

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

READ BEFORE USING THE DEVICE



Manufacturer's Model #: GM320TE (Combo)

ReliaMed® Reorder number: ZZA700

Operation Manual

**ReliaMed®**

Manufactured for ReliaMed®
Fort Worth, TX 76106
1-800-409-2848

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GENERAL DESCRIPTION

Electrical myostimulation has proven to be highly valuable as a method of pain therapy. With some restrictions, physicians or licensed practitioners can prescribe the unit to patients for home use. 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 unit creates electrical impulses. The intensity, duration, frequency per second and modulation of these impulses can be adjusted through the device controls.

SYSTEM COMPONENTS

Your device may include the following components or accessories:

- Unit
- Carrying case
- 2 Lead wires
- 4 Electrodes (1 pack)
- 9-volt battery
- Operation manual

If you are missing any of these items, please contact ReliaMed® at 1-800-409-2848 before using the unit.

LIMITED PRODUCT WARRANTY

Your ReliaMed® GM320TE COMBO TENS EMS unit is warranted to be free from defects in materials and workmanship occurring within one year from date of purchase, when used in strict accordance with the instructions provided with the ReliaMed® GM320TE COMBO TENS EMS unit. The sole remedy for a breach of this warranty is replacement of the defective materials or components. This warranty extends only to the original purchaser. The purchase receipt or other proof of date of original purchase is required before full replacement will be provided.

Please contact ReliaMed® at 1-800-409-2848.

ReliaMed® MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ALL SUCH WARRANTIES BEING HEREBY EXPRESSLY EXCLUDED.

The warranty described above does not extend to the normal wear of the product and is void if the product housing has been removed or if the product fails to function properly as a result of an accident, misuse, abuse, neglect, mishandling, misapplication, defective batteries, faulty installation, set-up, adjustments, improper maintenance, alteration, maladjustment of controls, modification, power surges, commercial use of product, use of product which differs from the suggested use set forth in the product instructions, service by anyone other than an authorized service center or acts beyond the control of the manufacturer.

ReliaMed® SHALL NOT BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES WHETHER ARISING UNDER CONTRACT, TORT, STRICT LIABILITY, STATUTE OR OTHER FORM OF ACTION OR ANY DAMAGES IN EXCESS OF THE COST OF THE REPLACEMENT OF THE PRODUCT.

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 or licensed practitioner. Follow your physician's or licensed practitioner's precise instructions, and let him/her show you where to apply the electrodes. For successful therapy, the correct application of the electrodes is an important factor. Carefully write down the settings your physician or licensed practitioner recommends.

The following statements apply to the TENS operation function:

Indications for use

This device is available by prescription only and is to be used only for symptomatic relief of chronic intractable pain as prescribed by a physician or licensed practitioner.

Contraindications

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

The following statements apply to the EMS operation function:

Indications for use

- Relaxation of muscle spasms
- Prevention or retardation of muscle 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/PRECAUTIONS

The following statements apply to 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 front and sides of the neck).
- The device is not effective for headaches.
- 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.
- 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 is a symptomatic treatment that suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
- TENS devices should be used only under the continued supervision of a physician or licensed practitioner.
- Do not use on broken skin.
- Effectiveness is highly dependent upon patient selection by a person qualified in pain management using TENS
- If the device treatment becomes ineffective or unpleasant, stimulation should be discontinued until re-evaluation by a physician or licensed practitioner.
- Always turn the device off before applying or removing electrodes.

- The device does not have AAP/APG protection.. An explosion hazard is possible if used in the presence of explosives, flammable materials or flammable anesthetics.



Precautions/Adverse Reactions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Skin irritation and electrode burns are potential adverse reactions.

The following statements apply to EMS operation function:



WARNINGS/PRECAUTIONS

- The device must be kept out of reach of children.
- 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 risk of injury.
- The safety of the 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 sinus (neck).
- 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.
- 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.
- EMS devices should be used only under the continued supervision of a physician.
- Do not use on broken skin.
- If the device treatment becomes ineffective or unpleasant, stimulation should be discontinued until re-evaluation by a physician/clinician.
- Always turn the device off before applying or removing electrodes.
- The device does not have AAP/APG protection. An explosion hazard is possible if used in the presence of explosives, flammable materials or flammable anesthetics.
- Caution should be used for patients with suspected or diagnosed epilepsy.

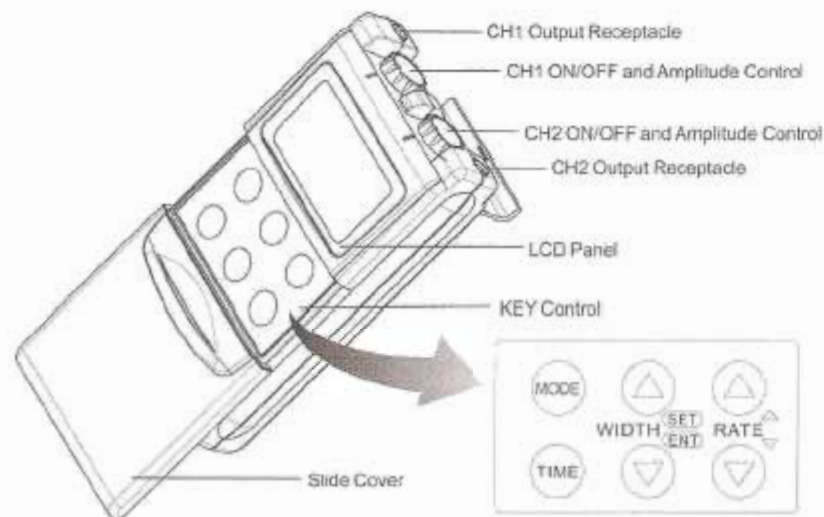


Adverse Reactions

- Skin irritation and electrode burns are potential adverse reactions. Stimulation should be stopped and electrodes removed until the cause of the irritation can be determined.
- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Always properly clean skin before use. If skin irritation occurs, discontinue use. Do not resume use of the ZZA700 Powered Muscle Stimulator (EMS) unit until you have seen your physician or licensed practitioner.

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 cap and slide cover protect accidental changes in settings.



THE DEVICE CONTROLS

Slide 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 Amplitude Control knobs are located on the top of the unit under the cap 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 seven modes are Burst (B), Continuous (C), Modulation (M), Strength-Duration and Rate modulation (SDR), Strength Duration and Width modulation (SDW), Synchronous (S) and Alternation (A).

Time

Treatment time can be preselected/set with Time key. There are three programs of fixed duration 15, 30 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- and 30-min symbols light on

60 min : 15-, 30-, and 60-min symbols light on

Continuous : 15- and 30-min symbols light on, and the 60-min symbol flashes

To reset timer, turn both channels off. When you are ready to begin another treatment cycle (at least rest for 5 seconds), turn the unit on as normal. The timer will be reset to its current setting.

Width ▲▼

The Width key regulates the pulse width for both channels.

Rate ▲▼

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

SET/ENT

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 and Cycle Off time. The

selected parameter will flash during adjust.



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

ATTACHING THE LEAD WIRES

Insert the lead wires into the output receptacle located on top of the unit by 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 unit, 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 caution 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 or licensed 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 packaging will provide instructions for care, maintenance and proper storage of your electrodes.

Be sure to use the electrodes provided by ReliaMed® and/or similar FDA legally marketed electrode the same size, or larger than, the electrodes that are provided with this GM320TE (Combo) TENS EMS unit.

CONNECTING THE DEVICE

IMPORTANT: Be sure both Amplitude Control knobs for Channel 1 and 2 are turned to the OFF position before connecting the device.

1. **Prepare the skin.** Always clean the electrode site with mild soap and water, rinse well and blot dry thoroughly. 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 or licensed practitioner. Apply a skin treatment or preparation, let dry and apply electrodes as directed. This will reduce the chance of skin irritation and extend the life of the electrodes.
2. **Connect lead wires to the electrodes.** Connect the lead wires to the electrodes before applying the electrodes to the skin.
3. **Place electrodes on skin.** Place the electrodes on the skin as recommended by your physician or licensed practitioner. 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.
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 that the unit is set to the proper settings as recommended by your physician or licensed practitioner.
6. **Adjusting channel amplitude control.** Locate the Amplitude Control knobs at the top of the unit. Slowly turn the Amplitude Control knob for Channel 1 clockwise until you reach the intensity recommended by your physician or licensed practitioner. Always start with the lowest intensity 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. If problems persist, stop treatment and contact your physician or licensed practitioner.

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 new 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 old battery from the device.
3. Place a new battery in the compartment. Note the proper polarity alignment indicated on both the battery and the compartment.
4. Make sure to safely dispose of the old battery.

CLEANING THE DEVICE

The 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 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 recheck.
2. 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 occur, the lead wires or electrodes may need to be replaced.
3. If the battery appears to be charged and the unit is not functioning, **turn both Amplitude Control knobs to the OFF position (counterclockwise) for about five seconds.** Next, gradually turn the Amplitude Control knob clockwise until

stimulation is felt. If device still is not working, turn the unit off and contact your ReliaMed®.

If any other problems occur, please consult or return the device to ReliaMed®. Do repair a defective device.

TECHNICAL SPECIFICATIONS

Channel:	Dual, isolated between channels
Pulse Amplitude:	Adjustable 0-80 mA peak into 500 Ω load each channel, constant current
Pulse Rate:	1 Hz-160 Hz (adjustable), 1 Hz/step (1-20 Hz), 5 Hz/step (20-160 Hz)
Pulse Width:	a. 50-260 μ s adjustable for TENS, 10 μ s/step b. 250 μ s fixed for EMS
Software Ramp Up:	By changing mode, the output will reset to zero; then, ramp up to its original setting intensity. It will protect users from a sudden surge
Patient Compliance Meter:	Shows the treatment times in hours
Patient Lock System:	Prevents the user from changing any fixed parameters set by the physician or licensed practitioner
Timer:	15-, 30-, and 60-minute; and continuous mode
LCD:	TENS - Shows modes, pulse rate, pulse width, timer and CH1/CH2 on LCD panel EMS - Shows modes, pulse rate, on time, off time, timer and CH1/CH2 on LCD panel

