

TENS & EMS & PMS

TENS XS MAX



Indications for Use

TENS (1,2,3,4,5,6,7,8,9,10,11,12):

To be used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

EMS (13,14,15,16,17,18,19,20,21,22,23,24):

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

PMS (25,26,27,28,29,30,31,32,33,34,35,36):

PMS is a hybrid mode of TENS and EMS.



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

2024-08-10 V1.0

Section 11.1
Proposed Labeling

[As required by 21 CFR 807.87(e)]

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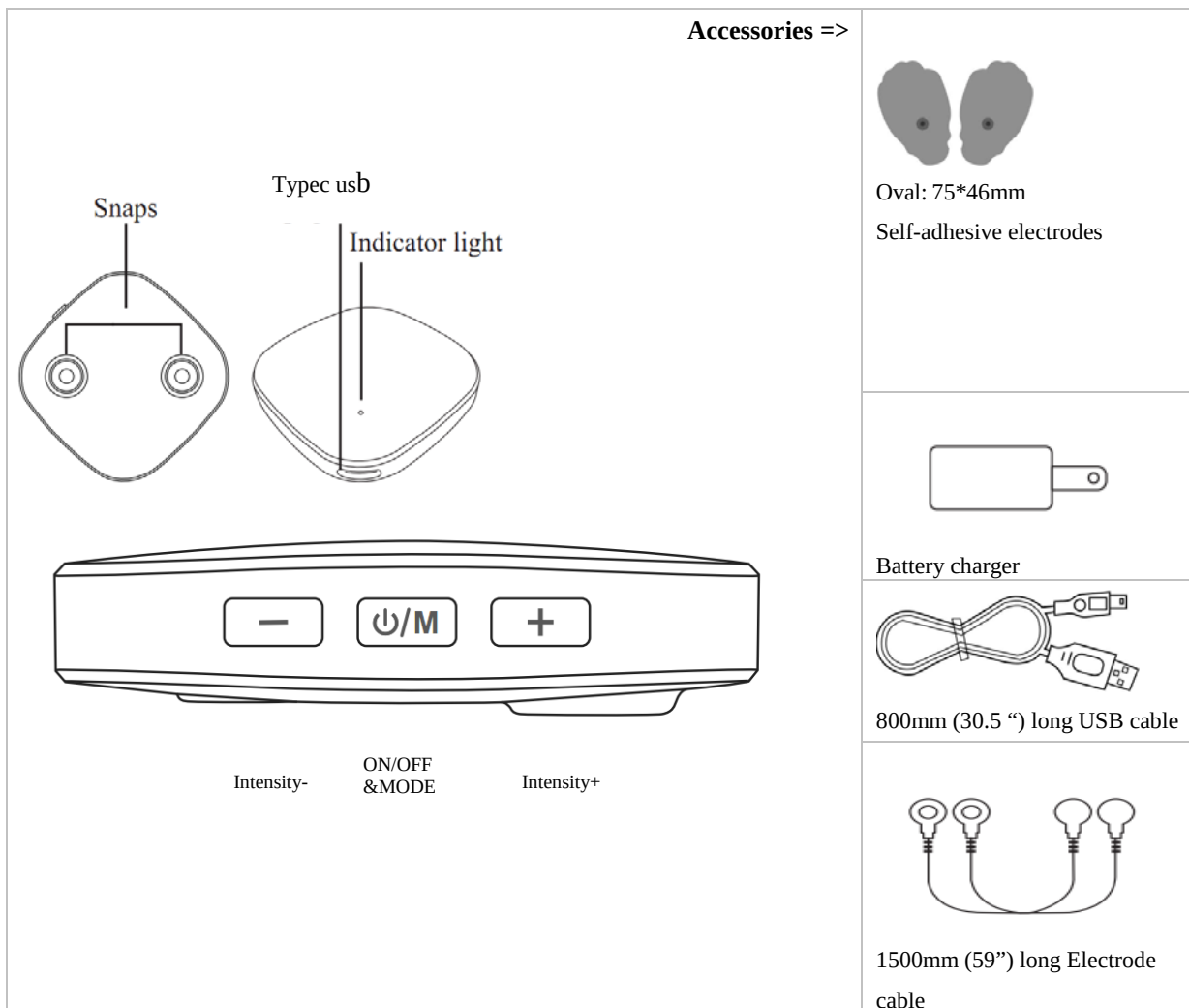
I. Foreword

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

Five key points for operations:

- 1) This device is intended for use on healthy skin.
- 2) The electrode pads are for single patient use.
- 3) Intensity is based upon your level of comfort.
- 4) Begin the first session with a low intensity and a short duration while learning how to operate.
- 5) If you feel pain, dizziness, or discomfort, call your physician.

Structure and Accessories:



Included in this package:

- * 1 controller
- * 2 pairs of electrodes [K181234] 2 output electrode cables
- * 1 USB cable
- * 1 charger Model: XY-1304-5V2A Input:100-240V-50/60Hz 0.35A Output:5.0V-2A
Store and transport ambient temperature: -20°C~55°C (4° -131° F), ≤93%RH, 700hPa~1060hPa
- * 1 User's manual

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II. Description of the Device

1. General Description of the Device

TENS XS MAX TENS & EMS is a portable and DC 3.7V battery powered multifunction device, offering both Transcutaneous Electrical Nerve Stimulation (TENS) and Powered Muscle Stimulation (EMS) qualities in one device.

TENS XS MAX TENS & EMS has 36 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/M Switch, Intensity Modification keys, Output socket, and USB port for battery charging.

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 12cm². The electrode pads are manufactured by SHENZHEN SINREL TECH LTD with 510(k) cleared Number K181234.

2. Definition of Contraindication, Warning and Precaution

Terminology	Meaning
Contraindication:	A contraindication indicates a situation in which the device should not be used.
Warning:	A warning indicates a situation which, if not avoided, could result in death or serious injury.
Precaution:	A precaution indicates a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment of other property.

2.1 Contraindication

- 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) **TENS ONLY:** Do not use this device on patients whose pain syndromes are undiagnosed.

2.2 Warnings

- 1) Use stimulation only to normal, intact, healthy, clean and dry skin.

The use of accessories and cables other than those specified by Yuehua Linrui, with the exception of cables sold by Yuehua Xinsen as replacement parts for internal components, may result in increased emission or decreased immunity of the device and unsafe.

It will take 1 hour to resume normal operation when the equipment is transferred from the lowest storage environment temperature to 20°C environment temperature.

It will take 1 hour to resume normal operation when the equipment is transferred from the highest storage environment temperature to 20°C environment temperature.

Simultaneous connection of a PATIENT to a high frequency surgical ME EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR;

Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output;

Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.

- 2) Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- 3) Do not apply stimulation front or over the neck because this could cause severe muscle spasms resulting in airway closure,

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difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

4) Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause heart rhythm disturbances, which could be lethal.

5) Do not use stimulation over, or in proximity to, cancerous lesions.

6) Avoid placing the pads over metal implants.

7) Do not use stimulation when charging the device, patients or those nearby may receive serious injury during fault.

8) Do not use stimulation while sleeping, swimming.

9) To consult your doctor before use if you have recently given birth, had an IUD fitted, or have heavy periods.

10) Do not use if wearing the device necessitates placement over areas at which drugs/medicines are administered (short-term or long-term) by injection (e.g. hormone treatment).

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- 11) Do not use if you have recently undergone a surgical procedure.
- 12) Do not use in case of critical ischemia of the limbs.
- 13) Do not use this device on children.
- 14) Do not bring the device into any MRI, CT, diathermy, RFID and electromagnetic security systems such as metal detectors environment or near any of this equipment.
- 15) No modification of this equipment is allowed.
- 16) Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- 17) Do not apply stimulation when in the bath, shower or a moist environment.
- 18) Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation may lead to risk of injury;
- 19) Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- 20) Consult your Physician before using the device if any of the following conditions apply to you:
 - If you have any serious illness or injury not mentioned in this guide.
 - If you take insulin for diabetes.
 - If you use the unit as part of a rehabilitation program.
- 21) Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.
- 22) The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation and recording; The size, shape, and type of electrodes may affect the safety and effectiveness of electrical stimulation and recording;
- 23) Do not use electrodes with other persons because of risks of adverse skin reactions and disease transmission.
- 24) Do not service or maintain while in use with the patient.
- 25) Only the patient is an intended operator, this equipment shall be only operated by patient himself
- 26) Only use for conscious people.
- 27) Do not touch the charging port while in use.
- 28) Simultaneous connection of a PATIENT to a high frequency surgical the EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
- 29) Operation in close proximity (e.g 1m) to a shortwave or microwave therapy the EQUIPMENT may produce instability in the STIMULATOR output.
- 30) Application of electrodes near the thorax may increase the risk of cardiac fibrillation. For the EQUIPMENT capable of delivering output values in excess of 10 mA or 10 V: Information on maximum output values available at the electrodes recommended by the manufacturer for use with the STIMULATOR.
- 31) Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.

2.3 Precautions

- 1) The long-term effects of electrical stimulation are unknown;
- 2) Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head;
- 3) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel). If this occurs, stop using your device and consult your physician;
- 4) Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians; and
- 5) Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- 6) Read User Manual before using this device for the first time. Keep this manual available whenever you use your Device.
- 7) The Device is intended for personal use on adult healthy skin only.

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- 8) Do not use the device 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.
- 9) Do not use the stimulator during pregnancy. Safety of the use during pregnancy has not been established.
- 10) The device 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.
- 11) Do not place pads over jewelry or body piercings.
- 12) The device should be used only with the leads and electrodes recommended by the manufacturer.
- 13) Never apply the pads to your skin with the power on, which will result in sudden shock. If during application, you want to move the pads to another body part, please pause the program currently running or shut down the device first, and then move

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the pads to the place that you want to stimulate.

14) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical short, do not connect two pads to each other.

15) Do not apply pads to the same spot for over 60 minutes at a time.

16) Do not use the product in the condition of air mixed with flammable gases.

17) Never use this product near a microwave oven, or other high frequency surgical equipment.

19) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

20) To reposition or remove the pads, always pause the program currently running or power off the device.

21) The device should be kept out of the reach of children.

22) Use 510k cleared and compatible electrodes recommended by the manufacturer; other electrodes may present a risk of unsuitable electrical characteristics with your stimulator.

23) Do not plunge the pads into water.

24) Do not apply solvents of any kind to the pads.

25) Wash skin thoroughly, and then dry it before applying the electrodes.

26) Apply the whole surface of the pads firmly to the skin. Do not use pads which do not adhere properly to the skin.

27) Stop using your unit if you are feeling light headed or faint. Consult physician if this happens.

28) You should also check that the conductive adhesive portion of the electrode has not dried out and check to see that it is still sticky and holds the electrodes firmly on the skin. If the conductive adhesive portion has become dry, the electrode should be replaced.

29) Minor redness at stimulation placement is a normal skin reaction. It is not considered a skin irritation, and it will normally disappear within 30 minutes after the electrodes are removed. If the redness does not disappear after 30 minutes from the removal of electrodes, do not use the stimulator again until after the excessive redness has disappeared.

30) Contact the manufacturer of the electrical stimulator or recording device if you do not know if the electrode can be used with the stimulation or recording device.

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TENS ONLY:

- 1) TENS is not effective for pain of central origin, including headache;
- 2) TENS is not a substitute for pain medications and other pain management therapies;
- 3) TENS devices have no curative value;
- 4) TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;

PMS ONLY:

- 1) The effectiveness of the Device depends greatly on a person's individual physical condition. It may not always be effective for every user.
- 2) Start all sessions in a sitting position (fig. a). If necessary, secure the limb(s) to be exercised before using this device.

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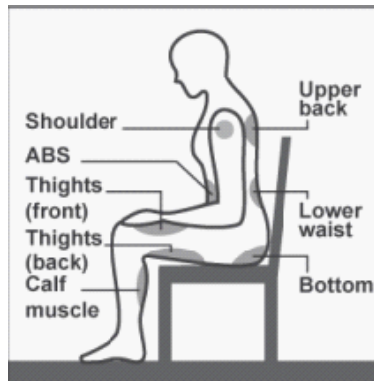


Figure a

2.4 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 near the eyes and to the head and face.
- 3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

3. Features and Essential performance

- * A easy to read LED display
- * Adjustable timer: 10~60 minutes
- * Strength level adjustment: 20 grades
- * Multiple program selection: 36 programs
- * Rechargeable lithium battery: DC 3.7V
- * Wide voltage design: AC 100-240V 50/60Hz
- * Output stability: The value of pulse duration, frequency do not deviate by more than $\pm 10\%$ and the amplitudes does not deviate by more than $\pm 20\%$ with a load resistance of 500Ohm.

4. Unit description

A. Turn on/off the Device

▲Note: Do not turn on the unit until all electrode pads and lead wires are properly attached.

- 1) Press the On/Off switch for three seconds, the LED lights up and the device turns on. Press the On/Off switch for three seconds again, the display goes blank and the device turns off.
- 2) The device will turn off automatically after the cure time has elapsed.
- 3) In an emergency you may also pull the connector(s) of lead wire from the device to remove the electrode pads.

▲Note: To prevent unpleasant electric shocks, never remove the pads while it is still turned on.

B. Display

The LED screen displays output program, intensity level, output channel, battery power and timer. You can short press On/Off/M key to select programs. The default value of TENS XS MAX is Program 1, Intensity 00, Timer 20min.

▲Note: We recommend the first time users to select program 1 at a low Intensity level to treat for 10 minutes per day, and then gradually up to 3 times a day. After a period of adaptation, you can use other programs and increase cure time and intensity.

*Program

The TENS XS MAX offers in totally 36 different preset treatment programs. All parameters are pre-programmed, except for the intensity and cure time.

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Short press On/Off/M key to select programs. Once you select a program, the corresponding program icon flashes every 500 milliseconds. **Note:** Please refer to chapter 3 “**User Instruction**” to learn how to choose the right treatment program and time.

**Intensity*

Once you select a program, gradually increase the intensity by pressing the “+” button, or decrease the intensity by pressing the “-” button, until you get the desired intensity level. There are twenty small black squares for intensity level, each of which represents one levels of intensity.

▲Note: If you change a program during this treatment, the intensity level will revert to the default value of “00” to protect your safety.

▲Note: You will feel the intensity increase or decrease as you select the intensity level. You can use this as a guide to select a level that is comfortable for you. At the precondition of acceptance, the intensity should be chosen as high as possible for the best effect but still feel comfortable.

**Timer*

The default power-on interval is 20 minutes. After the time runs out, the device will turn off automatically.

▲Note: If you change programs during the course of a therapy session, the treatment time will not reset unless you manually reset it by performing the steps described above.

**Battery power*

C. When the battery is low on power, the red led light flashes to indicate.

D. Connection of the electrode pads

Warning: To avoid an electrical short, never put two electrode pads together.

Precautions:

- Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical short, do not connect two pads to each other.

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- Do not apply pads to the same spot for over 60 minutes at a time.
- To reposition or remove the pads, always pause the program currently running or power off the device.
- Use 510k cleared and compatible electrodes recommended by the manufacturer; other electrodes may present a risk of unsuitable electrical characteristics with your stimulator.
- Apply the whole surface of the pads firmly to the skin. Do not use pads which do not adhere properly to the skin.
- You should also check that the conductive adhesive portion of the electrode has not dried out and check to see that it is still sticky and holds the electrodes firmly on the skin. If the conductive adhesive portion has become dry, the electrode should be replaced.

1) Choose one or two output port, connect the electrode cables with female socket to the output ports at the bottom of the unit.



2) Connect the electrode cables with snap button to the electrode pads before applying them to the Skin.



3) Remove the protective plastic shields from the electrode pads before placing the pads onto your skin.

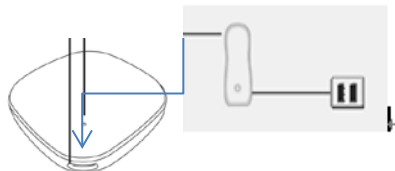
5. Charging the Battery

1) The Lithium battery can be recharged through only AC adaptor. Do not connect charging adaptor to a computer because the cybersecurity of the device has not been confirmed.

2) When the red **led** light flashes to indicate, it indicates that the battery needs to charge. Turn off the unit.

3) Connect the unit and the charger with USB extension cord. Plug charger into any power outlet, a green light shows that it is charging. The charging process will last approximately 3 hours. When charging is finished, the LCD will show a full battery cell.

4) The battery should be charged for 10 hours or so before first use. Only charge the device when battery is completely drained the first 2 times.



▲ Note:

- 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 Only use a charger that has been obtained from the manufacturer of the TENS XS MAX TENS & EMS device.

6. Program Parameter

We suggested that you initially experiment using each of the 36 programs. The program that gives you the most desirable sensations and comfort is the most appropriate one to use for your current condition.

Program	Pulse width	Frequency	Max. amplitude	TENS	EMS
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Program 1	140us	34.25Hz	36V	√	
Program 2	140us	9.25Hz	35V	√	
Program 3	140us	5.34Hz	35V	√	
Program 4	140us	104.4Hz	36V	√	
Program 5	140us	11.327Hz	35V	√	
Program 6	140us	5.982Hz	35V	√	
Program 7	140us	51.857Hz	36V	√	
Program 8	140us	10.18Hz	35V	√	
Program 9	140us	5.64Hz	35V	√	
Program 10	140us	25.60Hz	35V	√	
Program 11	140us	8.48Hz	35V	√	
Program 12	140us	5.07Hz	35V	√	
Program 13	240us	4.62Hz	30V		√
Program 14	240us	3.38Hz	30V		√
Program 15	240us	2.66Hz	31V		√
Program 16	240us	20.37Hz	30V		√
Program 17	240us	7.8Hz	30V		√
Program 18	240us	4.84Hz	30V		√
Program 19	240us	14.4Hz	30V		√
Program 20	240us	6.77Hz	30V		√
Program 21	240us	4.425Hz	30V		√
Program 22	240us	4.05Hz	30V		√
Program 23	240us	3.086Hz	30V		√
Program 24	240us	2.47Hz	31V		√
Program 25	200us	18.86Hz	33V	√	√
Program 26	200us	7.58Hz	33V	√	√
Program 27	200us	4.756Hz	33V	√	√
Program 28	200us	11.82Hz	33V	√	√
Program 29	200us	6.12Hz	33V	√	√
Program 30	200us	4.12Hz	33V	√	√
Program 31	200us	8.33Hz	33V	√	√
Program 32	200us	5.02Hz	33V	√	√
Program 33	200us	3.596Hz	33V	√	√
Program 34	200us	6.19Hz	33V	√	√
Program 35	200us	4.17Hz	33V	√	√
Program 36	200us	3.14Hz	33V	√	√

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III. User Instruction
*** Section 1 - For TENS purpose ***

1.1 Indications for Use

The TENS function of TENS XS MAX TENS & PMS is to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. Choose **program 1,2,3,4,5,6,7,8,9,10,11,12..**

Software version: TENS XS MAX _v11.hex

1.2 Direction for Use

1.2.1 Preparing the Skin for Running a Session

Proper preparation of the skin covered by the electrodes allows more stimulation to reach targeted tissues, prolongs electrode life, and reduces the risk of skin irritation. After connecting the lead wire(s) to the stimulator, use the following steps to prepare your skin at the electrode placement sites:

- 1) Determine the placement sites for the electrode pads (Refer to “**1.2.2 Regular TENS Application principles**” and “**1.2.3 Regular TENS Application Methods**”).
- 2) Wash the area with mild soap and water (do not use alcohol). Rinse and dry thoroughly.
- 3) When removing electrodes, always remove by pulling in the direction of hair growth.
- 4) It may be helpful to apply skin lotion on electrode placement area when not wearing electrodes.

1.2.2 Regular TENS Application principles

1) Find the exact pain point or the area where the muscles ache most. For best relief of pain, place the electrode pair from one channel on either side of the pain. (See Figure 1: Twin mode) or you may place one electrode on the painful site and the other near the site of pain.

2) Intensity: The intensity can be gradually increased up to the point when it becomes uncomfortable. Always stay below that point of discomfort.

3) Recommended application duration and program selection:

For first time user, choose program 1 at a low Intensity level to treat for 10 minutes per day, and then gradually up to 3 times a day. You may increase the intensity and time after you have become familiar with the device and the feel for the stimulation. Stay with program 1 for a few days before trying any of the other programs and intensity settings.

It is difficult to recommend a particular program for a specific type of pain and it is usually determined by the user’s feel of relief. However, if you do not feel any relief of pain after having tried different modes and intensities for a period, it is recommended that you consult with your physician.

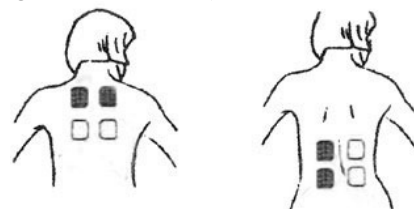
4) If the stimulation sensation becomes weaker or disappears, you may increase the intensity by pressing the up key (+) to a point when the stimulation becomes uncomfortable, but if the sensation does become uncomfortable, press the down key (-) to decrease the intensity. **Always stay under the point of discomfort!**

5) If you experience an adverse reaction (skin irritation/redness/burns /other painful sensation), or if you feel unusual discomfort, stop using the device immediately and consult with your physician.

6) There are two ways to place the pads, in twin or opposed modes.

Fix the two pads from **one** channel on either side of the pain area, or one electrode on the painful site and the other near the site of pain, but on the same side of body. If you want to use **both** channels at the same time, make sure that the second pair of electrodes is also fixed near the side of pain on the same side of the body (right under or over the first pair)

Figure 1: Twin mode (this is the correct mode)



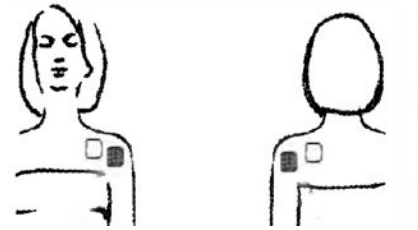
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Fixing the two or four pads respectively on the opposite sides of the body is not recommended and provides little benefit.

Figure 2: Opposed mode (not recommended)



1.2.3 Regular **TENS** Application Methods

Use the device for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

Users can choose **program 1,2,3,4,5,6,7,8,9,10,11,12.** for temporary relief of pain.

* Many people experience immediate relief from muscle pain, while others require several days of regular use to feel the benefits. The results vary and will depend upon your underlying conditions and how often you use the device. However, if you do not feel any relief of pain after having tried different modes and intensities for a period, it is recommended that you consult with your physician.

▲Note: Over-long time treatment and strong stimulation may cause muscular fatigue and may generate adverse effects. In order to avoid excessive treatment, make sure that at the beginning select short time (10 minutes) and low intensity to treat for a period, and gradually increase time and intensity after you adapt to the stimulation, but never exceed your comfort level. However, each treatment should last less than 60 minutes with at least 2 hours of rest between each use.

▲Note: The charts below are merely a suggestion for how to place the electrodes, what program to choose and how long to stimulate, but only after the user has gone through the starting procedure and is familiar with the device.

Depending on your feeling or objective, you may select the appropriate program combination for treatment.

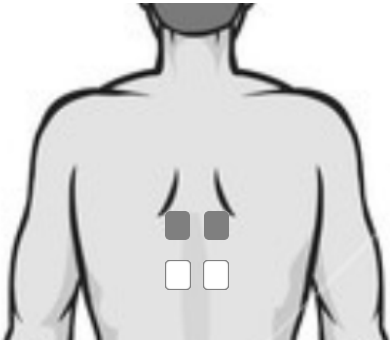
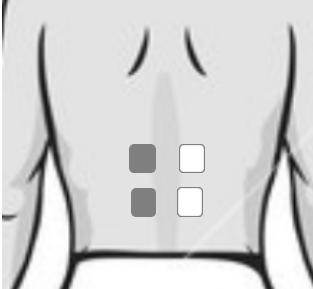
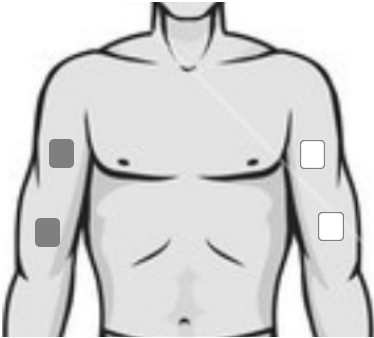
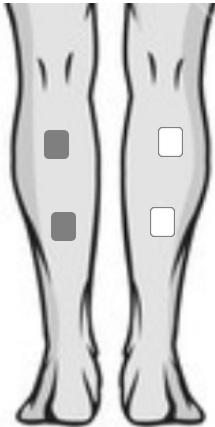
KEY: ■ ■ = electrode pads from one channel; □ □ = electrode pads from the other channel

● Pain in Neck		Use one or both channels, position the electrode pads at the back of the neck and over the top of the shoulders. Warning: never place pads on the side or front of the neck. Program 1 for 20-40 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use. * Keep the neck warm and avoid sleeping on a high pillow.
● Pain in shoulders		Using one or both channels, place pads on the front and back of the shoulder. Warning: do not place pads on the side or front of the neck. Program 4 for 20-40 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use. * Find the pain area and apply the electrodes at the anterior and posterior (inner & outer) shoulders. * Keep the area warm. Avoid sudden movements with the aching shoulders, gentle movements are advisable in the initial stage and full motions at a later stage.

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● Pain in Back		Using one or both channels, position pads on either side of the spine, covering area of pain. Program 5 for 20-40 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use. * Apply the electrodes to the pain area. * Avoid working in the same position in the initial phase and change the position at times.
● Pain in Waist		Using one or both channels, position electrode pads on either side of the spine at the site of the pain. Program 6 for 20-40 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.
● Pain in upper extremities (arm)		Attach the Pads to upper and lower arm. Program 3 for 20-40 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.
● Pain in lower extremities (leg)		Attach the Pads to upper and lower calf. Program 21 for 20-40 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.

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* Section 2 - For EMS purpose *

2.1 Indications for Use

The EMS function of TENS XS MAX TENS & EMS is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance. Choose **program13,14,15,16,17,18,19,20,21,22,,23,24.**

2.2 Direction for Use

2.2.1 Preparing the Skin for Running a Session

Proper preparation of the skin covered by the electrodes allows more stimulation to reach targeted tissues, prolongs electrode life, and reduces the risk of skin irritation. After connecting the lead wire(s) to the stimulator, use the following steps to prepare your skin at the electrode placement sites:

- 1) Determine the placement sites for the electrodes (Refer to “2.2.2 Regular EMS Application principles” and “2.2.3 Regular EMS Application Methods”).
- 2) Wash the area with mild soap and water (do not use alcohol). Rinse and dry thoroughly.
- 3) When removing electrodes, always remove by pulling in the direction of hair growth.
- 4) It may be helpful to apply skin lotion on electrode placement area when not wearing electrodes.

2.2.2 Regular **EMS** Application principles

- 1) Identify the targeted muscle which needs to be stimulated. In order to improve or facilitate muscle performance, place the two electrodes from one channel on opposite ends of the muscle or close to the belly of the muscle. (See Figure b)

If you like to work with both channels at the same time you may place the second electrode pair near the first pair or onto another muscle to be stimulated like the biceps on the opposite arm in Fig b below.

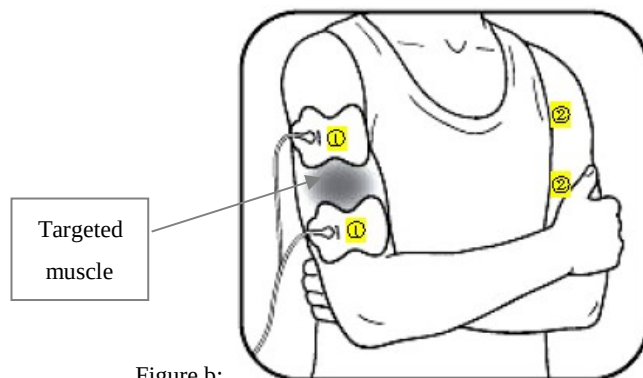


Figure b:

- 2) Intensity: The intensity can be gradually increased up to the point when it becomes uncomfortable. Always stay below that point of discomfort.
- 3) Recommended application duration and program selection:
For first time user, choose program 2 at a low Intensity level to treat for 10 minutes per day, and then gradually up to 3 times a day. You may increase the intensity and time after you have become familiar with the device and the feel for the stimulation. Stay with program 2 for a few days before trying any of the other Modes and intensity settings.
- 4) If the stimulation sensation becomes weaker or disappears, you may increase the intensity by pressing the up key (+) to a point when the stimulation becomes uncomfortable, but if the sensation does become uncomfortable, press the down key (-) to decrease the intensity. **Always stay under the point of discomfort!**
- 5) If after a period of muscle training, you do not achieve any benefit for muscle performance after having tried different modes and intensities, it is recommended that you consult with your physician.
- 6) If you experience an adverse reaction (skin irritation/redness/burns/other painful sensation), or if you feel unusual discomfort, stop using the device immediately and consult with your physician.

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7) Muscle training can be done everyday using alternate muscle groups every other day. The muscles can be stimulated 20-40 minutes per workout per muscle group. The abdominal muscles and calve muscles can be trained every day.

2.2.3 Regular **EMS** Application Methods

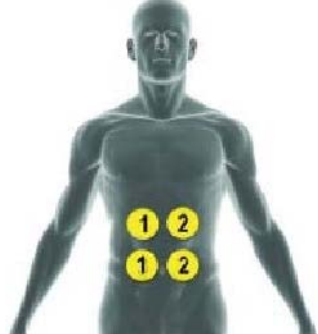
You can use the electrode adhesive pads on almost every muscle and joint area on your body. Please note that this device is intended to stimulate **healthy** muscles in order to improve or facilitate muscle performance. It is not intended as therapy for any medical condition.

Users can choose **program 2, 7-20, 22-24** to stimulate the following points to quickly facilitate muscle performance. In order to better improve the muscle performance, you may increase the intensity gradually to a level which is still comfortable and does not cause pain or discomfort. Furthermore, you should use the device regularly to maintain the benefit you may have gained during exercise.

▲Note: The charts below are merely a suggestion for how to place the electrodes, what program to choose and how long to stimulate, only after the user has gone through the starting procedure (above) and is familiar with the device.

Depending on your feeling or objective, you may select the appropriate program combination for muscle exercise. However, each workout should last **less than 60 minutes**, and the interval between two workouts should be longer than 12 hours. Since the strength programs deliver a training load, recovery is important to ensure that the body's capacity to absorb another workout is large.

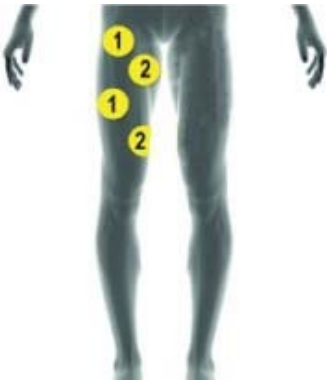
KEY: The number 1 pair of pads goes with one channel and the number 2 pair goes with the other channel.

(1) The Abdominals		<i>Follow the pad placement shown in the Chart. Make sure there is about a 1/4 inch gap between the electrode pads. This requires 2 pair of pads.</i> program 13 for 10-20 minutes, program 14 for 10-20 minutes; Frequency: once per day.
(2) The Biceps and Forearms		<i>Follow the pad placement diagram. The pads should be placed on the thickest part of the muscle towards the top of the arm about 1/4 inch between the pads where they come close to each other. This exercise will require 2 pair of pads for the biceps or 2 pair of pads for the forearms.</i> program 15 for 10-20 minutes, program 16 for 10-20 minutes; Frequency: 3 to 4 times per week.

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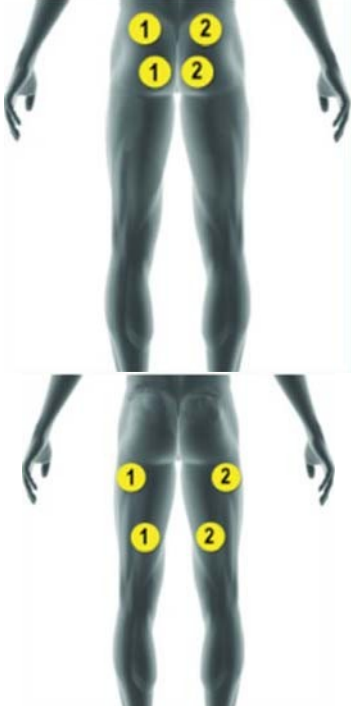
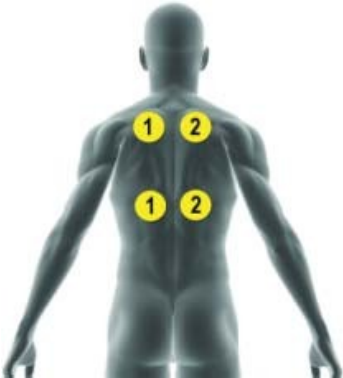
[As required by 21 CFR 807.87(e)]

(3) The Triceps		<i>Extend your arm downward with the palm of your hand facing towards the back. Draw an imaginary line from the center of your elbow to the top of the shoulder. Place one of the small pads on one side of the imaginary line and the other small pad on the opposite side. Make sure there is about a 1/4 inch gap between the pads.</i> program 15 for 10-20 minutes, program 16 for 10-20 minutes Frequency: 3 to 4 times per week.
(4) The Laterals		<i>Place the pads one above the other on each side of the diagram as shown. Pads should be slightly towards the front. Leave 1/4 inch space between pads. This requires 2 pair of pads.</i> program 17 for 10-20 minutes, program 18 for 10-20 minutes; Frequency: 3 to 4 times per week.
(5) The Front and Inner Thighs		<i>Follow the pad placement as shown in the diagram. Leave 1/4 inch gap between pads. This will require 2 pair of pads. Repeat the process for the left side.</i> program 19 for 10-20 minutes, program 20 for 10-20 minutes; Frequency: 3 to 4 times per week.
(6) The Calves		<i>Place the pads over the largest part of the muscles slightly towards the back of the leg so that the pads come closer together in the back. Leave 1/4 inch gap between pads. This requires 2 pair of pads.</i> program 21 for 10-20 minutes, program 22 for 10-20 minutes; Frequency: once per day.

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(7) The Back (including Trapezes or Shoulders and Deltoids or Upper Laterals)		<i>Follow pad placement diagram. The 2 pads from one channel should keep 1/4 inch gap inch from each other. The pad near the centerline, should keep 1 inch space from the centerline of the back.</i> <i>This requires 2 pair of pads.</i> Program 21 for 10-20 minutes, program 22 for 10-20 minutes; Frequency: 3 to 4 times per week.
(8) The Buttocks and Back Thighs		<i>Follow the placement diagram. Make sure there is about a 1/4 inch gap between the pads. This requires 2 pair of pads for Buttocks or 2 pair of pads for Back Thighs.</i> program 17 for 10-20 minutes, program 18 for 10-20 minutes; Frequency: 3 to 4 times per week.
(9) Back (Alternate exercise for the Shoulders and Lower Back)		<i>Follow pad placement diagram. Draw an imaginary line down the center of the back. Using one channel place the pads on the left side of the centerline. Put one pad on the top and one pad on the bottom. Now repeat the process for the right side using the second channel. Make sure the pads are each about one inch from the center of the back.</i> program 23 for 10-20 minutes, program 24 for 10-20 minutes; Frequency: 3 to 4 times per week.

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IV. Troubleshooting

Problems		Possible causes	Try this solution
No.	One pad feels stronger than the other.	This is normal. Different areas of your body will react differently.	Nothing needs to be done. Make sure the pads are sticky and are making good contact.
1	The intensity is not felt. Very weak intensity level.	Pads are not attached to the body firmly.	Attach both pads firmly to the skin.
		The transparent films are still stuck to the pads.	Peel off film on the adhesive surface of pads.
		The pads stacked together or overlap.	Do not stack pads together or overlap pads.
		The cord is not properly connected to the unit.	Connect cord correctly into the jack.
		The intensity setting is getting weak.	Increase the intensity level.
		The battery capacity is low.	Charge the battery.
2	The skin turns red or the skin feels irritated.	The adhesive surface of pads is dirty or dry.	Wash adhesive surface of pads softly with your fingertips for about 3 seconds under slow running water.
		The therapy time is too long or the intensity is set too high.	Reduce the application time or reduce the intensity.
		The electrode pad surface is worn out.	Replace electrode pad.
3	No power source; no display in LED.	The battery capacity is depleted.	Charge the battery.
4	Power cut off during use.	The battery is weak.	Charge the battery.
		The cord is broken.	Replace the cord.
5	It is difficult to attach the pad to the skin.	Have you removed the transparent film from the pad?	Peel off film on the adhesive surface of pads.
		Was the pad applied immediately after washing?	Dry the pad.
		Is the adhesive surface of the pad damaged?	Replace the pad.
6	Adhesive surface of pad is not sticky.	Are you using pad when perspiring?	Use when not perspiring, in a cool room.
		Were the pads stored under high temperature, high humidity, or direct sunshine?	Replace the pad.
7	Treatment interruption	The device was disturbed by other RF devices.	Wait a few minute and the device may recover automatically; Turn off the device and wait for a minute to restart; Move to another location for treatment.
If the above measures are not effective, contact SHENZHEN SINREL TECH LTD Tel: 0086-0755- 27211775; E-mail: llhxmTTT@163.com			

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[As required by 21 CFR 807.87(e)]

V. Service and Maintenance

1. Readjustments, alterations and repairs

- 1) Do not disassemble, repair or modify the device without authorization, you will void any warranty on the product.
- 2) The manufacturer is only responsible for the safety and performance of the TENS & EMS when readjustments, alterations and repairs are carried out by authorized individuals and when the TENS & EMS is used in accordance with the user instructions.
- 3) Qualified technicians who are familiar with the technical features of the device have been provided with circuit diagrams, PCB drawings, component lists and setting instructions by the manufacturer.

2. Cleaning and maintenance

The maintenance that patients can do:

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.
- 6) It does not need to be maintained by maintenance personnel during its expected service life.

B. For electrode pads:

- 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) 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 or alcohol and wipe away the dirty portion. This will allow a temporary restoration of the adhesive power. However, too much water or alcohol will result in loss of the adhesive power.
- 3) 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.

Regards buying new pads, you can send email to llhxmTTT@163.com or contact at 0086-0755- 27211775

Model Number:

- Large oval-Snap button: 75*46mm
(or other 510(k) cleared models with smallest area larger than 12cm²)

Shelf life: 2 years

Warning: The electrodes are intended for single patient use only! When the electrodes dry out and do not stick, buy new gels.

3. Storage

Caution: Do not store in a damp area. Dampness may affect the device and cause rust.

A. For the control unit:

- Normal working ambient temperature: 5°C~40°C (40-104°F), ≤80%RH, 700hPa~1060hPa
- Store and transport ambient temperature: -20°C~55°C (4° -131° F), ≤93%RH, 700hPa~1060hPa

B. For electrode pads:

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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. 2 years of shelf life.

The life span of electrode cord is 2 years.

The life span of adapter is 5 years

FCC Regulatory Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 00 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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4. Disposal



To dispose of the electrode, device and packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.

5. Warranty period

We give a warranty of 1 year from the date of purchase on TENS&PMS. This warranty does not cover cables and electrodes.

6. Manufacturer information

Manufacturer: SHENZHEN SINREL TECH LTD



Address: 3rd Floor, Building 5, A1 Ganghua Factory, No.27, Yongnan Road, Shajing Street,
Bao'an District, Shenzhen, China

Email: llhxmTTT@163.com

Tel: 0086- 0755-27211775

7. Adverse Event Report

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1) Report Online at

www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

2) Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

3) **Call FDA at 1-800-FDA-1088** to report by telephone

a) Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

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VI. Electromagnetic Compatibility

Important information regarding Electromagnetic Compatibility (EMC)

With the increased number of electronic devices such as PC and mobile (cellular) telephones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, Medical devices in use may be susceptible to electromagnetic interference from other device. Electromagnetic interference may result in incorrect operation of the medical devices and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electromagnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.

This unit has been thoroughly tested and inspected to assure proper performance and operation! This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, the following tables recommend minimum separation distances between portable and mobile RF communications equipment and the TENS unit.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 0 cm to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Caution:

- * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- * This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
- * Refer to further guidance below regarding the EMC environment in which the device should be used.

There is no guarantee that interference will not occur in a particular installation. Radiated or conducted electromagnetic signals can cause:

1) As to devices:

- Deviation of the values of pulse duration, amplitudes, and repetition frequencies, may impair the unit's essential performance. The device has passed EMC highest interference level test, and the parameters do not deviate the essential performance requirement.
- The device displays abnormally in LED.

2) As to patients:

- The sensitivity of stimulation may be weaker or stronger, but it does not produce safety issues.
- It cannot achieve expected effect.

If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:

- If feeling too weak or too strong stimulation, adjust the strength level to an acceptable level.
- If the device display is abnormal, power off and restart the device and check whether it shows properly.
- Re-orient or re-locate the affected device.
- Increase the separation between the unit and the affected device.
- Power the equipment from a source other than that of the affected device.
- Consult the service representative for further suggestions.

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1) Guidance and manufacture's declaration - electromagnetic emission

The TENS & EMS is intended for use in the electromagnetic environment specified below. The customer of the user of the TENS & EMS should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The TENS& EMS 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 emission CISPR 11	Class B	The TENS & EMS is suitable for use in all establishments, including domestic establishments 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

2) Guidance and manufacture's declaration - electromagnetic immunity

The TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of TENS & EMS 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	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ± 1 kV line(s) to line(s)	±0.5 kV, ± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _T ; 1 cycle and 70 % U _T ; 25/30 cycles Single phase: at 0° 0 % U _T ; 250/300 cycle for 5s	0 % U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _T ; 1 cycle and 70 % U _T ; 25/30 cycles Single phase: at 0° 0 % U _T ; 250/300 cycle for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TENS & EMS requires continued operation during power mains interruptions, it is recommended that the TENS & EMS be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz)	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical

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magnetic field IEC 61000-4-8			location in a typical commercial or hospital environment.
NOTE U _T is the a.c. mains voltage prior to application of the test level.			

3) Guidance and manufacture's declaration – electromagnetic immunity

The TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of TENS & EMS should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3V rms 150 kHz to 80 MHz 6 V in ISM bands between 0.15MHz and 80 MHz	3V rms 150 kHz to 80 MHz 6 V in ISM bands between 0.15MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the TENS & EMS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$ 150kHz to 80MHz $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.7 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 Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

NOTE 1 At 80 MHz and 800 MHz, 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.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio 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 TENS & EMS is used exceeds the applicable RF compliance level above, the TENS & EMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TENS & EMS.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

4) Recommended separation distances between portable and mobile RF communications equipment and the TENS & EMS

The TENS & EMS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TENS & EMS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TENS & EMS as recommended

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below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
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) according 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 propagation is affected by absorption and reflection from structures, objects and people.			