

[Note] • Please clean the forehead and the gel side of the electrode before using the device.

-01-

-03-

Instructions:

forehead securely.

4. The main unit magnetically

attaches to the electrode.

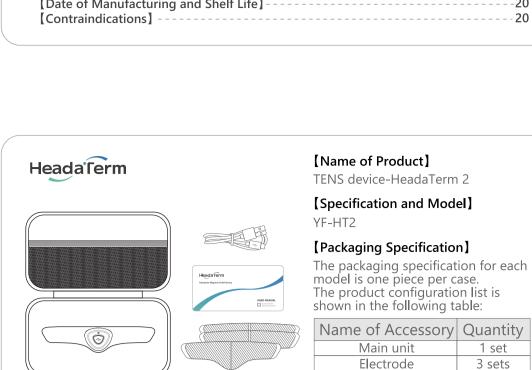
• The head strap may be used to prevent the electrode from detaching. • The device automatically turns off during low battery. • The device automatically stops treatment after 20 minutes of continuous use.

• Using the device while lying down provides the best user experience.

- Replace the electrodes as needed to provide optimal adhesive contact.

Table of Contents [QUICK START GUIDE] ------ 01 [Risks and Benefits of Device Use] -----21 [Name of Product] ----- 22 [Warnings] ----- 22 [Specification and Model]----- 02 [Precautions] ----- 25 [Packaging Specification] ----- 02 [Cleaning and Maintenance] ----- 26 [Instructions] ----- 03 [Disposal] ----- 27 [Structure of Product] ------ 16 [Guidance and Manufacturer's Declaration-[Electrode] ------ 18 Electromagnetic Emission] ----- 29 [Essential Performance]----- 18 [Labels and Marks] ----- 30 [Indications for Use] ----- 18 [EMC Information] ----- 32 [Operation Principle] -----19 [Typical Sensations Experienced During Treatment] ------19 [Date of Manufacturing and Shelf Life] ------20 [Contraindications] ------20

QUICK START GUIDE



Instruction manual

USB-C cable

achieve the best results.

6.2. Tear off the electrode from forehead

-06-

-10-

Indicator

Feedback

Blinks

periodically

Light off

Remains on for

2 seconds

Blinks for

2 seconds

-12-

1 set

1 set

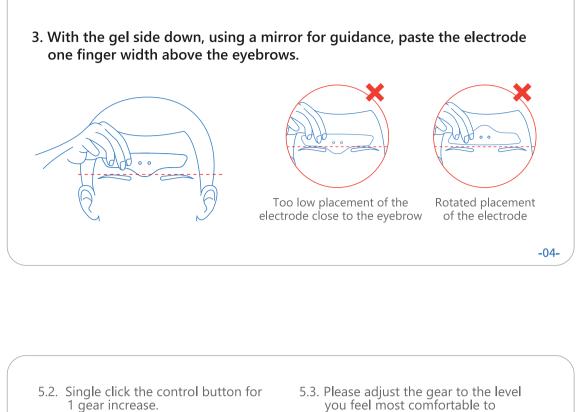
1. Clean the forehead with soap and water, 2. Peel off the plastic protective layer on the back of the gel side then dry it before using the device. of the electrode. This will help the electrode attach to the

5. Operating instructions

device is turned off.

5.1. Turn on: Press and hold the control

button for 2 seconds while the



Double click the control button for

1 gear decrease.

6. Remove the device

Operation

Decrease

gear

Turn off

Battery level

check (Fully battery charged)

Battery level

check (Low battery level)

(Structure of Product)

Main unit.

No.

1. Structure of the product:

Name

Control button

Actions

Tap the control

button twice

Long press the control

button for 2 seconds

Click the control

button in the power

off state

6.1. Remove the main unit from



7. Clean the main unit with tissue.

-09-

Operation Guide:

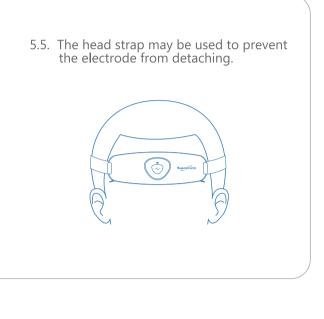
Operation

completed

In 9th gear

In 1st gear

-13-



8. Store the main unit into

Buzzer

Indicator

Light off

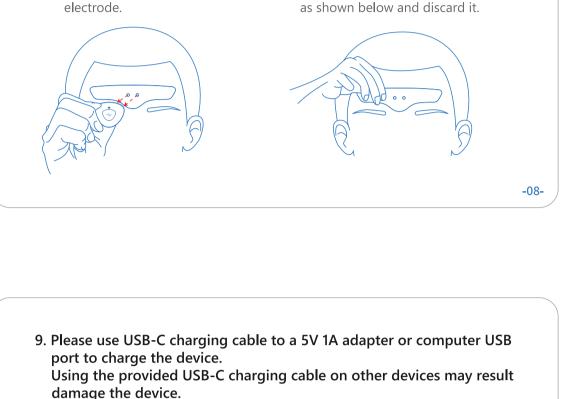
Blinks

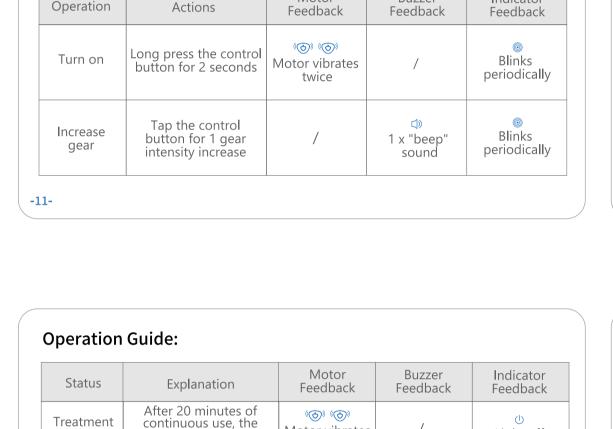
periodically

Blinks

periodically

canvas box.





Motor vibrates

twice

(O) (O)

Motor vibrates

twice

(O) (O)

Motor vibrates

twice

device automatically

shuts down

Maximum intensity,

cannot increase

any further

Minimum intensity,

cannot decrease

any further

2. Technical Parameters of Product

Output

Range of amplitude

Intensity of electrical

stimulation

Oscillogram

(Operation Principle)

[Risks and Benefits of Device Use]

potential injuries (see contraindications).

Forehead skin swelling and stinging.

Risks of device use:

Benefits of device use:

2. No drug side effects.

-21-

Load: $27 K\Omega + 47 nF$

-17-

Motor

Status	Explanation	Motor Feedback	Buzzer Feedback	Indicator Feedback
Low battery warning	Activates every five minutes when under 20% battery	((③)((⑤)((⑤)) Motor vibrates three times	/	® Blinks periodically
Charging	Charging the device with USB-C cable	/	/	Blinks periodically
Fu ll y charged	/	/	/	Remains on
Unable to be turned on	Insufficient battery to be turned on	/	/	/

Motor

Feedback

(O) (O)

Motor vibrates

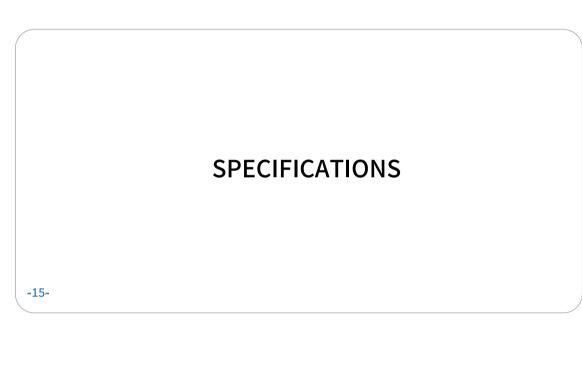
twice

Buzzer

Feedback

2 x "beep"

sounds



Mode

AC sharp-wave

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

Parameters

 $-60 \text{ V} \sim +60 \text{ V} \text{ (} \pm 3 \text{ V} \text{)}$

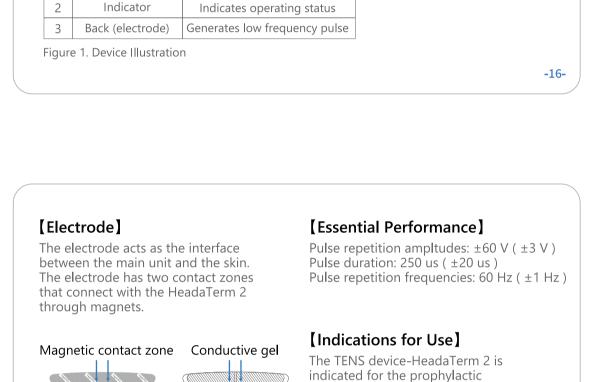
1~9

Pulse width

250 us (±20 us)

Frequency

60 Hz (±1 Hz)



treatment of episodic migraine in patients 18 years of age or older.

-18-

-20-

-22-

-24-

-26-

-30-

Function

Turns device on and off

Decrease/Increase intensity

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.
[Typical Sensations Experienced During Treatment]
 Note: User experiences will vary between individuals. 1. HeadaTerm 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.
-19-

1. Prophylactic treatment of episodic migraine through non pharmacological means.

Not adhering to the care regimen may result in ineffective treatment and

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

10. EMC WARNING: Use of this device adjacent to or stacked with other devices should

device and the other devices should be observed to verify that they are operating

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.

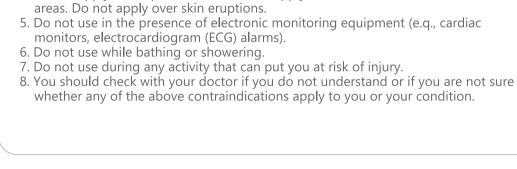
12. The device is incompatible with the simultaneous use of high frequency surgical

equipment as it may result in burns at the site of the stimulator electrodes and

Otherwise, degradation of the performance of this device could occur.

electromagnetic emissions or decreased electromagnetic immunity of this equipment

be avoided because it coud result in improper operation. If such use is necessary, this



2. Use the device only on the forehead.

may increase the risk of cardiac fibrillation

[Date of Manufacturing and Shelf Life]

2. Acute inflammation, hemorrhagic tendency, arrhythmia and epilepsy.

3. Tramatic brain injury, head trauma, or maxillo-facial injury. 4. Recent craniocerebral injury or maxillo-facial injury. 5. Brain tumor, meningitis or acute cerebrovascular stroke.

7. Unspecified pain or discomfort of unknown origin.

1. Do not use if expiration date on the device has passed.

3. Do not apply on the neck and chest. The application of electrodes close to the thorax

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

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

Step 2: Wipe the surface of the device with a soft cloth and 75% alcohol, especially the

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

Step 3: Visual inspection, if found that the surface is still contaminated, repeat the

17. Do not use the same electrode on multiple people. For important reasons of

4. Do not apply over open wounds. Do not apply over swollen, infected or inflamed

1. Metallic or electronic brain implants.

6. Implanted or wearable defibrillator.

See the packaging.

(Warnings)

Device shelf life: 24 months

[Contraindications]

	possible damages to the device. Also, do not use the device in close proximity (less
-23-	

3. Do not use if you are, or may be pregnant.

6. Long-term effects of chronic use of the device are unknown.

and result in improper operation.

normally.

device.

the manufacturer.

(Operating Conditions)

Relative humidity: 10 % \sim 80 % Atmospheric pressure: 86 \sim 106 kPa

Home self care environment.

[Precautions] 1. TENS device-HeadaTerm 2 is for patients with migraine per the indications for use.

2. If you have any metal implants, please consult your doctor before using the device.

5. You should use this unit only with the electrodes and accessories recommended by

4. If you have a history of head injury, please consult your doctor before using the

-25-(Disposal) Dispose device according to local state/county laws for electronic waste.

Normal operating conditions should comply with the following requirements:

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

Environment temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F)

RIOMAVIX SOCIEDAD LIMITADA[ES], RIOMAVIX LTD[EN] Calle de Almansa 55, 1D, Madrid 28039 Spain

Medical device

than 1 meter) to short wave or microwave therapy equipment as it may produce instability in the device output.

14. Do not modify without approval of manufacturer.

15. Suffocation risk in case of swallowing the 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.

[Cleaning and Maintenance]

second step until the surface is clean.

Charging Dock and USB-C Cable

alcohol-based cleaning product.

the following requirements:

[Labels and Marks]

No. Symbol

2

3

4

5

 \sim

SN

ⅉ

Relative humidity: 10 % \sim 80 %

Atmospheric pressure: 50 \sim 106 kPa

magnetic contact part connected to the electrode.

Step 1: Turn off the device.

hygiene, each user must have his or her own electrode.

[Storage] The product including conductive paste should be stored in accordance with

Environment temperature: - 20 °C ~ +55 °C (-4 °F ~ +131 °F)

Indoor, dry and well-ventilated, free from corrosive substances

Do not put excessive pressure device or store under heavy items.

been implemented.

MD

C€₀₅₃₇

IP22

11

12

13

-31-

-29-

SRN: ES-AR-000001202

occur.

[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

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SRN: CN-MF-000039679

Symbol No. Meaning (3) 7 Refer to instruction manual 8 UDI Unique device identification 9 Valid date of product/expiration date Batch number of product 10 LOT

The product has passed CE certification

Achieve IP22 under IEC 60529 standard

6	Z	Device contains a battery. Do not dispose in general waste stream/house hold trash.
A	div 1 Cuidanaa	
Appen	aix i - Guidance	and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS
1		Guidance and manufacturer's declaration – electromagnetic emission

Note! Please check all documents attached

Meaning

Manufacturing date of product

Serial number of product

Information of manufacturer

BF type

Appendix 2 - Guidance and ma	nufacturer's declaration -	- electromagnetic i	mmunity – for all EQUIPMENT and SYSTEMS
G	iuidance and manuf	acturer's decla	ration – electromagnetic immunity
The YF-HT2 TENS device-Head YF-HT2 TENS device-HeadaTe			gnetic environment specified below. The customer or the user of the nvironment.
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 hospita 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 % UT; 0.5 cycle At 0°,45°,90°,135°, 180°,225°,270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospita 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.

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:

	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 n closer to any part of the YF-HTZ TENS device-HeadaTerm 2, including cables, than the recommended separation distance calculated from th 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	$d = [\frac{3.5}{E_1}]\sqrt{P} = 80 \text{ MHz to } 800 \text{ MHz}$ $d = [\frac{7}{E_1}]\sqrt{P} = 800 \text{ MHz to } 2.7 \text{ GHz}$
		2.7 3112	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)

	(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.
-35	-

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

1		Guidance	e and man	ufacturer´s de	claration –	electromagnetic er	mission	
2		NS device-HeadaTer TENS device-Heada					below. The customer or th	ne user
3	Emissions	test	Compliar	nce		Electromagnetic environ	ment - guidance	
4	RF emiss CISPR1		Group	1	internal funct	ion. Therefore, its RF emi	2 uses RF energy only for i issions are very low and a nearby electronic equipm	re
5	RF emissi CISPR1		Class B		The YF-HT2 TENS device-HeadaTerm 2 is suitable for use in all establishments, including domestic establishments and those dire connected to the public low-voltage power supply network that			
6	Harmonic en IEC 61000		N/A				rectly	
7	flicker emis	/oltage fluctuations / flicker emissions N/A IEC 61000-3-3			supplies buildings used for domestic purposes.			
Appendix	3 - Guidance and				-		that are not LIFE-SUPPOR	RTING
						tromagnetic immu		
		ce-HeadaTerm 2 is ir IeadaTerm 2 should a				nment specified below. T	he customer or the user o	of the
lmr	nunity test	IEC 60601 test le	evel (Compliance level		Electromagnetic envi	ronment -guidance	
IEC 61000-4-6 6 V in ISN		3 V rms 150 kHz to 80 MH 6 V in ISM bands between 0,15 MH		N/A	closer to any cables, than equation ap	y part of the YF-HT2 TEN	ions equipment should be S device-HeadaTerm 2, in ration distance calculated v of the transmitter.	cluding
		80 MHz			$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	7		
						80 MHz to 800 MHz		
	diated RF 61000-4-3	10V/m 80 MHz to 2.7 GH	lz	10 V/m 80 MHz to	$d=[\frac{7}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz		
				2.7 GHz	watts (W) ac		ver rating of the transmitte er manufacturer and d is t n metres (m) ⁽²⁾	
	NT and SYSTEMS t	hat are not LIFE-SUF	PPORTING				the EQUIPMENT or SYST	EM -for
EQUIPMEN	NT and SYSTEMS t	nat are not LIFE-SUF mended separat equipn	PPORTING ion distan	ces between p the YF-HT2 TE	ortable and	d mobile RF comm HeadaTerm 2	unications	
The YF-HT	Recomr 2 TENS device-Heada NS device-HeadaTern	hat are not LIFE-SUF mended separat equipn iTerm 2 is intended for unit of a can help prevent ele	PPORTING ion distant nent and to use in an electre ectromagnetic in	ices between purche YF-HT2 TE	oortable and NS device-hent in which radia	d mobile RF comm HeadaTerm 2 ated RF disturbances are con n distance between portable		user of th
The YF-HT	Recomr 2 TENS device-Heada NS device-HeadaTern	hat are not LIFE-SUF mended separat equipn Term 2 is intended for on a 2 can help prevent ele lee YF-HT2 TENS device	PPORTING ion distant nent and to use in an electre ectromagnetic in	ices between p the YF-HT2 TE omagnetic environm nterference by maint as recommended bel	oortable and NS device-lent in which radia aining a minimur ow, according to	d mobile RF comm HeadaTerm 2 ated RF disturbances are con n distance between portable	unications ntrolled. The customer or the a and mobile RF communication of the communications equi	user of th

ppendix 4 - Recommended separation c	listances between portable and mobi	le RF communications equipment ar	d the FOUIPMENT or SYSTEM -for		
QUIPMENT and SYSTEMS that are not LI		o in communications equipment at			
Recommended se	paration distances between p	ortable and mobile RF com	nunications		
	quipment and the YF-HT2 TE				
he YF-HT2 TENS device-HeadaTerm 2 is intend F-HT2 TENS device-HeadaTerm 2 can help pro quipment (transmitters) and the YF-HT2 TENS	event electromagnetic interference by maint	aining a minimum distance between portal	ole and mobile RF communications		
	Separation distance according to frequency of transmitter m				
Rated maximum output of transmitter	150 kHz to 80 MHZ	80 MHz to 800 MHz	800 MHz to 2.7 GHz		
W	$d = [\frac{3.5}{V_1}]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	$d=\left[\frac{7}{E_1}\right]\sqrt{P}$		
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		
or transmitters rated at a maximum output po he frequency of the transmitter, where P is the lote 1: At 80 MHz and 800 MHz, the separatio lote 2: These guidelines may not apply in all si	maximum output power rating of the trans n distance for the higher frequency range a	mitter in watts (W) according to the transmoplies.	nitter manufacturer.		
		and telection from st			

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Heada Term