



plus24

SM TENS & PMS

User's Manual

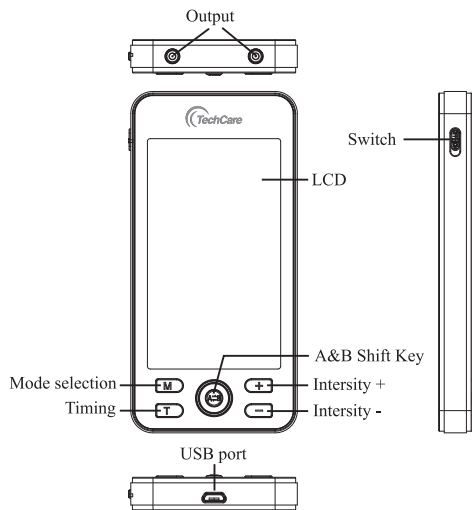


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Please read the user's manual carefully before
using the product

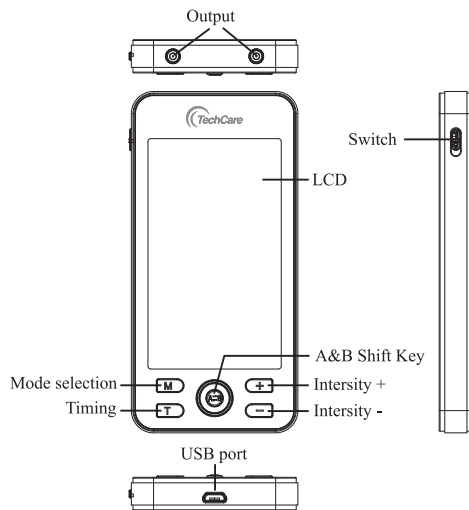
Instructions

1. Connect the wire to the machine.
2. Connect the pads to the wire.
3. Place both pads on the area you would like to use it on.
4. Both pads must be attached to the body for the machine to work.
5. Turn the machine on.
6. Upon turning the machine on, make sure to increase the strength to make the unit work.



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I. Foreword

Before operation, please read this user's manual carefully, and be clear about the instructions.

General Description of the Device

SM TENS&PMS has 24 operation modes, which can give certain electrical pulses through electrode adhesive pads to the suggested area of the body where the electrodes are placed.

The electronic stimulatory module has the operating elements of an ON/OFF Switch, Display screen, Mode Selection key, Intensity Modification keys, A&B Shift keys, Timing key, Output socket, and USB port for battery charging. The display screen can show battery power, selected mode, current intensity, time remaining of an application mode, and indication of a pause

The device is equipped with accessories of electrode pads, electrode cables, a battery charger, and one USB cable. The electrode cables are used to connect the pads to the device; the USB cable is used to connect the charger and the built-in lithium battery. All accessories, including USB cables, electrode pads, electrode cables, chargers can only be changed or replaced by a qualified person.

The electrodes are interchangeable. The application area of electrode pads must be larger than the smaller electrode pads.

Included in this package:

- * 1 controller
- * 2 pairs of electrodes [510(k) cleared]
- * 2 output electrode cables
- * 1 USB cable
- * 1 charger
- * 1 User's manual
- * 1 plastic holder

Your Name



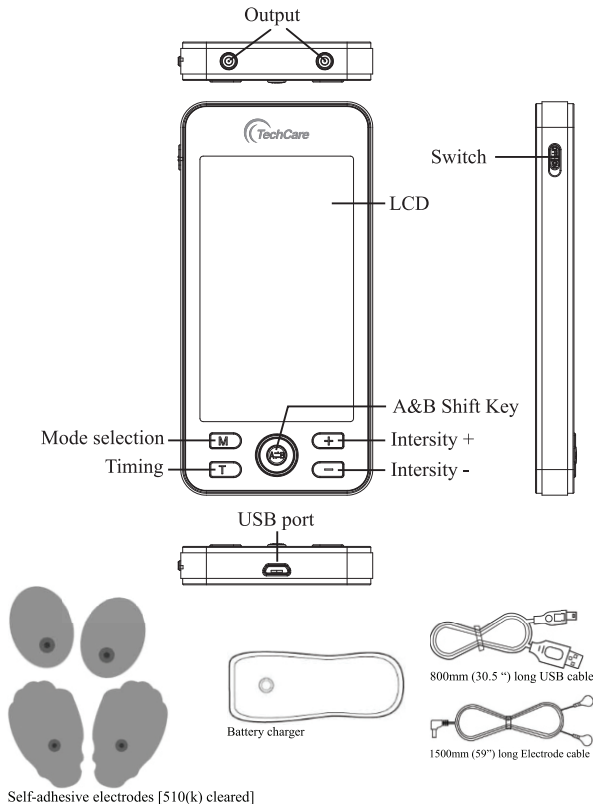
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7. Adverse Reactions

- 1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
- 2) Patients may experience headache and other painful sensations during or following the application of electrical stimulation.
- 3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

Tips:

Dear customers, in order to keep the stability of the machine, we suggest you charging it in every 3 months, even you don't use it, thank you !!

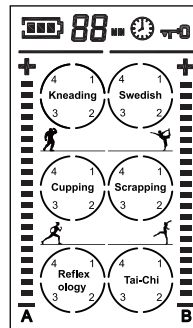
II. User manual

1. Description of the Device

1.1 Features

- * A large, easy to read LCD display
- * Adjustable timer
- * 24 Modes
- * Rechargeable lithium battery

1.2 Mode Description



We suggested that you initially experiment using each of the 24 modes. The mode that gives you the most desirable sensations and comfort is the most appropriate one to use for your current condition.

- 1) Intensity should be set at a level where you will feel some muscular vibration and involuntary muscle movements. It should be set to give a comfortable feeling and should not be painful.
- 2) Timing of application should be at least 10 to 20 minutes.
- 3) Frequency of the application should be at least one to three times per day.

2. General Operation Guidance

- 1) The SM TENS&PMS unit needs to be charged for up to 10 hours before the first use.
- 2) Connect the electrode cables to the output sockets at the top of the unit.
- 3) Connect the pads to the cables by snapping them on.
- 4) Use a damp towel to wipe the skin where you intend to put the pads, so as to remove any body oil, cosmetic or dirt. Remove the protective film and place the pads on the area making sure that both pads are on the skin and not overlapping.
Warning: To avoid an electrical short, never put two electrode pads together.
- 5) Turn on the unit by sliding the On/Off switch from Off to On.
Warning: Do not move pads or touch them with your hands during use, it may cause strong stimulation.
- 6) When you have turned on the unit, the LCD display will automatically show Mode 1. The “T” (Timer) will automatically choose the time duration of 20 minutes.
- 7) To change the modes, press the M (Mode) button. When the A letter in the LCD flashes, increase the intensity of A channel by pressing the + button and decrease the intensity by pressing – button. If you want to adjust the intensity of B channel, press the A=B shift key, the B letter in the LCD will flash. Repeat the same as above. The + / - button could control relative intensity of two output. The chosen power output depends on your comfort level. At the precondition of acceptance, the intensity should be chosen as high as possible for the best effect but still feel comfortable.
- 8) To set the time of use, press the T button. The auto time set is 20 minutes. Each press of the T button increases the time by 10 minutes. After the time runs out the device turns off automatically, and it can be restarted if treatment is needed to be continued. To lock the screen, long press the T button.
- 9) Sit back and enjoy the deep soothing sensations!

Notes: The SM TENS&PMS unit is very safe, the output intensity increases only by pushing the + key. Even if the intensity is increased to the maximum, it is within the safe range, but may feel uncomfortable. When the user switches the mode, the intensity will automatically go down to the minimum for safety reasons.

5. Precautions

- 1) Safety of powered muscle stimulator for use during pregnancy has not been established.
- 2) Caution should be used for patients with suspected or diagnosed heart problems.
- 3) Caution should be used for patients with suspected or diagnosed epilepsy
- 4) Caution should be used in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;
 - b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus;
 - d. Over areas of the skin which lack normal sensation.
- 5) 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.
- 6) Electrode placement and stimulation settings should be based in the guidance of the prescribing practitioner.
- 7) Power muscle stimulators should be kept out of the reach of children.
- 8) Power muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- 9) Portable power 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.

5. Precautions

- 1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- 2) Do not use this device on patients whose pain syndromes are undiagnosed.
- 3) Do not use this device during pregnancy.
- 4) Do not use this device on babies or infants who cannot express themselves.

* Refer to the user manual of the pads manufacturer (510K092546), or reference to the following suggestions:

1) Unplug the output cord from the output jack of the controller after each use. Cover both pads with the protective film before storage. Never fold the electrode pads.

2) Between uses, store the electrodes in the reusable bag in a shady place. Stockroom temperature: +5°C~+27°C (41-80°F) and humidity of 30%~80%. No need to sterilize.

3) Never apply the pads to any other surface other than your skin. If the pads become soiled or dirty, the adhesive power may decrease. In this case, moisten the surface of the pads with water and wipe away the dirty portion. This will allow a temporary restoration of the adhesive power. However, too much water will result in loss of the adhesive power.

4) The life of the electrodes varies depending on skin conditions, storage, amount of use, type of stimulation, and stimulation site. Electrode life may be extended by carefully following this Instruction for Use. The expired electrodes are to be recycled and do not harm environment.

Warning: The electrodes are intended for single patient use only!

4. Warnings

- 1) The long-term effects of chronic electrical stimulation are unknown.
- 2) Do not use stimulation over the main arteries around your neck.
- 3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- 4) Do not apply stimulation directly to the heart area across the chest or on the chest.
- 5) Do not use stimulation on your head or across your head.
- 6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins.
- 7) Do not use stimulation over, or in proximity to, cancerous lesions.
- 8) Do not use stimulation when charging the device.

10) There are six icons on the screen, press "M" button to change the six icons. Each icon contains different built-in modes, such as 1.2.3.4
11) If you need to turn off the device during stimulation, slide the On/Off switch to "OFF".

12) Before storing the TENS use the protective film to cover the electrode pads.

Notes:

- ① Never connects this product with a common headphone.
- ② Please do not touch the USB port when using the device. The USB port is only used to connect the charger, do not connect other devices.
- ③ The charger supplied by the manufacturer must in compliance with IEC/EN 60601-1, the use of unauthorized chargers can impair the safety.
- ④ The battery needs to be charged for up to 10 hours before the first use.

3. Cleaning and maintenance

A. For the control unit:

- 1) To keep the controller clean, use a soft and dry cloth for dust or a soft damp cloth for any dirt and smudges. Do not use any cleaning solutions to clean the controller and its pads.
- 2) Do not use or store the device where there are magnetic fields or electric waves (near TV set or speakers).
- 3) Do not place the devices in areas of high temperature, high humidity, or under direct sunlight.
- 4) Keep the device out of reach of children.
- 5) All worn accessories should be disposed of according to your local regulations.