Instruction Manual

TENS targeted
Neuromodulation

Version No.: US02

Emeterm

Note

- Before first use, charge the battery to over 60% capacity.
- Please clean the skin before wearing. The device should be applied to the correct position (P6).
- The time of use varies according to individual situation and users could adjust the intensity of the device according to the feeling of the symptoms.
- Under low temperature and low moisture climate (e.g. winter), it is recommended to start the treatment at least 30 minutes before experiencing nausea.

Video operation introduction

https://youtu.be/IGEt_n5uDVE

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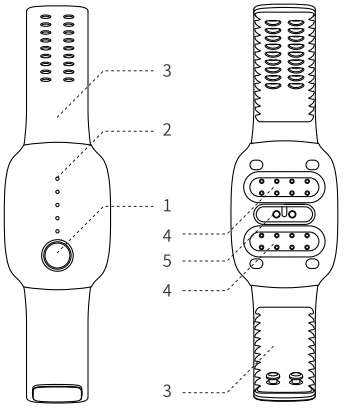
Quick Start Guide

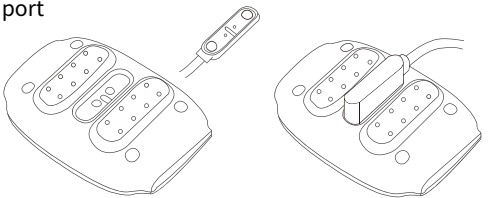
I. Device features



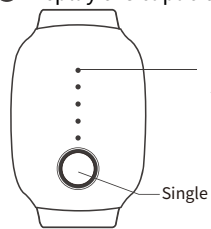
1. Control button
2. Indicator lights
3. Wristband
4. Electrodes
5. Charging port

II. Battery charging

❶ Connect the magnetic connector to the charging port



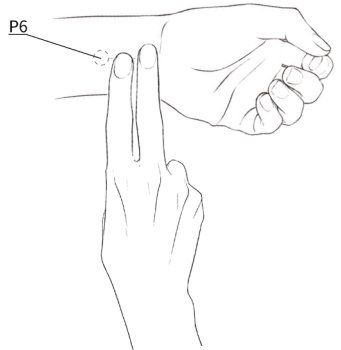
❷ Display the capacity of battery



Indicator lights	1	2	3	4	5
Battery level	20%	40%	60%	80%	100%

III. Wearing instructions

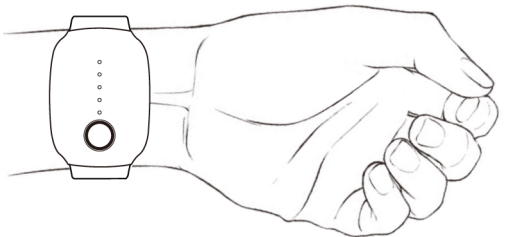
❶ Position(P6): 2-3cm away from the transverse wrist lines, with a width of about 2 fingers.



Attention.

The device should be applied to clean and healthy skin.

❷Wear the device.
Ensure skin is sufficiently in contact with electrodes.

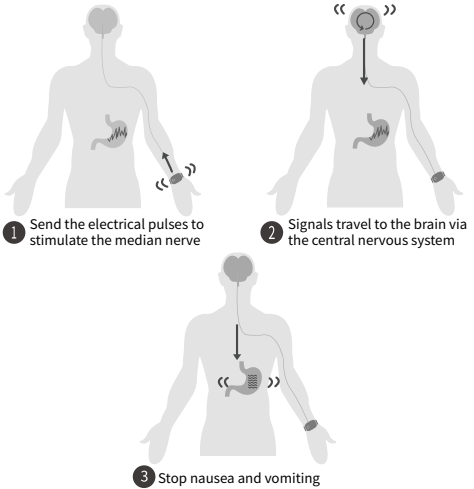


Attention:
The device should be applied to the correct position (P6).

IV. Operating instructions

Turn on	Press the button for 3 seconds
Turn off	Press the button for 3 seconds
Increase	Single click for 1 gear increase
Decrease	Double click for 1 gear decrease

V. Operating principles



Manual Instruction

Name of Product

TENS device-EmeTerm

Specification and Model

YF-ZTY-E1

Packing Specification

The packing specification for each model is one piece per case. The product configuration list is shown in the following table:

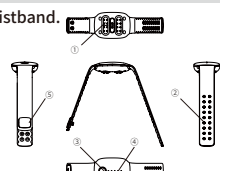
Name of Accessory	Quantity
Main unit	One set
Wristband	One set
Instruction files	One set

Please use CE certificated adapter and charging line.

Product Structure

1. Structure of the product: Main unit, wristband.

No.	Name
①	Electrodes
②	Wristband
③	Control button
④	Front side of host
⑤	Buckle



2. Technical Parameters of Product

Output	Parameters				
Gear range	1	2	3	4	5
Voltage	22.8V	28.8V	32.4V	34.0V	36V
Range of amplitude	-39.5V ～ +39.5V（±3V）				
Oscillogram	Mode		Pulse width		Frequency
	Orthogonal pulse sharp-wave		100μs（±10%）		33Hz（±3）

3. Battery information: 3.7V DC. 140mAh Lithium battery

Range of Application

TENS device-EmeTerm is a wearable device for the treatment of nausea and vomiting caused by motion sickness and pregnancy.

Contact Classification

Electrical Safety Applied Part is Type BF.

Duration of Contact

The maximum time of contact per use is up to 7 hours with a fully charged battery. Typically, the patient will remove the device when their symptoms are gone, therefore the the minimum duration of contact would be determined by different individual in accordance with their needs.

Cleaning Instructions

Keep the electrode area clean by using a damp cloth or alcohol. Please wipe the electrode after every use.

Contraindication

(1) Patients who are suffering from acute inflammation, hemorrhagic tendency, arrhythmia and epilepsy;
(2) People who have metal piece or cardiac pacemaker within their bodies;
(3) Please consult your physician if you have any other contraindications;
(4) People with craniocerebral injury or maxillo-facial injury recently;
(5) Patients with brain tumor, meningitis or acute cerebrovascular stroke;
(6) Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device without consulting professional physician. Such use could cause electric shock, burns, electrical interference, or death.

Warning

1. Please use the device according to the instruction manual in order to ensure a safe use.
2. Please do not use the device if you are suffering from skin ulceration, allergy, bleeding, infection or other types of open wounds.
3. Please do not use the device together with a high-frequency device. It is forbidden to put this device and a high-frequency device in the same treatment room.
4. It is not suitable for patients to adjust the device at a high gear in their first use of the device because they have not got prepared psychologically. After 2 to 3 times of treatment, patients can have gear up gradually.
5. It is not allowed to put the electrode on the unspecified part for use.
6. Patients who have medical electronic products in their bodies such as cardiac pacemakers, metal implants and so on are forbidden to use the device.

7. Patients who have metal foreign bodies in them are forbidden to use the device.
8. The electro-conductibility of the device varies with individual physique and surrounding environment, thus affecting the using effect.
It is general to intensify the electro-conductibility by gearing up the device, tightening the wrist strap, or applying conductive paste or appropriate amount of water on the wrist.
9. It is normal that a slight tingling will develop on the wrist while wearing the device. For users who have pruritus and tingling, they may wear the device on the other wrist. Generally, the pruritus and tingling will disappear in 24 hours.
10. Please clean the device before treatment.
11. If you are in the care of a physician, consult with your physician before using this device;
12. Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
13. Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal;
14. 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);
15. Do not apply stimulation over, or in proximity to, cancerous lesions;
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 or shower;
18. Do not apply stimulation while sleeping;
19. Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
20. Do not use the device on children, if it has not been evaluated for pediatric use.
21. Apply stimulation only to normal, intact, clean, healthy skin.

Precautions

1. Please consult your physician if you have any other concerns.
2. TENS devices have no curative value;
3. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
4. The long-term effects of electrical stimulation are unknown;
5. The safety of electrical stimulation during pregnancy has not been established (EmeTerm is approved by FDA for the indications of the treatment of nausea and vomiting caused by motion sickness and pregnancy.) ;
6. You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);
7. If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician;
8. If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician;
9. Use caution if you have a tendency to bleed internally, such as following an injury or fracture;
10. Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;

11. Use caution if stimulation is applied over the menstruating or pregnant uterus;
12. Use caution if stimulation is applied over areas of skin that lack normal sensation;
13. Keep this device out of the reach of children.

Adverse Reactions

1. You may experience skin irritation and burns beneath when the stimulation electrodes applied to your skin;
2. You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

Usage

Wearing: Place the contact plate (two metal electrodes) of the device at the center of the inner wrist, about 2 to 3cm from the wrist crease. Please ensure the control button is close to your body side, and then fasten the wrist wrap at a suitable tightness.

Starting up: Press the control button for 3 seconds to start up the device, and then the display lights from the first gear to the fifth gear will be on in turn and at last stay at the first gear. If the button light and the gear light flash intermittently at the same time, it means the product is working normally.

Gear range: The product has five gears (1, 2, 3, 4, 5 indicating the function goes from weak to strong) which are used to adjust the intensity of function. Users can select their suitable gears by themselves.
(1) Single click (shorter than 1 second) on the control button will increase one gear. Users can know the current gear through the display light (For instance, the first three display lights and the button light will be on if the device is at the third gear.).
(2) Double click on the control button will decrease one gear. Users

can know the current gear through the display light.

Power off: Press the control button for 3 seconds, and the display lights from the first gear to the fifth gear will be on in turn and then go out, indicating that the device is powered off.
State of charge:
(1) Single click on the control button under the power-off state will enable the gear display light to display the current state of battery capacity. The first gear to the fifth gear indicate that the battery capacity goes from 20% to 100%.
(2) Reminder of low power when the product is working: the product will be power-off automatically after the button light and the gear light flash for 15s at the same time.

Charging: The device should be charged by the attached USB cable which can connect to the chargeing port and the computer' s USB port. While charging the device, the device' s charging indicator light is on while the gear display light displays the progress of charging (after it is fully charged, all of the five gear lights will be on).

Maintenance

1. Keep the device clean, and use it following the usage steps.
2. Put the device in a dry and well-ventilated place. Do not put it under the window or beside the heating installation to protect it from heating and dampness.
3. It is not allowed to expose the device to environment with strong electromagnetic interference.
4. Please turn off the power after use.

Disposal

Dispose device according to your local state/country laws.

Operating Conditions

Normal operating conditions should comply with the following requirements:
Environment temperature: 5°C～40°C
Relative humidity: 10%～80%
Atmospheric pressure: 86kPa～106kPa

Storage

The product should be stored in accordance with the following requirements:
Environment temperature: -20°C～+55°C
Relative humidity: 10%～80%
Atmospheric pressure: 50kPa～106kPa
Indoor, dry and well-ventilated, free from corrosive substances
Great pressure is not allowed to be put on the product.

Date of Manufacturing and shelf life

See the packaging.
Device shelf life: 18 months

Manufacturing Enterprise and After-sale Service Agency

Manufacturer: WAT Medical Technology Inc. (WAT Med)
Add.: Room703-711, No.2 North Taoyuan Road, Ningbo, Zhejiang Province, P.R.C
Tel.: 86-574-65060811
Fax: 86-574-65060815
Email: info@watmedical.com

Labels and packaging marks

No.	Symbol	Meaning
1		Manufacturing date of product
2		Serial number of product
3		Note! Please check all documents attached
4		Information of manufacturer
5		Information of EU authorized representative
6		The product has passed CE certification
7		BF type
8		The product contains battery, so please don' t throw it away freely.
9		Refer to the Instruction Manual
10	IP22	The waterproof and dustproof grades of this product reach the standard

Effective Date: 2021-01-29 Rev. A/5 EN/US

Attachment: EMC-IT-CE-EN60601-1-2

1. Test summary

Test Reference Standard	Test Item	Result (Pass/Fail)	Remark
Emission Measurements			
CISPR 11	Conducted Emission	Pass	-
CISPR 11	Radiated Emission	Pass	-
EN 61000-3-2	Harmonic Current Emissions	N/A	-
EN 61000-3-3	Voltage Fluctuations and Flicker	Pass	-
Immunity Measurements			
EN 61000-4-2	Electrostatic Discharge	Pass	-
EN 61000-4-3	Radio-frequency Electromagnetic Field	Pass	-
EN 61000-4-4	Fast transients, Common Mode	Pass	-
EN 61000-4-5	Surges	Pass	-
EN 61000-4-6	Radio-frequency Common Mode	Pass	-
EN 61000-4-8	Power-frequency Magnetic Fields	Pass	-
EN 61000-4-11	Voltage Dips and Interruptions	Pass	-

2. Limit of Conducted Emission

Limits of conducted emission for AC mains power input/output ports		
Frequency range MHz	Limits dB(μV)	
	Quasi-peak	Average
0.15 to 0.50	66 to 56	56 to 46
0.50 to 5	56	46
5 to 30	60	50
Note: The lower limit shall apply at the transition frequencies.		

3. Limit of Radiated Emission

Frequency range MHz	Quasi-peak limits dB(μV/m)
30 to 230	40
230 to 1000	47

Note 1: The lower limit shall apply at the transition frequency.
Note 2: Additional provisions may be required for cases where interference occurs.

4. Limit of Electrostatic Discharge

Environmental phenomenon	Test specification	Units	Performance criterion
Electrostatic Discharge	±8 (Contact discharge) ±2, ±4, ±8, ±15 (Air discharge)	kV (Charge voltage) kV (Charge voltage)	No performance degradation which associated with basic safety and essential performance

5. Limit of Radio-frequency Electromagnetic Field (EN 61000-4-3: 2006+A1:2008+A2:2010)

Environmental phenomenon	Test specification	Units	Performance criterion
Radio frequency electromagnetic field	80 - 2700 3 80	MHz V/m (unmodulated, r.m.s) % AM (1kHz)	No performance degradation which associated with basic safety and essential performance

9. Limit of Electrical Fast Transients

Environmental phenomenon	Test specification	Units	Performance criterion
AC power lines			
Electrical fast transients	±2 5/50 100	kV (open circuit test voltage) Tr/Th (ns) Repetition frequency (kHz)	No performance degradation which associated with basic safety and essential performance
Signal and interconnecting cables			
Electrical fast transients	±1 5/50 100	kV (open circuit test voltage) Tr/Th (ns) Repetition frequency (kHz)	No performance degradation which associated with basic safety and essential performance

10. Limit of Surges

Environmental phenomenon	Test specification	Units	Performance criterion
AC power lines			
Surges	1.2/50 (8/20) ±0.5, ±1 line to line ±0.5, ±1, ±2 line to earth	Tr/Th (us) kV (open circuit test voltage) kV (open circuit test voltage)	No performance degradation which associated with basic safety and essential performance

11. Limit of Radio-frequency Common Mode

Environmental phenomenon	Test specification	Units	Performance criterion
Input AC power ports			
Radio-frequency common mode	0.15 - 80 3 80	MHz V (unmodulated, r.m.s) % AM (1kHz)	A
Signal and interconnecting cables			
Radio frequency common mode	0.15 - 80 3 80	MHz V (unmodulated, r.m.s) % AM (1kHz)	A

12. Limit of Power-frequency Magnetic Field

Environmental phenomenon	Test specification	Units	Performance criterion
Power-frequency magnetic field	50, 60 30	Hz A/m	No performance degradation which associated with basic safety and essential performance

13. Limit of Voltage Dips and Interruptions

Environmental phenomenon	Test specification	Units	Performance criterion
Input AC power ports			
Voltage dips	0 0.5	% residual cycle	B
	0 1	% residual cycle	B
	70 25	% residual cycle	C
Voltage interruptions	0 250	% residual cycle	C

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