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HeadTerm
Headache Migraine Relief Device

USER MANUAL
Headache Relief Without Medication

[Note]

- Please clean the forehead and the gel side of the electrode before using the device.
- Using the device while lying down provides the best user experience.
- The head strap may be used to prevent the electrode from detaching.
- The device automatically turns off during low battery.
- The device automatically stops treatment after 20 minutes of continuous use.
- Replace the electrodes as needed to provide optimal adhesive contact.

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QUICK START GUIDE

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[Name of Product]
TENS device-HeadTerm 2

[Specification and Model]
YF-HTZ

[Packaging Specification]
The packaging 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	1 set
Electrode	3 sets
Instruction manual	1 set
USB-C cable	1 set

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Instructions:

1. Clean the forehead with soap and water, then dry it before using the device.
This will help the electrode attach to the forehead securely.

2. Peel off the plastic protective layer on the back of the gel side of the electrode.

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3. With the gel side down, using a mirror for guidance, paste the electrode one finger width above the eyebrows.

Too low placement of the electrode close to the eyebrow
Rotated placement of the electrode

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4. The main unit magnetically attaches to the electrode.

5. Operating instructions
5.1. Turn on: Press and hold the control button for 2 seconds while the device is turned off.

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5.2. Single click the control button for 1 gear increase.

Double click the control button for 1 gear decrease.

5.3. Please adjust the gear to the level you feel most comfortable to achieve the best results.

Too weak
Too strong

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5.4. Turn off: Press and hold the control button for 2 seconds while the device is turned on.

5.5. The head strap may be used to prevent the electrode from detaching.

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6. Remove the device

6.1. Remove the main unit from electrode.

6.2. Tear off the electrode from forehead as shown below and discard it.

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7. Clean the main unit with tissue.

8. Store the main unit into canvas box.

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9. Please use USB-C charging cable to a 5V 1A adapter or computer USB port to charge the device.
Using the provided USB-C charging cable on other devices may result damage the device.

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Operation Guide:

Operation	Actions	Motor Feedback	Buzzer Feedback	Indicator Feedback
Turn on	Long press the control button for 2 seconds	Motor vibrates twice	/	Blinks periodically
Increase gear	Tap the control button for 1 gear intensity increase	/	1 x "beep" sound	Blinks periodically

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Operation	Actions	Motor Feedback	Buzzer Feedback	Indicator Feedback
Decrease gear	Tap the control button twice	/	2 x "beep" sounds	Blinks periodically
Turn off	Long press the control button for 2 seconds	Motor vibrates twice	/	Light off
Battery level (Fully battery charged)	Click the control button in the power off state	/	/	Remains on for 2 seconds
Battery level (Low battery level)	Click the control button in the power off state	/	/	Blinks for 2 seconds

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Operation Guide:

Status	Explanation	Motor Feedback	Buzzer Feedback	Indicator Feedback
Treatment completed	After 20 minutes of continuous use, the device automatically shuts down	Motor vibrates twice	/	Light off
In 9th gear	Maximum intensity, cannot increase any further	Motor vibrates twice	/	Blinks periodically
In 1st gear	Minimum intensity, cannot decrease any further	Motor vibrates twice	/	Blinks periodically

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Status	Explanation	Motor Feedback	Buzzer Feedback	Indicator Feedback
Low battery warning	Activates every five minutes when under 20% battery	Motor vibrates three times	/	Blinks periodically
Charging	Charging the device with USB-C cable	Motor vibrates three times	/	Blinks periodically
Fully charged	/	/	/	Remains on
Unable to be turned on	Insufficient battery to be turned on	/	/	/

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SPECIFICATIONS

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[Structure of Product]

1. Structure of the product: Main unit.

No.	Name	Function
1	Control button	Turns device on and off Decrease/Increase intensity
2	Indicator	Indicates operating status
3	Back (electrode)	Generates low frequency pulse

Figure 1. Device Illustration

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2. Technical Parameters of Product

Output	Parameters		
Range of amplitude	-60 V ~ +60 V (±3 V)		
Intensity of electrical stimulation	1-9		
Oscillogram	Mode	Pulse width	Frequency
	AC sharp-wave	250 us (±20 us)	60 Hz (±1 Hz)

Load: 27 KΩ ±47 nF

3. Battery information: 3.7V DC 60mAh Lithium battery

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[Essential Performance]
Pulse repetition amplitude: ±60 V (±3 V)
Pulse duration: 250 us (±20 us)
Pulse repetition frequencies: 60 Hz (±1 Hz)

[Indications for Use]
The TENS device-HeadTerm 2 is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

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[Operation Principle]

By releasing the low frequency pulse with a particular frequency and reaching the advanced nerve center of the cerebral cortex via the supraorbital nerve, device can adjust all signals causing headache which come from the biological and physical channels to stop or postpone the transmission of headache signal to cerebral center. Meanwhile, the device can improve an individual's ability to cope with headache symptoms by activating the release of endorphins in the body.

[Typical Sensations Experienced During Treatment]
Note: User experiences will vary between individuals.
1. HeadTerm 2 generates electrical impulses during its operation. The user may feel very minimal sensation or moderate tingling at the contact point.
2. Adjust the intensity as needed per each user's comfort.
3. The device will automatically stop treatment after 20 minutes of continuous use.

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[Date of Manufacturing and Shelf Life]
See the packaging.
Device shelf life: 24 months

[Contraindications]
1. Metallic or electronic brain implants.
2. Acute inflammation, hemorrhagic tendency, arrhythmia and epilepsy.
3. Traumatic brain injury, head trauma, or maxillo-facial injury.
4. Recent cranio-cerebral injury or maxillo-facial injury.
5. Brain tumor, meningitis or acute cerebrovascular stroke.
6. Unplanned or wearable defibrillator.
7. Impaired or worn out or discomform of unknown origin.

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[Risks and Benefits of Device Use]

Risks of device use:
Forehead skin swelling and stinging.

Benefits of device use:
1. Prophylactic treatment of episodic migraine through non pharmacological means.
2. No drug side effects.

Not adhering to the care regimen may result in ineffective treatment and potential injuries (see contraindications).

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[Warnings]

- Do not use if expiration date on the device has passed.
- Use the device only on the forehead.
- Do not apply on the neck and chest. The application of electrodes close to the thorax may increase the risk of cardiac fibrillation.
- Do not apply over open wounds. Do not apply over swollen, infected or inflamed areas. Do not apply over skin eruptions.
- Do not use in the presence of electronic monitoring equipment (e.g., cardiac monitors, electrocardiogram (ECG) alarms).
- Do not use while bathing or showering.
- Do not use during any activity that can put you at risk of injury.
- You should check with your doctor if you do not understand or if you are not sure whether any of the above contraindications apply to you or your condition.

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9. EMC WARNING: 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 equipment and result in improper operation.

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

11. EMC WARNING: Portable RF communications equipment (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 occur.

12. The device is incompatible with the simultaneous use of high frequency surgical equipment as it may result in burns at the site of the stimulator electrodes and possible damages to the device. Also, do not use the device in close proximity (less than 1 meter) to short wave or microwave therapy equipment as it may produce instability in the device output.

13. It is not recommended to connect the device with equipment not described in this user manual.

14. Do not modify without approval of manufacturer.

15. Suffocation risk in case of swallowing the electrode.

16. The device contains a battery. Misuse could result in fire/explosion/dangerous gas leak.

17. Do not use the same electrode on multiple people. For important reasons of hygiene, each user must have his or her own electrode.

18. This USB-C cable is only meant to charge this device, please note that there is a risk of damaging the product if connected to computers or other devices.

19. Not to use while sleeping.

20. Not to use while driving.

21. Not to use while operating machinery.

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[Precautions]

- TENS device-HeadTerm 2 is for patients with migraine per the indications for use.
- If you have any metal implants, please consult your doctor before using the device.
- Do not use if you are, or may be pregnant.
- If you have a history of head injury, please consult your doctor before using the device.
- You should use this unit only with the electrodes and accessories recommended by the manufacturer.
- Long-term effects of chronic use of the device are unknown.

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[Cleaning and Maintenance]

Step 1: Turn off the device.
Step 2: Wipe the surface of the device with a soft cloth and 75% alcohol, especially the magnetic contact part connected to the electrode.
Step 3: Visual inspection, if found that the surface is still contaminated, repeat the second step until the surface is clean.

Charging Dock and USB-C Cable
USB-C cable: Handle your cable carefully to avoid tangles. Keep the connectors at the ends of the cables clean. If they become dirty, clean them with a soft duster and an alcohol-based cleaning product.

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[Disposal]
Dispose device according to local state/county laws for electronic waste.

[Operating Conditions]
Normal operating conditions should comply with the following requirements:
Environment temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F)
Relative humidity: 10 % ~ 80 %
Atmospheric pressure: 86 ~ 106 kPa

Home self care environment
Portable RF communication equipment (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 connected. Otherwise, degradation of the performance of this device could occur.

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[Storage]
The product including conductive paste should be stored in accordance with the following requirements:
Environment temperature: -20 °C ~ +55 °C (-4 °F ~ +131 °F)
Relative humidity: 10 % ~ 80 %
Atmospheric pressure: 10 ~ 106 kPa
Indoor, dry and well-ventilated, free from corrosive substances
Do not put excessive pressure device or store under heavy items.

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[Guidance and Manufacturer's Declaration - Electromagnetic Emission]
The TENS device-HeadTerm 2 Connected is intended for use in the electromagnetic environment specified in the table. The customer or the user of the TENS device-HeadTerm 2 should ensure that it is used in such an environment.

Electromagnetic Interference
In order to regulate the requirements for EMC legislative compatibility with the aim of preventing unsafe product situations, the EMC IEC 60601-1-2:2014 edition standard has been implemented.

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[Labels and 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	☐	DF type
6	☐	Device contains a battery. Do not dispose in general waste stream/house hold trash.

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Appendix 2 - Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT AND SYSTEMS

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 15 kV contact ± 15 kV air	Electromagnetic environment - guidance
Electromagnetic transient / burst IEC 61000-4-4	± 1 kV for power 100 V for I/O	N/A	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, dips & short IEC 61000-4-11	0.5 U _n 10% cycle 0.2 U _n 10% cycle 0.5 U _n 10% cycle 0.2 U _n 10% cycle Drop phase of 0.5 U _n 0.2 U _n 10% cycle	N/A	Main power quality should be that of a typical commercial or hospital environment. In the case of the YF-HTZ TENS device-HeadTerm 2, requires constant operation during power mains interruptions. It is recommended that the YF-HTZ TENS device-HeadTerm 2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) IEC 61000-4-3	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_n is the a.c. mains voltage prior to application of the test level.

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Appendix 3 - Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT OR SYSTEM for EQUIPMENT AND SYSTEMS that are not LIFE-SUPPORTING

Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)	Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)
0.01	0.11	0.01	0.07
0.1	0.11	0.05	0.22
1	0.22	0.1	0.21
10	0.45	1.56	0.21
100	0.9	3.5	0.21

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Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE: 1) At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE: 2) These guidelines may not apply in all situations. Electromagnetic interference is affected by absorption and reflection from structures, objects and people.

(1) Field strengths from fixed transmitters, such as base stations for radio cellular/mobile telephony and land mobile radio, amateur radio and fixed broadcast used for terrestrial services (excluding fixed service mobile telephony) with antennas that are not directional should be less than the compliance level shown in the table. The YF-HTZ TENS device-HeadTerm 2 is used around the specified RF compliance level shown. The YF-HTZ TENS device-HeadTerm 2 should be operated to carry normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientation or relocating the YF-HTZ TENS device-HeadTerm 2.
(2) The frequency range 150 kHz to 80 MHz field strength should be less than 30V/m.

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HeadTerm

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