INTENSITY™ Twin Stim III

INSTRUCTION MANUAL

Richmar®

This manual is valid for the

InTENSity™ Twin Stim® III TENS/EMS Combo Stimulator

This user manual is published by Compass Health Brands.

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

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1. GENERAL INFORMATION

1.1 General Description

InTENSity™ Twin Stim® III stimulator is a portable electro-therapy device featuring two therapeutic modes: Transcutaneous Electrical Nerve Stimulation (TENS) and Electrical Muscle Stimulation (EMS), which are used for pain relief. The stimulator sends a gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The parameters of the device are controlled by the buttons on the front panel. The intensity level is adjustable according to the needs of the individual patient.

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.

1.3 Indication For Use

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

TENS:

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

EMS:

1. Relaxation of muscle spasm.
2. Increase of local 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 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 (especially the carotid sinus) 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, on the upper back and chest simultaneously, 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 NOT** 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:

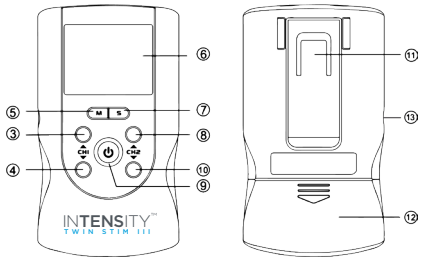
1. Skin irritation from the electrode gel and electrode burns are potential adverse reactions. If skin irritation occurs, discontinue use and consult your physician.

   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.

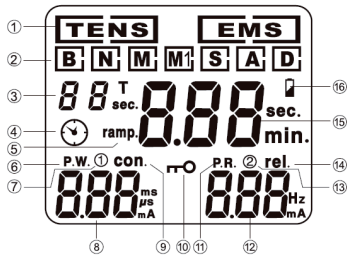
3. PRESENTATION

3.1 Front and Rear Panel



1. Output socket: electric signal output after connection of the cable with adhesive electrodes on channel 1.
2. Output socket: electric signal output after connection of the cable with adhesive electrodes on channel 2.
3. Increases [▲] the output intensity of channel 1. It is also used to set the application program and the parameter of the waveform in the setting state.
4. Decreases [▼] the output intensity of channel 1. It is also used to set the application program and the parameter of the waveform in the setting state, and to unlock the current treatment program.
5. Therapeutic mode [**M**] selection button; it also stops treatment and exits you out of the setting mode to return to the user interface.
6. LCD display: Shows the operating state of the device.
7. Parameter (setting) setting button
8. Increases [▲] the output intensity of channel 2. It is also used to set the application program and the parameter of the waveform in the setting state.
9. Parameter Selection [**S**] button: press the button to enter the setting state; you can select the different parameters in conjunction with the up [▲] and down [▼] buttons.
10. Press [⏻] to turn ON the device. Press [⏻] and hold for approximately 3 seconds to turn off the device. If device is locked, press [▼] before pressing [⏻] to turn off device.
11. Belt Clip.
12. Battery compartment cover.
13. AC Adapter connecting port

3.2 LCD Display



1. Displays therapeutic mode (TENS / EMS).
2. Displays therapeutic program for TENS" Burst(B), Normal (N), Modulation (M), and Modulation 1(M1) and EMS : Synchronous (S), Alternate (A), and Delayed (D) therapeutic modes.
3. Displays Delay time for EMS or displays the cycle time for TENS in setting state.
4. Timer symbol
5. EMS waveform of ramp up and ramp down time.
6. Display of waveform pulse width.
7. Displays channel 1.
8. Displays the output intensity for channel 1 (CH1) Displays waveform pulse width or EMS waveform of contraction (working) time in setting state.
9. EMS waveform of contraction (working) time.
10. The device is locked indicator
11. Displays the waveform pulse rate.
12. Displays the output intensity for channel 2 (CH2). Displays waveform pulse rate or EMS waveform of relaxation time in setting state.
13. Displays channel 2.
14. Displays the EMS waveform of relaxation time.
15. Displays the treatment time or EMS waveform of ramp up and ramp down time.
16. Low-battery indicator.

4. SPECIFICATIONS

4.1 Accessories

NO	DESCRIPTION	QTY
1	TENS/EMS Device (Item: DI3717)	1 each
2	Pair of Lead wires (Item: WW3005)	2/pk
3	2" x 2" White Cloth 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
Power supply	9.0 V Alkaline battery, type: 6LR61 Adapter output:9.0Vdc, 800mA (optional)
Operating Conditions	5°C to 40°C (41°F to 104°F) with a relative humidity of 30%-75%,atmospheric pressure from 700 to 1060 Hpa
Storage Conditions	-10°C to 50°C (14°F to 122°F) with a relative humidity of 10%-90%,atmospheric pressure from 700 to 1060 Hpa
Dimensions	4.5 × 2.55 × 0.9 inches (L*W*H)
Weight	0.28 lbs.(With battery)
Tolerance	There may be a ±5% tolerance of all setting and ±10% tolerance of output of intensity.
Timer	Adjustable from 1 to 60 minutes or continuous. Adjusts in 1 minute steps. Treatment time countdown is automatic.
Electrode Detection Function	The amplitude level will be reset to 0mA when the amplitude level is 12mA or greater and if an open circuit at either channel is detected.

Technical Specifications for Transcutaneous Electrical Nerve Stimulator (TENS) Mode

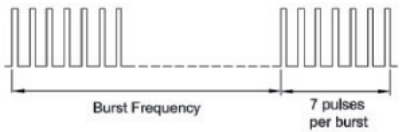
Waveform	Mono-phase square pulse wave
Pulse Amplitude	Adjustable, 0 ~ 105mA at 1000 ohm Load each channel, 1mA/Step.
Pulse Width	From 50 to 300μs, 10μs/step
Pulse Rate	Adjustable from 1 to 150 Hz, 1 Hz/step
Burst (B)	Burst rate: Adjustable 0.5~5Hz, Pulse Width Adjustable 50~300μs Frequency Fixed = 100 Hz
Normal (N)	The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value.
Pulse Width Modulation (M)	The pulse width is automatically varied in a cycle time. The pulse width is decreased from its original setting to 60% in setting cycle time, and then increased from 60% to its original setting in nest setting cycle time. In this program, pulse rate (1 to 150Hz), pulse width (50 to 300μs) and cycle time (5 to 30 seconds) are fully adjustable.
Pulse Width Modulation (M1)	The pulse rate is automatically varied in a cycle time. The pulse rate is decreased from its original setting to 60% in setting cycle time, and then increased from 60% to its original setting in nest setting cycle time. In this program, pulse rate (1 to 150Hz), pulse width (50 to 300μs) and cycle time (5 to 30 seconds) are fully adjustable.

Technical Specifications for Electrical Muscle Stimulation (EMS) Mode

Waveform	Mono-phase square pulse wave
Pulse Amplitude	Adjustable 0-105mA at 1000 ohm load each channel, 1 mA/step.
Pulse Width	Adjustable from 50 to 300μs, 10μs/step
Pulse Rate	Adjustable from 1 to 150 Hz, 1 Hz/step
Contraction time	Adjustable 1-60 seconds, 1 sec./step
Relaxation (OFF)	Adjustable 0-60 seconds, 1 sec./step
Ramp time	Adjustable, 1-6 seconds, 1 sec./step, The “On” time will increase and decrease in the setting value.
Synchronous (s)	Stimulation of both channels occurs synchronously. The “ON” time including “Contraction”, “Ramp Up” and “Ramp Down” time. ON TIME=Contraction + Ramp up + Ramp down.
Alternate (A)	The Stimulation of CH2 will occur after the 1st operation of CH1 is completed. In this program, The “ON” time includes “Contraction”, “Ramp Up” and “Ramp Down” time. The OFF Time should be equal to or more than the ON time. ON TIME=Contraction + Ramp up + Ramp down OFF TIME≥ ON TIME
Delay (D)	The Stimulation of CH2 will occur after the 1st operation of CH1 is started + Delay Time. In this program, the “ON” time includes “contraction”, “Ramp Up” and “Ramp Down” time. The OFF Time should be equal to or more than the ON Time + Delay Time. ON TIME=-Contraction + Ramp up + Ramp down.

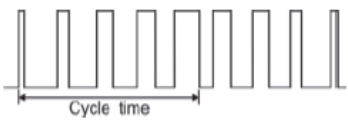
4.3 The Waveforms of the Stimulation Programs

Burst (B)

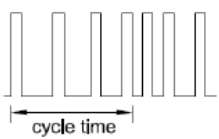


Normal (N)

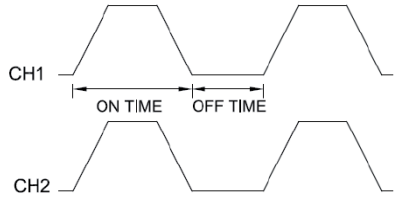
Pulse Width Modulation



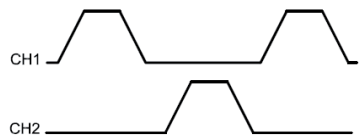
Pulse Rate Modulation



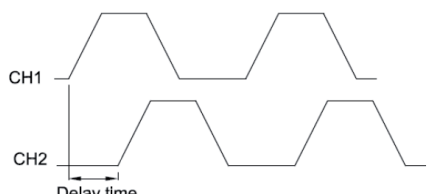
Synchronous (S)



Alternate (A)



Delay (D)

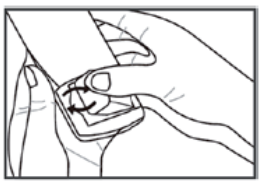


5. INSTRUCTIONS FOR USE

5.1 Battery

5.1.1 Check/Replace the Battery

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



1. Slide the battery compartment cover to open.
2. Insert the 9V battery into the battery compartment.
3. Make sure you are installing the battery properly. Be sure to match the positive and negative ends of the battery to the marking in the battery compartment of the device.
4. Press and push down the battery following the direction of the arrow indicated on the photo.
5. Replace the battery compartment cover and press to close.
6. If battery requires replacement, slide the battery compartment cover to open. Pull up the battery following the directions of the arrow indicated on the photo and insert a new 9V battery according to the above steps 2 to 5.

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 spent 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.

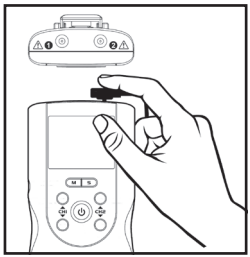
5.2 Connect Electrodes to Lead Wires

Insert the lead wire connector into electrode connector (standard 0.08 inch female connection). 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.
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.

⚠ CAUTION:

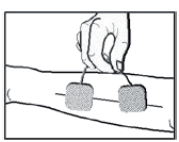
DO NOT insert the plug of the patient lead wire into any AC power supply socket.

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 FOR ELECTRODES:

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 to use the specific size provided by the manufacturer or, at a minimum, 1.5" x 1.5" self-adhering, square electrodes are used at the treatment area to avoid skin irritations or burns. For smaller electrodes, the max. current setting of the waveform should be appropriately reduced.
5. It is recommended not to exceed a current density of 2mA/cm^2, to avoid skin irritations or burns.
6. Ensure the entire surface of the electrode has good contact with the skin.

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 (pages 6-10 and throughout manual), as this powerful equipment is neither a toy nor a gadget!

To turn on the device, PRESS and RELEASE the ON/OFF ⏻ button. The operation page will appear on the LCD screen.

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 [**M**] button control.

⚠ CAUTION:

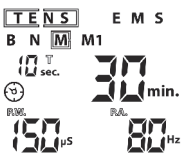
Consult your physician for your suitable therapeutic mode.

5.7 Steps to Set a New Program

5.7.1 TENS Setting

Press the [**S**] button to cycle and to enter the setting state. The settings can be adjusted according to the following steps:

Step 1: Set the Therapeutic Program
There are 4 programs available in TENS therapeutic mode – Burst (B), Normal (N), Pulse Width Modulation (M) and Pulse Rate Modulation (M1). The therapeutic program can be selected by pressing the up [▲] and down [▼] button. For example when you choose the “M” program, “M” will be outlined by a flashing box.



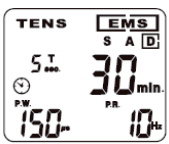
Step 2: Set Cycle Time (optional)
Cycle time is adjustable from 5 to 30 seconds. Only the modulation program has this parameter setting. Press the [**S**] button to cycle and to enter this menu, and then press the [▲] and [▼] buttons to adjust the cycle setting.

Step 3: Set Timer
Press the [**S**] button to cycle and to enter this setting. The treatment time is adjustable from 1 to 60 minutes or Continuous. Press the up [▲] or down [▼] button controls to adjust the setting. You can set the timer to "Continuous" mode by pressing the up [▲] control when it shows 60 minutes. The output will shut off when time is up. When in Continuous mode, you will need to manually turn off the device.

Step 4: Set Pulse Width
Pulse Width is adjustable from 50μs to 300μs. Press the [**S**] button to enter this menu, then press the up [▲] or down [▼] button to adjust the setting.

Step 5: Set Pulse Rate
Pulse rate is adjustable from 1 Hz to 150 Hz (0.5 Hz to 5 Hz for Burst). Press the [**S**] button to cycle and to enter this menu, and then press the up [▲] or down [▼] button to adjust the setting.

4.7.2 EMS Setting



Press the [**S**] button to cycle and to enter the setting state. The settings can be adjusted according to the following steps:

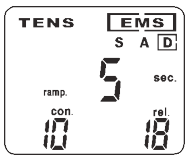
Step 1: Set the Therapeutic Program
There are 3 programs in EMS therapeutic mode available: Synchronous (S), Alternate (A) and Delayed (D). The therapeutic program can be selected by pressing the up [▲] and down [▼] button. For example, when you choose the "D" Program, "D" will be outlined by a flashing box.

Step 2: Set Timer
Press the [**S**] button to cycle and to enter this setting. The treatment time is adjustable from 1 to 60 minutes or Continuous. Press the up [▲] or down [▼] button to adjust the setting. You can set the timer to "Continuous" mode by pressing the up [▲] button when it show 60 minutes. The output will shut off when time is up. When in Continuous mode, you will need to manually turn off the device.

Step 3: Set Pulse Width
The pulse width determines the length of time each electrical signal is applied through the skin, and controls the strength and sensation of the stimulation. Pulse Width is adjustable from 50μs to 300μs. Press the [**S**] button to cycle and to enter this menu, and then press the up [▲] and down [▼] button to adjust the setting.

Step 4: Set Pulse Rate
The pulse rate determines how many electrical impulses are applied through the skin each second. Pulse rate is adjustable from 1 Hz to 150 Hz. Press the [**S**] button to cycle and to enter this menu, and then press the up [▲] and down [▼] button to adjust the setting.

Step 5: Set Delay Time (Optional)
Only the "Delay" therapeutic program has this parameter setting. Press the [**S**] button to cycle and to enter this menu, and then press the up [▲] and down [▼] button to adjust the setting.



Step 6: 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. When the ramp time is set, each contraction may be ramped up and down in order for the signals to come on and come off gradually and smoothly. The ramp time is adjustable from 1 to 6 seconds.

Step 7: Set Contract Time
The contract time controls the time of stimulation and can be adjusted by pressing the [**S**] button cycle to enter this menu, and then pressing the up [▲] and down [▼] button to adjust the setting. The stimulation of Channel 1 and Channel 2 is cycled on and off by the contraction and relaxation settings. The range is adjustable from 1 to 60 seconds.

⚠ CAUTION:

Contract time does not include the ramp up and ramp down time. ON time = Ramp up + Contract time + Ramp down.

Step 8: Set Relaxation (OFF) time
The Off Time controls the time of relaxation and can be adjusted. Press the [**S**] button to cycle and to enter this menu, and then press the up [▲] and down [▼] button to adjust the setting. The stimulation of Channel 1 and Channel 2 is cycled on and off by the contraction and relaxation settings. The range is adjustable from 1 to 60 seconds. In Alternate (A) program, the OFF Time should be equal to or more than the ON Time. (OFF TIME ≥ ON TIME)

5.8 Adjust Channel Intensity
Press the intensity control buttons up [▲] and down [▼] to control the intensity output. Slowly press the intensity button control until you reach the setting recommended by your physician or therapist. Repeat for the other channel, if both channels are to be used.

⚠ 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 12mA, the intensity will automatically reset to 0mA.

5.9 Safety Lock Feature

The Safety Lock Feature automatically activates by locking out your ability to operate the buttons when you have stopped setting the program or adjusting the intensity for 30 seconds. This is a safety feature to prevent accidental changes to your settings and to prevent accidental increases to the intensity levels. You can press either one of the down [▼] buttons to unlock the device.

5.10 Stop the Treatment

When you have activated the treatment timer, you can press the [**M**] button or the down [▼] button to control or stop the treatment.

⚠ CAUTION:

Default state, if the button is locked, you can press only one of the down [▼] buttons to unlock, and then press the [**M**] button or the down [▼] button to control stop the treatment.

5.11 Turn Off

Press and HOLD the [⏻] button for approximately 3 seconds to turn OFF the device or press the [**M**] button and return the device to 0mA.

⚠ CAUTION:

1. If there is no operation in the panel for 2 minutes in the waiting state, the device will turn off automatically.
2. In shutdown state, keep pressing the channel 2 down [▼] button first, and then press the [⏻] button at the same time to restore factory parameter settings.

5.12 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. PROGRAM

Mode	Program	Modulation Method	Frequency	Pulse Width	Treatment Time
TENS	B	Burst	0.5-5Hz	50-300μs	1-60 min, continuous
TENS	N	Continuous	1-150Hz	50-300μs	1-60 min, continuous
TENS	M	Pulse with Modulation	1-150Hz	50-300μs	1-60 min, continuous
TENS	M1	Frequency Modulation	1-150Hz	50-300μs	1-60 min, continuous
EMS	S	Synchronous mode	1-150Hz	50-300μs	1-60 min, continuous
EMS	A	Asynchro-nous mode	1-150Hz	50-300μs	1-60 min, continuous
EMS	D	Delay Mode	1-150Hz	50-300μs	1-60 min, continuous

7. CLEANING AND CARE

7.1 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.

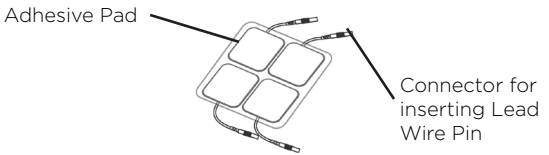
7.2 Cleaning the Device

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.

7.3 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 USE THESE ELECTRODES:

1. Attach the electrode to the lead wire.
2. Remove the protective backing from the electrode surface. **DO NOT** throw away the protective backing because it can be reused after the treatment session has been completed.
3. Place the tacky surface to the prescribed skin area by pressing the electrode firmly against the skin.

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.
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.

⚠ CAUTION:

1. **DO NOT** pull on the electrode wire. Doing so may damage the wire and electrode.
2. **DO NOT** apply to broken skin.
3. The electrodes should be discarded when they are no longer adhering to the skin.
4. The electrodes are intended for single patient use only.
5. If irritation occurs, discontinue use and consult your clinician.
6. Read the instructions for use of self-adhesive electrodes before application.
7. Always use the electrodes with the requirements of the IEC/EN60601-1, ISO10993-1/-5/-10 and IEC/EN60601-1-2, such as with CE mark, or are legally marketed in the U.S. under 510(K) procedures.

7.4 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.

7.5 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.

8. 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.	1. Try fresh batteries
		2. Ensure batteries are inserted correctly. Check the following contacts: All contacts are in place. All contacts are not broken.
Stimulation weak or cannot feel any stimulation	Electrodes 1. Dried out or contaminated. 2. Placement.	Replace and reconnect.
	Lead wires old/worn/ damaged.	Replace.
Stimulation is uncomfortable	Intensity is too high.	Decrease intensity.
	Electrodes are too close together.	Reposition the electrodes.
	Damages or worn electrodes or lead wires.	Replace.
	Electrode active area size is too small.	Replace electrodes with ones that have an active area no less than 16.0 cm^2 (4cm*4cm).
	May not operate the device according to the manual.	Please check the manual before use.
Intermittent output	Lead wires.	1. Verify connection is secure and firmly seated and no metal pins are exposed.
		2. Turn down the intensity. Rotate lead wires in socket 90°. If still intermittent, replace lead wire.

		3. 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. Refer to the programs on page 28
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 electrodes 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. If that does not work, replace with new electrodes.
	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.

9. 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.

10. 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.

11. 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	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			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 3 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 **$d = 1.2\sqrt{P}$**	80 MHz to 800 MHz **$d = 1.2\sqrt{P}$**	800 MHz to 2.7GHz **$d = 2.3\sqrt{P}$**
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 (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) 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.

12. 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

13. 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. (accessories, minus electrodes, have a six month warranty). 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. 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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