

ELEXIR

TRIGEMINAL NEUROSTIMULATION DEVICE FOR MIGRAINE PREVENTION & TREATMENT

FCC ID : 2BE9WELEXIRTPD-AH



ELÉXIR

USER MANUAL

NE-THIFU-010 Rev. 1

2024.01.09

GUIDANCE ON THE SYMBOLS USED IN THIS USER MANUAL

Symbol	Description	Symbol	Description
	Manufacturer		Date of Manufacture
	Follow Instructions for Use		General Warning Symbol
	Lot Number		Reference Number

GUIDANCE ON THE SYMBOLS USED IN THIS USER MANUAL

Symbol	Description	Symbol	Description
	Serial Number		Consult Instructions for Use
IP22	Degree of Protection against Ingress of Water or Particulate Matter		Type BF Applied Part
	Recyclable Packaging Material		Temperature Limitation

SYMBOLS USED IN THIS MANUAL

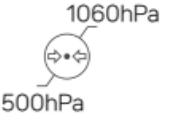
Symbol	Description	Symbol	Description
	Humidity Limitation		Atmospheric Pressure Limitation
	Western Europe Electronic and Electrical (WEEE)		

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Consult this manual for the proper use of the device.



Consult the instruction manual before the use of the accompanied electrodes.

1. PURPOSE OF PRODUCT USE

This product is a device used to alleviate migraine pain (100 Hz stimulation) and reduce the frequency of episodic migraine (60 Hz stimulation) by percutaneously applying low-frequency stimulation to the trigeminal nerves in the forehead area.

2. PRODUCT OVERVIEW

This product is intended to alleviate migraine pain and reduce the frequency of episodic migraine using the principle of neuromodulation, and two output modes (acute mode, 100 Hz / prevention mode, 60 Hz) can be selected and used according to the purpose of use.

The electrodes are attached to the forehead to deliver electrical stimulation to the upper branches of the trigeminal nerves through the skin, affecting the autonomic nervous system.

3. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTION

- CONTRAINDICATIONS

1. Subjects with an implanted metallic or electronic device in the head.
2. Subjects suffering from pain of unknown origin.
3. Subjects who have a cardiac pacemaker or implanted or wearable defibrillator.
(This may cause interference with pacing, electric shock, or death.)

- PRECAUTIONS

1. If you are, could be or planning to become pregnant, consult a doctor before using the ELEXIR device.
2. If you suspect or know that you have a heart or health problem, consult a physician before using the ELEXIR device.
3. If you have experienced seizures or have epileptic conditions, consult a physician before using the ELEXIR device.
4. If you have had a recent head injury, do not use the ELEXIR device until you have fully recovered.
5. Use the ELEXIR device with caution if you have sensory loss in the forehead or scalp.
6. The safety and efficacy of the ELEXIR device has not been demonstrated in subjects with medication overuse headache, chronic tension-type headache, chronic migraine, and refractory migraine.

- 7. The long-term effects of chronic use are unknown.
- 8. The ELEXIR device should only be used with the accompanied electrodes and accessories recommended by the manufacturer, Nu Eyne Co., Ltd.
- 9. The electrode has a current density of more than 2 mA/cm², requiring special attention during use.
- 10. This user manual is not a treatment guide or medical information. Therefore, you should consult your doctor for more information about the disease.
- 11. The lifetime of this device is 2 years.
- 12. After 2 years, the battery performance will drop dramatically and the device will be not available.

- **WARNINGS** 

- 1. Wear the ELEXIR device only in designated areas.
- 2. Do not wear the ELEXIR device on your neck and chest.
- 3. Do not apply over open wounds. Do not apply over swollen, infected or inflamed areas. Do not apply over skin eruptions.
- 4. Do not apply over, or near, nodular or cancerous lesions.
- 5. Do not use in the presence of electronic monitoring equipment.
- 6. Do not use during a shower, bath, or swimming. Do not use while sleeping.
- 7. Do not use during an activity that could be a risk of injury, such as driving a vehicle or operating machinery.
- 8. The ELEXIR device is intended to be used only on normal, intact, clean skin.
- 9. The effects of long-term use of the ELEXIR device are unknown.
- 10. Migraine may indicate that you have a serious medical condition. You should have them checked by a doctor.
- 11. If the frequency of headache is not reduced after prolonged use, ask a doctor.
- 12. You should check with your doctor if you do not understand or are not sure whether any of the above "Contraindications", "Precautions", or "Warnings" apply to you or your condition.
- 13. This product can be used for ages 15 and up. (It can be used from the age of 8 with the necessary training to understand this manual, but must be used under adult supervision for the first session.)
- 14. Do not drop the device. This may cause the malfunction.
- 15. Do not disassemble the device. Electrical shock may occur.

PROTECTION AGAINST ELECTRIC SHOCK

- Please do not disassemble or revamp the device intentionally.

A severe electric shock may occur if the exterior cover of the main body is removed.

- Please be cautious not to spill any liquids on the main body of the device.

It may cause a serious malfunction of the device and an electric shock.

Furthermore, please keep the device away from wet conditions which may create a high-voltage electric current entailing the high risk of electric shock and fire.

- Please do not use the device near an equipment that generates a strong electric fields, such as a television, or an appliance that uses using electromagnetic waves, etc.

- Please do not turn on the device when the main power connection is damaged.

- Please disconnect the power and store in a clean location when not in use for long-time to eliminate the risk of electric shock, short circuits and fire.

- Please disconnect the power in case of abnormalities such as floods, unnatural sounds, burning smell and smoke, and promptly contact to Customer Service.

- Please do not locate the device near flammable or combustible materials.

- Please do not use or operate when the device is covered with fabrics.

- Please ensure that the device is correctly positioned to prevent malcontact.

4. SIDE EFFECT INFORMATION

1. Drowsiness. This product may cause drowsiness. Do not use this product during activities that may pose risk of injury, such as driving a vehicle or operating machinery.
2. Skin flushing. After the product use, skin flushing may occur in areas where electrodes were attached. This is caused by increased blood flow and may last for some duration. Normally, it disappears in less than 15 minutes.
3. Skin allergy. Very rarely, there may be allergic reactions to this product. In the event of a temporary skin rash on the contact area, immediately stop use and contact the doctor or manufacturer (Nu Eye Co., Ltd.). The skin rash disappears within a few days, but anti-inflammatory ointment can also help.
4. Headache after use. Headache may occur after use of this product.

5. KEY COMPONENTS OF THIS PRODUCT

Product Set (This product consists of the following.)

- 1 Package box / 1 Instruction manual / 1 Storage pouch / 1 Storage plate
- 1 ELEXIR body / 3 Electrodes / 1 Charging cable

ELEXIR body (ELEXIR body has the following shape.)

- Color: White
- Dimensions: Width 60.0 mm x Length 44.0 mm x Height 17.6 mm
- Weight: Approximately 20.7 g

Front : There are two buttons on the front to turn the device on/off and control output intensity, and an LED indicator indicating battery usage and status.

Rear : This is where the electrodes are located.

Lower : This is where the charging port is located.

ELEXIR Electrodes

- Special electrodes developed for ELEXIR products are attached to the center of the forehead.
- The electrodes are magnetically connected to the connection ports located on the rear of the main body.
- Electrode (Dimensions: Width 78.00 mm × Length 32.86 mm / Weight: Approximately 3.67 g)



Cautions

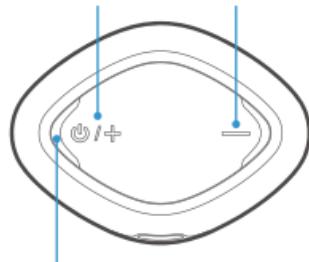
ELEXIR products must use the dedicated charging cable provided with the device.

DESCRIPTION OF THE DEVICE AND ITS ACCESSORIES

- **ELEXIR DEVICE**

A current output device for transcutaneous electrical stimulation treatment.

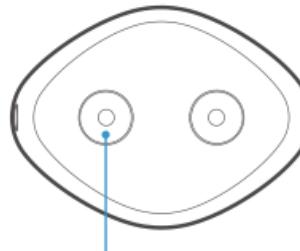
POWER ON/OFF
& INTENSITY UP



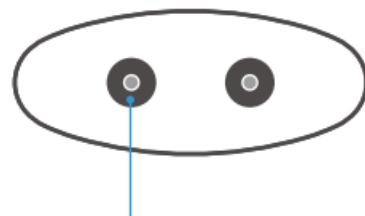
BATTERY USAGE & STATUS INDICATOR

- **ELEXIR Electrode**

It is connected to the main body of the current output device, which attaches to the skin and stimulates the nerves through current application.



DEVICE-ELECTRODE CONNECTION PORT

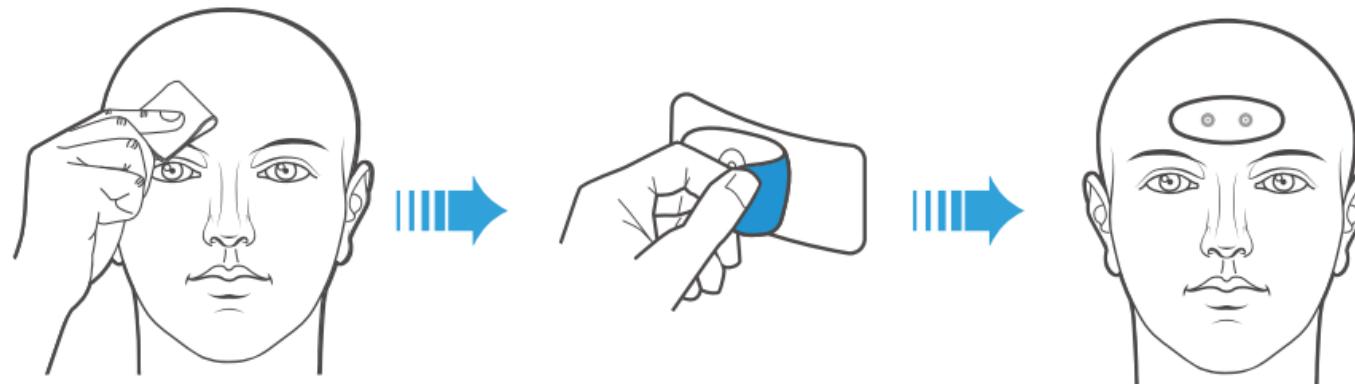


ELECTRODE-DEVICE CONNECTION PORT

6. DIRECTIONS FOR USE

- **APPLYING THE ELECTRODE PATCH**

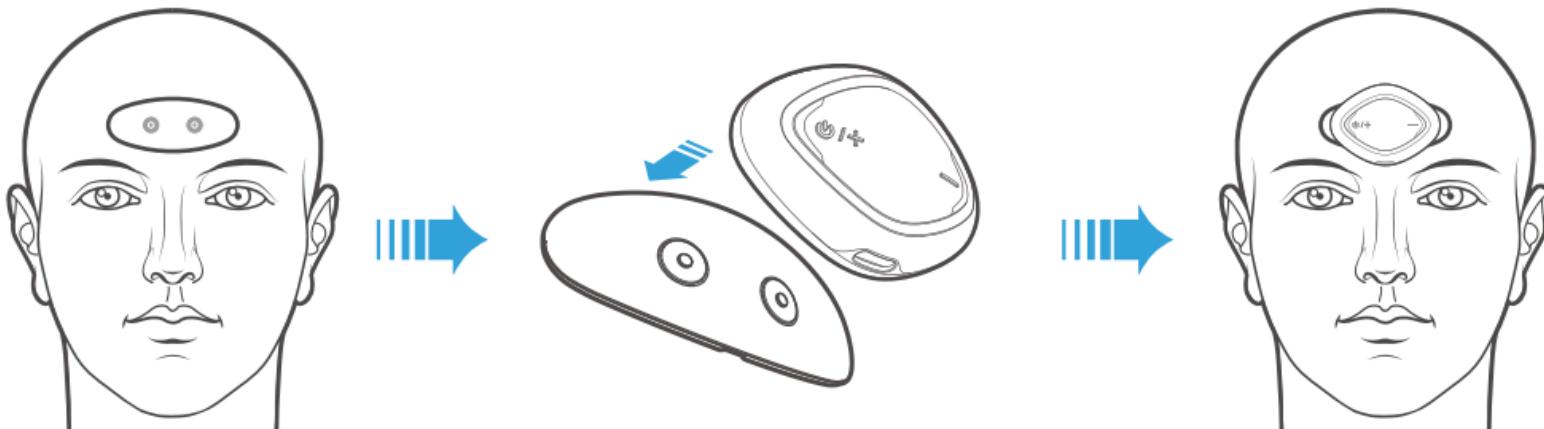
1. Wipe and dry the forehead before attaching the electrode patch as illustrated below.
2. Remove the protective transparent film from the ELEXIR electrode patch.
3. Place the electrode patch on the forehead above the eyebrow line.



6. DIRECTIONS FOR USE

- WEARING THE DEVICE

After placing the ELEXIR electrode patch on to the instructed region, connect the device as illustrated below.



AFTER PLACING THE ELECTRODE PATCH, WEAR THE DEVICE

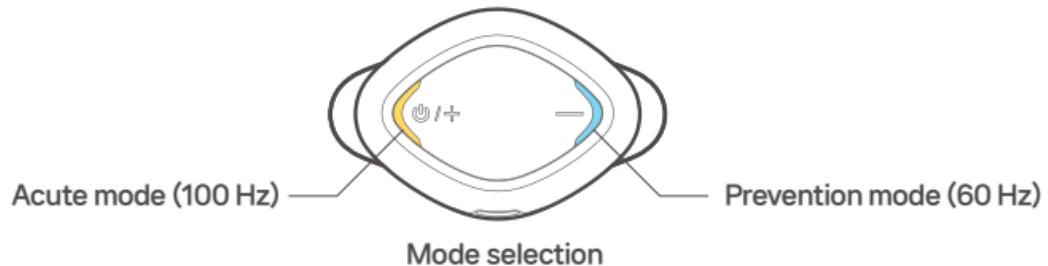
6. DIRECTIONS FOR USE

- POWER ON THE DEVICE

INITIATION OF TREATMENT

After the ELEXIR electrodes are attached and the device is worn properly, press the Power (+) button for more than 1 second until the device beeps to enter mode selection.:

- 1) In mode selection, the yellow light on the left indicates acute mode (Program 1, 100 Hz) and the cyan light on the right indicates prevention mode (Program 2, 60 Hz).
- 2) Start the treatment by pressing the button corresponding to the mode you want to use.



6. DIRECTIONS FOR USE

• DURING THE TREATMENT SESSION

CONDUCTING THE TREATMENT SESSION

A. The treatment lasts for 60 minutes (program 1, acute mode) and 20 minutes (program 2, prevention mode), accordingly. It runs automatically in stages. During the first few minutes, the sensation is very weak, even imperceptible to the point where you may not feel anything.

B. As the intensity of the stimulation increases, you may start to feel a vibration or a tingling sensation which intensifies with time. If you think the stimulus intensity is sufficient, you can press the stimulus intensity button to fix the intensity level. Even after you fix the intensity, you may adjust the stimulation intensity later on by pressing the (+) or (-) button.

C. The number of status LEDs lighting up during treatment varies depending on the total treatment time.

- 1LED for 1/3 of the total treatment time
- 2 LEDs for 1/3 to 2/3 of the total treatment time
- 3 LEDs for more than 2/3 of the total treatment time

6. DIRECTIONS FOR USE

D. Frequency of sessions

- Acute mode (Program 1) - [When symptoms occur]:

Use when a migraine occurs or when precursor symptoms occur.

- Prevention mode (Program 2) - [Once a day]:

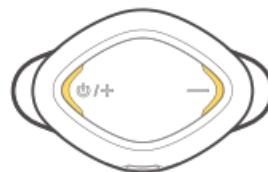
Use daily, even when not in pain, to prevent migraine headaches.

STATUS INDICATOR:

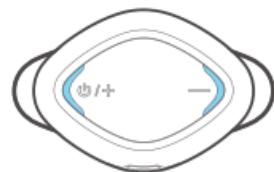
- Acute mode (Program 1): Yellow color
- Prevention mode (Program 2): Cyan color

BATTERY:

- Only when the charging cable is connected the remaining battery power can be checked with a green color LED.
- If the battery is at levels 3 (3 LED lights) -> Battery remaining capacity: 75 % or higher.
- Battery amount shortage is indicated by a flashing of red color LED.



Acute mode (100 Hz)



Prevention mode (60 Hz)

6. DIRECTIONS FOR USE

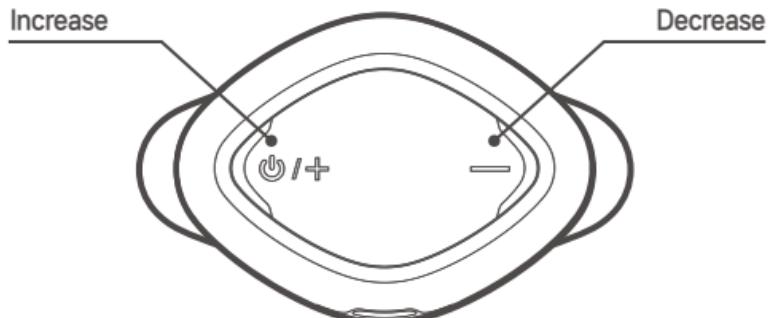
- CONTROLLING THE INTENSITY

ADJUSTING THE STIMULATION INTENSITY

Intensity can be adjusted (increased/decreased) in 0.5-mA intervals.

The stimulation intensity increases steadily in the initial 14 minutes. Press either "+" or "-" to fix the intensity at that level for the remaining time of treatment.

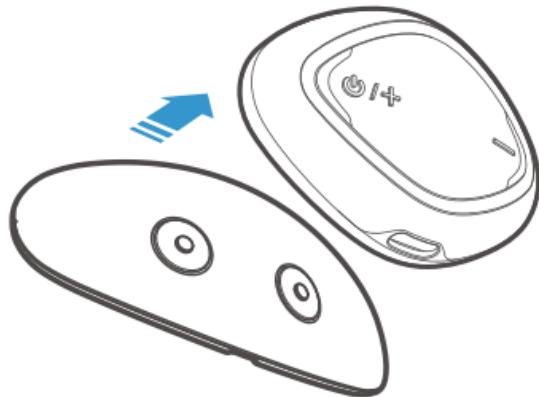
Each time you press the "+" or "-" button, it will correspondingly increase or decrease the intensity by 0.5-mA of the stimulation current.



6. DIRECTIONS FOR USE

- AFTER THE TREATMENT SESSION

- 1) Once the treatment session ends after 60 minutes (program 1, acute mode) or 20 minutes (program 2, prevention mode), the device will automatically turn off.
- 2) After removing the ELEXIR device from the electrode, store it in an appropriate place for reuse.
- 3) To reuse the electrode, attach it to the electrode storage plate, and store it in an appropriate place such as a storage pouch.



6. DIRECTIONS FOR USE

- INTERRUPTING THE DEVICE

STOPPING THE TREATMENT SESSION BEFORE COMPLETION

To stop the session before completion, press the Power (+) button for 3 seconds and the session will automatically stop. Afterwards, remove the unit when the power is off.

ACCIDENTAL INTERRUPTION

The device can stop the session on its own for the following reasons.

- The skin has not been fully cleansed.
- The electrode has not been placed correctly on the skin.
- The device is separated from the electrode.



Forced turn off: Press the Power (+) button for 3 seconds.

6. DIRECTIONS FOR USE

- ELEXIR APPLICATION

- 1) Sign up for membership and Login

- Create an account through membership registration and log in by using your login information.

- 2) Connecting to Bluetooth

- Turn on the device, click the device icon on the application screen, and select the appropriate device from the device list. *The device only needs to be paired once. After the first Bluetooth connection, the device will automatically pair when connected.

- 3) Control the device

- Mode selection: Select acute mode or prevention mode.
- Session progress: Check the remaining time, the current stimulation intensity, and the remaining battery. Adjust the stimulation intensity.
- Disconnect the Bluetooth connection and shut down the device as needed.

- 4) Record of use and settings

- The record of use is automatically recorded and can be checked at any time.
- Adjust notification settings, log out, and perform other settings from the settings screen.

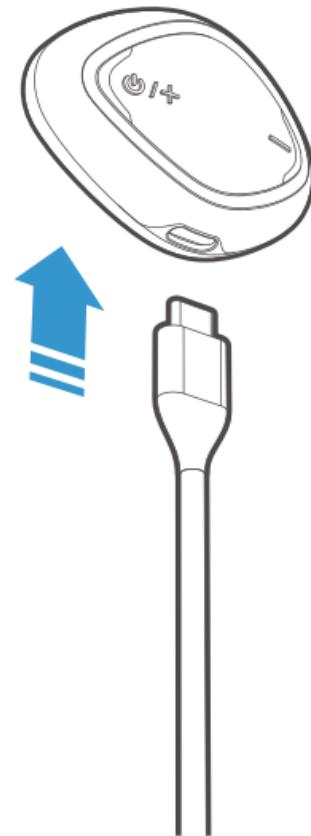
- 5) For more information about the application, visit the manufacturer's website (www.nueyne.com).



6. DIRECTIONS FOR USE

- RECHARGING THE DEVICE

Connect the charging adapter and cable using the USB port (indicated on the right) to charge the ELEXIR device.



7. GENERAL INFORMATION

• ELECTRODES

- 1) Please check the electrode package status.
- 2) Electrodes have to be used within 3 years of the date printed on the package.
- 3) Once you open the package, the electrode can be used for up to one month.
- 4) To maintain the electrode quality, it is essential to cleanse and degrease the forehead thoroughly before the session. After the session ends, attach it to the electrode storage plate and store it in an appropriate place such as a storage pouch.
- 5) Do not use the same electrode on different people. Due to hygiene and safety reasons, each user must have his or her own electrode.
- 6) Electrodes can be used up to 20 times depending on the user's environment, but 10 times is the recommended number of use.
- 7) For more information about the electrodes, visit the manufacturer's website (www.nueyne.com).

• OPERATING CONDITIONS

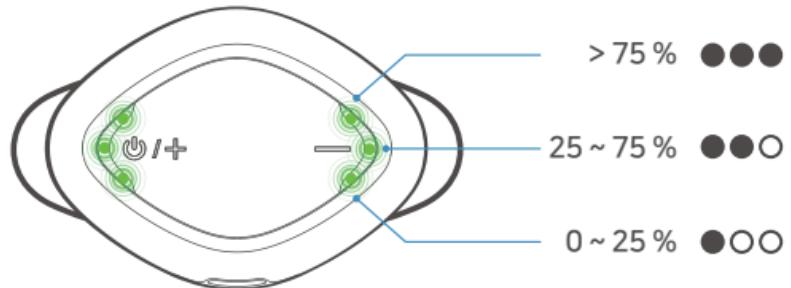
- 1) Do not use the ELEXIR device in a damp atmosphere such as a bathroom. The operating conditions must not exceed the following figures : Temperature (10 °C ~ 40 °C), Relative humidity (5 % ~ 85 %), Atmospheric pressure (700 hPa ~ 1060 hPa)

• STORAGE CONDITIONS

- 1) The storage conditions must not exceed the following figures: Temperature (-10 °C ~ 45 °C), Relative humidity (5 % ~ 85 %), Atmospheric pressure (500 hPa ~ 1060 hPa)

• CHARGING THE BATTERY

- The ELEXIR device is operated on a rechargeable 3.7 V LiPo battery.
- If the battery is insufficient, it will not operate.
- While charging, the green color LED lights up in 3 levels in accordance with the battery level.
- If the device is not in use for a long time, it is recommended to charge up to 2 battery levels every 3 to 6 months and store it in appropriate storage conditions.



• CLEANING YOUR UNIT AND DEVICE MAINTENANCE

- 1) To clean your device, only use an alcohol-based cleaning wipe that does not contain any solvents.
- 2) Never put the device in water.
- 3) Keep the cable untangled and clean during use.

8. TROUBLESHOOTING

Problems	Solutions
The device is on, but it is not operating, a red color LED is flashing, and the device is making a sound:	Make sure the battery is charged. Charge the battery.
The device is not operating properly and a red color LED abruptly lights up with a beep:	The device and the electrode are not properly connected: Make sure to wipe and dry the skin before applying the electrode. Try again with a new electrode. Check in front of a mirror whether the device is placed properly.
Stimulation is too weak:	- Press the  button
Stimulation is too strong:	- Press the  button

9. TECHNICAL INFORMATION

• POWER SUPPLY

- A rechargeable 3.7 V LiPo battery
- Charging time: 2 hours
- Battery shelf life: 300 cycles of complete charge-discharge. (It may vary depending on your use environment.)
- Maximum input voltage: 5.25 Vdc
- Please contact the manufacturer if the battery is defective and charging is not possible.



Replacement of the battery built into the product must only be carried out by the manufacturer, and any replacement is prohibited because replacement by an unskilled person (operator) may pose a risk.

• DEVICE AND CHARGING SYSTEM DISPOSAL

- At the end of its useful lifecycle, this device and its charging system should be disposed of in accordance with local and/or national environmental requirements. Please contact manufacturer for additional inquiries.

- **PACKAGE SIZE**

- Dimensions: 198 mm x 171.5 mm x 33 mm

- **Applied components**

- Electrode : Hydrogel

- Main body : LG Chem, Ltd. LUPOY PC 1301 EP-30

- LG Chem, Ltd. ABS AF305HT_900

- **IP22**

- Degree of protection against harmful ingress of particulate matter and water:

- 2: protected against particulate matter above 12.5 mm

- 2: protected against dripping water when tilted up to 15° from the vertical

- **PROGRAM PARAMETERS**

Parameters	Program 1 values	Program 2 values
Pulse frequency	100 Hz	60 Hz
Pulse width	250µs	250 µs
Maximum intensity	16 mA	16 mA
Ramp up time	14 min	14 min
Steady time	45 min	5 min
Ramp down time	1 min	1 min
Session	60 min	20 min

9. TECHNICAL INFORMATION

- **ELECTROMAGNETIC COMPATIBILITY**

- The only accessories to be used with the ELEXIR Device are the ELEXIR electrodes and the charging cable provided with the device. The use of accessories other than those specified may result in increased emissions or decreased immunity of the device and could be unsafe.

- **WARNING**

- Warning: Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and other equipments should be observed to verify that they are operating normally.
 - Warning: Use of accessories and cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

- **EMISSIONS TEST**

- **GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS**

The ELEXIR device is intended for use in the electromagnetic environment specified below.

The customer or the user of the ELEXIR device should assure that it is used in such an environment.

10. BASIC INFORMATION

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ELEXIR device 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.
RF emissions CISPR 11	Class B	The ELEXIR device 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.
IEC 61000-4-2	Level 4	
IEC 61000-4-3	Home Healthcare Environment	Test for electrical and mechanical safety is in accordance with "Common Standard for Electrical and Mechanical Safety of Medical Devices" Examination of electromagnetic safety is in accordance with "Common Standard for Electrical and Mechanical Safety of Medical Devices"
IEC 61000-4-8	30 A/m	

- In case of device malfunction or unexpected events, please contact the manufacturer.



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11. CONSUMER DISPUTE RESOLUTION STANDARDS

	Consumer Damage Type	Compensation details		
		Within the warranty period	After the warranty period has expired	
Performance and functional failures that occur naturally in normal use	Critical repair required within 10 days of purchase	Product exchange or purchase price refund	Chargeable repair	
	If significant repair of a major component is required within one month of purchase.	Product exchange or purchase price refund		
	If a replaced product requires significant repair within one month.	Product exchange or refund of purchase price		
	If exchange is not possible.	Refund of purchase price		
	In the event of a defect occurrence.	Free repair		
	The same defect was repaired, but the failure recurred (3rd time)	Product exchange or purchase price refund		
	A total of four repairs were made due to several failures, but the failure recurred (5th time)			
	If repair is not possible			
	If repair is not possible due to lack of repair parts	Refund by adding 10% of the purchase price to the flat-rate depreciation amount		
	If the consumer loses the product requested for repair			
	Damage incurred during the transportation process when purchasing the product	-		

	Consumer Damage Type	Compensation details	
		Within the warranty period	After the warranty period has expired
Consumer's intentional, negligent performance, functional failure	Paid repair	Paid repair	Paid repair
	If repair is not possible	Product exchange after payment of the amount equivalent to paid repairs	-
	<ul style="list-style-type: none"> - Where a failure occurs due to a natural disaster (fire, salt damage, earthquake, storm and flood damage, etc.) - Where a failure occurs due to an abnormality in the power supply used or a defect in the connection device - Failure caused by repair or alteration at a location other than the Nu Eyne Co., Ltd. or authorized service designation point - Replacement of consumable parts that wear normally in use - If it is an external cause other than a defect in its own product 	Paid repair	Paid repair

- * The above quality assurance period and compensation criteria are based on the Consumer Dispute Resolution Period notified by the Fair Trade Commission.
- * Matters not specified shall be subject to consumer dispute resolution standards.
- * If the product is not faulty, there may be a service charge, so please read the instruction manual.
- * Parts to be replaced during repair can be applied to parts of different origin or manufacturer than existing parts, and may not be new, but will operate normally and use functionally equivalent parts.
- * Some of the parts used in the product may be made in a country different from the country of manufacture.

11. CONSUMER DISPUTE RESOLUTION STANDARDS

Responsibility for paid services that the customer has to pay for

When applying for service to Nu Eyne Co., Ltd., the consumer has to pay for the following cases, even during the quality guarantee period.

- * Instructions for use and simple adjustments not requiring disassembling of the product
- * When the case or other parts are damaged by an external impact
- * In the event of malfunction due to penetration of dust, beverages, etc.
- * In the event of a failure due to the user's arbitrary disassembly and modification of the product

※ When you request a repair, you need to present this warranty with a proper purchase date to receive sufficient service, so please keep it well.

1. The warranty for this product is covered by the warranty as stated in the warranty.
2. The warranty period is calculated from the date of purchase, so please write down the date of purchase.
3. If the date of purchase cannot be confirmed, the warranty period will be applied from the date of manufacture or import customs clearance from 3 months later.
4. If used in an abnormal environment, the warranty period will be reduced by 50 %.
5. This guarantee will not be reissued.
6. In the case that the product is supplied under a separate contract, the warranty applies in accordance with the main contract.



Product Warranty

Up to one year from the date of purchase written below with the proof of purchase, the consumer is entitled to a free of charge repair or a replacement for the faults of manufacturing that occurred while using the product. All the support service fees of this product are free of charge only within the described warranty period.

Model Name :

Date of Purchase :

Serial Number :

Consumer Name :

Tel :

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: —Reorient or relocate the receiving antenna. —Increase the separation between the equipment and receiver. —Connect the equipment to an outlet on a circuit different from that to which the receiver is connected. —Consult the dealer or an experienced radio/TV technician for help.

[47 CFR 15.21] Pursuant to Section 15.21 of the FCC rules, changes or modifications to a Product by the user that are not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. The device meets the FCC Radio Frequency Emission Guidelines. Information on the product is on file with the FCC and can be found by inputting such Product's FCC ID (which can be found on the device) into the FCC ID Search form available at <https://www.fcc.gov/oet/ea/fccid>.

Product : ELEXIR

Model : TPD-AH2

Input : DC 3.7V

FCC ID : 2BE9WELEXIRTPD-AH

Frequency : 2 402 ~ 2 480 MHz (BLE)