Transcutaneous Electrical Nerve Stimulator

TENS 212

Instruction Manual

Read before using

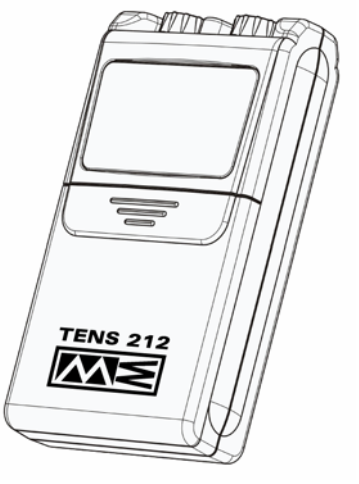


TABLE OF CONTENTS

GENERAL DESCRIPTION

Transcutaneous Neuromuscular Electrical Stimulation (TENS) has proven its high value as a method of pain therapy and is a great help to the experienced clinician. With some indications, medical practitioners can prescribe a unit to patients for the use at home. The TENS 212 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 a microprocessor for controlling the system.
The electronics of the unit create electric impulses: the intensity, pulse duration, pulse frequency and modulation of these impulses can be adjusted by a button or a knob.

SYSTEM COMPONENTS

Your device includes the following components or accessories:

- Unit
- Carrying case
- Lead wires / Electrodes (ME 2120)
- 9-volt battery
- Instruction Manual

WARRANTY

The TENS 212 is warranted against defects in materials and workmanship for a period of one year from date of purchase. During the applicable warranty period Mettler Electronics Corp. will, at its discretion, either repair or replace the Product without charge. Cables, electrodes, the case and battery are not covered under this warranty. For service under this warranty, the Product must be returned by the buyer within the applicable warranty period to Mettler Electronics Corp. **Shipping charges to and from Mettler Electronics Corp. under this warranty must be paid by the buyer. The buyer must also include a copy of the sales receipt or other proof of the date of purchase. If the Product is returned without proof of the date of purchase, it will be serviced as an out–of–warranty product at Mettler Electronics Corp.'s prevailing service rates.**
Alteration, misuse, or neglect of the Product voids this warranty. Except as specifically set forth above, Mettler Electronics Corp. makes no warranties, express or implied, including without limitation any implied warranty of merchantability or fitness for a particular purpose, with respect to the Product. If any implied warranties apply as a matter of law, they are limited in duration to one year.
Mettler Electronics Corp. shall not be liable for any indirect, special,

consequential or incidental damages resulting from any defect in or use of the Product.
Any legal action brought by the buyer relating to this warranty must be commenced within one year from the date any claim arises and must be brought only in the state or federal courts located in Orange County, California.
Some states do not allow limitations on how long an implied warranty lasts, or the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to the buyer. This warranty gives the buyer specific legal rights, and the buyer may also have other rights which vary from state to state.

INDICATIONS AND CONTRAINDICATIONS

Read the operation manual before using the device.
Federal law (USA) restricts the sale of this device to, or on the order of a physician, dentist, veterinarian or any other practitioner licensed by law of the state in which he/she practices. Observe your practitioner's precise instructions and let him/her show you where to apply the electrodes. For a successful therapy, the correct application of electrodes is an important factor. Carefully write down the settings your medical practitioner recommended.

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 transcerebrally (through the head). The use of this unit whenever pain symptoms are undiagnosed, until etiology is determined.
- Do not use TENS whenever pain syndromes are undiagnosed, until etiology is established.

WARNINGS AND PRECAUTIONS

⚠ Warnings
- The device must be kept out of the reach of children.
- The safety of this 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 licensed medical practitioner.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.

⚠ Precautions/adverse Reactions

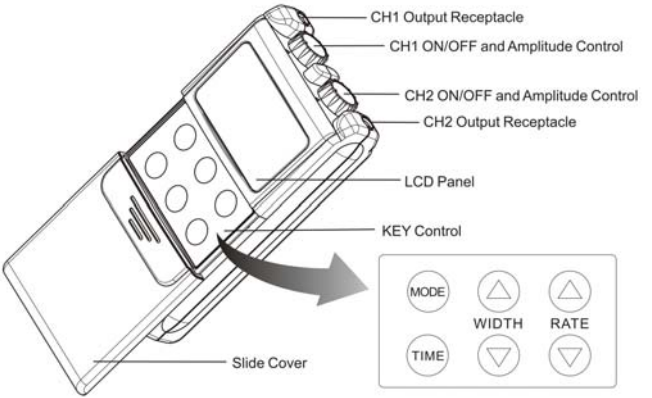
- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Stimulation should be stopped and electrodes removed until the cause of the irritation can be determined.
- Effectiveness is highly dependent upon patient selection by a person qualified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

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 cover prevents accidental changes in the settings during treatment.



THE DEVICE CONTROLS

Panel cover

A cover conceals the controls for Mode, Time, Width▲▼, 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 three modes are Burst (B), Continuous (C) and Modulation (M).

TIME

Treatment Time of device can be pre-selected or set with the Time key. There are three programs with fixed durations of 15, 30 and 60 minutes and one program of continuous output. Press the key until engaged in position desired.

15 min: 15 min symbol on.
30 min: 15, 30 min symbols on.
60 min: 15, 30 and 60 min symbols on.
Continuous: 15 and 30 min symbols on continuously and the 60 min symbol flashes.

WIDTH ▲▼

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

RATE ▲▼

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

ATTACHING THE LEAD WIRES

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

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

Note: Be careful when you plug and unplug the lead wires. Pulling on the lead wire instead of its insulated connectors may permanently damage the lead wire.

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

ELECTRODE SELECTION AND CARE

Your medical 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.

To avoid high current density, be sure to use electrodes that are no smaller than those provided with the TENS 212.

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, rinse well, and blot dry thoroughly prior to applying the electrode.
- 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 medical practitioner. 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.
- Do not use the electrode wire to remove the electrode from the skin. Peel it up from one of the edges of the electrode.
- 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 medical 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 medical 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 intensity to a comfortable level. Cease stimulation and contact your medical 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 replaced. 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 THE TENS 212

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.
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 occurs, 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 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 intensity:	Adjustable 0-80 mA peak into 500 Ω load each channel, constant current
Pulse Rate:	1Hz-160 Hz (adjustable), 1Hz/step (1-20 Hz), 5Hz/step (20-160 Hz)
Pulse Width:	50 μs – 260 μs (adjustable), 10 μs / step
Patient Compliance meter:	Shows the treatment times in hours.
Timer:	15, 30, 60 minutes and continuous mode
LCD:	Shows modes, pulse rate, pulse width, timer, CH1/CH2.

Function Modes:

B: Cycle Bursts, 2 Bursts / sec, 9pulses/Burst, 100 Hz, width is adjustable.

C: Continuous mode. Pulse rate, pulse width and intensity are 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, then returns to the setting value. Rate, width and intensity are fully adjustable.

Wave form: Asymmetrical Bi-phasic square pulse.

Voltage: 0-110 Volts (Open Circuit).

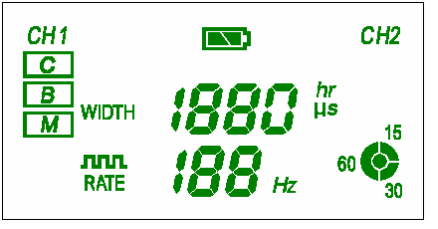
Max charge per pulse: 21 micro-coulombs

Power Source: 9-Volt Battery.

Dimensions: 108 mm(H) × 61.5 mm(W) × 25 mm(T).

Weight: 140 grams (battery included).

All electrical specifications are ±10% 500 Ω load.



Procedure for Setting the Compliance Meter *(Special For Clinician)*

When you want to see the compliance meter or reset it, follow the instructions below.

1. To enter the Compliance mode: First, switch the device off. Then, hold down the “Time” key as you turn on the TENS 212. If the “hr” symbol appears on the display, the device is now in doctor mode. If the “hr” symbol does not appear, turn the machine off and try again.
2. To see Compliance meter value: After you enter the Compliance mode, the patient compliance meter appears on the LCD with the ‘hr’ symbol.
3. To reset the compliance meter value: When you want to reset the compliance meter value for a new treatment cycle, follow the steps listed below:
   When you are in the Compliance mode, first press and release the ‘MODE’ key. Then press and release the ‘Rate ▼’ key. This will reset the treatment time hours to zero.
4. To exit the Compliance mode: Turn off the unit. The next time you turn it on it will be in the normal treatment mode.
5. User mode: Just turn on the unit without holding any keys, then you are in the treatment mode.

Printed in Taiwan IR9-54