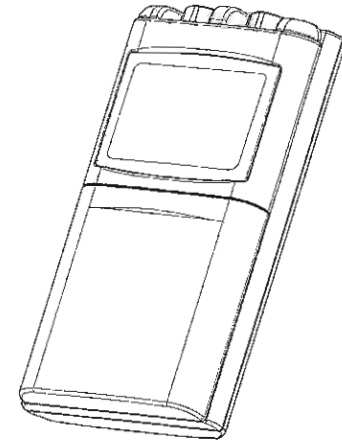


**Transcutaneous Electrical Nerve Stimulator (TENS)
Powered Muscle Stimulator (EMS)**

Read before using



FDA 510k

CE
0434

Model: GM300TE (Combo)

Operation Manual

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GENERAL DESCRIPTION

Electric myostimulation has proven its high value as a method of pain therapy and is a great help to the experienced therapist.

With some indications, physicians can prescribe unit to patients for the use at home. The unit is a dual-Channel electric stimulator for active treatment application, which is equipped with a Liquid Crystal Display indicating operation modes and output as well as an 8-bit micro computer for controlling the system.

The electronics of the unit create electric impulses: the intensity, duration, frequency per second and modulation of these impulses can be adjusted through the button or knob.

SYSTEM COMPONENTS

Your device may include the following components or accessories:

- Unit
- Carrying case
- Lead wires / Electrodes
- 9-volt battery
- Operation Manual

WARRANTY

This device carries a one-year warranty from the date of purchase. The warranty applies to the device and necessary parts and labor relating thereto. The distributor reserves the right to replace or repair the unit at their discretion.

The warranty does not apply to electrode, battery, lead wires, carrying case, damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.

INDICATIONS AND CONTRAINDICATIONS

Read the operation manual before using the device.

Federal law (USA) restricts this device to sale by or on the order of a physician. Observe your physician's precise instructions and let him show you where to apply the electrodes. For a successful therapy, the correct application of the electrodes is an important factor. Carefully write down the settings your physician recommended.

The following statements are available for TENS operation function

Indications for use

This device is a prescription device and only for symptomatic relief of chronic intractable pain.

Contraindications

- Any electrode placement that applies current to the carotid sinus (neck) region.
- Patients with implanted electronic devices (for example, a pacemaker) or metallic implants should not undertake.
- Any electrode placement that causes current to flow transcranially. (through the head) The use of unit whenever pain symptoms are undiagnosed, unit etiology is determined.
- The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

The following statements are available for EMS operation function

Indications for use

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

Contraindications

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

WARNINGS AND PRECAUTIONS

The following statements are available for TENS operation function



Warnings

- The device must be kept out of reach of children. ...
- The safety of device for use during pregnancy or delivery has not been established.
- Do not place electrodes on front of the throat. This may result in spasms of the laryngeal and pharyngeal muscles.
- Do not place the electrodes over the carotid nerve.
- The device is not effective for pain of central origin (headaches).
- The device may interfere with electronic monitoring equipment (such as ECG monitors and ECG alarms).
- Electrodes should not be placed over the eyes, in the mouth, or internally.
- These devices have no curative value.
- TENS devices should be used only under the continued supervision of a physician.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.



Precautions/adverse Reactions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Stimulation should be stopped and electrodes removed until the cause of the irritation can be determined.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
- If the device treatment becomes ineffective or unpleasant, stimulation should be discontinued until reevaluation by a physician/clinician.
- Always turn the device off before applying or removing electrodes.
- Skin irritation and electrode burns are potential adverse reactions.

The following statements are available for EMS operation function



Warnings

- The long-term of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the

- laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Stimulation should not be applied transcerebrally (across the head).



Precautions/adverse Reactions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
 - When there is a tendency to hemorrhage following acute trauma of fracture;
 - Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - Over the menstruating or pregnant uterus; and
 - Over areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Power muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- [FOR PORTABLE DEVICES ONLY] Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

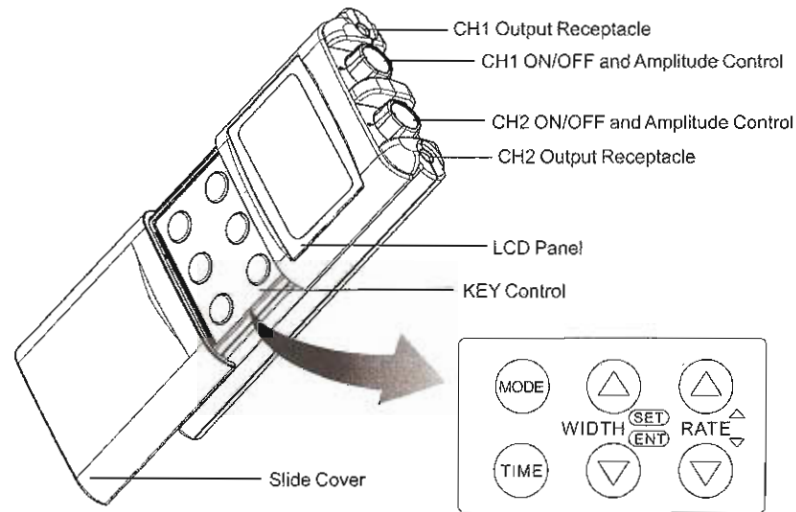
Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

DANGER

The device does not have AP/APG protection. Explosion hazard is possible if used in the presence of explosives, flammable materials or flammable anesthetics. Caution should be used when applying the device to patients suspected of having heart disease. Further clinical data is needed to show if there are adverse side effects on those with heart disease.

ABOUT THE DEVICE

Your device offers two controllable output channels. This device creates electrical impulses whose amplitude, duration, and modulation can be altered with the controls or buttons. The device controls are very easy to use and the slide cover protects accidental changes in settings.



THE DEVICE CONTROLS

Panel cover

A cover conceals the controls for Mode, Time, Width▲▼ (SET/ENT), Rate▲▼ (▲▼). Press the topside of the cover and pull down in order to open the cover.

Intensity

The intensity knobs are located on the top of the unit for the strength adjustment of the stimulation and also function as ON/OFF controls.

Mode

The Mode key is used to select / set the type of treatment utilized. The nine modes are Burst (B), Continuous (N), Modulation (M), Modulation Rate (MR), Modulation Rate and Width (MRW), Strength-Duration and Rate modulation (SDR), Strength Duration and Width modulation (SDW), Synchronous (S), Alternation (A).

TIME

Treatment Time of device can be pre-select / set with Time key. There are four programs fixed duration of 15, 30, 45 and 60 minutes and one program of continuous output. Press the key until engaged in position desired.,

15 min : 15 min symbol light on.

30 min : 15, 30 min symbols light on.

45 min : 15,30 and 45 symbols light on

60 min : 15, 30, 45 and 60 min symbols light on.

Continuous : the timer symbol become empty.

WIDTH ▲▼ (for TENS)

The pulse Width key regulates the pulse width for both channels.

RATE ▲▼ (for TENS)

The pulse Rate key regulates the number of pulse per second for both channels.

SET/ENT (for EMS)

The SET/ENT keys are used to select the type of treatment utilized. The type of treatment utilized includes cycle On time, On Ramp time, cycle Off time and Pulse Rate. The selected parameter will flash during adjust.

▲▼ (for EMS)

The ▲▼ keys regulate the number of On, Ramp, Off and Rate value. After completed new values setting, press ENT key to update the new value.

ATTACHING THE LEAD WIRES

The lead wires provided with the device insert into the jack sockets located on top of the unit. Holding the insulated portion of the connector, and pushing the plug end of the wire into one of the jacks. After connecting the wires to the stimulator, attach each wire to an electrode.

Lead wires provided with the device are compliant with mandatory compliance standards as set forth by the FDA.

Note: Use carefully when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

Caution: Never insert the plug of the lead wire into an AC power supply socket.

ELECTRODE SELECTION AND CARE

Your physician/practitioner should decide which type of electrode is best for your condition. Follow application procedures outlined in electrode packaging to maintain stimulation and prevent skin irritation. The electrode packaging will provide instruction for care, maintenance and proper storage of your electrodes.

Be sure to use the electrodes provided by the manufacturer and/or the similar FDA legally marketed electrode in particular the same cross section area.

TIPS FOR SKIN CARE

Good skin care is important for comfortable use of your device.

- Always clean the electrode site with mild soap and water solution, rinse well, and blot dry thoroughly prior to any electrode application.
- Any excess hair should be clipped, not shaved, to ensure good electrode contact

with the skin.

- You may choose to use a skin treatment or preparation that is recommended by your physician. Apply, let dry, and apply electrode as directed. This will both reduce the chance of skin irritation and extend the life of your electrodes.
- Avoid excessive stretching of the skin when applying electrodes, this is best accomplished by applying the electrode and smoothly pressing it in place from the center outward.
- When removing electrodes, always remove by pulling in the direction of hair growth.
- It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.

CONNECTING THE DEVICE

1. Prepare the Skin

Prepare the skin as previously discussed and according to instructions provided with your electrodes. Before attaching the electrodes, identify the area in which your physician/practitioner has recommended for electrode placement.

2. Connect lead wires to the electrodes

Connect the lead wires to the electrodes before applying the electrodes to the skin.

Note: Be sure both intensity controls for Channel 1 and 2 are turned to the "OFF" position.

3. Place Electrodes on Skin

Place the electrodes on the skin as recommended by your clinician.

4. Insert Lead Wire Connector to device

Plug end of lead wire into the channel output receptacle to be used, pushing plug in as far as it will go.

5. Select Treatment Settings

Check and be sure your unit is set to the proper settings as recommended by your physician/practitioner.

6. Adjusting Channel Intensity Control

Locate the intensity control knobs at the top of the unit. Slowly turn the intensity control knob for Channel 1 clockwise until you reach the intensity recommended by your medical professional. Always start with the lowest step and increase slowly. Repeat the same process for Channel 2, if appropriate.

If the stimulation levels are uncomfortable or become uncomfortable, reduce the

stimulation amplitude to a comfortable level. Cease stimulation and contact your physician/practitioner if problems persist.

BATTERY INFORMATION

A 9-volt disposable battery is provided with your unit. When the low-battery indicator appears, the battery has become too weak to power the unit and will need to be changed. At this point, the unit will shut off until a fresh battery is inserted.

CHANGING THE BATTERY

When the low-battery indicator appears on the LCD panel, the battery should be replaced with a fresh battery.

1. Remove the slide cover by pressing the top and sliding down until it is completely removed from the unit. This will reveal the battery compartment.
2. Remove the discharged battery from the device.
3. Place new battery in compartment. Note the proper polarity alignment indicated on both the battery and the compartment.

CLEANING FOR YOUR DEVICE

Your device may be cleaned by wiping gently with a damp cloth moistened with mild soap and water. Never immerse the device in water or other liquids.

Wipe lead wires with a damp cloth as above if they become soiled.

To properly store the device for an extended period of time, remove the battery from the unit. Put the unit and accessories in the carrying case and store in a cool, dry location.

TROUBLESHOOTING

If the device does not function properly:

1. Make sure the battery is properly installed, or replace the battery. Be sure to

- observe proper polarity markings when replacing the battery. If the low-battery indicator appears when the unit is turned on, replace the battery and check again.
- If the intensity has been adjusted and there is no stimulation, check that the lead wires are properly connected and the electrodes are in place. If the unit appears to be functioning and no stimulation occurs, the lead wires or electrodes may need to be replaced.
 - If the battery appears to be charged and the unit is not functioning, turn both **intensity Control Knobs to the OFF position (counter-clockwise) for about 5 sec.** Then gradually turn the intensity Control Knob clockwise until stimulation is felt. If device still is not working, turn the unit off and contact your distributor.

If any other problems occur, please consult or return the device to your distributor. Don't try to repair a defective device.

TECHNICAL SPECIFICATIONS

Channel:	Dual, isolated between channels
Pulse amplitude:	Adjustable 0-80mA peak into 500 Ω load each channel, constant current
Pulse Rate:	1Hz-160Hz (adjustable), 1Hz/step
Pulse Width:	a. 50-260 μ s adjustable for TENS, 1 μ s/step. b. 250 μ s fixed for EMS.
Software ramp up feature:	By changing mode, the output will reset to zero; then ramp up to its original setting intensity. This will protect users from a sudden surge.
Patient Compliance counter:	Shows the treatment times in minutes.
Patient Lock System:	Prevent the user from changing any fixed parameters set by the physician or licensed practitioner.
Timer:	15, 30,45, 60 minute and continuous mode selectable
LCD:	TENS - Show modes, pulse rate, pulse width, timer, CH1/CH2 and TENS on LCD panel. EMS - Show modes, pulse rate, on time, off time, timer, CH1/CH2 and EMS on LCD panel.

Function Modes:

TENS:

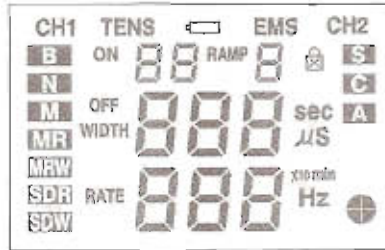
- B: Cycle Bursts, 2Bursts/sec, 9pulses/Burst, 100Hz, width is adjustable.
N: Continuous mode. Pulse rate, pulse width and intensity are full adjustable.
M: Modulated Width. Pulse width is automatically varied in an interval of 6 seconds. The modulation range of pulse width is from setting value to 35% less than the control setting value. And then returns to the setting value. Rate, width and intensity are fully adjustable.
MR: Modulated Rate. Pulse rate decreases 50% from setting value and then returns to the setting value. Total cycle time is 6 seconds. Rate, width and intensity are fully adjustable.
MRW: Modulated Rate and Width. The MRW consists of alternating modulated width and modulated rate so that one parameter is always decreasing while the other is increasing and vice-versa. Rate, width and intensity are fully adjustable.
SDR: Strength-Duration and Rate modulation. SDR consists of alternating modulated intensity (amplitude) and pulse rate so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse rate increase 45% from the modulated rate to the setting value and return to the modulated rate. Total cycle time is 6 seconds. Rate, Width and Intensity are full adjustable.
SDW: Strength-Duration and Width modulation. SDW consists of Alternating modulated intensity (amplitude) and pulse width so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse width increase 54% from the modulated width to the setting value and return to the modulated width. Total cycle time is 6 seconds. Rate, width and intensity are full adjustable.

EMS:

- S: Synchronous.
C: Constant.
A: Alternation.
On Ramp: Adjustable 1-8 seconds.
Cycle ON Time: Adjustable 1-30 seconds.

Cycle OFF Time: Adjustable 1-30 seconds.

Wave form: Asymmetrical Bi-phasic square pulse.
Max charge per pulse: 21micro-coulombs maximum.
Voltage: 0-110 Volt (Open Circuit).
Power Source: 9-Volt Battery.
Dimensions: 128mm(H) x70mm(W) x26mm(T).
Weight: 175 grams (battery included).
All electrical specifications are $\pm 10\%$ 500 Ω load.



Notes:

Appendix

Manual for Doctor mode (for physician or licensed practitioner use only)

It is possible for a physician or licensed practitioner to see the compliance meter, to reset the compliance meter or to lock/unlock the treatment parameters. This is achieved using doctor mode.

1. Enter to Doctor mode: Press and hold on 'TIME' key, then turn on the unit with channel 1/2 knob. If you can see the 'hr' symbol show on the LCD (the rate is 0 Hz), you are in the doctor mode. (Some model with 'min' symbol)
2. See Compliance meter value: After you enter the doctor mode, the compliance meter value is showing on the LCD with 'hr' symbol. (Some models with 'min' symbol)
3. Reset the compliance meter value: When the doctor want to reset the compliance meter's value for a new treatment cycle, you can do as the follow steps:
When you are in the doctor mode, press 'MODE' key first, then press the reset key. Thus, the value will be reset.
*reset key: 'Rate ▼' for TENS/EMS/Combo/IF/HV; '▼' for EMS (C).
4. Lock the parameter: After the doctor finish setting the prescription parameters, the doctor can lock the parameters to prevent a patient from altering the settings. When the doctor finish the prescription parameters, turn off the unit. Then enter the doctor mode (refer to step 1) first. And press the 'MODE' key first, then press the lock key. Thus, the lock symbol will display on the LCD. It is OK, then you can turn off the unit. The next one normally turn on the unit, all the parameters already been locked (the lock symbol show on the LCD). The patient can only adjust the amplitude knobs for his comfortable intensity.
*lock key: 'Width ▲' for TENS/Combo; 'SET' for EMS; 'Rate ▲' for IF/HV
5. Unlock the parameter: When the doctor want to change the prescription parameters which had been locked, you must to unlock it first. The follow steps are to unlock the parameters:
Enter the doctor mode. Press the 'MODE' key first, then press the unlock key. Thus, the lock symbol will disappear. It is ok for unlock function. Turn off the unit, next time normally turn on the unit, you can re-adjust all the parameters again.
*unlock key: 'Width▼' for TENS/Combo; 'ENT' for EMS; 'Rate ▲' for IF/HV
6. Exit the doctor mode: Turn off the unit, it will leave the doctor mode.
7. User mode: Normally turn on the unit (without hold on any key), then you are on the user mode.