User Manual

Model TX6224

Version 1.0

Wireless TENS & EMS Unit

Please read this manual carefully before using the device

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1 General Description of the Device

1 General Description of the Device

TX6224 Wireless TENS & EMS Unit is a portable and DC 3.7V built-in rechargeable battery powered multifunction device, offering both Transcutaneous Electrical Nerve Stimulation (TENS) and Electrical Muscle Stimulation (EMS) qualities in one device.
TX6224 Wireless TENS & EMS Unit has 24 operation programs, 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 LCD display screen, Intensity buttons, Time button, P button and USB port for battery charging.
The LCD display screen can show time remaining of an application program, battery power, program number and intensity.
The device is equipped with accessories of electrode pads, and one USB cable. The Wireless Pods 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, can only be changed or replaced by a qualified person.
The electrode pads are interchangeable.

- The electrode pads manufactured by GMDASZ MANUFACTURING CO., LTD. with 510(k) cleared number K160138.
- The electrode pads manufactured by Reno Medical Ltd. with 510(k) cleared number K170744.

2 Tens and Ems Device Introduction

1 About TENS & EMS

Thank you very much for using the transcutaneous electrical nerve stimulator and/or powered muscle stimulator.
This device is a portable electrotherapy device, featuring two therapeutic modes, Transcutaneous electrical nerve stimulator (TENS) and electrical muscle stimulation (EMS), which are used for temporary pain relief and electrical muscle stimulation. The stimulator sends gentle electrical current to underlying nerves and muscle groups via electrodes applied on the skin.
The parameters of the device are controlled by the buttons, and the intensity level is adjustable according to your needs.

2 EXPLANATION

2.1 EXPLANATION OF TEMPORARY PAIN

Temporary pain is a warning system and the body’s method of telling us that something is wrong. Temporary pain is important, without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies. So that temporary pain is a necessary warning signal of trauma or malfunction in the body.
Aside from its value in diagnosis, long-lasting persistent temporary pain serves no useful purpose.
Then, how does temporary pain arise?
Temporary pain does not begin until the coded message travels to the brain where it is decoded, analyzed, and then reacted to. The temporary pain message travels from the

injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The temporary pain message is then interpreted, referred back and the temporary pain is felt.

2.2 EXPLANATION OF TENS

Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive, drug free method of controlling temporary pain. TENS uses tiny electrical impulses sent through the skin to nerves.

TENS does not cure any physiological problem; it only helps control temporary pain.

TENS does not work for everyone. However, in some patients it is effective.

2.3 HOW TENS WORKS

TENS is intended to be used to temporarily relieve temporary pain.

The TENS unit sends comfortable impulses through the skin that stimulate the nerve endings in the treatment area. This stimulation may temporarily reduce or eliminate the temporary pain sensation the patient feels. Temporary pain relief varies by individual patient, mode selected for therapy, and the type of temporary pain. In some patients, the reduction or elimination of temporary pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, temporary pain is only modified while stimulation occurs.

Necessary, you need discuss this method of temporary pain management treatment with your physician or therapist.

2.4 EXPLANATION OF EMS

Electrical Muscle Stimulation (EMS) works by sending electronic pulses to the muscle and stimulating healthy muscles in order to improve or facilitate muscle performance.

2.5 How EMS works

EMS uses an external power source (stimulator) and electrodes attached to the skin to deliver electrical impulses to the muscles, which are stimulated to contract, thus fulfilling the function of EMS.

3 Intended Use

1) TENS

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

2) EMS

The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.

3 WARNINGS AND PRECAUTIONS

1) For you use this device safely, please read this user manual carefully before your first use, please keep this user manual with your device for future reference.

2) IMPORTANT SAFETY INFORMATION

Read instruction manual before operating. Be sure to comply with all “Contraindications”, Warnings”, “Cautions” and “Adverse reactions” in the manual. Failure to follow instructions may cause harm to user or device.

1 Contraindications

- People who are pregnant, in labor, or menstruating.
- People with suspected or confirmed heart disease, high blood pressure, or epilepsy.
- People who have an implanted defibrillator, cardiac pacemaker, or any other implanted metallic or electronic device.
- People with baryodynia disease, acute diseases, tumours, diabetes, convulsive disorders,

tuberculosis, infectious diseases, fever, and skin diseases.
- People with serious arterial circulatory problems in the lower limbs and abdominal or inguinal hernia.
- People who are unable to express their thoughts or intentions, or operate the device on their own.
- People who suffer from nausea or dizziness.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture;
- Unattended patient who is noncompliant, emotionally disturbed, has dementia, or a low IQ.
- Keep out of the infants, toddlers, and children.
- This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- Do not apply stimulation in the presence of electronic monitoring device (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
-Do not use this device if the patient has a demand-type cardiac pacemaker or any implanted defibrillator.
- Do not use the device on children.

2 Warnings

2.1 Prohibited Areas
- Areas of the head, face, thorax, heart, throat, or genital area and their vicinities- Areas that could induce current/stimulation to flow through the carotid sinus region (anterior neck) or trans-cerebrally (through the head),particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the throat or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur, and contractions may be strong enough to close the airway or cause difficulty in breathing.
- Areas where the skin lacks normal sensation.
- Areas near or on cancerous lesions.
- Areas of skin erosion caused by conditions such as varicose veins, phlebitis, thrombophlebitis, and thrombosis.
- The area of the trigeminal nerve if you have a history of herpes zoster induced trigeminal neuralgia.
- The following areas should not have electrode pads used simultaneously as they may cause heart rhythm disorders or even death:
  - Areas on both sides of the chest (left and right or front and back) or through the chest.

2.2 Prohibited Activities

1) Do not Use the device when,
- Showering or bathing, sleeping, exercising, driving, or operating machinery, and any other activities where interference is not permissible.
- The wire is broken or the lead wire connection port is broken or loose.
- The electrode pads are unstuck, deformed, damaged, or not intact.
- magnetic resonance imaging.

2) Do not use the product in,

- Any environment with a high temperature, such as direct sunlight, near explosives, gasses, extremely flammable materials, or near fire.
- Air mixed with flammable an aesthetic gas or oxygen or nitrous oxide mixed with flammable an aesthetic gas.
- Close proximity (less than 1 meter) to shortwave, microwave therapy or other high frequency device.

3) Do not use the product with,
- Any topically applied creams or ointments.
- Other devices that send electrical pulses to your body.
- An ECG meter, high frequency surgical device, or any other medical device.

4) Do not connect two pads during operation.

5) Do not use of unapproved accessories, cables, detachable parts, and materials instead of those specified or provided by the device's manufacturer.

6) Do not disassemble, repair, or modify when without authorization, the warranty will be void. If you encounter any issues with the device, please do not hesitate to contact us.

2.3 EMC Warnings:

Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally."

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation."

This product is sensitive to electromagnetic interference, and the following cases may interfere with normal use:
- When talking on the mobile phone.
- Near the base station for signal transmission (broadcast, television, communications, radar, navigation, etc.).
- Near high radiation medical instruments such as nuclear magnetic resonance.
- Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

The user should be away from these instruments or occasion as soon as possible if the essential performance of the device is degraded or lost due to EM DISTRUBANCES. The essential performance of the device should be restored. If not, please contact customer service.

3 Cautions

This device is for single patient use only.

Apply stimulation only to normal, intact, clean, healthy skin.

Keep yourself informed of the contraindications.

Accessory Requirements:
- When transferring the device to another patient, replace the used pads with new ones.
- The device should only be used with the electrodes that are recommended by the manufacturer.

You should stop using the device and consult with your physician if you experience any

adverse reactions from the device:

- Pain or discomfort during or following the application of electrical stimulation.
-Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or silicone rubber. If rash develops or temporary pain persists, discontinue use and consult a doctor.
- Isolated cases of skin irritation have occurred at the site of the electrode placement following long-term application.

To prevent potential adverse events, such as electric shock:

- Please do not turn on the device until it has been properly connected.
-To move the pads to another body part, first return the current level to zero and then move them to the desired location.
-Turn the device off before pasting and removing the electrode pads.

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

-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.

NOTE: 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.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

4 Precautions

- The device is MR unsafe.
- Inhalation or swallowing of small parts: Keep the device out of the reach of children.
- Potential allergic reactions to accessible materials used in the ME EQUIPMENT.

Storage and disposal:

- Keep the device out of pets, pests or children's reach. They will damage the device to cause not correct output performance with uncomfortable stimulation.

- The device may be degraded by lint, dust, light (including sunlight) to cause not correct output performance with uncomfortable stimulation.
-As the device has a built-in lithium-ion battery, it should not be discarded at end life and needs to be recycled to reduce environmental pollution.
TENS devices have no curative value.
TENS is not effective for pain of central origin, including headaches.
TENS is not a substitute for pain medication and other pain management therapies.
TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
The long-term effects of chronic electrical stimulation are unknown.

5 Adverse Reactions

-Skin irritation and burns beneath the electrodes have been reported with the use of TENS devices.
-If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if any problems persist.
-Headache and other temporary painful sensations during or following the application of electrical stimulation near your eyes, to your head and face.
- Potential allergic reactions due to the electrical stimulation or gel including skin irritation, redness, burning or hypersensitivity.
Note: Always use electrodes that are legally marketed and sold in the United States under 510K guidelines.
- You should stop using the device and consult with your physician if you experience any adverse reactions from the device.

6 Submitting Adverse Event Reports to FDA

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
Use one of the methods below to submit voluntary adverse event reports to the FDA:
Report Online at
www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home.
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 which is available at
www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf.

Call FDA at 1-800-FDA-1088 to report by telephone.
Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

7 Intended for Population

The “Patient” is an intended user.
Adults who suffer from sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arms), and lower extremities (leg) due to strain from exercise or normal household work activities can use this Device.
However, it should not be used by children, pregnant women, or anyone who has an implanted metallic or electronic device. Ask your physician if you have any questions related to your health.
Notes,

1) This part is about the safety information. It is intended to help you use it safely, prevent injury and avoid situation which could result in damage on the device. It is important for you to read this information carefully.
2) Please note that the original recognized accessories, detachable parts and material which are approved by standard.
3) Please do not disassemble and replace the parts of the device (including batteries), please contact the maintenance personnel for the maintenance and disassembly of the device.

8 Potential Electromagnetic and Other Interference

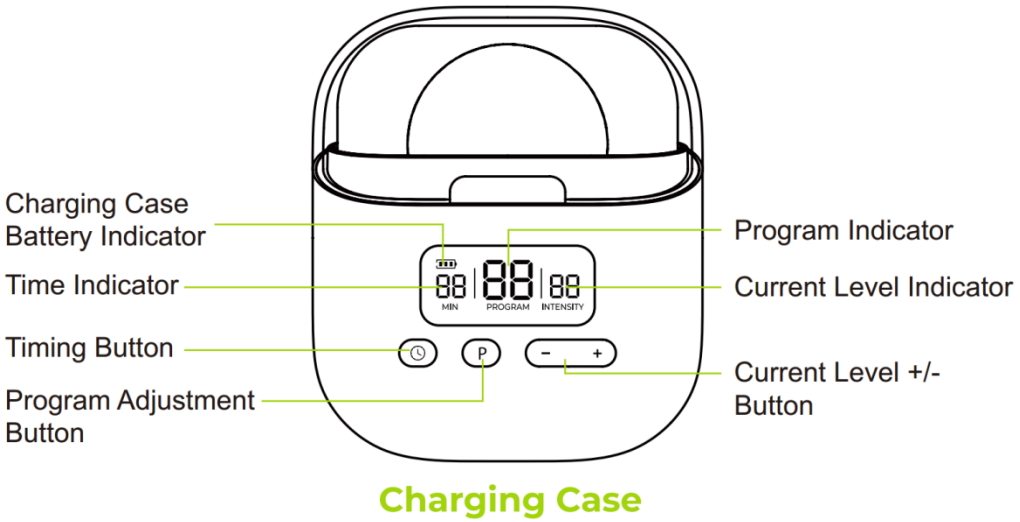
This device may be sensitive to electromagnetic interference, and the following cases may interfere with normal use:

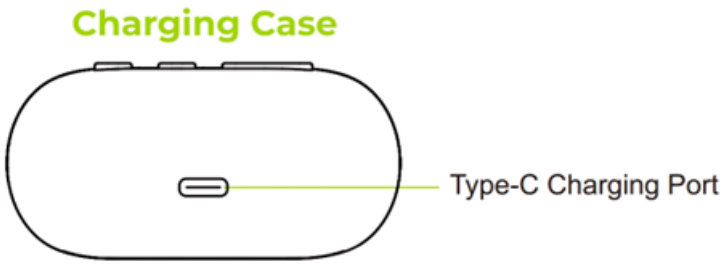
- When talking on the mobile phone.
- Near the base station for signal transmission (broadcast, television, communications, radar, navigation, etc.).
- Near high radiation medical instruments such as nuclear magnetic resonance.

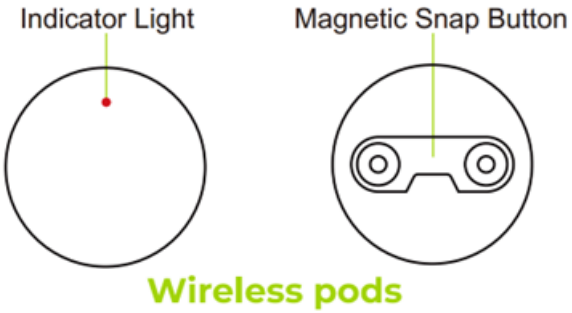
The user should be away from these instruments or occasion as soon as possible if the function of the device is degraded or lost due to EM DISTRUBANCES, Then the function of the device should be restored. If not, please contact your local dealer.

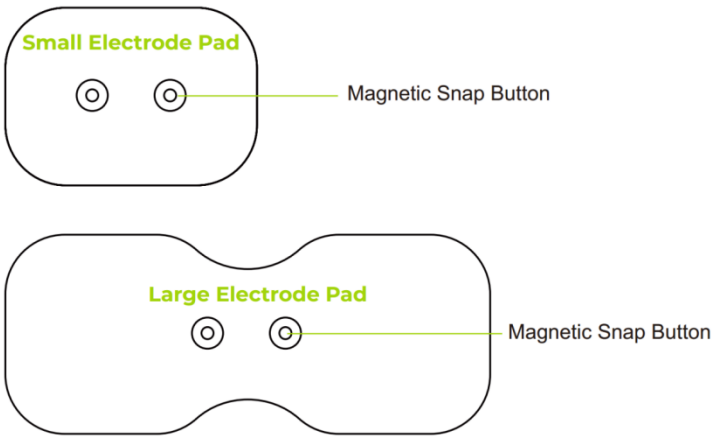
4 Structure and Accessories

1 Illustrations









2 Package

- Charging case
- Wireless pods
- Pairs of electrode pads
- Type-C Cable
- User Manual

5 Before Use

Before operating the device, please read following carefully,

5.1 Please apply the electrode pads to flat areas of the body for use. Using them on uneven parts of the body may cause the edges of the pads to lift.

5.2 Ensure the electrode pads are fully applied to the body before adjusting to the current level.

5.3 Turn the current level to 0 before peeling the electrode pads off the skin. Peeling the pads without doing so may result in a shock sensation when fingers touch the gel.

5.4 By holding the "-" button for 2 seconds, or short pressing the "P" button, you can quickly adjust the current level to 0 and the Wireless Pods will stop outputting current.

5.5 Please make sure the Wireless Pods are tightly connected to the electrode pads with no noticeable gaps where the magnetic snaps can be seen.

5.6 Like wireless earbuds, this device does not require manual shutdown. The charging case screen will turn off automatically after 15 seconds of inactivity. Press any button or open the lid to reactivate the screen.

5.7 The battery should be charged for approximately 10 hours before first use.

5.8 You may experience tingling, trembling, or muscle pulling when using the device, so please try out all the modes and select the one that's most comfortable for you.

5.9 For initial use, the current level should be set between 1-5. If you feel the current level is weak in 1-2 minutes, gradually increase it and select the most comfortable setting.

5.10 It is recommended to use the device for 20-30 minutes and to stop using it when pain is relieved.

6 How to use

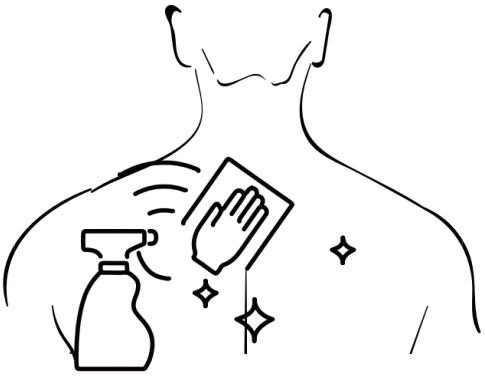
1 Wireless Pod Lighting Indicator Meaning

Wireless Pods Location	Lighting Indicator	Meaning	Solution
Inside the Charging Case	No light.	Wireless Pod is fully charged.	No action required.
	Flashing red light slowly, every two seconds.	Wireless Pod is not fully charged.	No action required.
Outside the Charging Case	Blue light is always on.	The Wireless Pod connects properly to the charging case and the pad, and the pad securely attaches to the body.	It's the right state. No action required.
	No light.	Wireless Pod run out of power.	Return the Wireless Pod to the charging case for charging.
		Wireless Pod shutdown due to extended periods of inactivity.	Place the Wireless Pod back into the charging case and take it out for use.
	Flashing red light rapidly, three times per second.	Wireless Pod battery is below 10%.	Return the Wireless Pod to the charging case for charging.
	Flashing blue light slowly, every two seconds.	The Wireless Pod is connected to the charging case properly but disconnects from the pad or the pad is not attached properly to the body.	Ensure that the pad is fully connected to the Wireless Pod and securely attached to the body.
	Flashing blue light rapidly, three times per second.	Wireless connection failed.	Place the Wireless Pod back into the charging case and take it out to reinitiate the wireless connection.

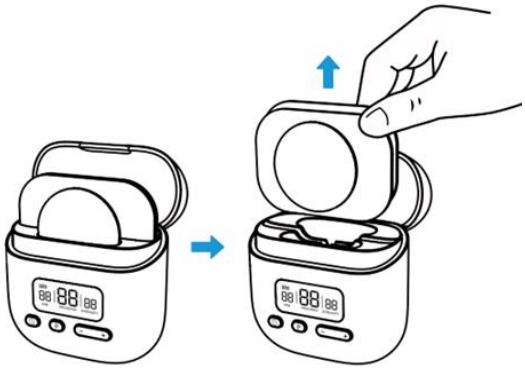
2 Steps of Operating the Device

1) Clean your skin before use, and make sure the application areas are dry, with no sweat, and no oil.

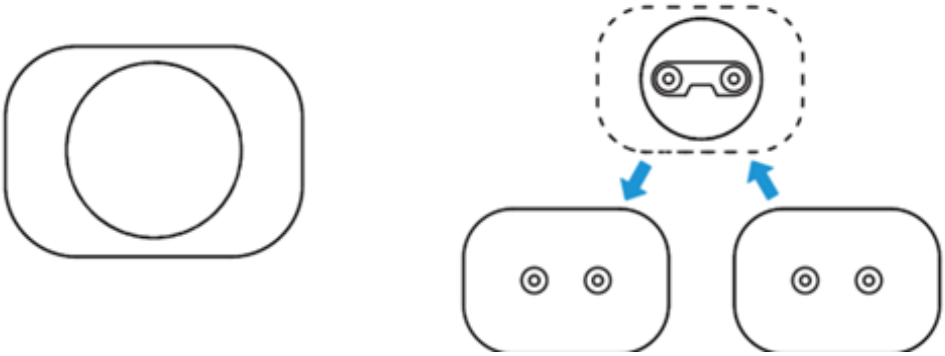
Note: The application areas should have no wounds and areas lacking sensation should not be used. Excessive hair on the skin should be shaved off or dampened with warm water.



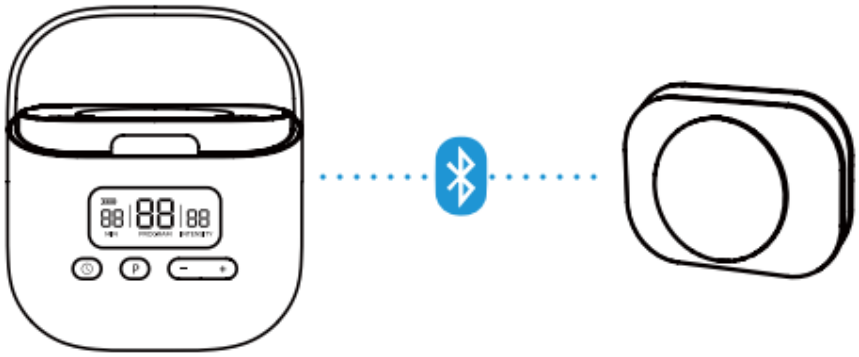
2)Take out the Wireless Pods and electrode pads from the charging case together.
Note: You may take out one or both according to your needs; a single pod will still function properly.



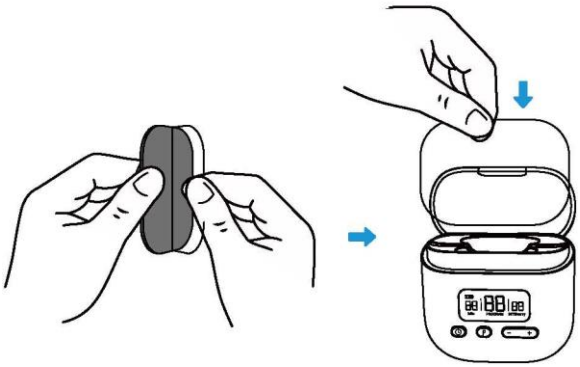
3)The Wireless Pods attach to the electrode pads with magnetic snaps, and the electrode pads can be detached from the Wireless Pods for replacement.



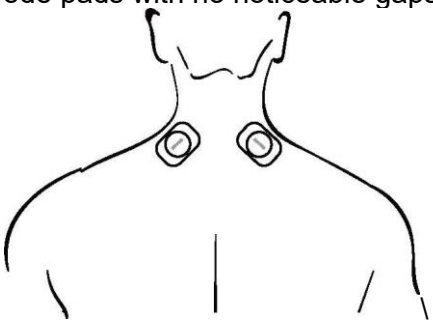
4)Within three seconds after taking, it out, the blue light on the Wireless Pods will change from fast-flashing to slow-flashing, indicating a stable wireless connection. The Pods can be remotely controlled via the charging case.
Note: If after five seconds the light remains fast flashing, you need to put the Wireless Pods back into the charging case and take them out to reinitiate the wireless connection.



5)Peel off the protective plastic shields from the electrode pads and put them back in the charging case for storage.
Note: The protective plastic shields protect the electrode pads' conductive gel layer. Please be careful not to discard them, otherwise the electrode pads will not be reusable.



6)Place the electrode pads on the desired area. At this time, make sure that the electrode pad is tightly connected to the Wireless Pod.
Note: If you need to switch to a larger pad, detach the Wireless Pod from the small pad and attach it to the larger one. Please make sure the Wireless Pods are tightly connected to the electrode pads with no noticeable gaps where the magnetic snaps can be seen.

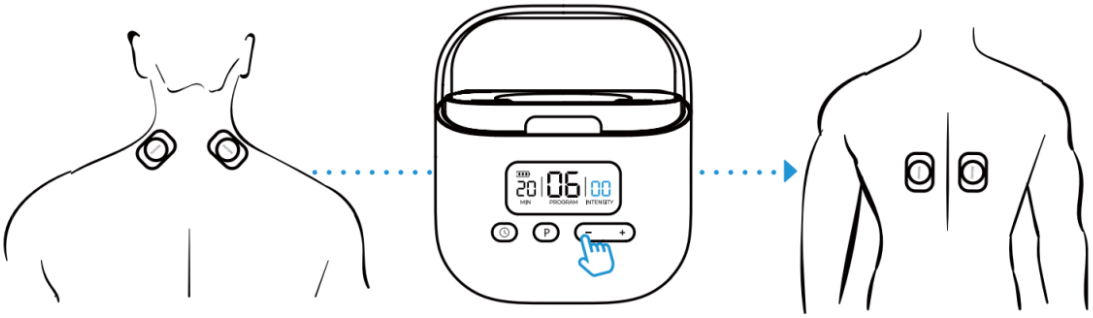


7)Press the P button to select a program. Please check the "Program Recommendation" content for the recommended program for different body parts.

8)Press the “-” or “+” button to adjust the current level. For first use, the current level should be set between 1-3. If you feel that the current level is weak after 1-2 minutes of adaptation, you can gradually increase it and choose the most comfortable setting.
NOTE: The current level will revert to the lowest setting with each program selection.

9)Press the “ ” to set a timer for 10 to 90 minutes.
NOTE: It is recommended to use it for 20 to 30 minutes each time.

10)If you want to adjust the location of the pads, press and hold the “-” key until the current level is at 0, then gently peel off the pad by grasping the edge and stick it to the new location. Note: Touching the gel area of the pad directly without reducing the current level to 0 may result in an electric shock.



7 After use

After use, long-press the “-” key to turn the current level to 0 and then pinch the edge of the pad to peel the pad off the body.
Align the protective plastic shields on the gel layer of the electrode pads to ensure that all the gel is covered.
Put the electrode pads with the protective plastic shields back into the charging case.
Close the lid of the charging case.
Store them at room or cool temperature (between 5℃-35℃/41℉-95℉) and keep them out of direct sunlight.

1 Cleaning Requirements

1) Wash the area of skin you will be placing the electrodes on with soap. Rinse thoroughly and dry the area completely before and after placing electrodes.
2) Inspect your electrodes before every use. Replace electrodes as needed. Reusable electrodes can cause slight skin irritation, lose adhesion properties and deliver less stimulation if overused.
3) The electrodes should be discarded when they are no longer adhering to the skin.
4) It may be helpful to improve repeated electrode application by spreading a few drops of water over the adhesive side and turning the surface up to air dry. Over saturation with water will reduce the adhesive properties.

2 Tips for Electrode Pads Care

1) Never apply electrodes over irritated or broken skin.
2) The electrode type: It is a kind of hydrogel, and it is a kind of medical silicone.
3) We advise you to obtain replacement electrodes that are the same type, have the same dimensions and same connectors as those you distribute with your device.
4) The electrodes should be discarded when they are no longer adhering to the skin.
5) The electrodes are intended for single patient use only.
6) Always use the electrodes with the requirements of the ANSI/AAMI/ES 60601-1, ISO10993-1/-5/-10 and IEC/EN60601-1-2, such as with CE mark, or are legally marketed in the U.S. under 510(K) procedures.

3 Maintenance

1) Please put where children can't reach it.
2) The gel surface of the electrode pad should be kept clean and avoid dirt like dust, oily substances, sticky substances, etc., otherwise the stickiness will be decreased.
3) Please paste the protective films back onto the pads after use.
4) Please don't wipe the gel surface with a paper towel.
5) Please do not scrape the gel surface with nail, brush, etc.
6) Electrode pads are consumables with the service life of generally 20-30 times. If the pads are not sticky or the stimulation becomes weak, you should change the pads in time. When you reorder the electrode pads, the electrode pads must be FDA-cleared electrode pads, please consult the manufacturer, The following is electrode pads’ manufacturer information:

1. Manufacturer: GMDASZ MANUFACTURING CO., LTD
1) 510(K) Number: K160138
2) Tel: +(01)931-6254938.
3) Add: Building #1, HMB 3rd Industrial Zone, Baoan District, Shenzhen, Guangdong China. 518052.

2. Manufacturer: RENO MEDICAL LIMITED.
1) 510(K) Number: K170744

2) Tel: +(86) 86-21- 22815850.
3) Add: MNC2246 RM1007,10/F, Ho King Comm CTR, 2-16Fa Yuen Street, Mongkok, KL, Hong Kong Xinjiang, CN. 999077.

7) The battery of this device is polymer battery, after a long period of non-use, confirm the battery power before using again.
8) Do not put the unit in the place exposed to sunlight, high temperature, humidity, lots of dust, or the place close to fire, easy to vibrate or shock.

4 Storage and Disposal

1) Storage
   a) For prolonged pauses in treatment, store the device in a cool dry room and protect it against heat, sunshine and moisture and remove the battery to avoid battery leaking.
   b) Store the device in a cool, well-ventilated place.
   c) Never place any heavy objects on the device.
   d) The time required for ME device to heat up from the lowest storage temperature to ready for use between uses: 30 minutes, the time is the temperature rise from -25°C to 5°C
   e) The time required for ME device to cool from the maximum storage temperature to ready for use between uses: 30 minutes, the time is the temperature cooling down from 70°C to 40°C.
2) Disposal
   Please dispose of the device in accordance with the laws in your area and contact the local authorities to determine the proper method of disposal of the used device and accessories.

8 Troubleshooting

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. It should be none of these measures correct the problem, the device should be serviced.

PROBLEM	CAUSE	SOLUTION
The screen does not light up when pressing buttons or opening the charging case.	Due to long-term non-use, the battery is exhausted and enters low-power protection mode.	Charge it and try turning it on again.
After taking the Wireless Pod out of the charging case, the blue light continues to flash 3 times per second instead of remaining on.	Wireless connection failed.	Place the Wireless Pod back into the charging case and take it out to reinitiate the wireless connection.
After taking the Wireless Pod out of the charging case, the blue light continues to flash every two seconds instead of remaining on.	The Wireless Pod is connected to the charging case properly but disconnects from the pad or the pad is not attached properly to the body.	Ensure that the pad is fully connected to the Wireless Pod and securely attached to the body.
When the Wireless Pod is outside the charging case, the light glows red.	Wireless Pod battery is below 10%	Put the Wireless pod back into the charging case and charge it for about 2 hours.
Wireless pod does not light up any color when outside the Charging Case.	Wireless Pod run out of power.	Put the Wireless pod back into the charging case and charge it for about 2 hours.
	Wireless Pod shutdown due to extended periods of inactivity.	Place the Wireless Pod back into the charging case and take it out for use.
After correctly attaching the Wireless pod and pad to the body, adjusting the current level to 5 or above does not result in feeling any electrical stimulation.	Wireless connection disconnected.	Check the Wireless pod. If the blue light flashes 3 times per second, put the Wireless pod back into the charging case and take it out after 1 second to reinitiate the wireless connection.
	Wireless pod and electrode pad are not connected properly.	Separate the Wireless pod from the electrode patch and reattach it, making sure there is no noticeable gaps where the magnetic snaps can be seen.
After correctly attaching the Wireless pod and pad to the body, adjusting the current level to 5 or above does not result in feeling any electrical stimulation.	Poor contact between the pads and the skin.	Attach pads to the skin (no hair, unbroken and flat) firmly.
	The electrode pad has been used too many times and has lost its stickiness, resulting in poor contact.	Replace the electrode pad with a new one.
After correctly attaching the Wireless pod and pad to the body, adjusting the program or current level on the charging case did not result in corresponding adjustments to the Wireless pod.	Wireless connection failed.	Put the Wireless pod back into the charging case and take it out after 1 second to reinitiate the wireless connection.

When closing the transparent cover of the charging case, it is unavoidable to come into contact with the wireless pod or electrode pad.	The Wireless pod is placed upside down in the charging case.	Make sure the two charging contacts of the Wireless Pod are facing downwards when you place it into the charging case.
The Wireless pod cannot be charged after being put back into the charging case.	The Wireless pod is placed upside down in the charging case.	Make sure the two charging contacts of the Wireless Pod are facing downwards when you place it into the charging case.
Unable to charge the charging case.	The charging cable is not plugged in properly.	Unplug and plug again.
	Charging cable failure.	Replace a charging cable of the same type.
	Power adapter is damaged.	Replace the other 5V output adapter.
Can't adjust the current level/ program/time.	Buttons are stuck or damaged.	Check whether any buttons are sunk or stuck.
The adhesive on the pads is not sticky.	The pads are damaged or deteriorated.	Replace the pads.
	Pads are stored in a place with high temperature, high humidity, or direct sunlight.	Replace the pads.
The adhesive on the pads is not sticky.	Excessive hair in the application areas.	Make sure the application areas are not hairy.
	Use pads on non-flat surfaces.	Use pads on flat muscle groups.
The skin turns red, or the skin feels irritated.	Dirty skin or broken skin.	Clean your skin and air-dry it, do not use the pads on the broken skin.
	Excessive usage time or the current level is too high.	Shorten the application time (20 minutes are recommended) or decrease the current level.
	Allergic to the pads.	Stop using it immediately and seek professional medical help.
One pad feels stronger than the other.	This is normal. Different body areas react differently.	Try to change the position of the pads.
	Different sized electrode pads were used at the same time.	It is recommended to use a pair of electrode pads of the same size.
The current level felt is very weak.	The current level of the setting is weak.	Increase the current level and wait for 1 minute to feel the pulse.
	Low battery.	Charge the battery and a full charge may need 2hours.

	Pads are not attached to the body firmly.	Attach both pads firmly against the skin.
If there's a sense of shock.	Before the wireless pod and the electrode pad is connected to the body, the current level was adjusted to above 1.	Before the wireless pod and the electrode pad is connected to the body, make sure the current level is set to 0.
	Before the current level returns to 0, tear off the electrode pad with your fingers.	Please adjust the current level to 0 before detaching the electrode pad from your body. You can quickly return the current level to 0 by long pressing the "-" button.
Power cuts off during use.	Low battery.	Charge the battery and a full charge may need 2hours.
	The countdown is finished.	Set the time for your device with the "T" button from 10- 90 minutes and the continuous mode (infinite time).
If the above ways can't solve the problem, please contact our customer service.		

9 Device Features

1 Features of the Device

1) Liquid crystal display
2) Backlight
3) 2 wireless pods with built-in 90mAh rechargeable battery,
4) Adjustable timer, up to 90 mins.
5) 24 different modes
6) 1 main unit charging compartment, built-in 600mAh rechargeable battery
7) 30 levels of intensity settings
8) Allows 1-2 pairs of pads to be used on different target areas at the same time.
9) Application: Self-adhesive electrode pads

2 Specification

This device:
Application class: Type BF
Protective class: Class II

Power

Input voltage DC 5V, rated current of the device: ≤ 30mA, charging power of the device: ≤ 2.5W

Li-ion battery: 3.7 V DC

10 Program Parameter

1 Output Parameters

Information on the output waveform(s), including any D.C. component, pulse durations, pulse repetition frequencies, maximum amplitude of output voltage and/or current, and the effect of load impedance on these parameters.

Effect of load impedance, 500Ω

TENS/EMS	Mode	Amplitudes(V) 500Ω	Frequency (Hz)	Pulse Duration (μs)
TENS	P01	40	100/10-100	100
TENS	P02	40.2/33.2/35.4/36	2~131	100
TENS	P03	41.6/40	100/130	100
TENS	P04	34.2/38.6	130/100	100
TENS	P05	39.5	1.4(100)	100
TENS	P06	40	8(100)	100
TENS	P07	40	1.5(100)/8(100)	100
TENS	P08	41/41/40.5	1.3(100)/3.5-10(100)/100-70-100	100
TENS	P09	40	98	100
TENS	P10	40.5/41.5	4(100)/100	100
TENS	P11	38.5	100/130	100
TENS	P12	40.5/40	2.6-1.4(100)/100	100
EMS	P13	40	100	100
EMS	P14	40	100	100
EMS	P15	40	100	100
EMS	P16	42	100	100
EMS	P17	40	100	100
EMS	P18	42	100	100
EMS	P19	42	100-70-100	100
EMS	P20	42	7(100)	100
EMS	P21	40.5	100	100
EMS	P22	37.5	100	100
TENS	P23	42.25/41/42.25	1.7(100)-100/100/100	100
TENS	P24	42	2-10(100)/100-70-100/2-10(100)/100-70-100	100

2 Program Recommendation

Body parts	Mode's suggestion
Neck	Modes: 8、18、23、24
Shoulder	Modes: 4、5、8、9
Waist	Modes: 5、6、18、23
Arm	Modes:4、 7、9、14、15、16、17、22
Back	Modes: 1、2、3、4、12、13
bottom	Modes: 3、7、20
Abdomen	Modes: 9、11、12
leg	Modes: 3、7、9、11、12、16、17

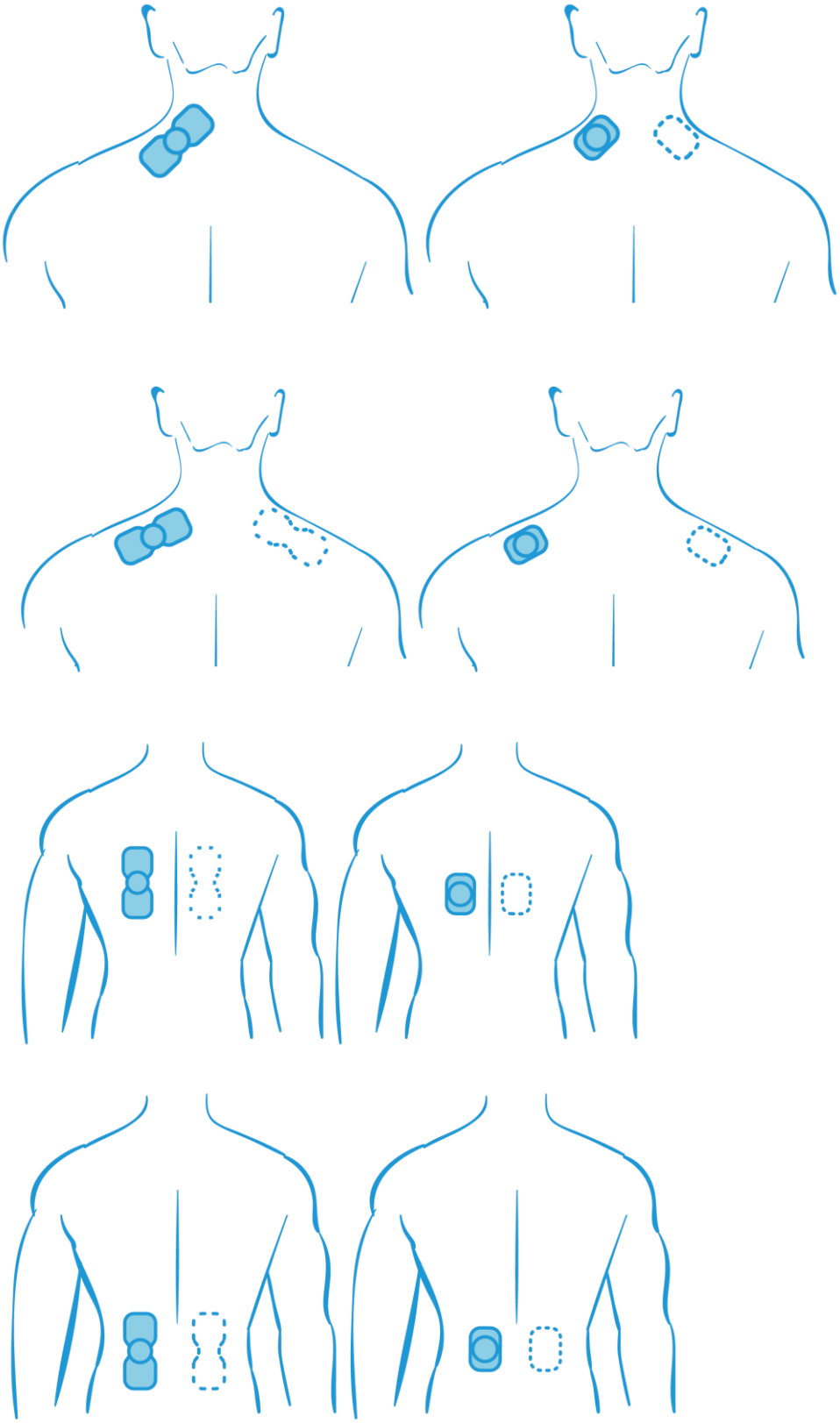
11 Regular TENS Application Methods

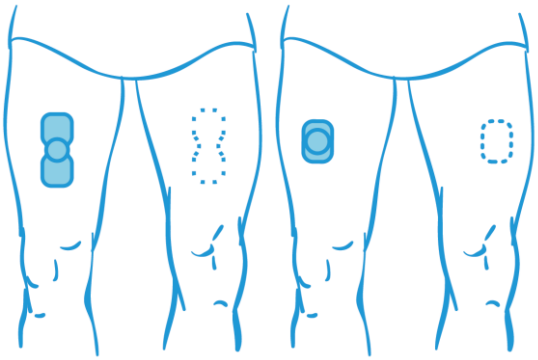
1 TENS Mode Instruction

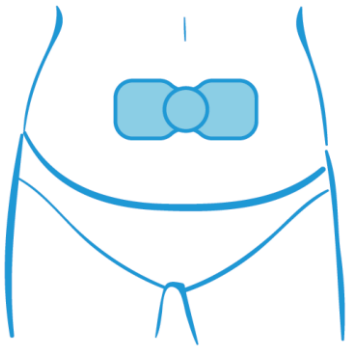
When you select the TENS mode you need, then the therapeutic program, Cycle time, therapeutic time, pulse width and pulse rate are all default in this device.

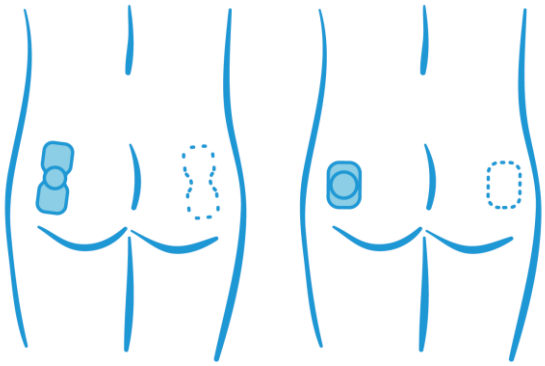
1) Position placement of the electrodes: Both ends of the temporary painful area, within 3~5cm from the temporary painful area or directly on the temporary painful area.
2) How often to use stimulation? After one stimulation is completed, it is recommended that the time for the next stimulation is 30 minutes later.
3) How long to use the programs/modes? it is recommended that you do not exceed 180 minutes one day.
4) How often treatments should be given? Recommend you consult a physician.
5) How long it may take for temporary pain relief to occur during a treatment session? Generally, there is a temporary pain relief effect within a short period of time (such as 3~5 minutes) after use. If there is no temporary pain relief after using for more than 30 minutes, please consult a doctor in time.

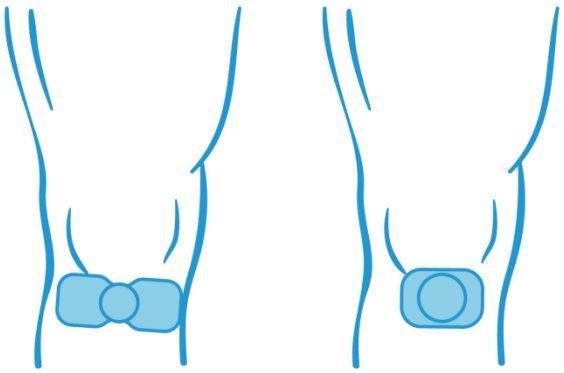
2 TENS Schematic of recommended electrode placement at the stimulation site

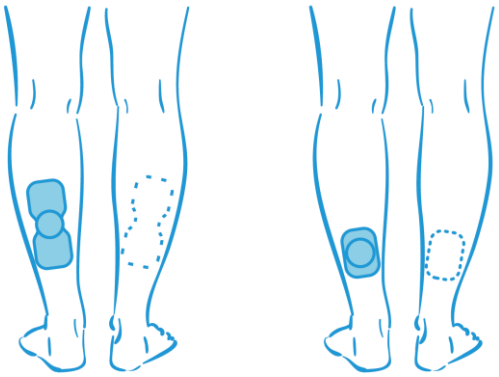


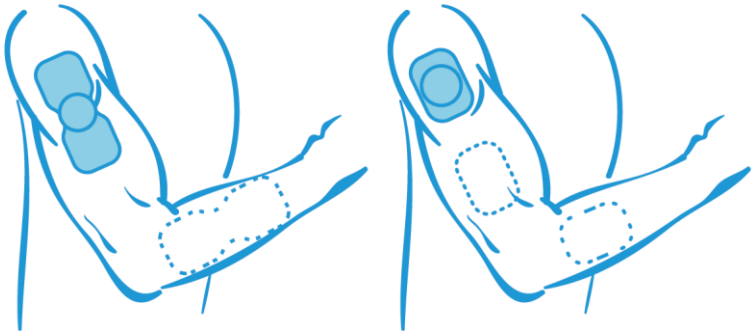


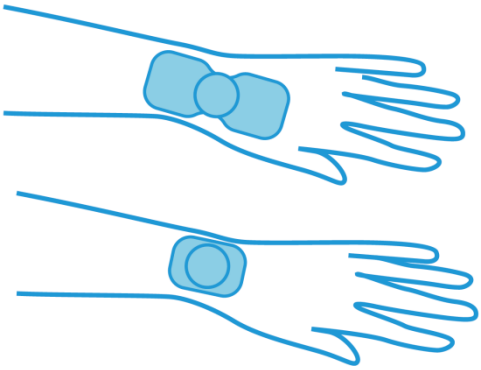












12 Regular EMS Application Methods

1 EMS Mode Instruction

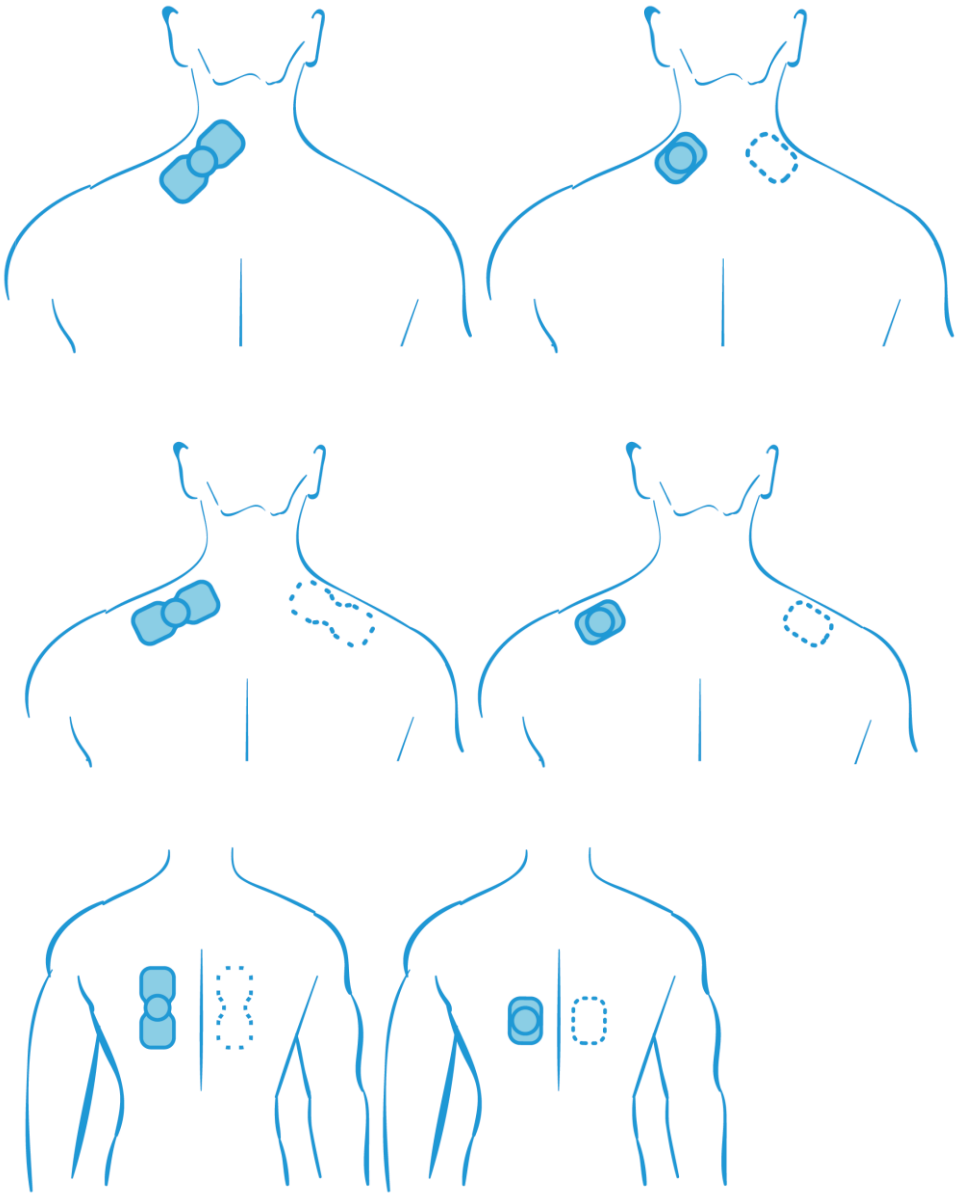
When you select the EMS mode you need, then the therapeutic program, cycle time, therapeutic time, pulse width and pulse rate are all default in this device.

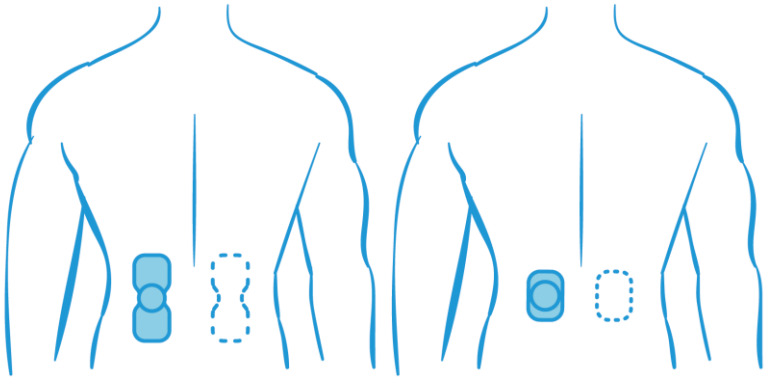
1) Position the electrodes to obtain optimal contraction: In order to get the best contraction for muscle stimulation, please put the electrode pads directly on the largest part of the muscle you intend to stimulate or the ends of the muscle you intend to stimulate.
2) When you begin an exercise regimen, we advise you use stimulation twice one day, and 30~60 minutes once.
3) How long to use the stimulation? Within your suitable intensity range, we recommend that you

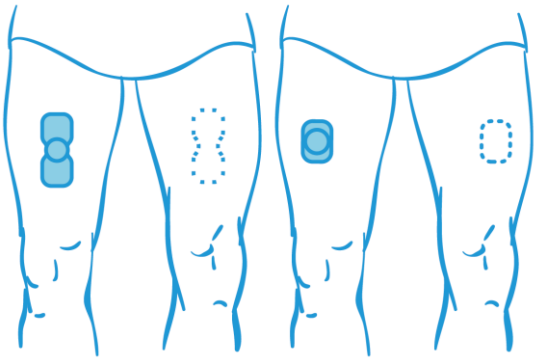
no more than 20 minutes each time.

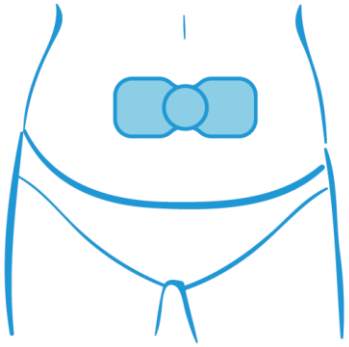
4) When increases stimulation? After you adapt to the intensity of stimulation, you can slowly increase the intensity of stimulation according to your exercise needs.
5) Which programs/modes should be used in each exercise regimen session? You can choose anyone in the 24 modes.
6) How to use each program/mode when increasing the exercise regimen? When you want to increase the exercise regimen, you can choose the appropriate mode according to your stimulation experience. At this time, the more decisive factor is the intensity.

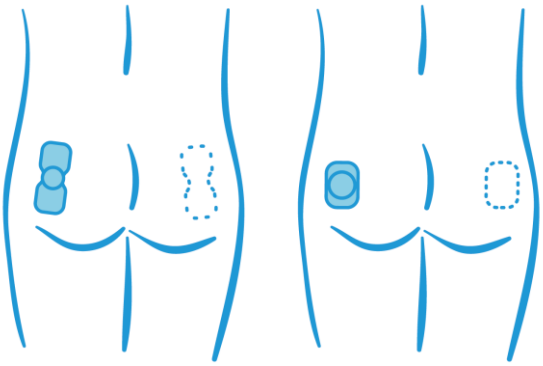
2 EMS Schematic of recommended electrode placement at the stimulation site

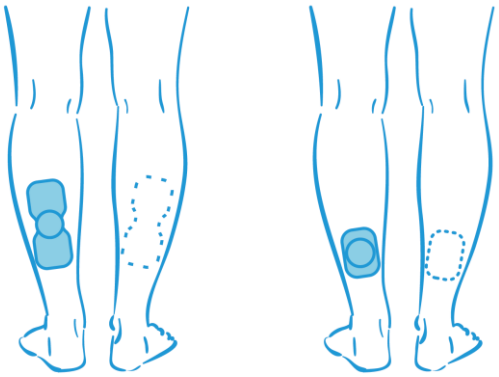


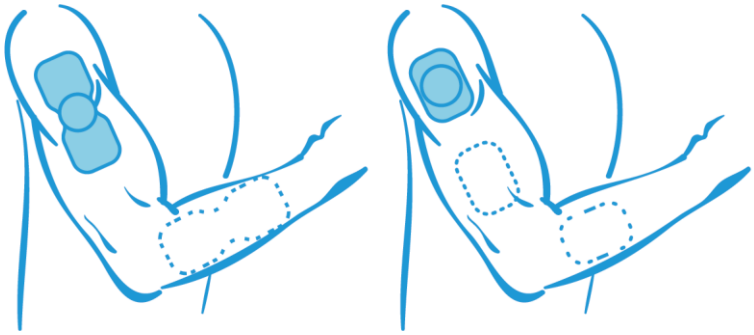












13 Electromagnetic Compatibility

1 Technical Description

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is compliance for each EMISSIONS test specified by the standard, e.g. EMISSIONS class and group.		
Emissions	**Compliance**	**Electromagnetic environment-- guidance**
RF emissions CISPR 11	Group 1	The device 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 device.
RF emissions CISPR 11	Class B	The device 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	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
The device is compliance for each IMMUNITY test specified by the standard, e.g., IMMUNITY test level.		
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**
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
Radiated RF EM fields. IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line.	±0.5 kV, ±1 kV line-to-line.
Conducted disturbances induced by RF fields. IEC 61000-4-6	3V 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz
Power frequency magnetic field immunity IEC 61000-4-8	30A/m,50/60Hz	30A/m,50/60Hz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T: 0.5 cycle [a)] At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°.	0% U_T: 0.5 cycle [a)] At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°.
	0% U_T: 1 cycle 70% U_T: 25/30 cycles	0% U_T: 1 cycle 70% U_T: 25/30 cycles

	Single phase: at 0°	Single phase: at 0°
	0% U_T: 250/300 cycles	0% U_T: 250/300 cycles
NOTE a) U_T is the AC. mains voltage prior to application of the test level;		

Table 3

Guidance and manufacture's declaration – electromagnetic immunity			
The Wireless TENS & EMS Unit is intended for use in the electromagnetic environment specified below. The customer or the user of Wireless TENS & EMS Unit should ensure 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	3 Vrms 150 kHz to 80 MHz outside ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands	3 Vrms 6 Vrms	Portable and mobile RF communications device should be used no closer to any part of the Muscle and Nerve Stimulator TENS & EMS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 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	3 V/m 80 MHz to 2.5 GHz 10 V/m 80 MHz to 2.6 GHz	3 V/m 10 V/m	
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.			
a) 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 Wireless TENS & EMS Unit is used exceeds the applicable RF compliance level above, the Wireless TENS & EMS Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Wireless TENS & EMS Unit.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications device and the Wireless TENS & EMS Unit			
The Wireless TENS & EMS Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless TENS & EMS Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications device (transmitters) and the Muscle and Wireless TENS & EMS Unit as recommended below, according to the maximum output power of the communications device.			
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 2.5 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**
100	**11.667**	**11.667**	**23.333**
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.			

2 Information Related to EMC

2.1 Labeling related EMC

1) The environments of use for which this device is suitable to be used/exposed

Home Healthcare Environment: any environment where personnel with medical training are not continually available to oversee or administer the use of medical devices. This includes, but is not limited to, outdoor environments (e.g., streets, sidewalks, parks), office environments, office buildings, schools, vehicles, emergency shelters, independent living retirement homes, personal residences, dormitories, independent living retirement homes, restaurants and cafes, shops, stores, markets, cars, buses, trains, boats, ambulances, churches, libraries, theaters and stadiums and so on.

2) There is no essential performance associated with EMC with this device.
3) Power supply: Electrode battery specifications: 3.7V 90mah.Charging compartment battery specifications: 3.7V 600mah.
4) As of the date of manufacturing, there have been no reported or potentially harmful medical device-related events associated with the EMC of this device. It includes medical device nonconformities that have no related harm, medical device malfunctions that have no related harm, and procedure-related complications with no related harm.
5) Accessories and other device compatible with this device have not been identified.
6) If the functions or performance are lost or degraded due to EM disturbances, you can switch off the device and switch it on again or, alternatively, you can use it again in a home healthcare environment, Alternatively, you can contact us if the device still doesn't work (see the contact information in page 39).
7) The compliance level for each emissions and immunity test, please see above table 1, table 2 and table 3.
8) Electromagnetic interference may cause loss or degradation of the function/performance of the medical device, therefore, the following device faults may be caused by electromagnetic interference:
a) Display Errors: Electromagnetic interference can cause display errors which causes you to misuse the device.
b) Device crashes or malfunctions: electromagnetic interference may be overload circuits, damage chips or crash software in the device. This may result in the device not working properly or buttons invalid, crashing or failing to boot.
c) Safety hazards: electromagnetic interference may constitute a safety impact on this device, i.e. distortion of the intensity control, resulting in the actual output intensity exceeding the set intensity, and even leading to the user's sense of electric shock.
When any of these abnormalities occur, stop using the device immediately and contact the manufacturer.
2.2 Explanations about the EMC of common electromagnetic emitters
Do not expose this device to those RF emitters or other specific potential sources of electromagnetic interference, such as Wireless power transfer (WPT) , 5G cellular, security systems (e.g., electromagnetic anti-theft systems (EAS), and metal detectors), Diathermy and electrocautery.

14 Manufacturer information

1 Medical Disclaimer

All information is intended for you general knowledge only and is not a substitute for medical advice or treatment for specific medical conditions. We cannot and do not give you medical advice. You should seek prompt medical care for any specific health issues and consult your health care provider before purchasing any product(s). The information contained here is intended to provide broad consumer understanding and knowledge of product offered.
The information should not be considered complete and should not be used in place of a visit, call, consultation or advice or your health care provider. Should you have any healthcare-related questions, please call or see your healthcare provider promptly. You should never disregard medical advice or delay in seeking it because of something you have read here.

2 Contact Information

Manufacturer Name: Changsha Anxiang Medical Technology Co., Ltd.
Address: 9th Floor, R&D Center and Supporting Projects 101, No. 18 Shaoshan Middle Road, Dongtang Street, Yuhua District, Changsha, Hunan, China.
Postal Code: 410000
Email: yoyo.yang@yuwen-tech.com

3 Precautions to be taken in the event of changes in the performance of me device or me system.

Me device, me systems and accessories require professional hygienic maintenance prior to re-use. When the ME device is transferred to another patient, please contact us for the relevant service.

4 Meanings of Symbols

Meanings of symbols used for marking described in instructions for use	
	MR Unsafe
	Caution!
	Type BF applied part
IP22	Protected against solid foreign objects of 12,5 mm ⌀ and greater; Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
	Refer to instruction manual
	Serial Number
	Lot Number
	Manufacturer information
	WEEE Label

15 Warranty

1 Parts Service Life

Control unit: 2 years.

Batteries: repeated charge and discharge 500 times. The 2 output pods are all turned on, use the highest frequency mode, and the intensity is adjusted to the maximum.

Software version: First edition

2 Declaration of conformity

Changsha Anxiang Medical Technology Co., Ltd. declares that the device complies with following normative documents, ANSI AAMI ES60601-1, IEC60601-1-2, IEC60601-1-11, IEC60601-2-10, ISO10993-5, ISO10993-10