



USER MANUAL



# **USER MANUAL**

NE-BW-KRIFU-01 Rev. 01 2024.12.10

## Guide to symbols and certification marks

symbols	explanation	symbols	explanation
	KC Mark: National Integrated Certification M ark (Ref. Ministry of Trade, Industry and Ene rgy Notice (제2022-0220호)	$\wedge$	General warning sign
	Must follow the instructions (Ref. KS S ISO 7010-M002)	<b>≋∘</b> I	Separate disposal mark symbol (non- recyclable) (Ref. Article 4 of the Guidelines on Separate Disposal Marking)
[]i	Need to refer to the user manual (Ref. KS S ISO 7000-1641)	비닐큐 OTHER	Separate disposal mark symbol (non- recyclable) (Ref. Article 4 of the Guidelines on Separate Disposal Marking)
-10 °C	Transport and storage temperature range (Ref. KS S ISO 7000-0632)		Manufacturer's mark (Ref. KS P ISO 7000-3062)
85% (½) 5% RH	Transport and storage humidity limits (Ref. KS S ISO 7000-2620)		date of manufacture (Ref. KS P ISO 7000-2497)
1060hPa (5-0) 500hPa	Transport and storage pressure limits (Ref. KS S ISO 7000-2621)	LOT	Manufacturer's placement or lot number (Ref. KS P ISO 7000-2492)

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- 10. Consumer dispute resolution standards
  - \* Product Warranty Certificate





Product Name: WITHNOX

Model Name: BPSPW1

WITHNOX set

Product Set (This product consists of the following.)

Components	quantity	Explanation	
user manual	1	instructions for use	
WITHNOX device	1	device	
WITHNOX electrode	21	WITHNOX electrode	
USB-C cable	1	power cable	
base station	1	device charging and environ	nent information measuremen
storage pouch	1	electrode storage pouch	
electrode storage plate	1	electrode storage plate	
base station pouch	1	base station storage pouch	
adapter	1	charging adapter	

#### WITHNOX device

The WITHNOX device has the following specifications.

color : white

size: 45.00 mm (W) \* 44.00 mm(H) \* 18.80 mm (D)

font: On the front there are two buttons to control the power and output intensity. There is an LED display that shows the battery charging status and operating status.

electrode.

The WITHNOX device's movement detection sensor measures the quality of sleep.

#### WITHNOX electrode

The WITHNOX electrode has the following specifications.

size: 78.00 mm (W) \* 32.86 mm(H)

After attaching to the skin, it is connected to the WITHNOX device and stimulates the nerves through electric current.

Due to the characteristics between the instrument and the electrode. only the WITHNOX electrode is designed to work with the instrument.

back: On the back there two connectors for charging and the WITHNOX. The WITHNOX electrode has two connectors that are connected via magnets.



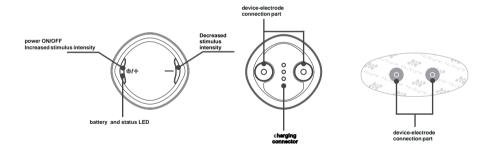
Caution: WITHNOX devices are used with unique components that may pose exceptional risks.

#### WITHNOX device

It is a device that outputs current for percutaneous trigeminal nerve stimulation.

#### WITHNOX electrode

After being attached to the forehead, it is connected to the WITHNOX device and transmits electric current to stimulate the nerves.



The base station serves to charge the WITHNOX device while collecting sleep environment information and transmitting it to the server via Wi-Fi and BLE.

The base station has the following specifications.

color: white

size :129.00 mm (W) \* 74.00 mm (H) \* 38.00 mm (D)

front : Temperature and humidity measured from internal sensors are displayed on the status display.

(current time and battery charge status are also displayed.)

top : The touch buttons can be used to adjust the information displayed on the status display and the brightness of the base station. The charging port can be opened to charge the WITHNOX device.

**bottom**: The button that operates the AP mode of the base station.

back : There is a USB-C connector for power supply.



Indirect lighting (mood lamp)

status display

adjust brightness (touch button)

device charging port

adjust the status display window (touch button)

#### ※ AP (Access Point) mode:

It forms its own Wi-Fi network, enabling communication with other devices, and cad connect to the home Wi-Fi network to communicate with the server.

### 2. Principles of action

This product uses the principle of trigeminal nerve stimulation to help improve sleep quality and concentration through 120Hz electric pulse stimulation.

Electrodes are placed on the forehead to transmit electrical stimulation through the skin to the upper branch of the trig eminal nerve.

### 3. Purpose of use

During sleep, electrical pulse stimulation is transmitted through the skin to the trigeminal nerve in the forehead area to help improve sleep quality and concentration.

### 4. Cautions in use or precaution in use

#### Prohibitions

- 1. Do not use WITHNOX for the following users.
  - Subjects with metal or electronic devices implanted in the head
  - Subjects with unexplained pain
  - Subjects with pacemakers or implanted or wearable defibrillators

- 2. Do not use in the following cases.
  - Body parts other than forehead
  - Do not use on neck.
  - Do not use on chest.
  - Do not use after brain surgery or head trauma

### 4. Cautions in use or precaution in use

#### Cautions

- 1. If you suspect or know that you have a heart or health problem, consult your physician before using the WITHNOX device.
- 2. If you have recently suffered a head injury, do not use this device until you have fully recovered.
- 3. If you have any loss of sensation in your forehead or scalp, be careful.
- 4. This device must be used with electrodes and accessories recommended by the manufacturer.
- 5. This device is not a medical device.
- 6. This device has a lifespan of 4 years.
- 7. After 4 years of use, battery performance may deteriorate rapidly and become unusable.
- 8. Not recommended for children under 7 years of age.
- 9. If any problems occur, stop using it immediately and contact the NuEyne Service Center (02-6953-8420).



Children aged 7-12 years should read the instructions and use under adult supervision.

#### Using WITHNOX device

- Do not use on patients with heart disease or serious medical conditions.
- Keep out of reach of children under 7 years of age.
- Apply only to clean, normal, undamaged skin.
- Do not use on neck and chest area.
- Do not use in environments with electronic monitoring equipment.
- Do not use while showering, bathing, or swimming.
- Do not use during activities that may result in injury, such as operating machinery.
- 3. If you are not sure which of the warnings and cautions apply to your condition, you should consult your doctor.
- 4. Do not drop this device. This may cause malfunction.
- 5. Do not disassemble this device arbitrarily. This may cause electric shock.

#### 4-1. Protection from electric shock

- Do not intentionally disassemble or modify the device. This device may cause electric shock if the outer cover of the main body is removed.
- Be careful not to spill liquid on the device. This may cause serious malfunction of the device and electric shock.
   Also keep the device away from wet environments that may generate high voltage currents, which pose a risk of electric shock and fire.
- Do not use the device near equipment that generates strong electric fields, such as home appliances that use electromagnetic waves,
- Do not turn on the appliance if the main power connection is damaged.
- To avoid the risk of electric shock, short circuit, or fire, turn off the power and store in a clean place when not in use for a long period of t ime.
- If any abnormal conditions such as water leakage, noise, burning smell, or smoke occur, turn off the power and contact the manufacturer immediately.
- Do not place equipment near combustible or combustible materials.
- Do not use or operate the instrument while covered with cloth.
- Place the instrument in the correct position to avoid contact failure.
- If the battery comes into contact with a metal object, excessive current will be generated and the temperature will rise. This can cause burns, electric shock, or damage to the battery.
- Use only batteries approved by the manufacturer. Using other batteries may cause damage to the battery and the device.

### 5. Side Effect Information

If you experience the following symptoms after use, consult your doctor.

1. headache 2. itching 3. woozy 4. nausea

5. skin rash 6. drowsiness 7. exhaustion 8. tingling

9. increased/lost appetite

#### Electrode preparation and attachment

- 1. Wipe and dry the forehead well before attaching the electrodes as shown in Figure 1 below.
- 2. Remove the protective film on the electrode.
- 3. Attach the electrodes above the eyebrows and on the forehead as shown below.



Figure 1. Electrode application site

#### Wearing the device

Wear the device as shown in Figure 2 below.

When worn, the device is stably attached to the electrodes attached to the forehead by magnetic force.



Figure 2. Device wearing appearance

#### Device operation

- 1) After the electrodes and device are properly connected, press the (+) button for 1 second to turn on the device.
- 2) After the device is turned on, press the (+) button once briefly to start the treatment.

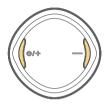




Figure 3. Power on appearance

#### Operation

- 1) Operating time lasts up to 9 hours.
  - (However, you can adjust the operating time to 7-9 hours through the app.)
- The stimulus repeats 30 seconds on, 1 second ramp down/30 seconds off, 1 second ramp up for the set time.
- 3) When the set time is over, the device will automatically stop.
- 4) Button lock is automatically activated after 5 minutes of operation.
  You can disable it by double-clicking the power (+) or (-) button.
  - \* Button lock/unlock can be controlled via the device and app.
- 5) It is recommended to use it once day for at least 7 hours.
- 6) You can check the elapsed and remaining operating time in the app.



#### Status indicator:

- Program: Yellow LED
- Button lock: When the button is operated, Puple LED

#### Battery indicator:

- When the battery is low: Red LED
- (For more information, please refer to Device Battery

Level in 7. General Information.)

Figure 4. status indicator

#### Stimulation control method

- When the device is activated, stimulation operates at the minimum current intensity (0.2 mA) and is maintained at this intensity.
- Each time you press the (+) or (-) button, the stimulation intensity is adjusted by 0.2 mA.
- The stimulation intensity can be adjusted from 0.2 mA to 5.0 mA in 0.2 mA increments.

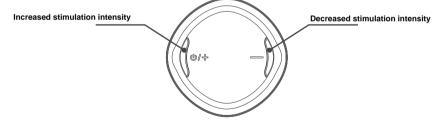


Figure 5. Increased or decreased stimulation intensity

#### End of operation

Press the power button for more than 3 seconds to stop before the operation is complete. After that, disconnect the electrode and the device when the power is off.

#### The device may be interrupted on its own due to the following reasons.

- If the forehead area is not completely wiped clean
- Electrodes are not placed correctly on the forehead
- If the device and the electrode are disconnected

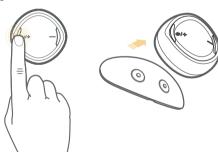


Figure 6. end of power

#### How to store and manage after use

- 1) After the set time has elapsed, the device will automatically turn off.
- 2) After detaching the device from the electrodes, store it in the base station for reuse and recharging.
- 3) To reuse the electrodes, attach them to the electrode storage plate and store them in and appropriate storage location or storage pouch.
- 4) For long-term storage, store the base station in a dedicated pouch.

#### Charging the device

- To charge the device, insert the device into the base station when charging the device.
- 1) Connect the base station to the USB-C cable and adapter.
- 2) Press the top of the base station as indicated by an arrow open the charging port (Figure 1).
- 3) Insert the device with the charging connector facing down. (Figure 2).
- 4) Close the charging port on the base station (Figure 3).
- Check the charging status shown in the base station status display window (Figure 4).

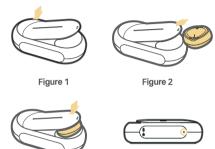


Figure 3

Figure 4

- The base station connects to the server via Wi-Fi communication and transmits information about light and noise to the server in addition to the information displayed on the status display (temperature and humidity).
- \* The base station is equipped with temperature, humidity, illuminance (brightness), and noise sensors to collect information about the surrounding environment.
- 2) When the WITHNOX device is inserted into the base station, charging begins and the charging status is displayed on the status display.
- 3) The status display on the base station will display time, temperature, and humidity in that order each time you touch the control button.
- \* The status display on the base station displays the current time by default.
- 4) The base station includes a mood lamp (indirect lighting) function, which can be controlled via the brightness control button on the top of the base station.
- \* The mood lamp on the base station is initially set to automatically adjust its brightness depending on the lighting conditions.
- \* Each time you touch the brightness adjustment button, the brightness changes in thefollowing order. (100%, 75%, 50%, 25%, Off, Auto)
- \* Each time you adjust the brightness, the current brightness status is displayed in the status display window.

#### 1) Sign up and log in

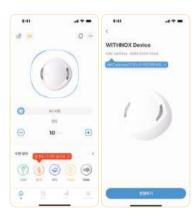
- Create an account by signing up and log in by entering your login information.

#### 2) Bluetooth connection

- Turn on your device, select the device icon on the application screen, and then select the device you want to use from the device list.
- \*\* The device requires one-time user registration.
  After the first connection, user registration is omitted.

#### 3) Device Control

- Device operation: Start, you can adjust the intensity of stimulation.
- Operation progress: You can check the remaining time, current stimulation intensity, remaining battery level, and notification status.
- If necessary, you can disconnect Bluetooth and power off the device.



#### 4) Usage history and settings

- Usage history is automatically recorded and can be checked at any time.
- After logging out, you can set up another device from the settings screen.

#### 5) Export data FILE

- Data can be exported to a Report File to manage usage records.
- \* For more information about the application, please refer to the homepage.(www.nueyne.com)
- \* You can register and use multiple devices with one account.
- \* It has a notification function in case of malfunction or stop working of the device.

#### 7. General information

#### Electrode

- 1) Check the condition of the electrode package.
- 2) The electrode can be used up to 3 times depending on the user environment, but 2 times are recommended.
- 3) The electrode can be used for up to 1 month after opening.
- 4) To reuse the electrode, please wipe and dry the forehead surface well before use.
- 5) Although it is a non-sterile product for reuse, there is a risk of cross-infection when used on multiple people, so do not use it cross- wise.
- 6) For additional information, please check the manufacturer's website. (www.nueyne.com)
- 7) Expiration date: It must be used within 3 years from the manufacturing date indicated on the electrode packaging(unopened).

#### Software

- 1) Software that controls the operation of WITHNOX
- 2) WITHNOX / WITHNOX\_APP

#### 7. General information

#### Operating conditions

1) Do not use the WITHNOX device in humid places such as bathrooms.

Operating conditions must not exceed the following values.

- Temperature (10 °C to 40 °C), Relative humidity (5 % to 85 %), Pressure (700 hPa to 1,060 hPa)

#### Storage conditions

- 1) Storage conditions must not exceed the following values.
  - Temperature (-10 °C  $\sim$  45 °C), Relative humidity (5 %  $\sim$  85 %), Pressure (500 hPa  $\sim$  1,060 hPa)

#### **Device Maintenance**

- 1) Please keep the device clean by using only alcohol-based materials.
- 2) Do not put it in water.
- 3) If foreign substances get on the charging connector, use a soft cloth and an alcohol-based cleaning tissue.

### 7. General information

[ Device Battery remaining ]

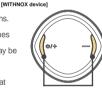
#### [ Base Station ]

- When charging begins, the green LED on the base station will blink.
   When charging is complete, the green LED is still on.
- If there is no device, the green LED will not light.

1) If the battery is low, the device will not work.

[ Base Station 1

- 2) When the battery is low, it will notify you with a beep sound in the following situations.
- When starting treatment, if the battery is low, a short beep sound will be repeated 3 times and then treatment will start. (for stable operation of the device, the device power may be turned off during treatment depending on the usage environment.)
- If the device is not able to cure when powered on, it will emit two short beeps and repeat three times in total before shutting down.
- When the battery is low when the device is shut down, the device will repeat three beeps and then shut down.
- When the above notification appears, please charge the device.
- If the device will not be used for a long time, we recommend inserting it into the base station, storing it at room temperature, and charging it once every 3 to 6 months.



Battery charging LED

Battery and status LED

## 8. Problem-solving methods

Problems	
If the device is turned on but not working, or the red LED is blinking and the device is making a sound	- Check battery charge status - Charging the battery
When operating the device, if the device does not operate and the red LED continues to appear after the beep sound	Poor contact between the device and the electrodes  - Make sure the skin is cleaned and dried well before attaching the electrodes.  - Use a new electrode.  - Check if the device is attached in the correct position by looking in the mirror.
If the intensity of the stimulus is weak	- Press the (+) button
If the intensity of the stimulus is strong	- Press the (-) button

#### 9. Technical information

#### **Output Information**

- Rechargeable 3.7 V LiPo battery
- Number of uses on a full charge: 3 times
- Charging time: approximately 2 hours
- Battery life: 500 times of full charge / discharge
- Maximum input voltage (USB Type-C): 5.25 Vdc
- If you have any problems with your battery, please contact the manufacturer.



Do not disassemble this device arbitrarily.

This may result in electric shock. For repairs and battery replacement, please contact the NuEyne Service Center (02-6953-8420).

#### Disposal of the device and base station

- Please dispose of it according to the regulations of each country of use.

### 9. Technical information

#### Product size

- device: 45.00 mm (W) \* 44.00 mm (H) \* 18.80 mm (D)
- base station: 129.00 mm (W) \* 74.00 mm (H) \* 38.00 mm (D)

Pulse frequency	120 Hz
Pulse Width	250 μs
maximum strength	Up to 5mA under user control
Time of use	7-9 hours of sleep (Operating time can be set between 7 and 9 hours using the mobile application.)
Repeat cycle	30 seconds on, slowly decrease over 1 second / 30 seconds off, slowly increase over 1 second

### 9. Technical information

#### **Electrical Compatibility**

- Accessories that can be used with the WITHNOX device are the electrodes and charging system (base station) that come with the device.
- Using components not provided by the manufacturer may be unsafe and may cause malfunction..

#### Wireless specifications

- device

Operating Frequency: This device operates in the frequency range of 2.402 GHz to 2.48 GHz.

- base station

Operating Frequency: This device operates in the frequency range of 2.402 GHz to 2.48 GHz.

## 10. Consumer dispute resolution standards

		Compensation Details	
	Types of consumer damage	Within the warranty period	After the warranty perio
In case of performance or functional failure that occurs naturally under normal use conditions.	If major repairs are required within 10 days of purchase	Product exchange or refund of purchase price	
	If repairs are required for critical parts within 1 month of purchase	Product exchange or free repair	Paid repair
	If the exchanged product requires major repairs within 1 month	Refund of purchase price	
	When exchange is not possible	Refund of purchase price	
	In case of defect	free repair	
	Repaired for the same defect, but the failure occurred again (3rd time)		
	The failure occurred again despite repeated repairs (5th time)		
	If repair is not possible	Product exchange or	Refund of the remaining amount after depreciation plus 10% of the purchase price
	If repair is not possible because repair parts are not available	refund of purchase price	
	If the customer's product is lost		
	Damage that occurred during transportation when purchasing a product		-

	Types of consumer damage	Compensation Details	
	Types of consumer damage	within the warranty period	After the warranty period
Performance functional failure due to user's intention or negligence	If repair is possible	free repair	free repair
	If repair is impossible	Product exchange after collecting the amount corresponding to paid repairs	-
- If a malfunction occurs due to a natural disaster (fire, salt damage, earthquake, flood damage, etc.)			
- If a malfunction occurs due to a problem with the power supply or a defective connected device			
- If a failure occurs due to repair or modification at a location other than NuEyne or an authorized service center		free repair	free repair
- If a consumable part that normally wears out during use is replaced			
- If the cause is an external cause that is not a defect in the product itself			

- The stated warranty period and compensation standards are based on the Consumer Dispute Resolution Standards announced by the Fair Trade Commission.
- Any matters not specified will follow consumer dispute resolution standards.
- Please be sure to read the user manual as service fees may apply if the product is not defective...
- Parts that are replaced during repairs may be from a different country of origin or manufacturer than the existing parts, and may not be new parts, but parts that operate normally and are functionally equivalent are used.
- Some of the components used in the product may be manufactured in a country other than the country of manufacture.

### Consumer dispute resolution standards

#### Responsibility for paid services for which customers have to pay

When applying for service, in the following cases, the consumer must pay separately even during the quality guarantee period.

\*When using the instructions and making simple adjustments without disassembling the product.

\*When the case, etc. is damaged by external impact.

\*When malfunction occurs due to ingress of dust, beverages, etc.

\*When a malfunction occurs due to the user disassembling or modifying the product arbitrarily.

\*\* When requesting repairs, you must present this warranty with the purchase date written on it to receive adequate service,

#### so please keep it in a safe place.

10.

- 1. The quality guarantee for this product is covered by the contents stated in the warranty.
- The quality assurance period is calculated from the date of purchase, and the purchase date is confirmed by the product warranty (including the purchase receipt).
- If the purchase date cannot be confirmed, the quality assurance period is applied by considering 3 months (reflecting the distribution period) based on the manufacturing date or import customs clearance date.
- 4. If used in an abnormal environment, the quality assurance period is shortened by 50%.
- 5. This warranty will not be reissued.
- 6. In case of supply under a separate contract, the warranty contents are applied according to the main contract.
- 7. Parts retention period: 5 years from the product manufacturing date.



# **Product Warranty Certificate**

Customers can receive free service for one year for failures that occur while using the product.

This product is free of charge within the quality warranty period only in Korea.

flodel name :	
ate of purchase :	Buyer:
Nanufacturing number.:	Tel:
Homepage: www.n	Nu Eyne Room 608, 6th floor, 28, Digital-ro 30-gil, Guro-gu, Seoul Juyyne com I Email: info@pueyne com I Tel: 02-6953-8420

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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: WITHNOX Device Model: BPSPW1-MD FCC ID: 2BE9W-BPSPW1-MD

Product: WITHNOX Base Station

Model: BPSPW1-BS

FCC ID: 2BE9W-BPSPW1-BS

