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HeadaTerm

Headache Migraine Relief Device

USER MANUAL

Headache Relief Without Medication

Version NO.: US01

Return & Help Center

For any product failure not related to user error, please contact us for a free replacement.

【Note】

- Relieve Migraine: 86% Effective in Reducing Migraine Pain Levels. The device is used to relieve migraine, not to eliminate them completely.
- Please clean the forehead and the gel side of the electrode before using the device.
- For the best experience, use the device while lying down and secure the electrode with the head strap if necessary.
- The device will automatically turn off when the battery is low. If it has not been used for an extended period, ensure it is fully charged before using it again.
- The device automatically stops treatment after 60 minutes of continuous use.
- Replace the electrodes as needed to provide optimal adhesive contact.

- For first-time use, it is recommended to start at a low gear level (1-2) to better adapt to the tingling sensation. Increase the gear as needed in subsequent sessions.
- For acute migraine treatment: Complete a 60-minute treatment session. If the migraine persists, start another 60-minute session.
- For migraine prevention: Accumulate a total of 60 minutes of use per day. Regular use over time yields better results.
- Ensure the device is turned off before removing it from the forehead.

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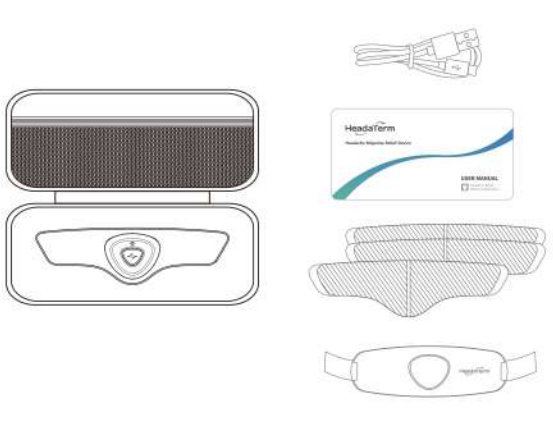
QUICK START GUIDE

HeadaTerm



【Name of Product】
TENS device-HeadaTerm 2

【Specification and Model】
YF-HT2

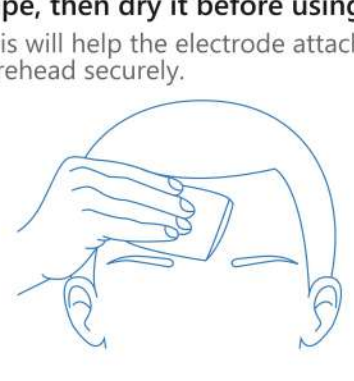
【Packaging Specification】
The packaging specification for each model is one piece per case.
The product configuration list is shown in the following table:

Name of Accessory	Quantity
Main unit	1 set
Electrode	3 pads per pack
User manual	1 set
USB-C cable	1 set
Head strap	1 set

Note: Electrode pack quantity varies by version.

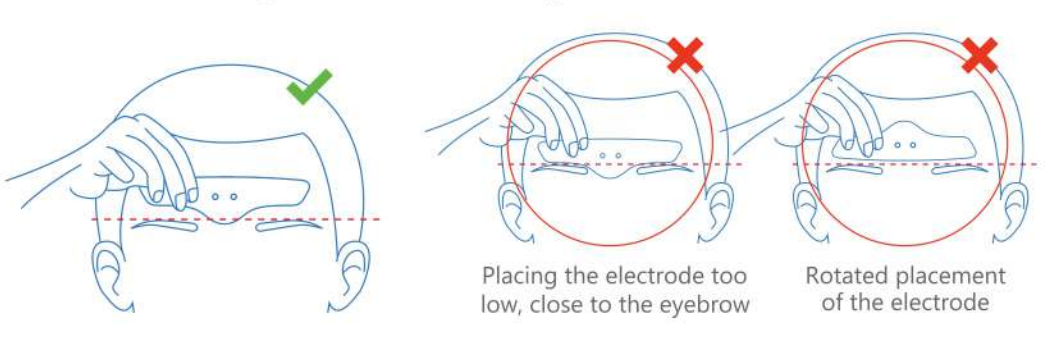
Instructions:

1. Clean the forehead with a cleansing wipe, then dry it before using the device.
This will help the electrode attach to the forehead securely.



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

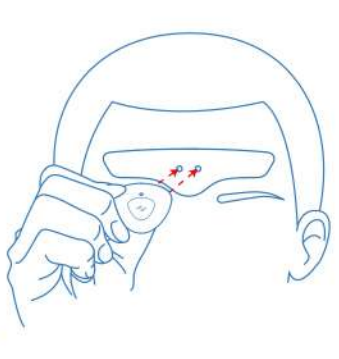
3. With the gel side facing down, use a mirror for guidance and place the electrode one finger-width above the eyebrows.



Placing the electrode too low, close to the eyebrow

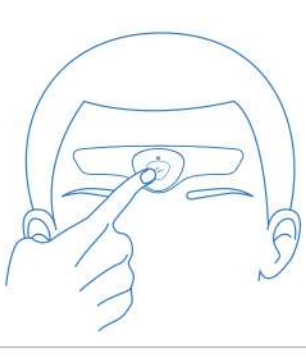
Rotated placement of the electrode

4. The main unit magnetically attaches to the electrode.



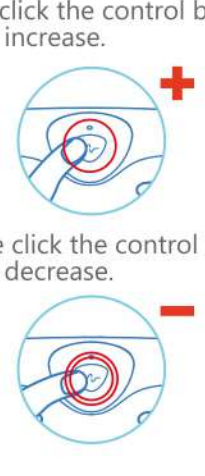
5. Operating instructions

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

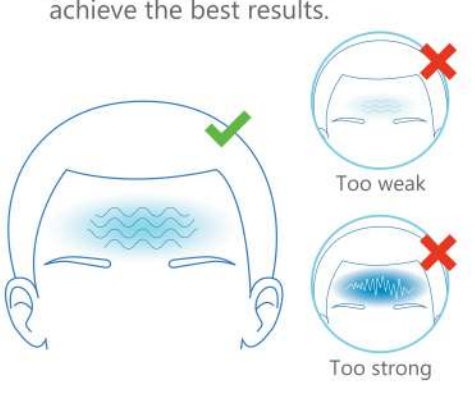


5.2. Single click the control button for 1 gear increase.

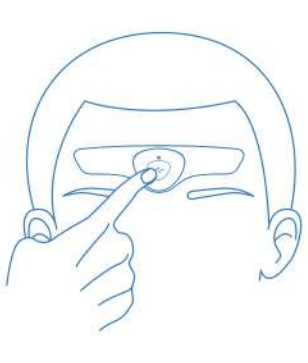
Double click the control button for 1 gear decrease.



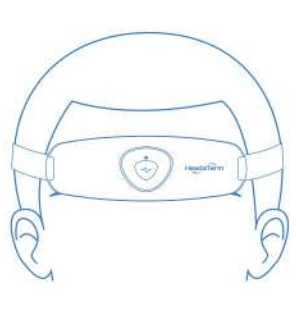
5.3. Please adjust the gear to the level you feel most comfortable to achieve the best results.



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

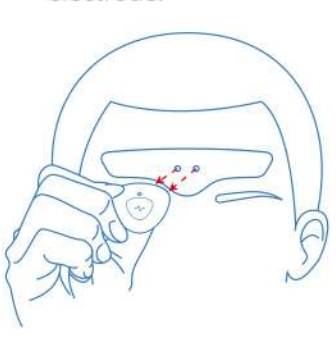


5.5. The head strap may be used to prevent the electrode from detaching.

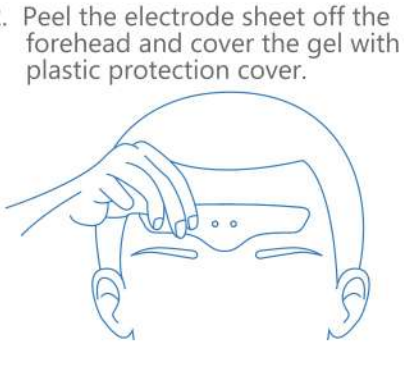


6. Remove the device

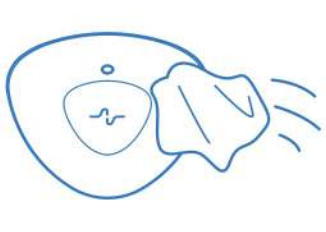
6.1. Remove the main unit from electrode.



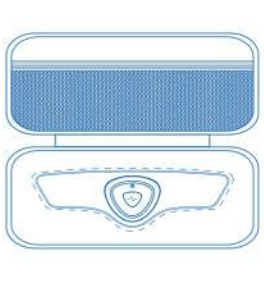
6.2. Peel the electrode sheet off the forehead and cover the gel with the plastic protection cover.



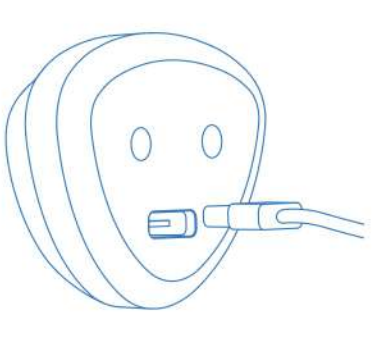
7. Clean the main unit with a cleansing wipe.



8. Store the main unit and electrodes in the storage box.



9. Please use CE or FCC certified adapter.It is recommended to use the computer USB port to charge the device.



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

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 check (Fully battery charged)	Click the control button in the turn off state	/	/	Remains on for 2 seconds
Battery level check (Low battery level)		/	/	Blinks for 2 seconds

Operation Guide:

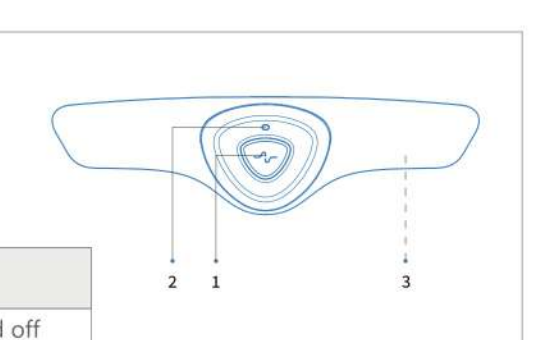
Status	Explanation	Motor Feedback	Buzzer Feedback	Indicator Feedback
Treatment completed	After 60 minutes of continuous use, the device automatically shuts down	Motor vibrates twice	/	Light off
In 9th gear	Maximum intensity, cannot increase any further	Motor vibrates twice	/	Blinks periodically
In 1st gear	Minimum intensity, cannot decrease any further	Motor vibrates twice	/	Blinks periodically

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	/	/	Blinks periodically
Fully charged	/	/	/	Remains on
Unable to be turned on	Insufficient battery to be turned on	/	/	/

SPECIFICATIONS

【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

2. Technical Parameters of Product

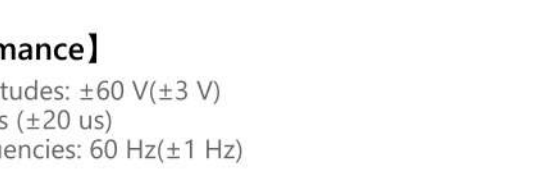
Output	Parameters		
Range of amplitude	-60V~+60V(±3V)		
Intensity of electrical stimulation	1~9		
Oscillogram	Mode	Pulse width	Frequency
	AC sharp-wave	250us(±20us)	60Hz(±1Hz)

Load: 27KΩ+47nF

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

【Electrode】

The electrode acts as the interface between the main unit and the skin. The electrode has two contact zones that connect with the HeadaTerm 2 through magnets.



【Essential Performance】

Pulse repetition ampltudes: ±60 V(±3 V)
Pulse duration: 250 us (±20 us)
Pulse repetition frequencies: 60 Hz(±1 Hz)

【Indications for Use】

The TENS device-HeadaTerm 2 is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

【Operation Principle】

By releasing the low frequency pulse with a particular frequency and reaching the advanced nerve center of 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.

【Date of Manufacturing and Shelf Life】

See the packaging.
Device shelf life: 36 months

【Contraindications】

1. Presence of metallic or electronic implants in the brain, or a pacemaker.
2. Acute inflammation, hemorrhagic tendency, arrhythmia, or epilepsy.
3. Traumatic brain injury, head trauma, or maxillofacial injury.
4. Brain tumors, meningitis, or acute cerebrovascular stroke.
5. You should check with your doctor if you do not understand or are unsure whether any of the above contraindications apply to you or your condition.

【Risks and Benefits of Device Use】

Risks of device use:

1. A stinging sensation may occur on the forehead.
2. If you experience pain, try lowering the intensity by double-clicking the control button to decrease the level.

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).

【Warnings】

1. Do not use in the presence of electronic monitoring equipment (e.g., cardiac monitors, electrocardiogram (ECG) alarms).
2. Do not use while bathing or showering.
3. Do not use during any activity that can put you at risk of injury.
4. 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.
5. EMC WARNING: Use of this device adjacent to or stacked with other devices should be avoided because it coud 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.
6. 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.

7. 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.
8. Do not modify without approval of manufacturer.
9. Suffocation risk in case of swallowing the electrode.
10. The device contains a battery. Misuse could result in fire/explosion/dangerous gas leak.
11. Do not use the same electrode on multiple people. For important reasons of hygiene, each user must have his or her own electrode.

【Precautions】

1. TENS device-HeadaTerm 2 is for patients with migraine per the indications for use.
2. If you have any metal implants in your brain or head, please consult your doctor before using the device.
3. If you have a history of head injury, please consult your doctor before using the device.
4. You should use this unit only with the electrodes and accessories recommended by the manufacturer.
5. The device is clinically proven to relieve migraines. Its effects on other symptoms are still being studied.

【Cleaning and Maintenance】

HeadaTerm 2 Main Device

Step 1: Turn off the device.
Step 2: Wipe the surface of the device with a cleaning wipe, especially the magnetic contact area connected to the electrode.
Step 3: Perform a visual inspection. If the surface is still contaminated, repeat step 2 until it is clean.

USB-C Charging Cable

Handle the cable carefully to avoid tangling. Keep the connectors at both ends of the cable clean. If they become dirty, clean them with a cleaning wipe.

HeadaTerm 2 Electrodes

After use, reattach the protective film to the electrode pads to prevent dust and debris buildup. Store them in the original storage box to preserve adhesion and prolong their lifespan.

【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 healthcare 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.

【Storage】

The product including the electrode 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: 50 ~ 106 kPa
Indoor, dry and well-ventilated, free from corrosive substances
Do not put excessive pressure device or store under heavy items.

【Guidance and Manufacturer's Declaration - Electromagnetic Emission】

The TENS device-HeadaTerm 2 Connected is intended for use in the electromagnetic environment specified in the table. The customer or the user of the TENS device-HeadaTerm 2 should ensure that it is used in such an environment.

Electromagnetic Interference

In order to regulate the requirements for electromagnetic compatibility with the aim of preventing unsafe product situations, the EMC IEC 60601-1-2 4th edition standard has been implemented.

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【Labels and Marks】

No.	Symbol	Meaning
1		Manufacturing date of product
2	SN	Serial number of product
3		Note! Please check all documents attached
4		Information of manufacturer
5		BF type
6		Device contains a battery. Do not dispose in general waste stream/house hold trash.

No.	Symbol	Meaning
7		Refer to instruction manual
8	UDI	Unique device identification
9		Valid date of product/expiration date
10	LOT	Batch number of product
11	MD	Medical device
12	CE 0537	The product has passed CE certification
13	IP22	Achieve IP22 under IEC 60529 standard

Appendix 1 - Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer´s declaration – electromagnetic emission		
2	The YF-HT2 TENS device-HeadaTerm 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the YF-HT2 TENS device-HeadaTerm 2 should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR11	Group 1	The YF-HT2 TENS device-HeadaTerm 2 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 CISPR11	Class B	The YF-HT2 TENS device-HeadaTerm 2 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.
6	Harmonic emissions IEC 61000-3-2	N/A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

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

Guidance and manufacturer´s declaration – electromagnetic immunity			
The YF-HT2 TENS device-HeadaTerm 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the YF-HT2 TENS device-HeadaTerm 2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential 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 EN 61000-4-11	0 % U_T ; 0.5 cycle At 0°,45°,90°,135°, 180°,225°,270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the YF-HT2 TENS device-HeadaTerm 2 requires continued operation during power mains interruptions, it is recommended that the YF-HT2 TENS device-HeadaTerm 2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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_T is the a. c. mains voltage prior to application of the test level.			

Appendix 3 - 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-HT2 TENS device-HeadaTerm 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the YF-HT2 TENS device-HeadaTerm 2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the YF-HT2 TENS device-HeadaTerm 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m)(2)

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,(1) 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 is affected by absorption and reflection from structures, objects and people.			
(1):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-HT2 TENS device-HeadaTerm 2 is used exceeds the applicable RF compliance level above, The YF-HT2 TENS device-HeadaTerm 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the YF-HT2 TENS device-HeadaTerm 2. (2):Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Appendix 4 - 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-HT2 TENS device-HeadaTerm 2			
The YF-HT2 TENS device-HeadaTerm 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the YF-HT2 TENS device-HeadaTerm 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the YF-HT2 TENS device-HeadaTerm 2 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHZ $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	/	0.035	0.07
0.1	/	0.11	0.22
1	/	0.35	0.70
10	/	1.106	2.21
100	/	3.5	7
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.			

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