

Note

- Please clean your forehead (including sweat, cosmetics and dust) before wearing device.
- It is recommended to keep sitting or lying down during the use.
- Once the device is turned on, the intensity will increase to the highest level within 5 minutes. During this period, **press the button once to stop the increase and maintain the intensity.**
- Add a drop of water to the gel, and it will return to viscous state.
- Please turn off device **FIRSTLY**, then remove from forehead.

<https://youtu.be/SrMwuebZwkc>



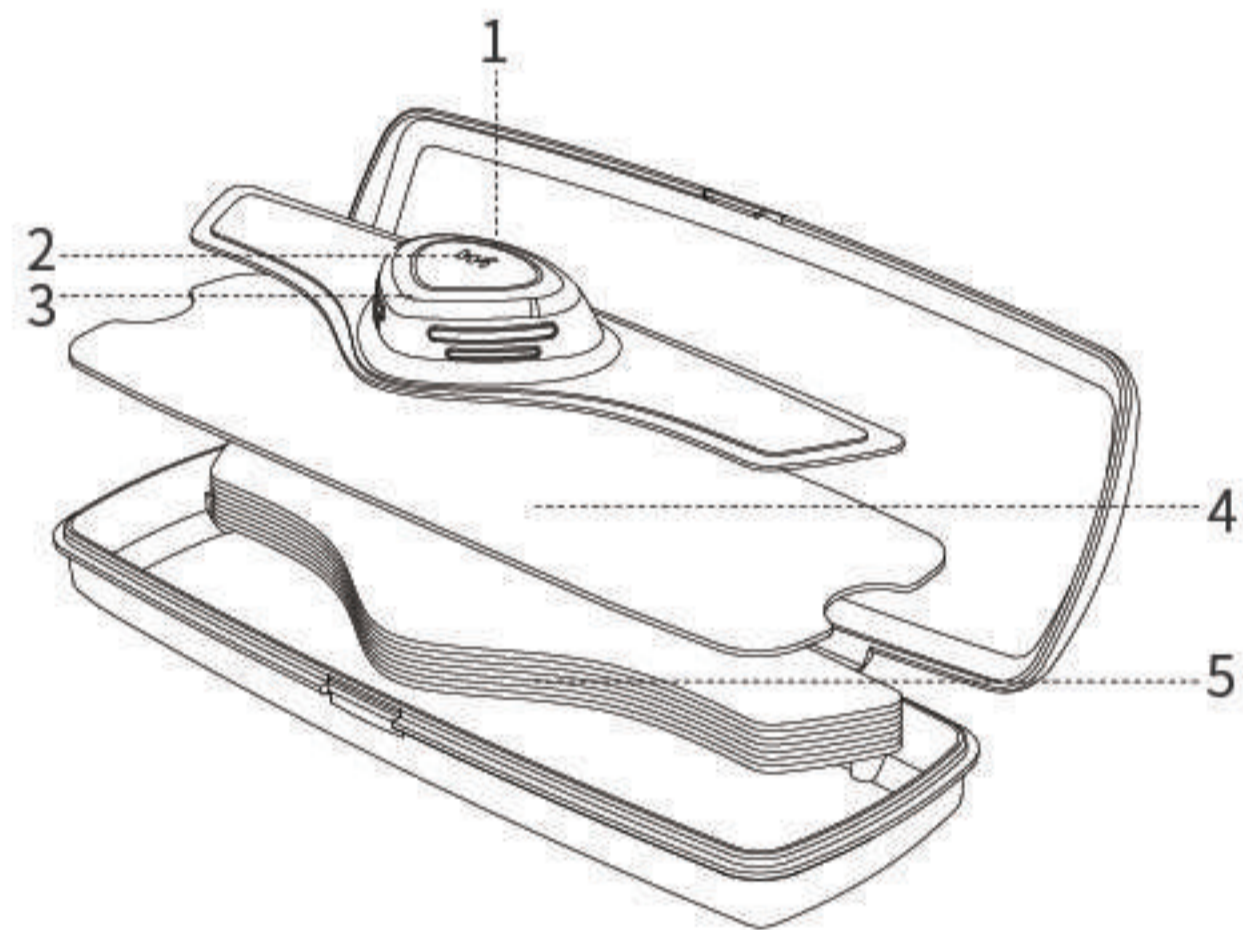
WAT Med

Innovative Self-Care Medical Device Supplier

Quick Start Guide

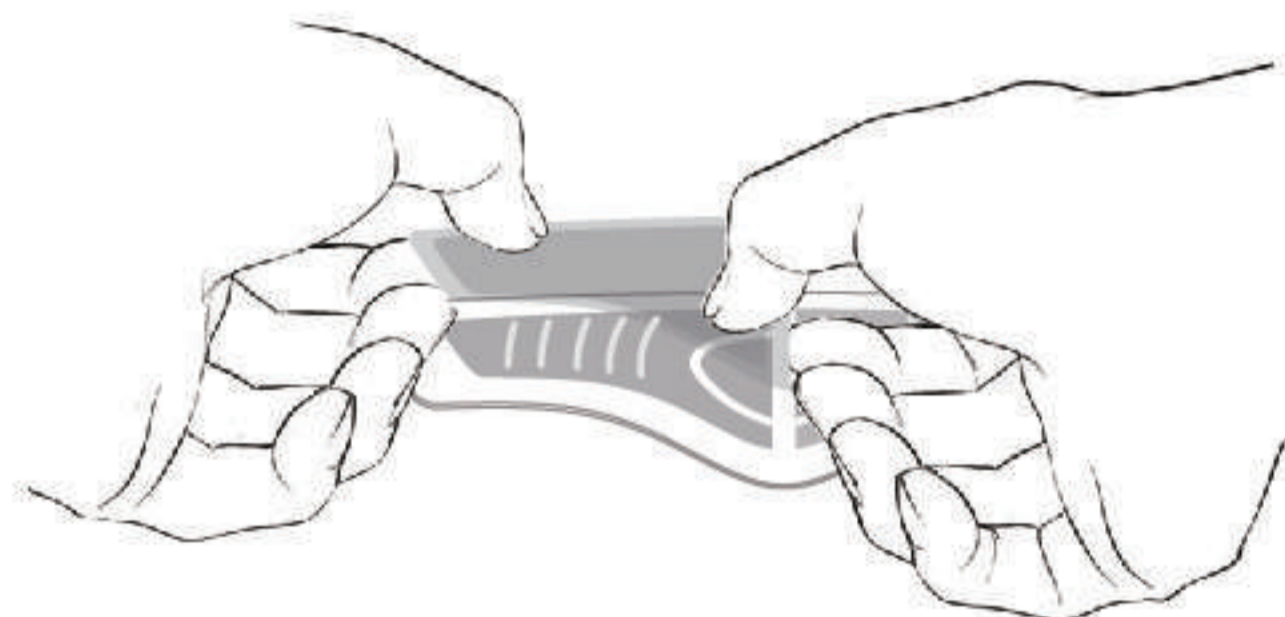
I. Device features

1. Indicator light
2. Button
3. Buzzer
4. Mirror
5. Conductive paste

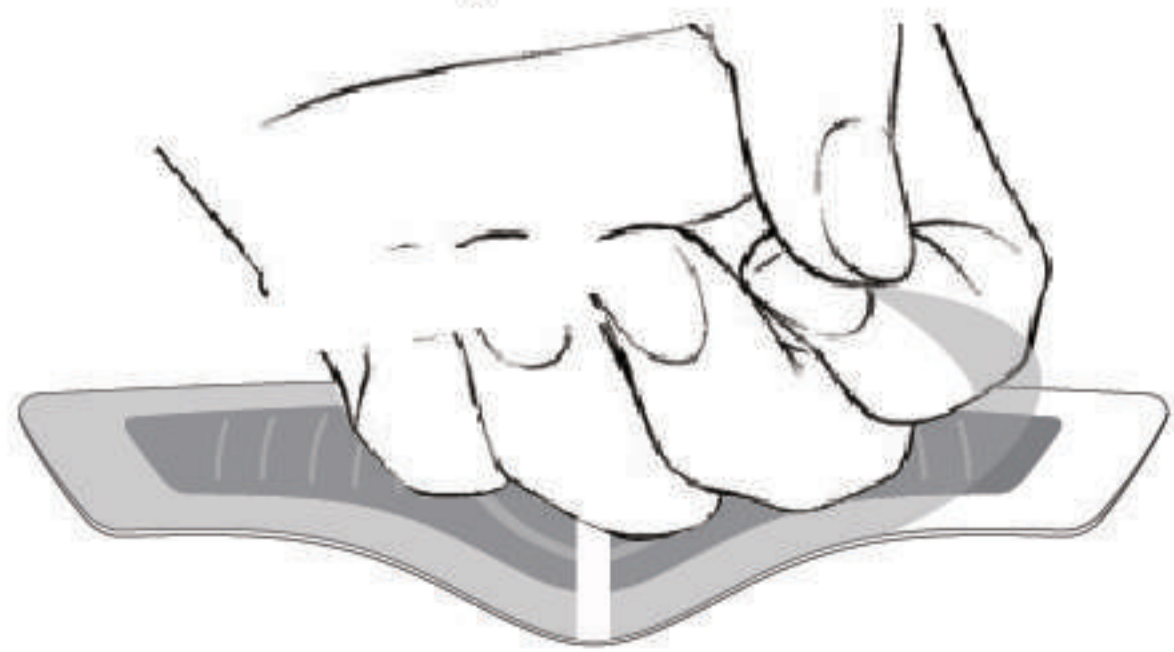


II. Preparation

- 1 Tear off the blue side thin film. Paste two conductive gels on the backside of the host machine respectively.

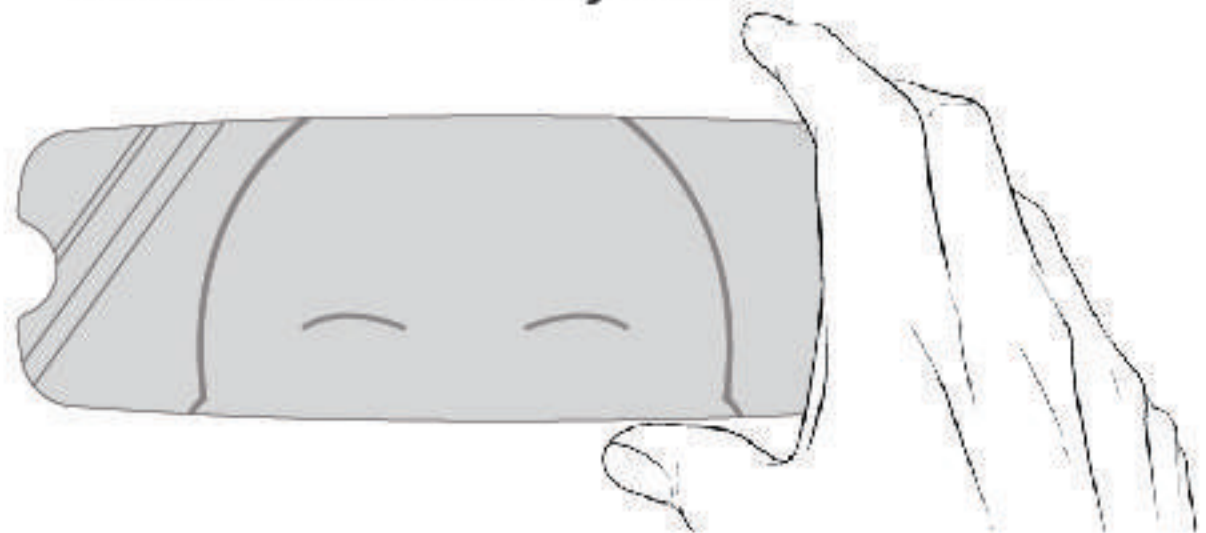


- 2 Tear off the transparent side thin film.



III. Wearing instructions

- 1 Align the mirror surface plaster to the forehead, the device should be applied to clean and healthy skin

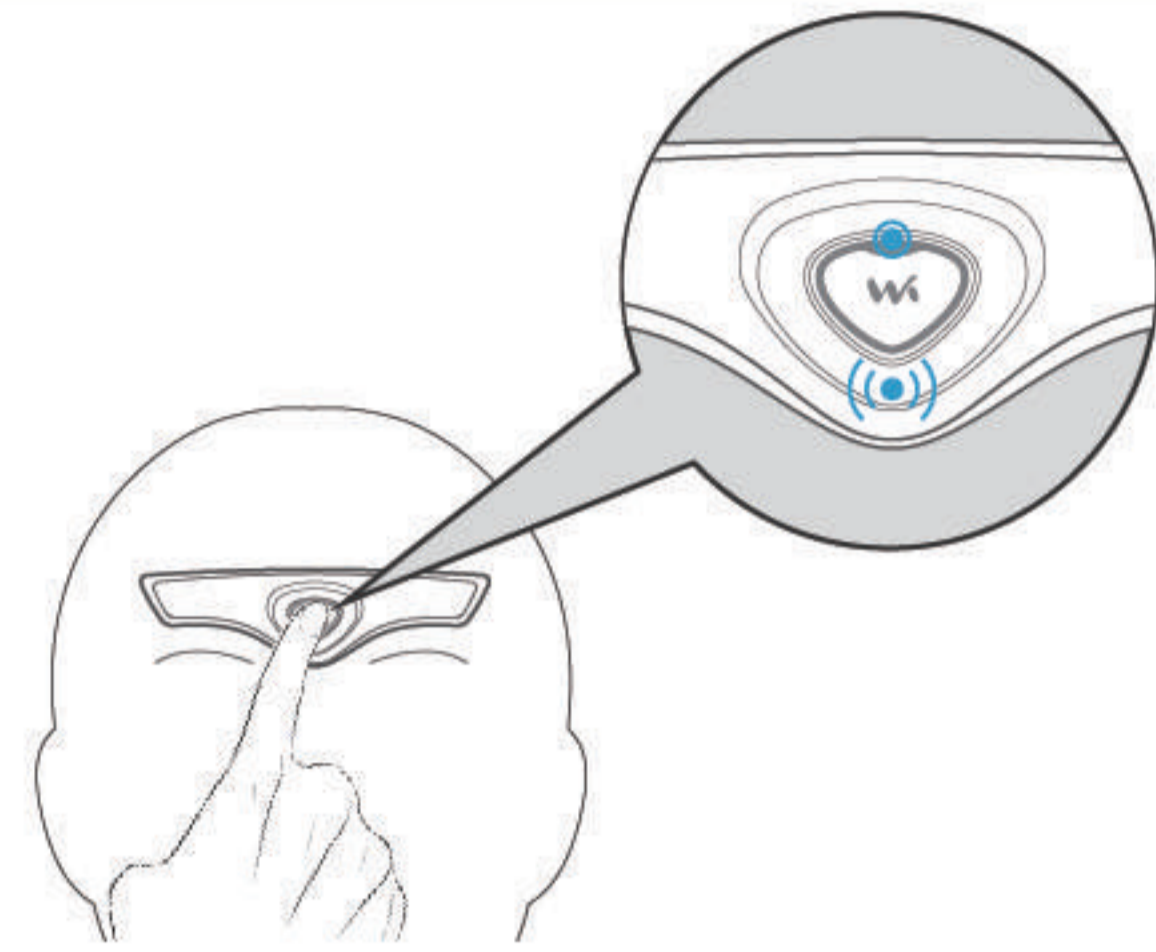


- 2 Paste host machine
Position: 1cm over the eyebrows



IV. Operating instructions

Turn on	Press the button for 1.5 seconds
Turn off	Press the button for 1.5 seconds
Intensity	Single click, the buzzer will give one sound

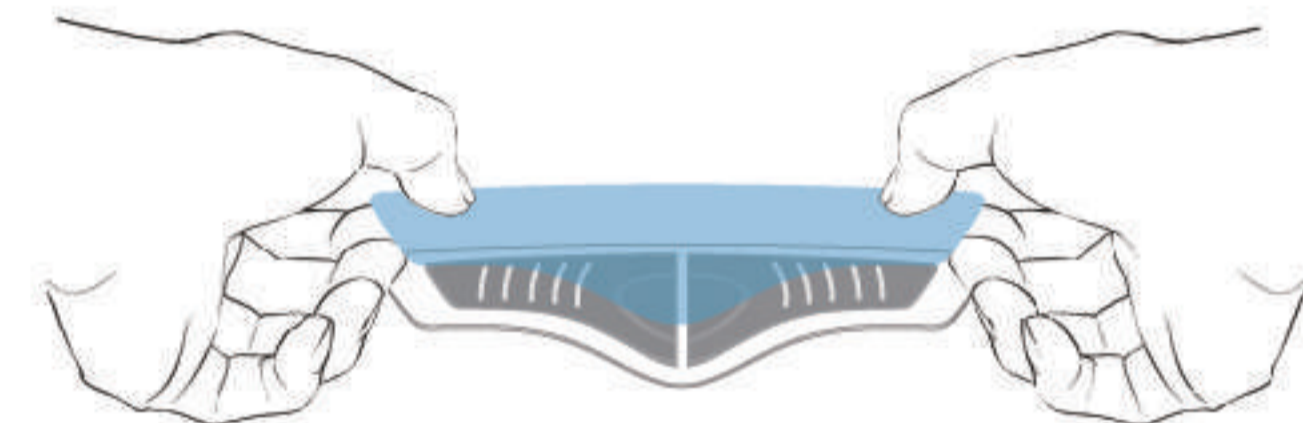


Attention

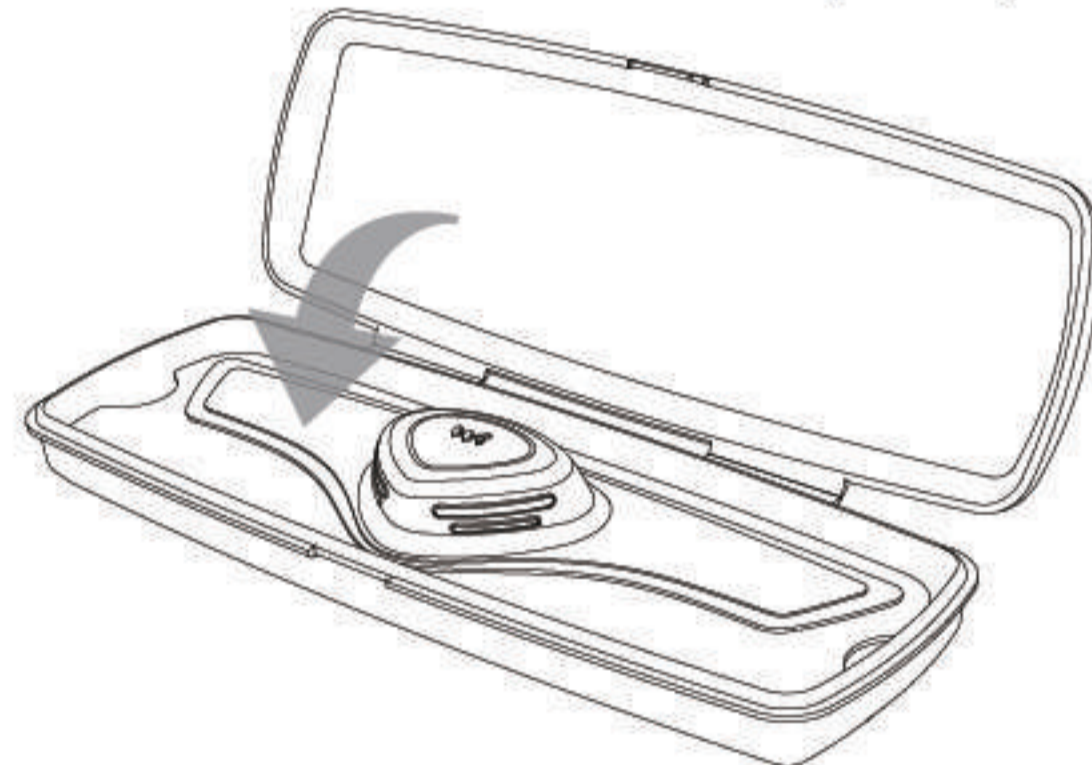
Turn off the device firstly, then tear it off slowly to avoid hurting the skin and damaging the conductive paste.

V. Storage

- 1 Place back the blue side thin film



- 2 Store the device as shown by the picture



Questions & Answers

When to use TENS device-HeadTerm?

You can use your TENS device-HeadTerm either before or after your headache symptoms start, and leave it on for as long as your symptoms last.

How long will the device remain active?

TENS device-HeadTerm is designed to function for more than 7 hours. Actual battery life will vary depending on patient usage.

When I press the button, I hear a continuous beep for 2 seconds and the device does not start.

The battery is empty: Change a new device.

When the device starts, it stops directly with a repeated sound.

The connection between the device and the skin is not good: Make sure to clean the skin before applying the conductive paste. Try again with a new conductive paste. In front of the mirror, check that the device is placed correctly.

Manual Instruction

Name of Product

TENS device-HeadTerm

Specification and Model

YF-HT-W1

Packing Specification

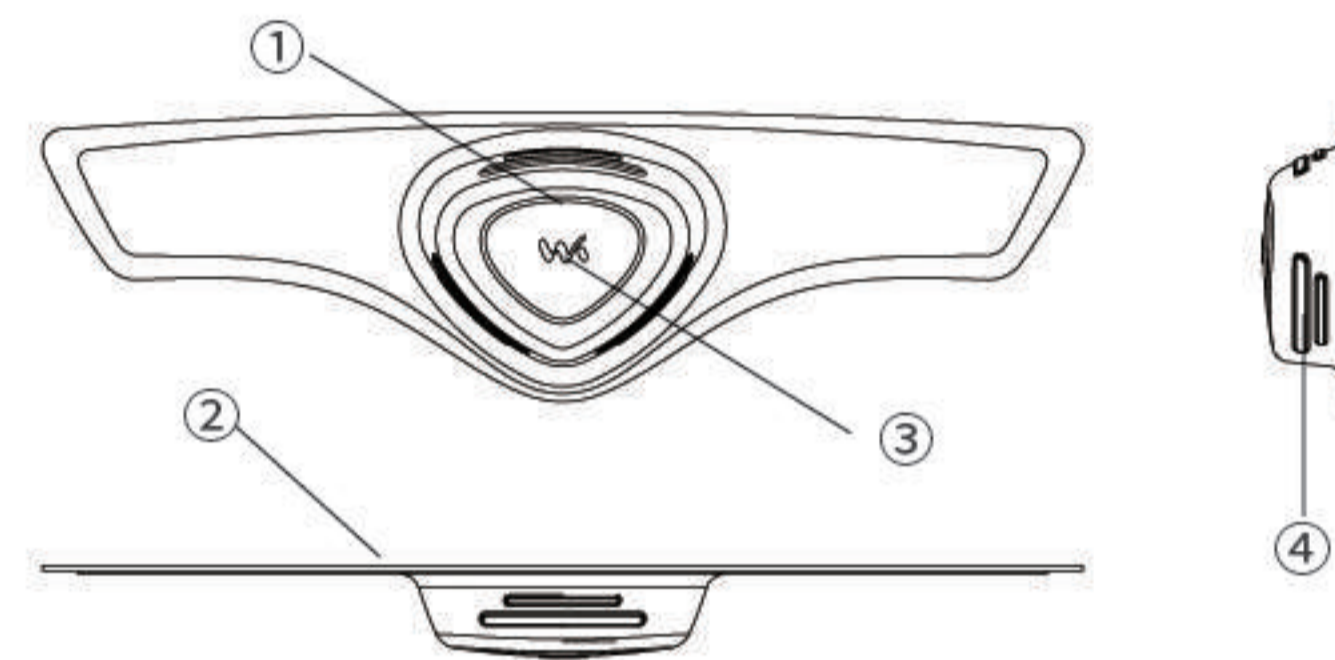
The packing specification for each model is one piece per case. The product configuration list is shown in the following table:

Name of Accessory	Quantity
Main unit	One set
Conductive paste	Three sets
Instruction files	One set

Product Structure

1. Structure of the product: Main unit and conductive paste

No.	Name
①	Indicator light
②	Back (electrode)
③	Control button
④	Side (anti-skid texture)



2. Technical Parameters of Product

Output	Parameters		
Range of amplitude	-60V ~ +60V(±3V)		
Oscillogram	Mode	Pulse width	Frequency
	AC sharp-wave	125us(±10us)	50Hz(±1)

3. Battery information: 3V DC. CR2032 button cell

Range of application

TENS device-HeadTerm is an anti-migraine device for the treatment of migraine headaches, including well-being, stress/depression, headache, insomnia, facial pain.

Contact Classification

Electrical Safety Applied Part is Type BF.

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) People with any **implantation materials** inside the cranium;
- (4) People with **craniocerebral injury or maxillo-facial injury** recently;
- (5) Patients with **brain tumor, meningitis or acute cerebrovascular stroke;**
- (6) Please consult your physician if you have any other contraindications.
- (7) Subjects suffering from pain of unknown origin.
- (8) Patients who are suffering from skin ulceration, allergy, bleeding, infection and so on.

Disposal

Dispose device according to your local state/country laws.

Usage

Wearing: Stick two pieces of conductive paste on the back of the device (There should be a certain space between the two pieces of conductive paste). Stick the device 1cm

above the place between the eyebrows, and stick the two straps on the skin fully, without any peel on the edge.

Starting up: The buzzer rings twice and the indicator lamp lights up and flickers twice intermittently after you press the control button on the host for 1.5 seconds.

Gear range: The device is equipped with the intensity adjustment function, and users can select the most suitable gears. The intensity of device keeps going up after the device is started. After it rises to the suitable intensity, you can make a short press on the control button to lock the current intensity after the buzzer rings once and the indicator lamp flickers once intermittently.

Working time: Start up the device with one press on the button, and it will be automatically power-off after being used for 20 minutes in single use.

Power off: After you press the button for 1.5 seconds, the buzzer will ring for five times, and the indicator light will go out after keeping on for 1 second.

Frequency

More than one 20-minute per day is not recommended because the safety and effectiveness of the TENS device-HeadTerm when used more than once per day has not been studied.

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 the environment with strong electromagnetic interference.
4. Please turn off the power after use.
5. Please stick the plastic sheet on the conductive silica gel after use, so as to protect the device against dust.
6. Please replace the conductive silica gel on the back in time if it is not adhesive enough.

Warning

1. Use the TENS device-HeadTerm only on the forehead.
2. Do not apply on the neck.
3. Do not apply on the chest.
4. Do not apply over open wounds. Do not apply over swollen, infected or inflamed areas. Do not apply over skin eruptions.
5. Do not apply over, or close to, cancerous lesions (skin abnormalities that could be cancer).
6. Do not use in the presence of electronic monitoring equipment (e.g., cardiac monitors, electrocardiogram (ECG) alarms).
7. Do not use in the bath or shower.
8. Do not use while sleeping.
9. Do not use during any activity that can put you at risk of injury.
10. Do not use the product together with a high-frequency device. Do not put this device and a high-frequency device in the same treatment room.
11. Apply stimulation only to normal, intact, clean skin.
12. The long term effects of using the TENS device-HeadTerm are unknown.
13. Migraines may indicate that you have a serious medical condition. You should have them checked by a doctor.
14. If the frequency of your headache is not reduced after 2 or 3 months of use, ask your doctor.
15. You should check with your doctor if you do not understand or if you are not sure whether any of the above "Contraindications" or "warnings" apply to you or your condition.

16. The TENS device-HeadTerm is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

Precautions

1. You should ask a doctor before using the TENS device-HeadTerm if you are, could be or could become pregnant.
2. You should ask your doctor before using the TENS device-HeadTerm if you suspect or know that you have problems with your heart.
3. You should ask your doctor before using the TENS device-HeadTerm if you have ever and had a seizure. You should ask your doctor before using the TENS device-HeadTerm if you have been diagnosed with epilepsy.
4. If you have had a recent head injury, you should not use the TENS device-HeadTerm until you have fully recovered.
5. You should use caution if there has been any loss of feeling in the skin of your forehead or scalp.
6. The safety and effectiveness of the TENS device-HeadTerm has not been demonstrated for subjects with medication overuse headache, chronic tension-type headache, chronic migraine, and refractory migraine.
7. The TENS device-HeadTerm will not cure your migraines. It will not reduce the severity of your migraine attacks.
8. The long-term effects of chronic use of the unit are unknown.
9. You should use this unit only with the conductive paste and accessories recommended by the manufacturer.

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: 12 months.
 The longest working time of this product once is about 20 minutes (±5s), and the cumulative hours used is not less than 7 hours.

Manufacturing Enterprise and After-sale

Manufacturer: WAT Medical Technology Inc.
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 Tel.: 86-574-65060811
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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 do not throw it away freely.
9		Refer to the Instruction Manual
10		The waterproof and dustproof grades of this product reach the standard

European Authorized Representative

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Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The YF-HT-W1 TENS device-HeadTerm is intended for use in the electromagnetic environment specified below. The customer or the user of the YF-HT-W1 TENS device-HeadTerm should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	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	< 5 % U _r (>95 % dip in U _r) for 0.5 cycle 40 % U _r (60 % dip in U _r) for 5 cycles 70 % U _r (30 % dip in U _r) for 25 cycles < 5 % U _r (>95 % dip in U _r) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the YF-HT-W1 TENS device-HeadTerm requires continued operation during power mains interruptions, it is recommended that the YF-HT-W1 TENS device-HeadTerm be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U _r is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The YF-HT-W1 TENS device-HeadTerm is intended for use in the electromagnetic environment specified below. The customer or the user of the YF-HT-W1 TENS device-HeadTerm should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the YF-HT-W1 TENS device-HeadTerm including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{f} \right] \sqrt{P}$ $d = \left[\frac{3.5}{f} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{f} \right] \sqrt{P}$ 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 metres (m).b 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	3 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 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 YF-HT-W1 TENS device-HeadTerm is used exceeds the applicable RF compliance level above, the YF-HT-W1 TENS device-HeadTerm should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the YF-HT-W1 TENS device-HeadTerm. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the YF-HT-W1 TENS device-HeadTerm				
The YF-HT-W1 TENS device-HeadTerm is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the YF-HT-W1 TENS device-HeadTerm can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the YF-HT-W1 TENS device-HeadTerm as recommended below, according to the maximum output power of the communications equipment				
Rated maximum output of transmitter	Separation distance according to frequency of transmitter			
	150 kHz to 80 MHz $d = \left[\frac{3.5}{f} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{f} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{f} \right] \sqrt{P}$	
0.01	/	0.12	0.23	
0.1	/	0.38	0.73	
1	/	1.2	2.3	
10	/	3.8	7.3	
100	/	12	23	
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres(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.				

Attachment: Annex of Report IEC60601-1-2 Manufacturer's Declaration of the EUT

Guidance and manufacturer's declaration – electromagnetic emission –for all EQUIPMENT and SYSTEMS

1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The YF-HT-W1 TENS device-HeadTerm is intended for use in the electromagnetic environment specified below. The customer or the user of YF-HT-W1 TENS device-HeadTerm should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The YF-HT-W1 TENS device-HeadTerm 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.
5	RF emissions CISPR 11	Class B	The YF-HT-W1 TENS device-HeadTerm is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	N/A	
7	Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	