self-adhesive electrodes are not positioned on the body.
3. **NEVER** remove the self-adhesive electrodes from the skin while the device is turned on. You will feel an uncomfortable electrical shock.
4. It is recommended that, at a minimum, 1.5” x 1.5” self-adhering, square electrodes are used at the treatment area.

5.4.3 Electrode Placement

The placement of electrodes can be one of the most important parameters in achieving success with this therapy. Of utmost importance is the willingness of the physician to try the various styles of electrode placement to find which method best fits the needs of the individual patient.

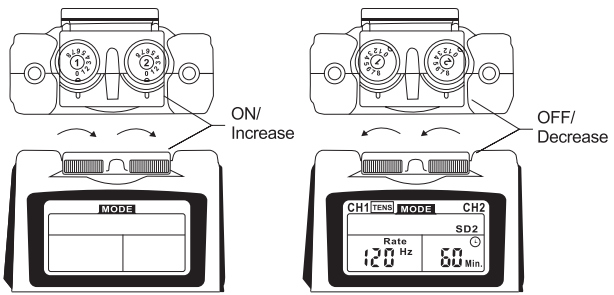
Every patient responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive, speak to your physician about alternative stimulation settings and/or electrode placements. Once an acceptable location has been achieved, mark down the electrode sites and the device settings, so the patient can easily continue treatment on their own.

5.5 Turning On the Device

Before using the device for the first time, you are strongly advised to take careful note of the contraindications and safety measures detailed at the beginning of this manual (page 7-11 and throughout manual), as this powerful equipment is neither a toy nor a gadget!

To turn on the device, turn the dial (above the channel being used for treatment) clockwise slowly until there is a click and a beep.

⚠ **WARNING: DO NOT** turn any further as this will start the stimulation of the corresponding channel. Repeat with CH2 channel, if being used.



5.6 Select the Therapeutic Part Program

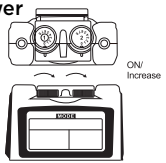
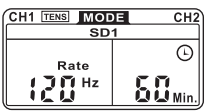
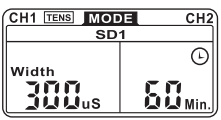
There are two therapeutic modes available –TENS and EMS. The therapeutic mode can be selected by pressing the [**MODE**] button control.

⚠ CAUTION:

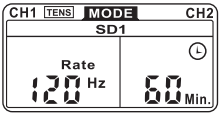
Consult your physician for your suitable therapeutic mode.

5.7 Steps to Set a New Program

5.7.1 TENS Setting

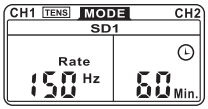
Step 1: Turn on the Power 	After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, turn the channel dial at the top of the device, clockwise, until there is a click and a beep. DO NOT turn any further as this will start the stimulation. The menu will reveal on LCD. Notice the indication of power and function on the LCD.
Step 2: Select a Mode 	There are 5 programs available in TENS therapeutic mode available – Burst (B), Normal (N), Modulation (M), SD1 and SD2 To choose which TENS mode to use for treatment, press the [**MODE**] button until one of the modes mentioned above, displays on the screen. The setting will be stored in 2 seconds after selection unless [**MODE**] is pressed again.
Step 3: Set Pulse Width 	Pulse Width is adjustable from 50 μs to 300 μs. Press [**SET**] control to enter this menu, then press [▲] or [▼] to adjust the setting.

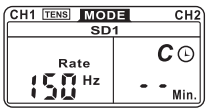
Step 4: Set Pulse Rate



Pulse rate is adjustable from 2 Hz to 150 Hz (0.5 Hz to 5 Hz for Burst). Press the [**SET**] button to cycle and to enter this menu, and then press the up [▲] or down [▼] button to adjust the setting.

Step 5: Set Timer





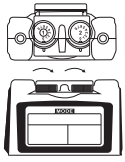
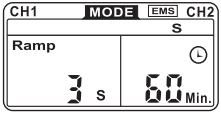
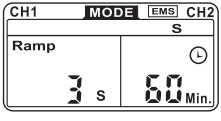
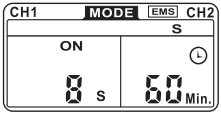
Continuous

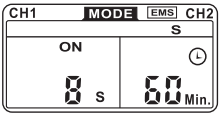
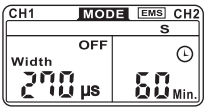
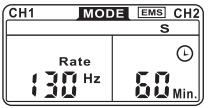
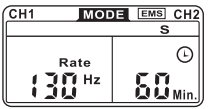
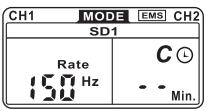
The treatment time is adjustable from 5-60 minutes or Continuous (C). Press the [**SET**] button to cycle and to enter this menu, and then press the [▲] and [▼] buttons to adjust the cycle setting. You can set the timer to "Continuous" mode by pressing the up control until it shows 60 minutes, then press up [▲] one more time to show "C" next to the timer. The output will shut off when time is up. When in Continuous mode, you will need to manually turn off the device.

Step 6: Start Treatment

To start treatment, ensure which Channel you have connected, then turn the dial for that channel very slowly (in small increments) and hold for 2 seconds before turning again. Keep turning clockwise until desired, strong, but comfortable stimulation occurs. Repeat with Channel 2, if using for treatment. Then close the Safety Cap to avoid any accidental bumps which will result in sudden spikes/ shocks of stimulation.

5.7.2 EMS Setting

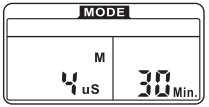
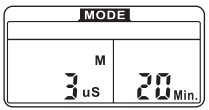
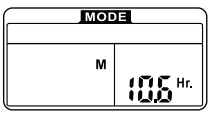
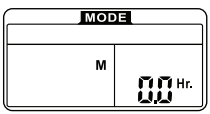
Step 1: Turn on the Power 	After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, turn the channel dial at the top of the device, clockwise, until there is a click and a beep. DO NOT turn any further as this will start the stimulation. The menu will reveal on LCD. Notice the indication of power and function on the LCD.
Step 2: Select Mode 	The EMS mode can be selected by pressing the [**MODE**] Button until EMS is displayed on the screen. EMS will display (S) Synchronous first. Press the [**MODE**] button again to display (A) Alternate. The setting will be stored in 2 seconds after selection unless [**MODE**] is pressed again.
Step 3: Set Ramp Time 	The ramp time controls the time of the output current that increases from 0 to the setting level; and from the setting value back to 0. The ramp time is adjustable from 1-6 sec. Press the [**SET**] button until “Ramp” flashes on the screen. Then press up [▲] or down [▼] to desired time.
Step 4: Set On Time 	The On Time controls the time of stimulation. Press [**SET**] again to display the “ON” or “Contraction” time. This is adjustable from 1-90 seconds. Press the up [▲] or down [▼] until the desired time is reached. **Note**: The “ON” time includes the ramp up and down time so the setting should be no less than 2x the “Ramp” time. (ON TIME≥Ramp up + Ramp down)

Step 5: Set Off Time 	Press [**SET**] again to display the "OFF" or "Relaxation" time. This is adjustable from 2-90 seconds. Press the up [▲] or down [▼] until the desired time is reached. **Note**: In Alternate Mode, the "OFF" time should be equal to, or more than the "ON" time (OFF TIME≥ONTIME)
Step 6: Set Pulse Width 	Pulse width is adjustable from 50 µs to 300 µs. Press the [**SET**] button to cycle and to enter this menu, and then press the up [▲] and down [▼] button to adjust the setting.
Step 7: Set Pulse Rate 	The pulse rate determines how many electrical impulses are applied through the skin each second. Pulse rate is adjustable from 2 Hz to 150 Hz. Press the [**SET**] button to cycle and to enter this menu, and then press the up [▲] and down [▼] button to adjust the setting.
Step 8: Set Timer   Continuous	The treatment time is adjustable from 5-60 minutes or Continuous (C). Press the [**SET**] button to cycle and to enter this menu, and then press the [▲] and [▼] buttons to adjust the cycle setting. You can set the timer to "Continuous" mode by pressing the up control until it shows 60 minutes, then press up [▲] one more time to show "C" next to the timer. The output will shut off when time is up. When in Continuous mode, you will need to manually turn off the device.

Step 9: Start Treatment

To start treatment, ensure which Channel you have connected, then turn the dial for that channel very slowly (in small increments) and hold for 2 seconds before turning again. Keep turning clockwise until desired, strong, but comfortable stimulation occurs. Repeat with Channel 2, if using for treatment. Then close the Safety Cap to avoid any accidental bumps which will result in sudden spikes/ shocks of stimulation.

5.7.3 Compliance Meter

Check & Delete Individual Record	
This unit can store 60 sets of operation records. Total treatment time up to 999 hours can be stored.	
 	Press [**MODE**] button and turn on the power simultaneously. The LCD will show the number of records and operation time. Press the [▲] and [▼] button to check each record. To delete a record, press [**SET**] control for 3 seconds.
Check & Delete Accumulative Record	
 	At the individual records menu, press [**MODE**] button to switch to accumulative record menu. Press the [**SET**] control first, then press the [**MODE**] control simultaneously for 3 seconds and all of the records will be deleted followed by a beeping sound.

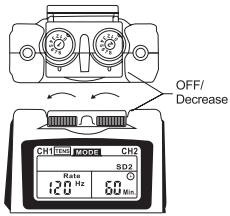
⚠ CAUTION:

1. If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your medical practitioner if problems persist.
2. When using TENS or IF therapeutic mode, if the electrodes are not placed firmly on the skin or the device is not connected to the electrodes and the stimulator's output intensity surpasses 10mA, the intensity will automatically reset to 0mA.

5.8 Turn Off or Stop Treatment

Turn the channel being used for treatment counter clockwise until it cannot turn further. The LCD screen will turn off, unless both channels are being used. If both channels are being used, this will need to be done to both CH1 and CH2 to stop treatment.

Turn each Channel dial at the top of the device counter clockwise until the screen shuts off.



5.9 Low Battery Indicator

A battery symbol is shown flashing on the display when the battery is almost empty. The battery should be replaced with a new battery as soon as possible. However, the unit may continue to operate for an extended period of time depending on the setting and intensity level.

6. CLEANING AND CARE

6.1 Tips for Skin Care

Follow these suggestions to avoid skin irritation, especially if you have sensitive skin:

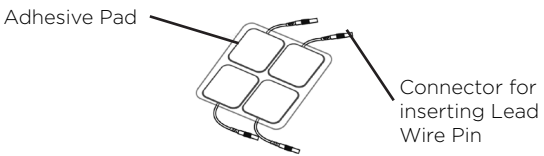
1. Wash the area of skin you will be placing the electrodes on with soap. Rinse thoroughly and dry the area completely before and after placing electrodes.
2. Excess hair may be clipped with scissors; **DO NOT** shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. 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 during treatment down time when you are not wearing electrodes.
8. **NEVER** apply electrodes over irritated or broken skin.

6.2 Cleaning the Device

1. Remove the battery from the device before you clean the device.
2. Clean the device after use with a soft, slightly moistened cloth. For hard to clean situations, you can also moisten the cloth with mild soapy water.
3. **DO NOT** use any chemical cleaners or abrasive agents for cleaning.

6.3 Electrodes

1. Use this device only with the leads and electrodes provided by the manufacturer. Use only the electrode placements and stimulation settings prescribed by your physician or therapist.
2. It is recommended, at minimum, 1.5" x 1.5" self-adhering electrodes be used at the treatment area.
3. Inspect your electrodes before every use. Replace electrodes as needed. Reusable electrodes can cause slight skin irritation, lose adhesion properties and deliver less stimulation if overused.



Reusable, Self-adhering electrodes

TO REMOVE YOUR ELECTRODES:

1. Lift the corner of the electrode and gently remove it from the skin.
2. It may be helpful to improve repeated electrode application by spreading a few drops of cold water over the adhesive side and turn the surface up to air dry. Over saturation with water will reduce the adhesive properties. This can only be done once and then the electrodes need to be replaced.
3. Between uses, place the electrodes back onto the protective sleeve and insert them into the resealable bag and store in a cool dry place.

6.4 Cleaning the Electrode's Cords

Clean the electrode cords by wiping them with a damp cloth. Coating them lightly with talcum powder will reduce tangles and prolong their life.

6.5 Maintenance

1. Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
2. The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
3. Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.
4. Check the unit before each use for signs of wear and/or damage. Replace worn items as required.

7. TROUBLESHOOTING

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced.

Problem	Possible Cause	Solution
Display fails to light up	Battery contact failure.	Try fresh batteries.
		Ensure batteries are inserted correctly.
		Check contacts are in place.
		Check contacts are not broken.
Stimulation weak or cannot feel any stimulation	Electrodes are dried out or contaminated.	Replace and reconnect.
	Electrode placement.	
	Lead wires old/worn/ damaged.	Replace.
Stimulation is uncomfortable	Intensity is too high	Decrease intensity.
	Electrodes are too close together.	Reposition the electrodes.
	Damaged or word electrodes or lead wires.	Replace.
	Electrode active area size is too small.	Replace electrode with ones that have an active area no less than 16.0cm² (4cm x 4cm).
	May not operate the device according to the manual.	Please check the manual before use.
Intermittent output	Lead wires.	Verify connection is secure and firmly seated and no metal pins are exposed.
		Turn down the intensity. Rotate lead wires in socket 90°. If still intermittent, replace lead wire.
		If still intermittent after replacing the lead wire, a component may have failed. Call your distributor or the manufacturer.
	Program option in use.	Some programs will seem intermittent. This is expected.

Stimulation is ineffective	Improper electrode and applicator placement unknown.	Reposition electrode and applicator.
		Contact clinician.
The skin becomes red and/or you feel a stabbing pain	Using the electrodes on the same site every time.	Reposition the electrodes. If at any time you feel pain or discomfort stop use immediately.
	The elctrodes are not sticking onto the skin properly.	Ensure the electrode is stuck securely on the skin.
	The electrodes are dirty.	Replace with new electrodes.
	The surface of the electrode was scratched.	Replace with new electrodes.
Output current stops during therapy	The electrode pads come off the skin.	Turn off the device and stick the electrode pad firmly to the skin.
	The cable is disconnected.	Turn off the device and connect the cable.
	The power of the batteries has been exhausted.	Replace them with new batteries.

8. STORAGE

1. For prolonged pauses in treatment, store the device in a cool dry room and protect it against heat, sunshine and moisture and remove the battery to avoid battery leaking.
2. Store the device in a cool, well-ventilated place.
3. **NEVER** place any heavy objects on the device.

9. DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at a toxic waste collection point or through an electrical retailer. Please dispose of the device in accordance with the laws in your area.

10. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user assures 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 CISPR 11	Group 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	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply	Not applicable	Main power quality should be that of a commercial or hospital environment.
	±1 kV for input/ output lines		
Surge IEC 61000-4-5	±1 kV differential mode		
	±2 kV common mode		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle		
	40% UT (60% dip in UT) for 5 Cycles		
	70% UT (30% dip in UT) for 25 Cycles		
	<5% UT (>95% dip in UT) for 5 sec		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60501 test level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF Communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d=[\frac{3.5}{V1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m80 MHz to 2.5 GHz	3 V/m	$d=[\frac{3.5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz to 2.5 MHz
			Where P is the maximum output power rating of the transmitter In watts (W) according to the. 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, a should be less than the compliance level in each frequency range b. 

NOTE I. At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM 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 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
2. Over the frequency range 150 kHz to 80 MHz, field strength should be less than (Vi) W/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.

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

Rate maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	800 MHz to 2,5 GHz $d=[\frac{3.5}{V1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
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 9m0 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) accordable to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propogation is affected by absorption and reflection from structures, objects and people.

11. GLOSSARY OF SYMBOLS

LOT	Batch code
SN	Serial number
	Attention: Read the operating instruction before use! Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s.
	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
	Type of protection against electric shock: Class II Equipment
	Refer to instruction manual
	Do not insert the plug into AC power supply socket.
	Timer
	Low Battery
	Increment
	Decrement

12. WARRANTY

Please contact your dealer in case of a claim under the warranty. If you have to send the unit back to your provider, 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 year 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 or replacement 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. non-observance 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 retailer.
    - Accessories which are subject to normal wear and tear.

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.

1. All products must be returned in original packaging and must contain all components, accessories and user manuals. If any components are missing, you will be responsible for the cost of the replacement component and the 25% restocking fee.
2. All returns must be approved with a Return Authorization Number. Please call our Customer Service Team at (800) 376-7263 to obtain a Return Authorization Number. Provide the following information when calling:
    - Item Number
    - Original Order Number
    - Product Serial Number/Lot Number
    - Reason for Return
3. The Return Authorization Number must be marked clearly on the returned carton and is valid for 10 business days from the date of issue.
4. Returned merchandise must be in the same unit of measure as originally purchased.

5. Return Labels or Call Tags can be issued by our customer service department to return merchandise.
6. Associated fees and return freight charges will apply. All returns of dropshipped items are subject to a restocking fee as well as inbound and outbound freight charges.
7. Returns will not be accepted on items that are:
    - Missing their serial number
    - Special order items
    - Returned more than 30 days after delivery
    - Returned without notification

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