INSTRUCTIONS FOR USE
Felix™ NeuroAI™ Wristband
Version 1.2

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Fasikl Incoporated

About this manual

Thank you for purchasing Felix™ NeuroAI™ Wristband. For safety, please be sure to read this manual before use, especially the content of "Safety Information". Please maintain this document for future reference.

Product information

Product name: Felix™ NeuroAI™ Wristband

Product Registration Certificate No.:

Production License Number:

Production enterprise / registrant

Manufacturer Name: Fasikl Inc.

Manufacturer address:8500 Normandale Lake Blvd, Suite 400, Bloomington, MN 55437, USA

TEL:+1 (507) 403-7680.

Contract Manufacturer: Hangzhou Fasikl Technology Co., LTD

Production Address: Room 311-q,3rd Floor, C Building, No.33Yueming Road, Xixing Street, Binjiang District, Hangzhou City, Zhejiang Province, China

Version information

This IFU may be upgraded due to software upgrades without prior notice.

- IFU version number: V1.2
- Release date: October 16, 2024
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Table of Contents

1. Introducing Felix™ NeuroAI™ Wristband System

1.1. Indications for Use

The Felix™ NeuroAI™ Wristband is indicated to aid in the relief of upper limb tremors following closed-loop stimulation in adults with essential tremor.

1.2. Use Specification

Felix™ NeuroAI™ Wristband is intended to be used in the clinic and at home. The device can be operated by healthcare professionals and patients. User needs to be trained prior to operating the device.

1.3. Felix™ NeuroAI™ Wristband components

The Felix™ NeuroAI™ Wristband is composed of the Stimulator, Connector Band, Electrode Band, Strap, a wireless charger and a mobile app (with the function of artificial intelligence to automatically adjust the stimulation intensity), as shown in Figure 1.

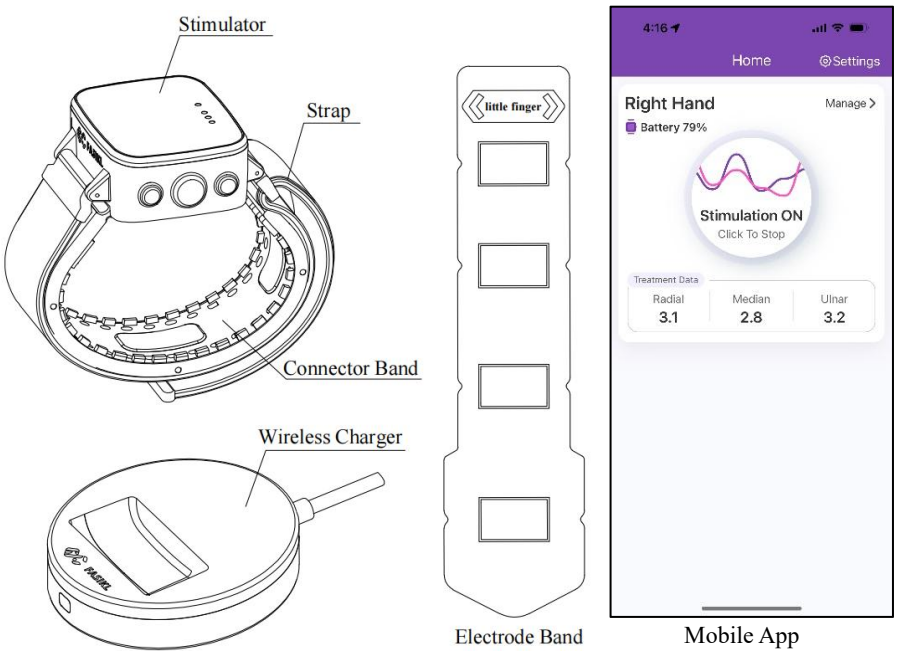


Figure 1. Schematic diagram of the Felix™ NeuroAI™ Wristband components

1.3.1. Felix™ NeuroAI™ Stimulator

The Felix™ NeuroAI™ Stimulator consists of a cover plate, main button, auxiliary buttons and housing, as shown in Figure 2.

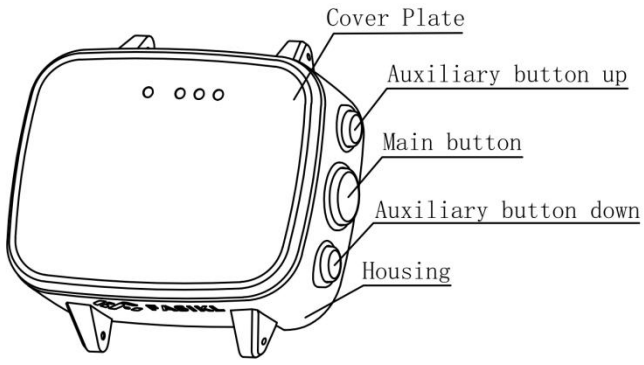


Figure 2. Schematic diagram of the Stimulator

1.3.2. Connector Band

The Connector Band consists of a flex circuit, the Connector Band main body, the Velcro and the Contact Pads, as shown in Figure 3. There are four Contact Pads with the return directly below the body of the Stimulator, and the other three contact pads correspond to the radial nerve, median nerve, and ulnar nerve. The edge of the Connector Band is marked with white dots, which help to align the Connector Band and the Electrode Band . Connector Bands are replaceable.

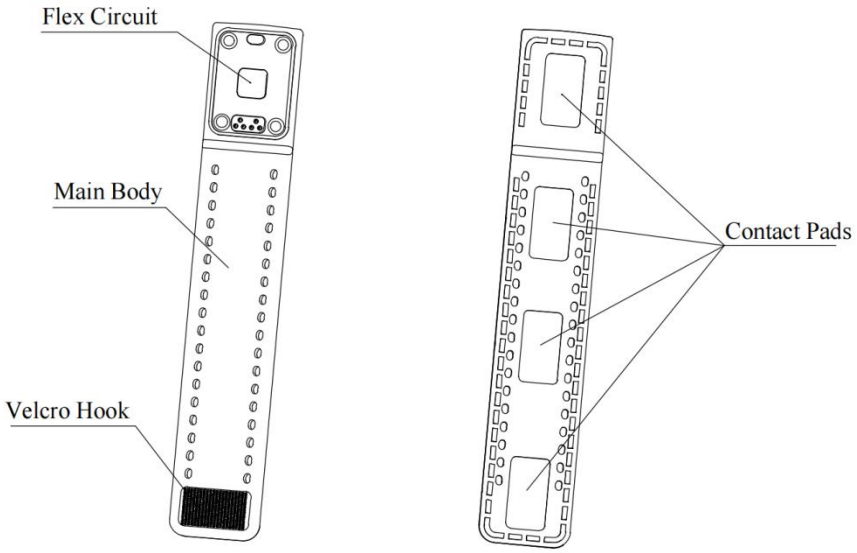


Figure 3. Schematic diagram of the Connector Band

1.3.3 Electrode Band

Electrode Band is composed of Electrode protective film, Conductive strip, Hand tear label, Non-woven fabric and Hydrogel electrode piece, as shown in the following schematic diagram 4. It has two sides, one side of the Conductive strip is combined with Connector Band, and the other side is fitted with the skin of the human wrist. Non-sterile delivery, disposable.

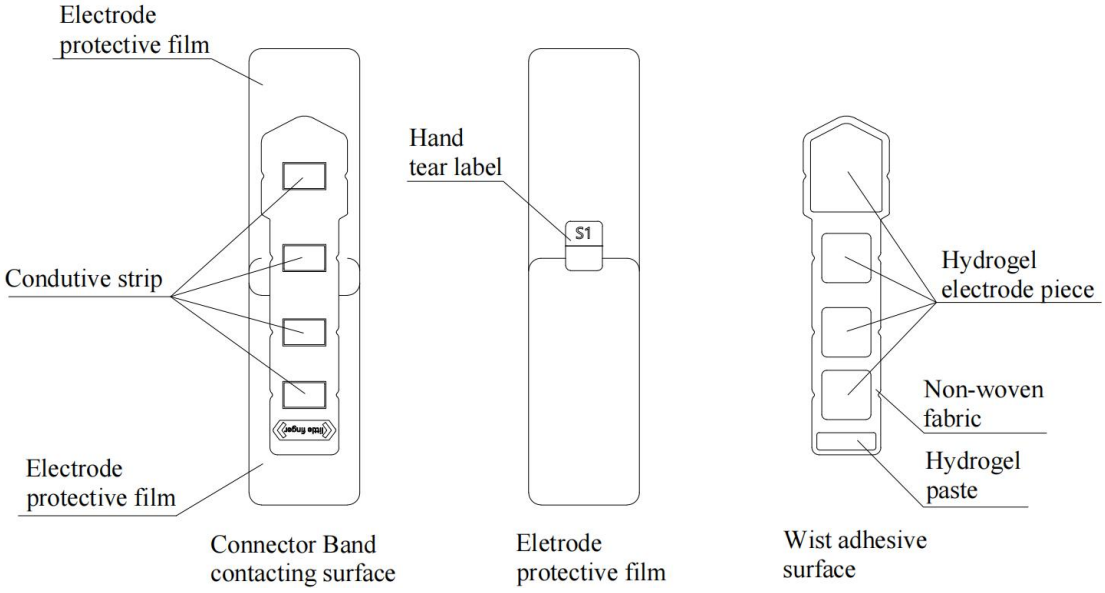


Figure 4 Schematic diagram of Electrode Band

1.3.4 Wireless Charger

The wireless charger consists of a case, indicator light and USB wiring harness, as shown in Figure 5. Use with a 5V1A USB power supply (This product does not come with a 5V1A USB power adapter. Users need to bring their own power adapter that meets this specification for use).

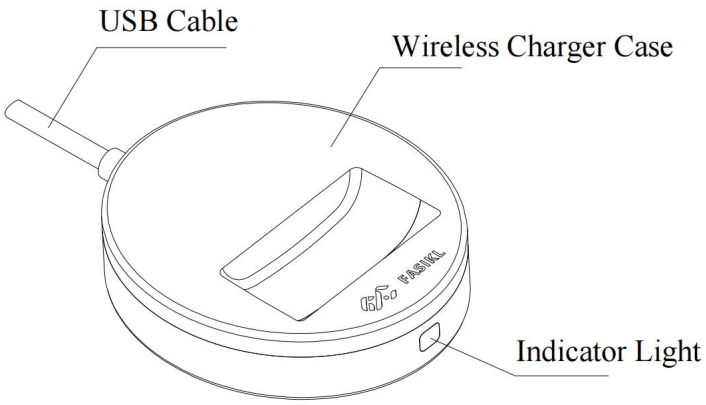


Figure 5 Schematic diagram of the wireless charger

1.4. Model code

The model code of the Felix™ NeuroAI™ Wristband is: Felix-G1.

The Connector Bands and Electrode Bands are designed to match different wrist dimensions, as shown in Table 1 below.

Table 1 Connector Band and Electrode Band model codes

	Connector Band			Electrode Band		
Small	CB1-S1			EB1-S1		
Medium	CB1-M1	CB1-M2	CB1-M3	EB1-M1	EB1-M2	EB1-M3
Large	CB1-L1		CB1-L2	EB1-L1		EB1-L2

1.5. Scope of Delivery

The standard accessories contained in the product package are shown in Table 2 below. The Connector Band replacement period is 6 months. The Electrode Band replacement is 1 day.

Table 2 Quantity of product components

SN	Accessory name	unit	quantity
1	Felix™ NeuroAI™ Stimulator	piece	1
2	Connector Band	piece	1
3	Electrode Bands	Box (30 pcs)	1
4	Wireless Charger	piece	1
5	Instructions For Use	document	1
6	Certificate of Quality	sheet	1
7	Felix™ App Installation Program	sheet	1

2. Safety Information

2.1. Contraindications

This product should not be used in the following cases:

1) Patients with suspected epilepsy or confirmed epilepsy;
2) Pregnant women;
3) In the areas of swelling, infection, inflammation, or skin ulceration, open wounds, or cancerous lesions.

2.2. Warnings

1) Do not use the equipment in the environment of high frequency surgical equipment, it can cause burns, and/or equipment failure. Do not use the equipment within 1 meter of short wave or microwave therapy equipment, which may cause an unstable output of stimulator. Wearing the device is not recommended during X-ray examination, as it can interfere with the diagnosis. Do not use the device near high power equipment such as high-voltage cables, ultrasonic equipment, or defibrillators, and do not use the equipment under strong electromagnetic field (such as medical radio frequency equipment that radiates interference signals or electrical fast transient/burst signals);
2) This device can only be worn on the wrist. Do not use in non-wrist areas (such as head, eyes, mouth, heart, neck (carotid sinus), chest and upper back, etc.), which may lead to health problems;
3) When used close to the chest, the electrodes increase the risk of cardiac fibrillation;
4) Do not use this device during the following activities:
   - sleeping
   - driving
   - bathing or swimming
   - operating machinery
   - any activity where an involuntary muscle contraction could give rise to an injury
5) Do not use this device near flammable liquids, smoke or chemicals；
6) Stop stimulation while fueling a vehicle with gasoline to prevent an explosion and risk of injury；
7) Do not stimulate open, cancerous wounds or rash, excessive swelling, red skin, infected, inflamed areas;
8) Stop stimulation if you want to remove or charge the device;
9) The stimulation intensity is probably too high if it causes discomfort or skin irritation；
10) The long-term effects of chronic electrical stimulation are unknown; when the stimulation intensity of 8 mA or higher has a current density higher than 2 mA / cm^2, the user should pay special attention to the corresponding risks;
11) Do not immerse the device in water and do not use in high humidity places such as the bathroom;

2.3. Cautions

1) Users must read the Instructions for Use carefully before operating the device;
2) Pregnant women should not use this product；
3) Avoid dust, direct sunlight and pests when storing, and it is recommended to store it in the original package when not in use;
4) When the device is not in use, keep it out of the reach of children and pets;

5) Avoid forming condensation on the device. When moving the device from cold temperature to warm temperature, put it in a sealed plastic bag, and then slowly wait for the temperature to change to adapt to the environment;
6) Before use, the skin should be cleaned according to section "2.5 Skin Care Guidelines" in this manual;
7) Use with caution in people with skin sensory disorders or skin abnormalities;
8) Use with caution in patients with bleeding and clotting disorders;
9) Patients with an implanted stimulator needs to consult a doctor about whether they can use this product;
10) The following conditions should be used under the supervision and assistance of caregivers familiar with the use of the equipment:
    - Elderly patients who are unable operate the device independently;
    - People with hand motor coordination disorders;
    - People who are receiving medication that affects memory, comprehension or ability to perform operations;
    - People with cognitive impairment;
    - People with difficulty in physical activities.
11) To avoid product damage and work abnormalities, please note the following:
    - Do not place the equipment on, in or near a heat source. Overheating may damage the device or battery, and may cause the explosion of the device or battery;
    - Do not drop the device on a hard surface as this may damage the device and/or the battery;
    - The stimulator case may crack if the device falls or is hit significantly, and if the case breaks, do not use the device, it may cause injury;
    - Do not contact the electrodes with other conductive parts (including grounding), do not expose the equipment to electric shock or expose the equipment to any static electricity;
    - Do not modify the device as it is not safe and is not allowed. The battery of the device is not field serviceable. Attempting to replace the battery can lead to risks；
12) When charging, do not place the charger on a metal table, and remove metal objects from nearby the device to avoid heating of metal foreign bodies；
13) Do not use the device during charging;
14) Do not dispose this device in the trash. Disposing of the device and its accessories and packaging (including batteries, plastic bags, foam, carton) shall comply with local laws and regulations. Illegal disposal may cause environmental pollution.

2.4. Adverse Reactions

The following are possible minor/moderate risks or adverse reactions that may occur with the use of the device:

1) Discomfort with stimulation (e. g., stinging, electrical tingling, skin pain, soreness, weakness, nausea, etc.);
2) Skin irritation (such as redness, itchy skin, dry skin, rash, electrical irritation burns, etc.);
3) Skin discoloration;
4) Unintended muscle contractions;
5) Worsening of tremor.

In the unlikely event that any of the following more significant issues occur, stop using the device immediately and contact the research coordinator:

1) Signs of significant and persistent discomfort with stimulation, skin irritation, ulcers, electrical irritation, burns, or signs of injury;
2) Significant or sustained increase in muscle tightness or stiffness;
3) During the stimulation process, there is a sense of pressure in the chest;
4) Swelling of the arms, wrist, or hand.

2.5. FCC related safety information

1) Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user’ s authority to operate the equipment.
2) Shielded cables must be used with this unit to ensure compliance with the Class B FCC limits.
3) This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
    a. this device may not cause harmful interference, and
    b. this device must accept any interference received,including interference that may cause undesired operation.

NOTE: This equipment 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:

a. Reorient or relocate the receiving antenna.
b. Increase the separation between the equipment and receiver.
c. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
d. Consult the dealer or an experienced radio/TV technician for help.

2.6. Skin Care Guidelines

Healthy and hydrated skin works best with stimulation. Practice gentle skin care daily following this guide.

2.6.1. Clean:

a. When cleaning skin, use lukewarm water. Avoid long baths and showers.
b. Avoid harsh soaps and those with fragrance which tend to dry out the skin. Recommended soaps are Dove, Olay and Basis. Skin cleansers are recommended over soap. Look for Cetaphil Skin Cleanser, CeraVe Hydrating Cleanser and Aquanil Cleanser.
c. Avoid vigorous scrubbing with a washcloth.

2.6.2. Rinse:

a. Remove any cleanser from the skin thoroughly with water. Avoid alcohol, as it drys out the skin.

2.6.3. Blot or pat dry:

a. Avoid vigorous drying with a towel. Instead, blot the skin so that there is some moisture left on the skin.

2.6.4. Apply a moisturizing cream:

a. Immediately after blotting the skin, apply a moisturizing cream (not lotion). This helps to seal moisture in the skin. Some recommended creams are CeraVe and Cetaphil.

Always check the skin for irritation, redness, or rash when putting on and taking off Felix™ NeuroAI™ Wristband. If any skin irritation is noted, please contact the provider of the Felix™ NeuroAI™ Wristband.

2.7. Function for safe use by the patient

The patient is the intended operator. The functions designed of the product include power on/off, Bluetooth connection, adjust stimulation intensity, turn stimulation on/off, and wireless charging. All these functions can be used safely by patients. None of these functions cannot be used safely.

2.8. Normal environmental use conditions

Ambient temperature range:	5℃～40℃
Relative humidity range:	5%～90%
Atmospheric pressure range:	70kPa～106kPa

- When the ambient temperature is 20°C, the time required for the device to warm up from the minimum storage temperature -10°C to be ready for use is 2 hours.
- When the ambient temperature is 20°C, the time required for the device to cool down from the maximum storage temperature of 60°C to be ready for use is 2.5 hours.

3. Setting up the Felix™ NeuroAI™ Wristband

3.1. Nerve site selection – performed in-clinic or via video conference

The location of the peripheral nerves in the wrist area (median nerve, ulnar nerve and radial nerve) of each patient is slightly different. Trained healthcare professional or manufacturer personnel will locate the appropriate stimulation sites. If not done properly, the electrode will not cover the target nerves and the stimulation will not be effective.

3.2. Connector Band and Electrode Band size selection

Connector Band and Electrode Band are available in 6 sizes, 1 for small, 3 for medium, and 2 for large. After the stimulation site is determined, the distance of the corresponding carpal nerve is measured, and then the corresponding Connector Band and Electrode Band specification is selected according to Table 3.

Table 3 Specification selection table

Connector Band and Electrode Band specifications	Range from radial to median nerve (mm)		Range from ulnar nerve to median nerve (mm)		Range of midpoint to median nerve (mm)	
CB1-S1/EB1-S1	22.1	38.1	17.4	33.4	50.3	76.3
CB1-M1/EB1-M1	27.7	43.7	32.7	48.7	57.5	83.5
CB1-M2/EB1-M2	33.9	49.9	18.7	34.7	61.9	87.9
CB1-M3/EB1-M3	24.9	40.9	21.6	37.6	64.5	90.5
CB1-L1/EB1-L1	36.9	52.9	24.9	40.9	69.2	95.2
CB1-L2/EB1-L2	35.2	51.2	36.6	52.6	73.1	99.1

ATTENTION: If there are multiple sizes that overlap, select the optimal specifications according to the actual nerve position.

3.3. Assembly of Felix™ NeuroAI™ Wristband

As shown in Figure 6 below, the strap is turned inside out and the Connector Band is connected to the main body of the Stimulator by aligning the 4 magnets. Press gently to make sure the connection is secure.

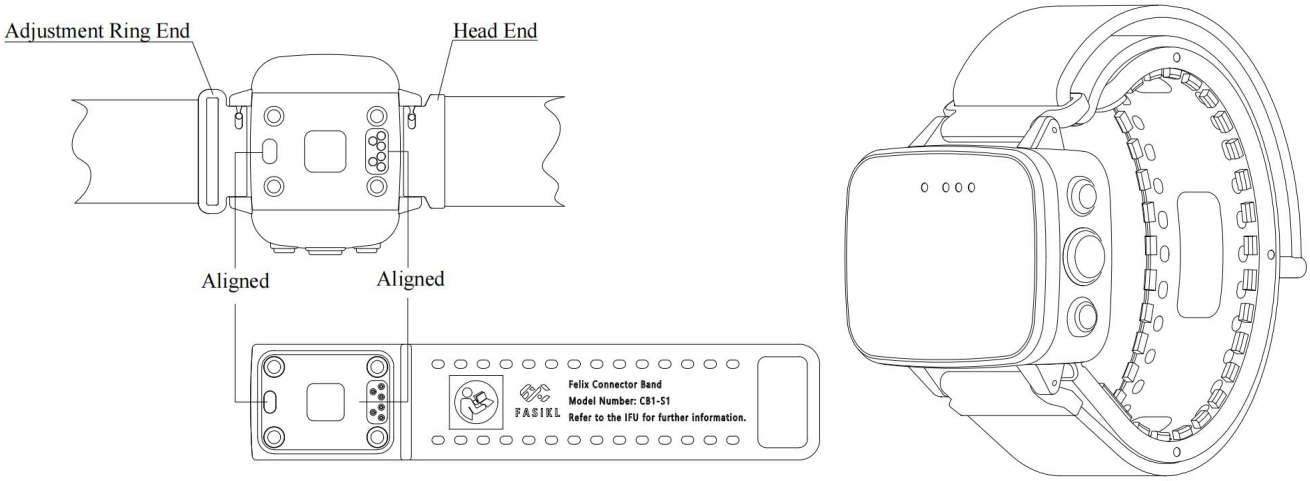


Figure 6. Product assembly and completion diagram

⚠ ATTENTION:

① The Head End of the strap is connected to the 6 points side of the Stimulator.

② The adjustment ring end of the strap is connected to the other side.

3.4. Power on and off the Felix™ NeuroAI™ Wristband

Press and hold the main (middle) button on the side of the stimulator for about 3 seconds until the green indicator lights up, indicating that the device is turned on. To shut off the stimulator press and hold the main (middle) button for about 3 seconds until all indicators turn off, indicating that the device has been turned off.

3.5. Putting on the Electrode Band

ATTENTION: Use a new Electrode Band every day.

The Electrode Band has four rectangular contacts (as shown in Figure 7 below). When the patient gets the Electrode Band, the positioning of the hydrogel electrodes is designed to align with the location of the nerves in the wrist. To apply an Electrode Band, follow these steps to ensure that the Electrode Band is accurately applied.

a. There are two sections of protective film over the hydrogel pads.
b. To apply the Electrode Band, first find the black rectangle on the back of the Electrode Band. You will align the black rectangle with the median nerve. Note the little finger sticker which goes on the pinky side of the wrist (as shown in Figure 7 below).
c. Flip over the Electrode Band and peel off the protective film using the size tab to expose the median and ulnar nerve gel pads (as shown in Figure 8 below).
d. Apply the Electrode Band to the median nerve first, then secure it over the ulnar nerve.
e. Peel off the remaining protective film to expose the radial nerve and the return electrode locations.
f. The return electrode is the largest, it is positioned behind the wrist and will be located under the main body of the Felix™ device.

g. Ensure complete skin contact by gently pressing each location and check the alignment of the Electrode Band.

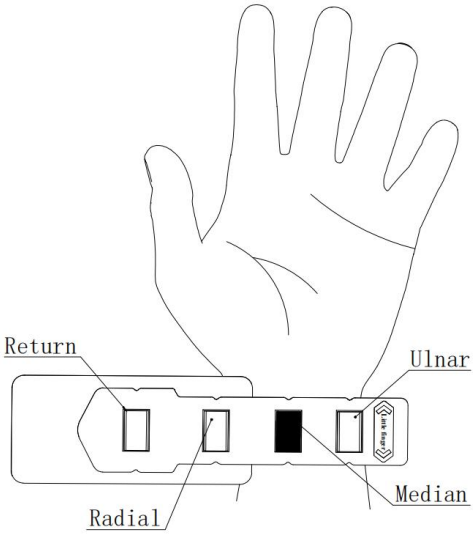


Figure 7 Schematic diagram of the Electrode Band placement

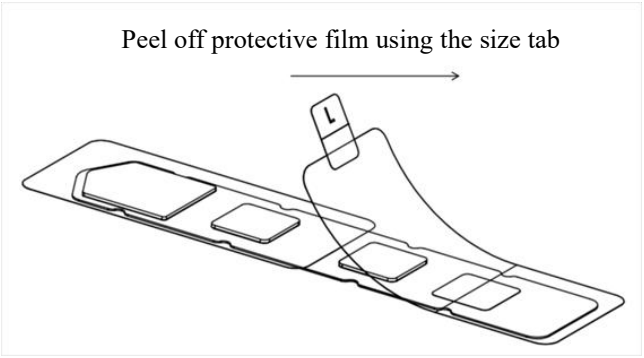


Figure 8 Peeling off the Electrode Band protective film

⚠ ATTENTION:

- The Electrode Band must be used with the Connector Band of the Felix™ NeuroAI™ Wristband.
- The Electrode Band needs to be replaced if it is no longer sticky.

3.6. Putting On the Felix™ NeuroAI™ Wristband

a. Please ensure that the Velcro of Connector Band is neatly bonded to the inner surface of the outer strap, ensuring that Connector Band is not exposed to the outside of the outer strap. This can prevent Connector Band from shortening its service life due to abnormal stress.

b. Hold the device so the buttons are on the right side and the lights are on top. The band should be loose enough to allow you to slide your hand through it.

c. Slide your hand into the strap.

d. Align the white dots on the side of the Connector Band with the notches on the Electrode Band to ensure proper positioning. (Figure 9)

e. Tighten the strap to prevent the Felix™ device from moving over the electrodes.

f. It is important that the Felix™ device and the Electrode Band remain aligned throughout the day.

g. The band should be comfortably snug around your wrist without causing discomfort or preventing wrist motion.

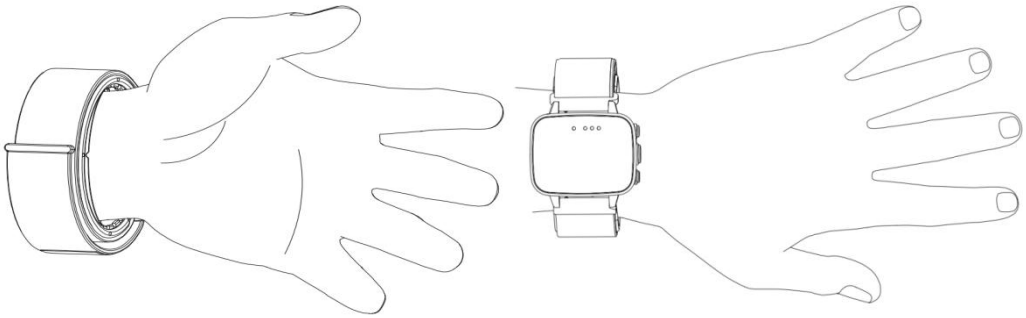


Figure 9 Align white dots on the Connector Band with the notches of the Electrode Band

⚠ATTENTION:

- The Connector Band must be used together with the Electrode Band;
- Ensure alignment of the notches on the side of the Electrode Band and the white dots on the side of the Connector Band and that they are parallel. Manually adjust the alignment if needed;
- During stimulation, the strap should remain snug. The alignment of the Connector Band and the Electrode Band needs to be checked regularly. Shifting of the Connector Band during wrist movement may result in direct contact between the Connector Band and the skin at the wrist, which may cause skin stinging. Further, the Connector Band should maintain alignment with the Electrode Band contacts, or the circuit will be broken. If the Connector Band and Electrode Band lose contact, a red light will blink on the device, stimulation will stop, and the App will display a message indicating poor electrode contact. The position of Connector Band must be adjusted to start the stimulus again.
- The strap should not be too tight and should allow free movement of the wrist and blood flow. After wearing, gently shaking your wrist should not cause displacement of the device.

3.7. Taking Off the Felix™ NeuroAI™ Wristband

a. Turn off the Stimulator;

b. Loosen the strap and remove the Felix™ NeuroAI™ Wristband;

c. Remove the Electrode Band and discard properly.

3.8. Applied part of the device

Applied part of the device is Electrode Band.

4. Calibration and Stimulation with Felix™ NeuroAI™ Wristband

4.1. Felix™ App Installation and Network Requirements

a. Install the Felix™ app on your phone by scanning the QR code located on the product box and follow the on-screen instructions；

b. The mobile application requires Bluetooth enabled and authorize the application to use Bluetooth, enable Location Services for the Felix™ App, and an active internet connection through Wi-Fi or data network.

4.2. App Login

The first connection will be done by following the steps, and then the mobile app will automatically connect.

a. Turn on the Felix™ NeuroAI™ Wristband and the phone. The green light on the face of the Felix™ NeuroAI™ Stimulator will turn on when the device is turned on;

b. Open the "Felix" App on the phone;

c. When logging in, Apple users offer 4 login methods (Figure 10-1).

a) You can use your email address or mobile phone number to send a verification code；

b) You can log in using the Apple ID;

c) You can use Google verification.

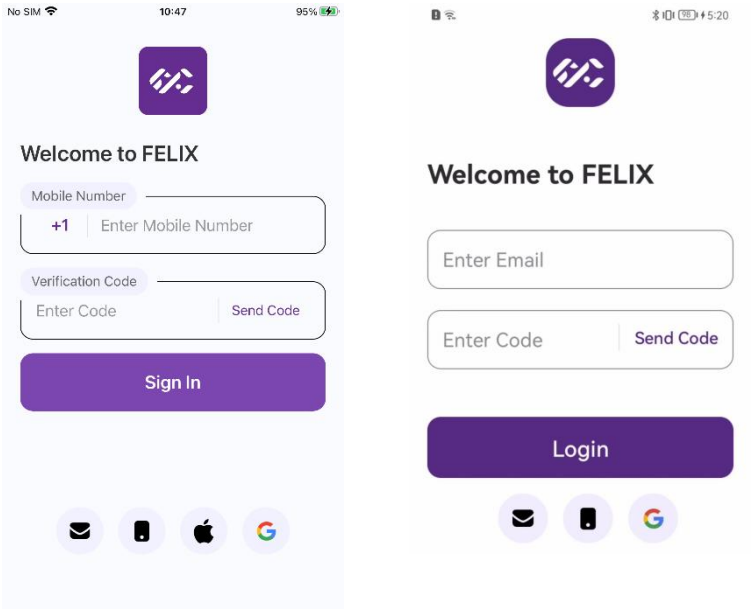


Figure 10-1 and 10-2 Login interface diagram

d. When logging in, Android users offer 3 login methods (Figure 10-2).

a) You can use your email address or mobile phone number to send a verification code;

b) You can use Google verification.

e. If the login is successful, the app will automatically enter the "Add Device" page;

4.3. Add a Device

a. On the “Add Device” page, click on the device you want to add. (Figure 11-1)

NOTE: The numbers displayed on the screen match the last four digits of the serial number located on your Felix™ NeuroAI™ Stimulator. Once the connection is successful, the blue light will light up on the face of the Stimulator.

4.4. Side Selection

a. Next, select the side (left or right) that the device will be worn on. (Figure 11-2).

b. Then click "Next" to enter the calibration page (Figure 11-3).

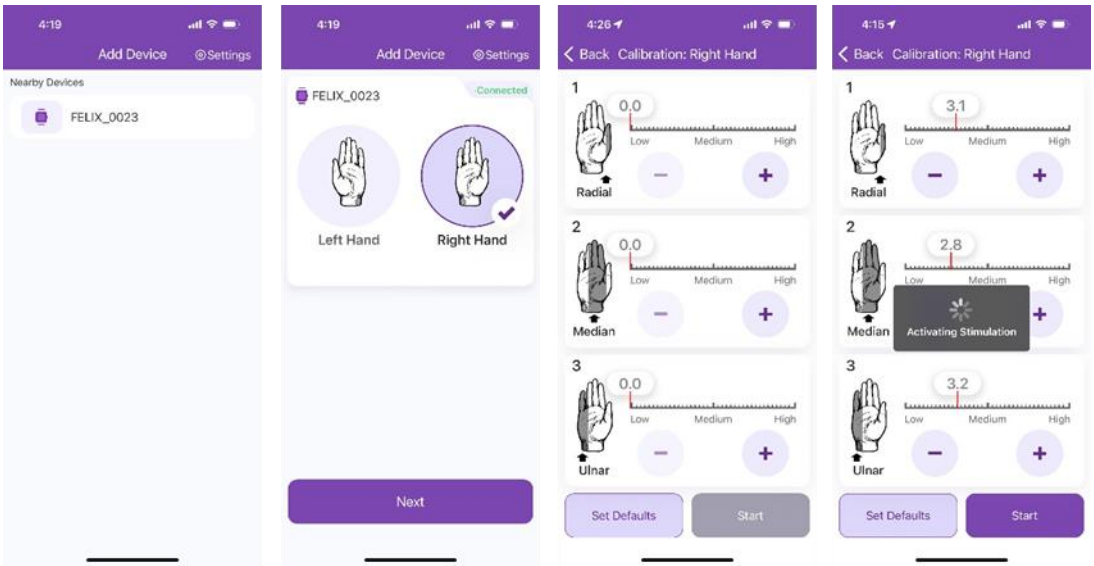


Figure 11-1, 11-2, 11-3, and 11-4 are shown on the app interface

⚠ ATTENTION:

- The operation of the Felix™ NeuroAI™ Stimulator requires the support of the App. Please do not exceed 9 feet between the mobile phone and the Felix™ NeuroAI™ Stimulator during the stimulation treatment. Bluetooth will disconnect between the mobile phone and the Felix™ NeuroAI™ Stimulator if this distance is exceeded, and the Felix™ NeuroAI™ Stimulator will lose APP control.

4.5. Calibration

a. Use the + or – buttons to adjust the maximum stimulation level on each of the three nerves.

b. Once you have adjusted each nerve to your maximum tolerable intensities, click the "Start" button on the bottom of the screen. This will start stimulation on all three nerves and the app will display the message "Activating Stimulation". (Figure 11-4)

c. Next, the app will display a message asking if the stimulation intensities are satisfactory. (Figure 11-5) You will be prompted with the option to refine these settings or start treatment by clicking on either button in the app.

d. If you click on "No, refine settings", you will return to the calibration screen where you can adjust each nerve as needed to set your maximum tolerable intensities. Continue to do this until you are satisfied with the levels of stimulation you have chosen. Once you click "Yes, start treatment", the app will return to the home screen where you will see an animated button indicating that stimulation is "ON". (Figure 11-6)

⚠ ATTENTION: Based on clinical data, the maximum tolerable stimulation levels are usually between 3.5 and 5.5mA as set in calibration. Individual patient's level can be higher or lower than this value depending on their tolerance.

⚠ ATTENTION: Stimulation will never exceed these values throughout the day, but it is also normal for you to feel lower stimulation or no stimulation at all. This is all part of the automatic treatment optimization.

⚠ ATTENTION: The first time you start stimulation each day you will be prompted to calibrate the Felix™ device. If calibration is desired throughout the day, you can find the option to calibrate in the manage menu on the home screen. The process for calibration here is the same. (Figure 11-7 *Calibration button is highlighted*)

⚠ ATTENTION: When the stimulation is turned on, the green light on the device will flash, and it will also flash during the adjustment of stimulation intensity. When the stimulation stops, the green light on the device will stop flashing and remain constantly on.

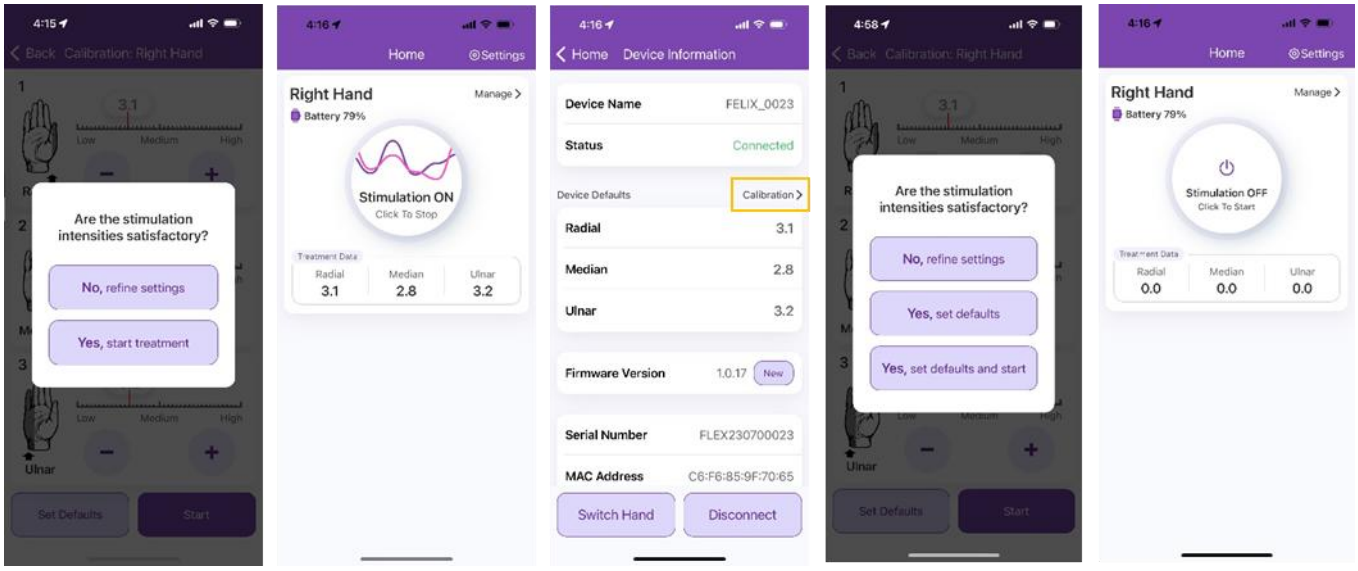


Figure 11-5, 11-6, 11-7, 11-8 and 11-9 are shown on the app interface

⚠ ATTENTION: Patients need to self-confirm that the electrodes are positioned over the target nerve. If the electrodes are positioned over the target nerve, there is a tingly sensation in the palm and/or the fingers connected to each nerve. If the patient's sensation is only confined to the skin under the electrodes and the sensation does not radiate to the wrist and fingers, the electrodes are not covering the target nerve and the electrodes need to be repositioned.

4.6. Default Settings (Clinic personnel only)

a. In the Calibration page, set the maximum intensities and then click on “Set Defaults” button on the bottom of the screen. (Figure 11-3)

b. This will start stimulation on all three nerves and the app will display the message “Activating Stimulation”. (Figure 11-4)

c. Next, the app will display a message asking if the stimulation intensities are satisfactory.(Figure 11-8)

d. Click the "Yes, set defaults and start" or “Yes, set defaults” button. Changing the default settings requires a password, which is provided to the clinical site during training.

e. Each day will begin with the default settings.

⚠ ATTENTION: If there is a Bluetooth connection between the device and the mobile application, and the phone is connected to the Internet, the stimulation will be stimulated by AI and the stimulation intensity will change in real time. If the mobile application network is not connected, then the stimulation will be based on the existing intensity.

4.7. Stimulation

Once calibration is complete and stimulation is active you will be on the home screen. Here you can click on the Start and Stop buttons to start and stop stimulation. (Figure 11-6 and 11-9) A quick press of the middle button can also start and stop the stimulation.

⚠ ATTENTION:

- The flashing green LED light on the device indicates that stimulation is active.

4.7.1. Artificial Intelligence (AI) Controlled Stimulation

Stimulation is controlled by an AI algorithm running on a cloud server (AI server). Felix has a build-in sensor to collect movement information. This data, together with other device information, will be sent to the AI server continuously via the mobile App while the device is powered on and the smartphone is connected to the internet. During stimulation, the AI algorithm continuously calculates and identifies stimulation parameters that will most likely result in tremor reduction, and sends the parameters to the device via the mobile App.

4.7.2. Fallback modes:

a. Bluetooth disconnection during stimulation: in case of Bluetooth disconnection between Felix and the mobile app, stimulation will be set at the parameters right before the disconnection and until reconnection.

b. Internet disconnection during stimulation: in case of internet disconnection in the mobile app, stimulation will be set at the parameters right before the disconnection until reconnection.

c. Device error: in case of a device error, stimulation will be paused and can be manually resumed after error has been resolved.

4.8. LED Indicator Lights

There are 4 LED indicator lights on the face of the Felix™ NeuroAI™ Stimulator and one LED indicator light on the charging base. The meaning of the LED indicator lights is shown in Table 4 below.

Table 4. Meaning of the indicator light

function	(From Left) indicator light 1 is white	indicator light 2 green	Indicator light 3 blue	Indicator light 4 red	Charger base Indicator light white
Power Off	/	/	/	/	/
Power ON	/	Solid Green	/	/	/
Mobile phone app connection	/	Solid Green	Solid Blue	/	/
Stimulation Active	/	Blinking green light	Solid Blue (Bluetooth disconnection light off)	/	/
Charging	White while charging. When fully charged light is off	/	/	/	White while charging. When fully charged light is off
Abnormal electrode fitting; Voltage anomaly;	/	/	/	blinking red light	/

error					

ATTENTION：

- When the red light of the device flashes, it may be one or more of the three conditions: "electrode fitting abnormality", "voltage abnormality" and "device error". For the specific one, please check the mobile application.
- When "electrode fitting abnormality" occurs, please readjust the position of the connecting strap to eliminate the abnormality, and then restart stimulation;
- When "voltage abnormality" and "device error" appear, it is recommended to restart the device. If the problem persists after restarting, it is recommended to contact your equipment supplier for repair or inspection.

5. Caring for Felix™ NeuroAI™ Wristband

5.1. How to Charge the Felix™ NeuroAI™ Wristband?

- When the device needs to be charged, the wireless charging dock is connected to the power supply, the side of the device without buttons is put into the charging dock, the white indicator light of the charging dock is lit, and the white indicator light of the device is lit at the same time, indicating that the charging is connected. If you need to stop charging or disconnect from the network power supply, you can pick up the device, as shown in Figure 12 below.
- When the device is fully charged, the indicator light will turn off, and it takes about 2.5 hours from 0% charge to full charge.
- In daily use, try not to wait for the battery to run out of power before charging (no need to "deep discharge and deep charge").
- The battery level is monitored in real-time in the mobile application. When it shows low battery level, it is recommended to stop using it and recharge it.
- The product does not come with a power adapter, and the patient needs to choose a 5V/1A USB adapter.

⚠ATTENTION:

- Treatment needs to be stopped before charging;
- When charging, be sure to use the wireless charger produced by the Fasikl;
- Do not charge the battery for more than 24 hours, and do not charge the battery by other means.
- （FCC ID:2BMCX-FELIX2）This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20cm between the radiator & your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

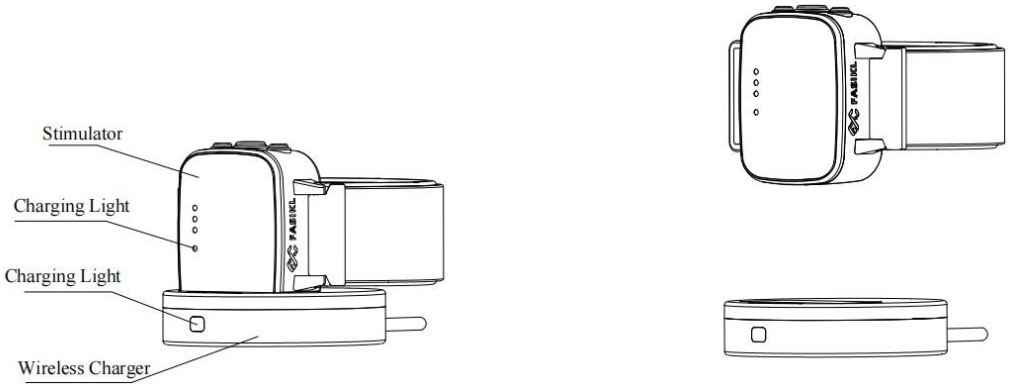


Figure 12 Schematic diagram of the device charging

5.2. How to Clean the Felix™ NeuroAI™ Wristband?

Cleaning and disinfection of the main unit and Connector Bands

Cleaning: Turn off the device and wipe the surface of the device with a dry, dust-free soft cloth for cleaning.

Disinfection: Turn off the equipment, use a clean dust-free soft cloth dipped in 70%-80% ethanol disinfectant (there should be no drops) and wipe the outer surface of the equipment and the Connector Band no less than 2 times, the action time is not less than 3 minutes, and then use a dry dust-free soft cloth to wipe off the residual liquid. Never spill disinfectant on the device nor the Connector Bands.

The above operation is recommended once a week.

⚠ATTENTION:

- The main unit and Connector Band need to be cleaned and disinfected regularly, please use the method recommended in this manual;
- The Connector Band can be reused, but only for the same patient. If the device and the Connector Band change users, they need to be cleaned and disinfected;
- The device must be turned off before cleaning or disinfecting;
- Ethanol is flammable, there should be no open flame when using, and people with alcohol allergies should use it with caution;
- During the cleaning and disinfection process, the disinfectant should be appropriate to prevent the liquid from entering the equipment;
- Do not disassemble the main machine without authorization, and the internal parts do not need to be cleaned by the user;
- After disinfection, it is necessary to check whether the parts have any traces of damage, and if any damage is found, it should be stopped.

5.3. Maintenance Guidelines for the Felix™ NeuroAI™ Wristband

⚠ATTENTION:

- It is the responsibility of the user to maintain and care for the equipment;
- In the event of a malfunction or damage to the device, contact the equipment supplier immediately and do not open the case of the device without authorization;
- If there is an abnormal phenomenon during the operation of the equipment, such as the equipment is heating and

abnormal noise, please stop using it immediately and contact your equipment supplier for repair or inspection. Only engineers authorized by Fasikl can carry out repairs.

5.4. How to Store and Ship the Felix™ NeuroAI™ Wristband?

Storage:

The product should be kept in a cool, dry and ventilated environment, avoiding contact with fire and heat sources. In order to prolong the life of the built-in lithium battery of the device, the best storage and transportation temperature between two uses is recommended to be -10°C to 60°C, the optimal humidity is 5-90%, and the atmospheric pressure range: 70 k~106kPa. To prevent the battery from being over-discharged, it is recommended to charge it every 3 months, and if the storage time is more than one year, it is recommended to perform a charge and discharge cycle once a year to activate the battery.

Shipping:

This product can be transported by general means of transportation, and it should be protected from violent collision, extrusion, vibration, rain and snow splashing during transportation. When transporting, the maximum transport temperature does not exceed 60°C.

Electrode Band: It should be stored in a cool, dry, and ventilated environment, with a storage and transportation temperature of 0 ℃ -40 ℃, humidity of ≤ 93% (non condensing), and atmospheric pressure of 70kPa -106kPa.

6. Technical Specifications

Feature	Felix™ NeuroAI™ Wristband
Operating Environment (Hardware and Software)	External control software components (mobile application program): compatible with Android 13, iOS14, iOS15, iOS16, iOS17; Processor Model: Android: performance equivalent or higher than Tensor G1, number of cores: eight cores and above, frequency: not less than 2.4 GHz; Apple: the performance is equal to or higher than the Apple A10, the number of cores: 4 cores and above, frequency: not less than 2.2GHz; Internal Storage: Android: Total memory: no less than 6 GB RAM, available memory capacity: not less than 2 GB RAM; SD card: not less than 128 GB. Apple: total memory: no less than 2 G RAM, available memory capacity: no less than 1 G RAM; SD card: no less than 128G.
Data Collection	When Felix is powered on, device diagnostic information and movement data (captured by the built-in sensor) are continuously collected via the smartphone app. The smartphone app will upload the data to a secure cloud server through internet connection. Data will be stored on the secure cloud data server for at least 180 days. No data will be collected when Felix is powered off.

THERAPY SESSION			
Time	Felix can be worn for a whole day (about 14 hours) with AI adjustment		
Start Therapy	Press the middle key on the Stimulator or click Start on the App		
Stop Therapy	When stimulated, press the middle key on the Stimulator to stop the stimulation. Or click stop on the App		
Intensity Increase/Decrease	The default value of the patient's comfort stimulation intensity is set jointly by the physician and the patient during the first treatment in the medical institution. Once this default value is established, the Felix AI system will implement real-time parameter adjustments based on this value and the severity of individual tremors in the patient. However, the adjusted output value will be strictly limited to a range that does not exceed the preset default value. If this default value needs to be adjusted in the future, patients should make changes through medical professionals.		
CONDITIONS THAT WILL TERMINATE OUTPUT			
Time	Under the regulatory mechanism of Felix AI, based on the specific condition of the patient, the system will automatically set the stimulus output to 0 for several periods of time during a day's wearing period; In addition, patients can also manually terminate the stimulation output.		
OUTPUT			
Waveform	Biphasic symmetric,rectangular	Maximum Output Voltage (+/-10%)	5 V @ 500 Ω ;100 V @ 10 kΩ
Regulated Current or Voltage	Constant Current	Maximum Output Current (+/-10%)	10 mA @ 500 Ω;10 mA @ 10 kΩ
DC Component	0 （±100mV ）	Load Impedance, Expected Range (+/-20% tolerance)	Min: 500 Ω Max: 10 kΩ
Pulse Duration	650 μ s	Pulse Repetition Frequency	56-500Hz（±10%）
Pulse Pattern	The stimuli received by the three nerves exhibit the same waveform, but there are differences in		

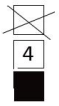
	the number of repeated stimuli.
POWER	
Battery Type	Permanent rechargeable battery, not serviceable or replaceable
Power Source	DC 5V 1A
Duration	A 500mAh fully charged battery can support patients wearing it all day long
ELECTRODES	
Type	The Electrode Band is designed in six different specifications to accommodate various wrist sizes of the human body.
Number of Electrodes	4
Dimensions	Return electrode：948mm² Stimulating electrode：397mm²
Maximum Current Density RMS	Return electrode：1.05mA/cm² @ 500 Ω Stimulating electrode：2.52mA/cm² @ 500 Ω
Maximum Average Power Density	0.032W/cm² @ 500 Ω
ENVIRONMENTAL	
Operating Parameters: Temperature Range Relative Humidity Range Atmospheric Pressure Range	5-40°C (41-104°F) 5-90% 70kPa～106kPa
Transport and Storage Parameters (Felix system): Temperature Range Relative Humidity Range Atmospheric Pressure Range	-10°C-60°C (14-140°F) 5-90% 70kPa～106kPa
Transport and Storage Parameters (Electrode Band): Temperature Range Relative Humidity Range Atmospheric Pressure Range	0°C-40°C (32-104°F) ≦93% non-condensing 70kPa～106kPa
Expected Service Life of Stimulator and Wireless Charger: 5 years	

Network connected App	The purpose of the app to connect to the network	To achieve intelligent adjustment of stimulation intensity
	The required characteristics of the network connected to the app	The mobile phone can be connected to Wi-Fi or cellular data
	The configuration required for the network connected to the app	Equivalent to 4G network and above
	Technical specifications for APP network connection, including data security specifications	Data encryption using HTTPS technology
	Expected traffic between the app, the network, and other devices on the network	The tremor data and stimulation intensity parameters collected by the device, and the expected flow through the network router: None
	List of Dangerous Situations in the Event of a Network Failure	In the event of a network failure, the device will be stimulation at a default intensity and will not cause danger.

⚠ ATTENTION:

- Connection of the PEMS to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;
- These risks should be identified, analyzed, evaluated, and controlled;
- Subsequent modification of the network may introduce new risks requiring its analysis；
- Modifications to network include changes to network configuration; new items added to network; broken items on network; device update to network; equipment upgrade to network.

7. List of Symbols

	Type BF Applied Part(s)		Date of manufacture
	Use by date		Refer to the Instructions for Use
	Lot number		Attention
	Keep dry		Non-ionizing radiation
	temperature extremes		The number of stacking layers shall not exceed 4 layers
	Humidity limit		Atmospheric pressure limit
	Serial number		This way up
	Single use	IP22	classification of waterproof

8. Date of Manufacture and Expiration Date

- Date of manufacture: see outer packaging.
- Felix™ NeuroAI™ Wristband expected service life: 5 years.
- Connector Band shelf life: 3 years; expected service life: 6 months.
- Electrode Band shelf life: 2 years; expected service life: Non-sterile, disposable.

9. Electrical safety classification

Electric shock protection type: internal power supply equipment;

Electric shock protection level: The BF-type application part;

Waterproof grade: IP22 (2: represents the diameter of 12.5 mm particles from entering the equipment, 2: represents the equipment can withstand 15° drip);

According to the degree of safety in using with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: the equipment is not AP and APG equipment;

Operation mode: continuous operation.