



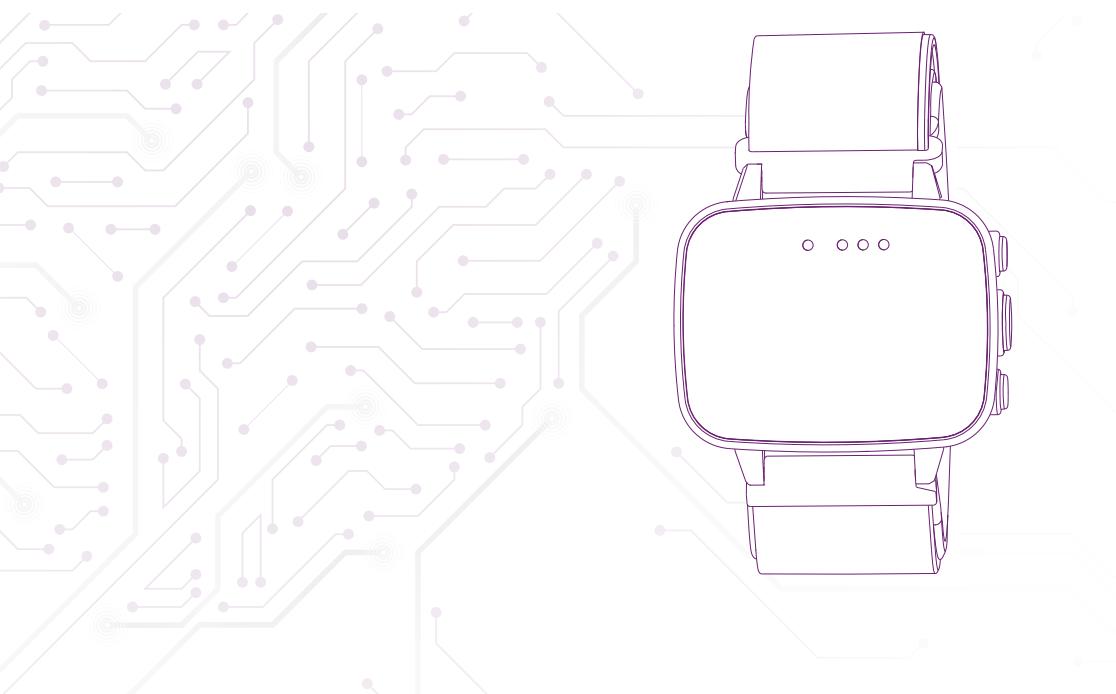
# **INSTRUCTIONS FOR USE**

## **Felix™ NeuroAI™**

## **Wristband**

Version 1.2

Rx only



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## 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.

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## Product Information

Product name: Felix™ NeuroAI™ Wristband

Product Registration Certificate No.:

Production License Number:

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## Production Enterprise / Registrant

Manufacturer Name: Fasikl Inc.

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

TEL: 800-324-5359

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## Version Information

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

- IFU version number: V1.3
- Release date: May 7, 2025
- This IFU is the copyright of Fasikl Incorporated

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# 1 Introducing Felix™ NeuroAI™ Wristband System

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## 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.

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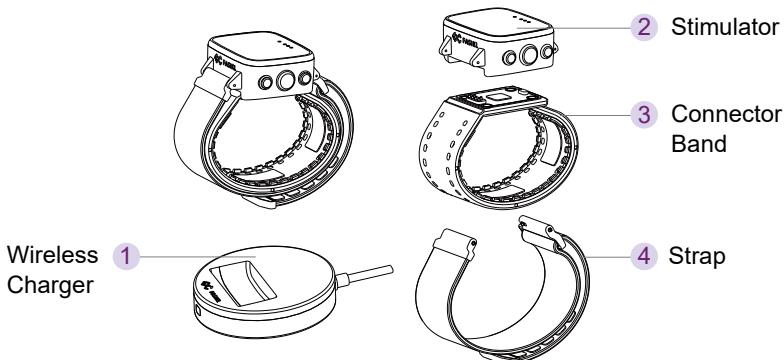
## 1.2 Use Specification

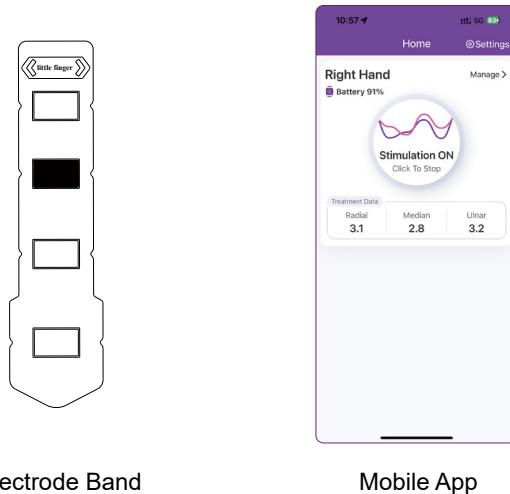
Felix™ NeuroAI™ Wristband is intended to be used in the clinic and at home. The device can be operated by healthcare professionals and patients. User needs to be trained prior to operating the device.

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## 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.

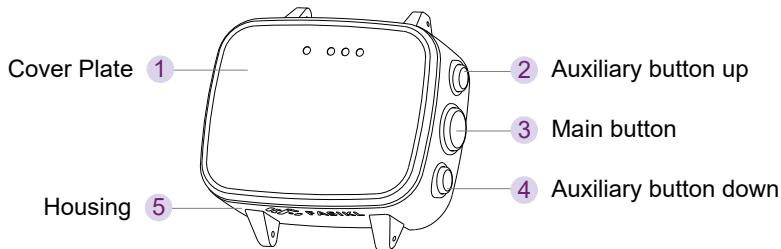




**Figure 1 Schematic Diagram of the Wireless Charger**

### 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.

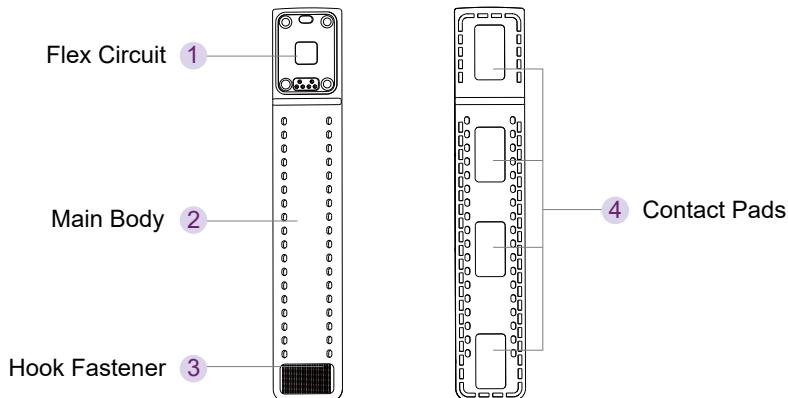


**Figure 2. Schematic Diagram of the Stimulator**

### 1.3.2 Connector Band

The Connector Band consists of a flex circuit, the Connector Band main body, the Hook Fastener, and the Contact Pads, as shown in Figure 3. There are four Contact Pads which consist of the return electrode directly below the body of the Stimulator, and the other three contact pads corresponding to the radial nerve, median nerve, and ulnar nerve. The edge of the Connector Band

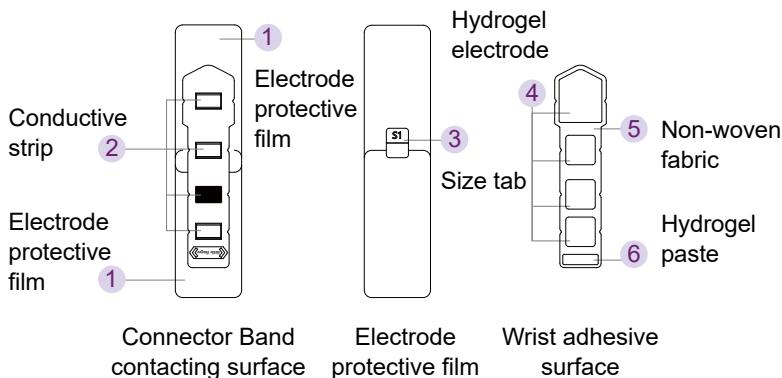
is marked with white dots, which help to align the Connector Band and the Electrode Band . Connector Bands are replaceable.



**Figure 3**  
**Schematic Diagram of the Top and Bottom of a Connector Band**

### 1.3.3 Electrode Band

The Electrode Band is composed of the Electrode protective film, Conductive Strips, a Size Tab, Non-woven fabric, and Hydrogel Electrodes, as shown in the following schematic diagram (Figure 4). It has two sides, one side with the Conductive Strips is combined with Connector Band, and the other side with the Hydrogel is fitted on the surface of the wrist. The Electrode Band is single use, non-sterile and disposable.



**Figure 4 Schematic Diagram of Electrode Band**

### 1.3.4 Wireless Charger

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

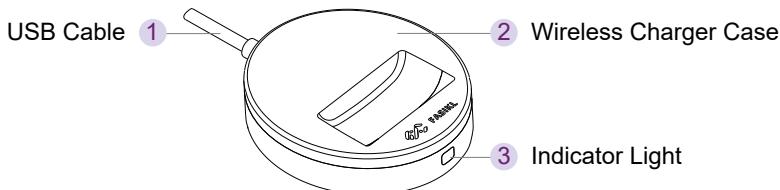


Figure 5 Schematic Diagram of the Wireless Charger

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## 1.4 Model Number

The model number 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 Numbers**

	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 should be replaced daily following use.

**Table 2 Quantity of Product Components**

Item	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.

### 2.2 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 is magnetic resonance (MR) unsafe and should not be worn in a magnetic resonance imaging (MRI) scanner.
- 3) Keep this device 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, stents and shunts.
- 4) 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.
- 5) 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
- 6) Do not use this device near flammable liquids, smoke, or chemicals.
- 7) Stop stimulation while fueling a vehicle with gasoline to prevent an explosion and risk of injury.
- 8) Do not stimulate open, cancerous wounds or rash, excessive swelling, red skin, infected, or inflamed areas.
- 9) Stop stimulation if you want to remove or charge the device.
- 10) The stimulation intensity is too high if it causes discomfort or skin irritation.

- 11) The long-term effects of chronic electrical stimulation are unknown. When the stimulation intensity in the calibration page of the app is set to 8 or above, the user should be especially mindful of potential risks associated with stimulation at this level.
- 12) Do not immerse the device in water and do not use in high humidity places such as the bathroom.

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## 2.3 Cautions

- 1) Users must read the Instructions for Use carefully before operating the device.
- 2) Only use the electrode and connector bands made by the manufacturer.
- 3) Safety of the Felix device during pregnancy has not been established.
- 4) Avoid dust, direct sunlight and pests when storing, and it is recommended to store it in the original package when not in use.
- 5) When the device is not in use, keep it out of the reach of children and pets.
- 6) Avoid condensation forming 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.
- 7) Before use, the skin should be cared for according to section "2.5 Skin Care Guidelines" in this manual.
- 8) Use with caution in people with skin sensory disorders or skin abnormalities.
- 9) Use with caution in patients with bleeding and clotting disorders.
- 10) Patients with an implanted device near the proximity of the stimulation site should consult a doctor about whether they can use this product.

11) 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 who are receiving medication that affects memory, comprehension or ability to perform operations;
- People with cognitive impairment;

12) 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, as 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;

13) 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.

14) Do not use the device during charging.

15) 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, flaky skin, bumpy rash, electrical irritation burns, etc.).
- 3) Skin discoloration (darkening or lightening of skin tone).
- 4) Unintended muscle contractions.
- 5) Worsening of tremor.
- 6) Worsening of arthritis of the hand, joint pain.

In the unlikely event that any of the following more significant issues occur, stop using the device immediately and contact the supplier where you received the Felix device:

- 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.

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## 2.5 Skin Care Guidelines

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

### 2.5.1 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.

### **2.5.2 Rinse:**

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

### **2.5.3 Blot or Pat Dry:**

- a. Avoid vigorous drying with a towel. Instead, blot the skin to gently dry.

### **2.5.4 Apply a Moisturizing Cream Regularly, but not Immediately Prior to Putting on the Device:**

- 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.

### **2.5.5 Apply Felix on Intact Skin That is not Moist or Wet:**

- a. Make sure that the wristband is applied on intact skin that has been thoroughly dried and not on damp skin (e.g. make sure skin is dried off after handwashing, prior to application of the wristband). Do not apply wristband on skin that is irritated (red, flaky, itchy, weeping).

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

Treatment of skin reactions:

- a. Do not use the device on irritated skin. Give the area with skin irritation a break for a few days and continue gentle skin care on the affected area. During this time, you may use the wristband on intact skin on the opposite hand.

- b. If mild symptoms of redness, itchiness, flaking continue or recur, seek advice from a medical professional. Stop use and seek help if there are symptoms of: blistering, pain, or spreading swelling or warmth on the area.

## 2.6 Normal Environmental Use Conditions

Ambient temperature range:	5°C ~ 40°C (41°F ~ 104°F)
Relative humidity range:	5% ~ 90%
Atmospheric pressure range:	70kPa ~ 106kPa

- When the ambient temperature is 20°C(68°F), the time required for the device to warm up from the minimum storage temperature -20 ) to be ready for use is 2 hours.
- When the ambient temperature is 20°C(68°F), the time required for the device to cool down from the maximum storage temperature of 60 °C(140°F) 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 Under the Supervision of a Trained Personnel

The location of the peripheral nerves in the wrist area (median nerve, ulnar nerve and radial nerve) of each patient is slightly different. Trained personnel will work with the patient to locate the appropriate stimulation sites. First, using the cross-bar shaped tool, mark the location of the Median nerve. Then a sizing sticker will be applied to the wrist; aligning the position of the Median nerve with the mark on the sticker. Then the locations of the Ulnar and Radial nerve and finally the position of the midpoint on the back of the wrist will be marked on the sticker. The sticker will be removed from the wrist and applied to the intake form. 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 Bands and Electrode Bands are available in 6 sizes, 1 for small, 3 for medium, and 2 for large. The sizing sticker used in the previous step will have the dimensions in mm required to determine the appropriate size of electrode band and connector band. Use Table 3 below to determine the best size. Confirm the size during calibration and ensure the proper feeling and placement of the stimulation over the nerves.

**Table 3 Specification Selection Table**

Connector Band and Electrode Band specifications	Range from radial nerve 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



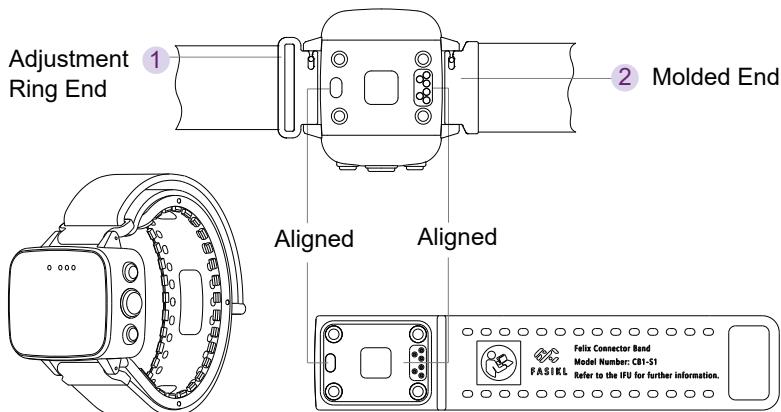
### ATTENTION:

- If there are multiple sizes that overlap, select the optimal size specifications according to the actual nerve position and validate the position during calibration.

### 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:

- The molded end of the strap is connected to the 6 points side of the Stimulator.
- 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.

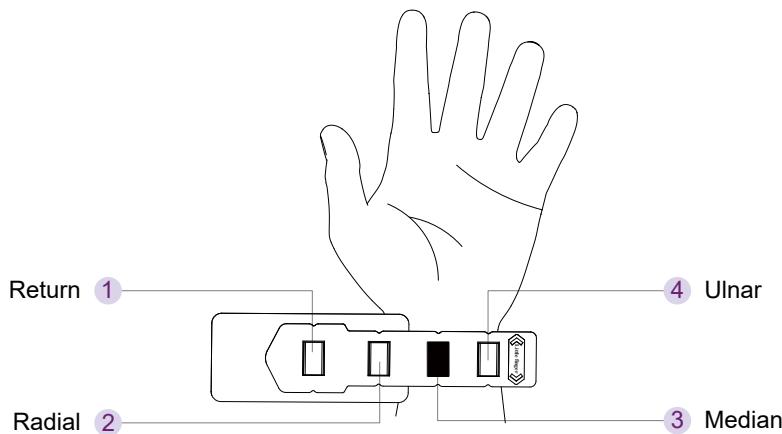
## 3.5 Putting on the Electrode Band



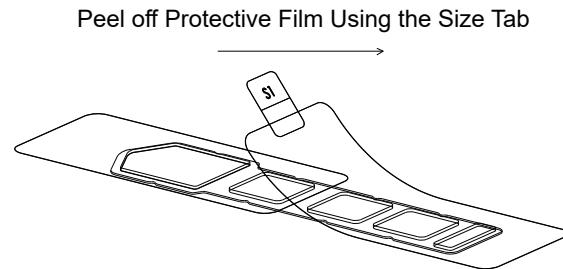
**ATTENTION: Use a new Electrode Band every day.**

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™ NeuroAI™ 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**



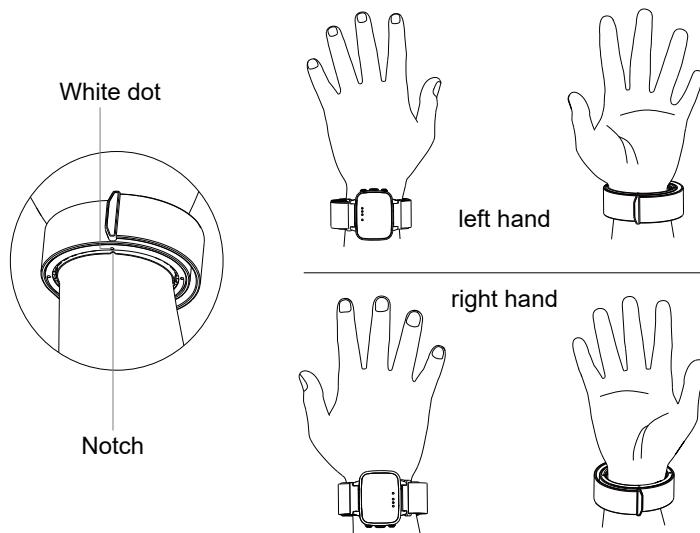
**ATTENTION:**

- 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.

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## **3.6 Putting On the Felix™ NeuroAI™ Wristband**

- a. Please ensure that the hook fastener of the Connector Band is perfectly aligned with the inner surface of the outer strap, and that the Connector Band is not visible outside the edge of the outer strap. This will reduce physical stress on the Connector Band and will maximize its service life.
- 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 stimulation 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.

## 4 Calibration and Stimulation With the Felix™ NeuroAI™ Wristband

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### 4.1 Felix™ App Installation and Network Requirements

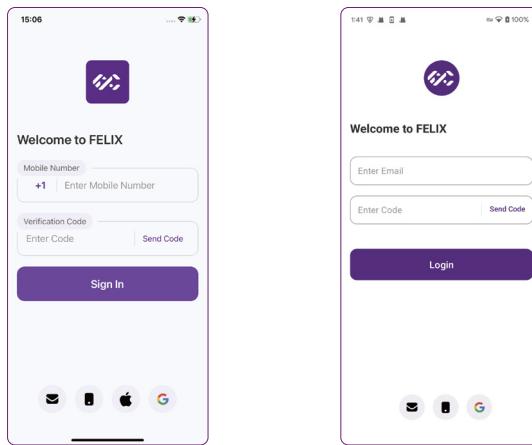
- a. Install the Felix™ app on your phone by scanning the QR code located on the product box and follow the on-screen instructions.
- b. Requires Bluetooth and Location Services to be enabled. The Felix™ App also requires an active internet connection through Wi-Fi or data network.

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### 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 for the first time, Apple users have 4 login methods (Figure 10-1).
  - i. You can use your email address or mobile phone number to send a verification code;
  - ii. You can log in using the Apple ID (only available on the iOS app);
  - iii. You can use Google verification;



**Figure 10-1 and 10-2 Login Interface**

- d. When logging in for the first time, Android users have 3 login methods (Figure 10-2).
  - i. You can use your email address or mobile phone number to send a verification code;
  - ii. You can use Google verification;
- e. If the login is successful, the app will automatically enter the "Add Device" page.
- f. After successfully logging in, you can add additional login credentials on the account page. Subsequently, you can access the app using any of the login methods you have added.

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## 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.



### ATTENTION:

- The operation of the Felix™ NeuroAI™ Stimulator requires the support of the Felix™ 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.

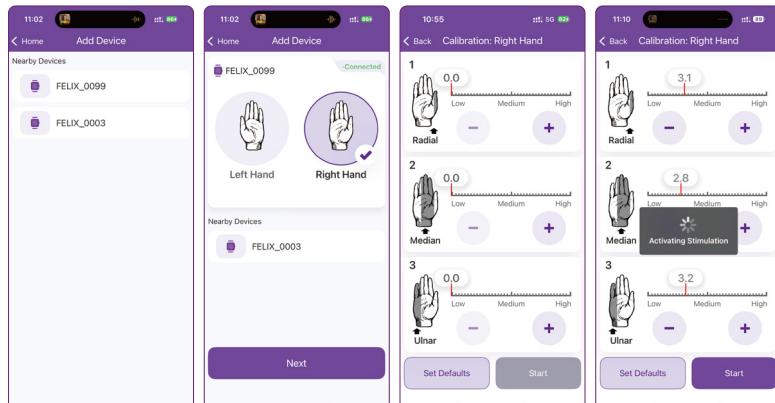
## 4.4 Side Selection

- 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).



### ATTENTION:

- If you wish to switch the side that you wear the Felix™ device on, please contact the supplier that provided the Felix™ device for assistance.



**Figures 11-1, 11-2, 11-3, 11-4 Show the App Interface**

## 4.5 Calibration

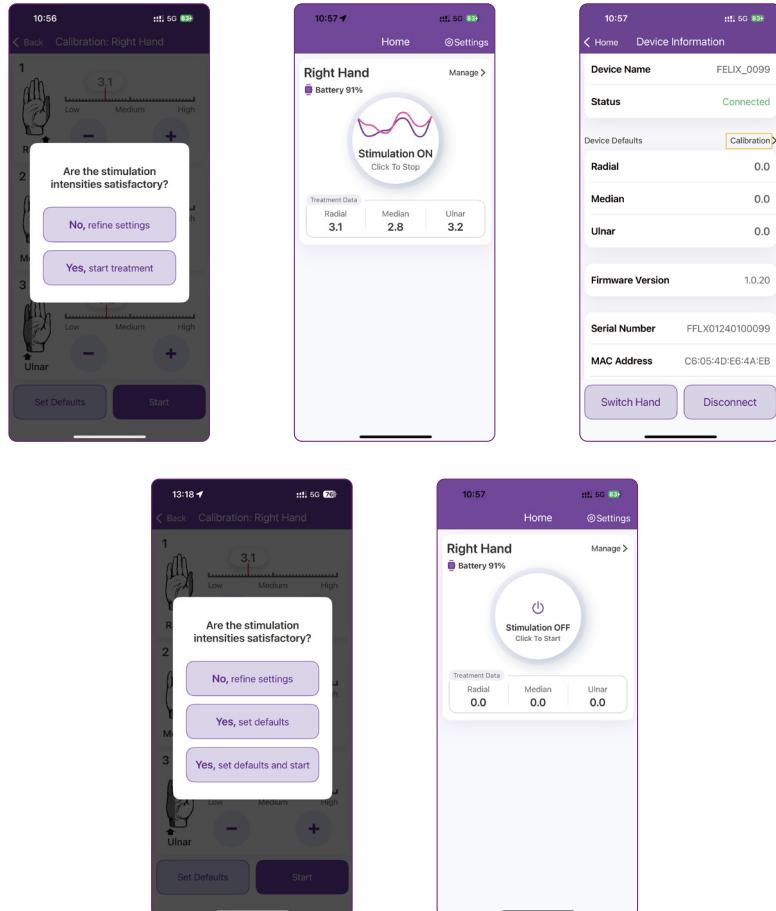
- a. Use the + or – buttons to adjust the maximum stimulation level on each of the three nerves.
- b. Once you have adjusted each nerve to your maximum tolerable intensities, click the “Start” button on the bottom of the screen. This will start stimulation on all three nerves and the app will display 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 5.5 as set in calibration. Individual patient's level can be higher or lower than this value depending on their tolerance.
- 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.
- The first time you start stimulation each day you will be prompted to calibrate the Felix™ NeuroAI™ 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).

- 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.



**Figures 11-5, 11-6, 11-7, 11-8, 11-9 Show 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

- 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 built-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.

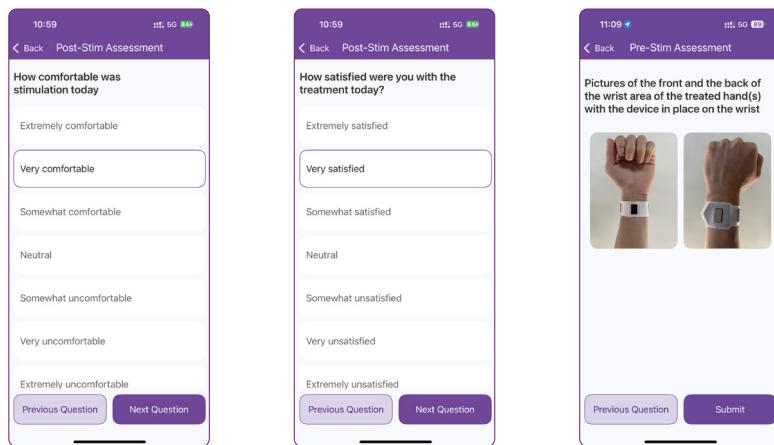
### 4.7.3 Survey

Following the schedule below, the Felix™ App will prompt the user to answer questions about satisfaction and comfort in a survey prior to starting stimulation. The app will also ask you to take pictures of the electrode band on your wrist. To help take pictures, use the volume button on the side of your phone to take the picture. Once you are done, click on the submit button and the survey will be uploaded to your account.

The schedule of the survey is as follows:

- Daily for the first 5 days.
- Weekly after the first 5 days and up to 60 days.
- Monthly after 60 days.

Completing the survey is optional but strongly encouraged.



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## 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 are 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 discon- nection light off)	/	/
Electrode misalignment; Voltage anomaly; error	/	/	/	blinking red light	/
Charging	White while charging. When fully charged light is off	/	/	/	White while charging. When fully charged light is off



**ATTENTION:**

- When the red light of the device flashes, it may be one or more of the three conditions: "electrode fitting misalignment", "voltage abnormality", or "device error". For the specific cause of the error, please check the mobile application.
- When "electrode fitting misalignment" occurs, please readjust the position of the connecting strap and check the tension, and then restart stimulation.

- When "voltage abnormality" or "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?

- To charge the device, the wireless charging dock is connected to the power adapter (not supplied), the side of the device without buttons is put into the charging dock. When the white indicator light of the charging dock and the white indicator light of the device are lit at the same time, the charger 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 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.

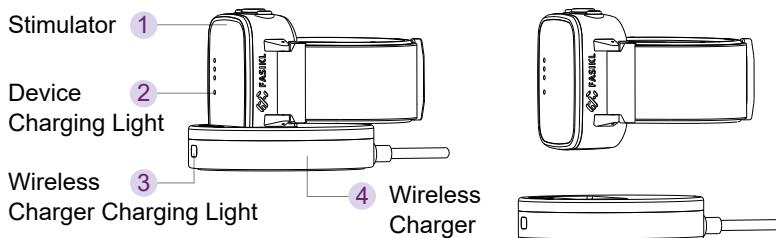
The product does not come with a power adapter, and the patient needs to utilize a 5V/1A USB adapter.



#### ATTENTION:

- Treatment needs to be stopped before charging.
- When charging, be sure to use the wireless charger provided by Fasikl.

- Do not charge the battery for more than 24 hours.
- If the wireless charger white indicator light is flashing, remove the Felix™ NeuroAI™ Wristband from the wireless charger and wait until the white light stops flashing. Then replace the Felix™ NeuroAI™ Wristband back into the wireless charger.
- (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 at least two times for at least 3 minutes each time, and then use a dry dust-free soft cloth to wipe off the residual liquid. Never spill disinfectant on the Felix™ device nor the Connector Bands.

Disinfection is recommended once a week.



#### ATTENTION:

- The Felix device is a reusable device for single-patient use.
- 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.
- 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, care should be taken to prevent the disinfectant liquid from entering the equipment.
- Do not disassemble the Stimulator without authorization as 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, do not use and contact the equipment supplier.

## 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.
- If there is an unexpected experience 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.

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## 5.4

# How to Store and Ship the Felix™ NeuroAI™ Wristband?

### Storage and Transportation:

The product should be stored in a cool, dry, and well-ventilated environment, protected from direct sunlight and kept away from open flames, sparks, or heat sources. To ensure optimal longevity of the built-in lithium battery, maintain storage and transportation temperatures between -20°C and 60°C (-4°F and 140°F), avoiding transportation at extreme temperatures. The operating atmospheric pressure should remain within 70 kPa to 106 kPa. To prevent over-discharge, recharge the battery every 3 months when not in use; for storage periods exceeding 12 months, perform a full charge/discharge cycle annually to maintain battery health and performance.

### Electrode Band:

The Electrode Band should be stored in a cool, dry, and well-ventilated environment, protected from direct sunlight. When stored in a fixed warehouse (not during transportation), it is recommended that the temperature be maintained within the range of 0°C to 40°C (32°F to 104°F). During transportation, the recommended temperature range is from -30°C to 50°C (-22°F to 122°F), avoiding transportation at extreme temperatures. The relative humidity should be ≤ 93%, and the atmospheric pressure should be within the range of 70 kPa to 106 kPa.

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## 5.5

# How to Update the Felix™ NeuroAI™ Wristband Software

### 5.5.1 iOS Application

- a. If a new version is available, the application will display a message.
- b. By clicking the “Update” button on the message, the application will automatically open App Store. The App Store will display the Felix application.

- c. Click the “Update” button to update the application.

### **5.5.2 Android Application**

- a. If a new version is available, the application will display a message.
- b. By clicking the “Install” button, the Android application will automatically open the system package installer to download and install the newest application.
- c. The patient should grant permission for the installation first.

### **5.5.3 Felix™ NeuroAI™ Wristband Firmware**

- a. When a Felix™ NeuroAI™ Wristband is connected to the application, the application will check for any new firmware updates.
- b. If a new version is available, the application will display a message.
- c. By clicking the “Start” button on the message, the application will upgrade the firmware.
- d. During the upgrade, patients should follow the instructions on the application.

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## **5.6**

## **How to Reset the Felix™ NeuroAI™ Wristband**

When necessary, reset the Felix™ NeuroAI™ Wristband by following the steps below:

- a. Make sure the Felix™ NeuroAI™ Wristband is powered on but stimulation is off.
- b. Click the up button of the Felix™ NeuroAI™ Wristband.
- c. Click the down button of the Felix™ NeuroAI™ Wristband.

- d. Hold the middle button for 3 seconds to shut down the Felix™ NeuroAI™ Wristband. All 3 LEDs will briefly flash to indicate the correct sequence.
- e. Power on the Felix™ NeuroAI™ Wristband and connect it to the mobile application.
- f. Make sure to login using the same method as before to retrieve account information.

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## 5.7

## Backup and Restoration of Device Data and Configuration

Device data and configuration are automatically stored on both the mobile application and the cloud server. There is no action needed from the user. To restore device configuration, connect the device to the mobile application and ensure the mobile device has a stable network connection. If it is necessary to login to the mobile application, e.g., after a device reset, make sure to login using the same method as before.

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## 5.8

## Recommendations for Wi-Fi and Smartphone Settings for Cybersecurity Purposes

### 5.8.1 For Wi-Fi:

- a. Avoid using open Wi-Fi.
- b. Enable WPA2 or WPA3 encryption protocol for the Wi-Fi password.
- c. Check and update the router's firmware regularly.
- d. Disable uncommon services such as remote management and file sharing.
- e. Ensure that only authorized personnel have physical access to the router.

### 5.8.2 For the Smartphone:

- a. Enable password, Touch ID, or Face ID.
- b. Do not use a jailbroken iPhone or a rooted Android smartphone.
- c. Prevent unauthorized physical access to the smartphone.

## 6 Technical Specifications

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### STIMULATION SESSION

Time	Felix™ can be worn for a whole day and can be charged as needed.
Start Stimulation	Press the middle key on the Stimulator or click Start on the app
Stop Stimulation	When finished, 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 will need to see the supplier that provided the Felix™ device.

## CONDITIONS THAT WILL TERMINATE STIMULATION

Time	<p>The device uses an AI algorithm to set optimal stimulation parameters to reduce tremor. In some instances, the optimal parameter may actually be no stimulation.</p> <p>Patients can also manually terminate the stimulation output.</p>
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## 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	650µs	Pulse Repetition Frequency	56-500Hz (±10%)
Pulse Pattern	The stimuli received by the three nerves exhibit the same waveform, but there are differences in current amplitude and the number of repeated stimuli.		

## POWER

Battery Type	Permanent rechargeable Li-ion battery, 3.7 V, 500 mAh, not serviceable or replaceable
Power Source	DC 5V 1A
Duration	A 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:948mm <sup>2</sup> Stimulating electrode:397mm <sup>2</sup>
Maximum Current Density RMS	Return electrode:0.26 mA/cm <sup>2</sup> @ 500 Ω Stimulating electrode:0.61 mA/cm <sup>2</sup> @ 500 Ω
Maximum Average Power Density	0.75 mW/cm <sup>2</sup> @ 500 Ω

## ENVIRONMENTAL

Operating Parameters: Temperature Range Relative Humidity Range Atmospheric Pressure Range	5°C ~ 40°C (41°F ~ 104°F) 5% ~ 90% 70kPa ~ 106kPa
Transport and Storage Parameters (Felix system): Temperature Range Relative Humidity Range Atmospheric Pressure Range	-20°C ~ 60°C (-4°F ~ 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°F ~ 104°F) ≤93% 70kPa ~ 106kPa
Applied Part of the Device	Applied part of the device is Electrode Band.

Feature	Felix™ NeuroAI™ Wristband
<b>Operating Environment (Hardware and Software)</b>	<p>External control software components (mobile application program): compatible with Android 10 and above; iOS 14 and above;</p> <p><b>Processor Model:</b></p> <p><b>Android:</b> number of cores: eight cores and above, frequency: not less than 2.4 GHz;</p> <p><b>Apple:</b> number of cores: 4 cores and above, frequency: not less than 2.2GHz;</p> <p><b>Internal Storage:</b></p> <p><b>Android:</b> Total memory: no less than 8 GB RAM, available memory capacity: not less than 2 GB RAM; Storage: not less than 128 GB.</p> <p><b>Apple:</b> total memory: no less than 2 GB RAM, available memory capacity: no less than 1 GB RAM; Storage: no less than 128 GB.</p> <p><b>Network:</b></p> <p>A stable network connection is required.</p> <p><b>Wi-Fi:</b> enable the WPA2 or WPA3 encryption protocol; avoid using open Wi-Fi; enable firmware; ability to connect to the Felix server with a latency of less than 500 ms is acceptable, while a latency below 300 ms is considered optimal.</p> <p><b>Cellular Data:</b> ability to connect to the Felix server with a latency of less than 500 ms is acceptable, while a latency below 300 ms is considered optimal.</p>
<b>Data Collection</b>	<p>When the Felix™ NeuroAI™ Wristband is powered on, device diagnostic information and movement data (captured by the built-in sensor) are continuously collected via the mobile application. The mobile application 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 the Felix™ NeuroAI™ Wristband is powered off.</p>

<b>Open Ports and Interfaces</b>	<p>Port 443</p> <p>This port is used for HTTPS traffic. It ensures secure communication over the network by using SSL/TLS encryption.</p> <p>This port is essential for secure web traffic. It handles all HTTPS requests, ensuring data integrity and confidentiality between client and server.</p>
<b>Cybersecurity Information</b>	<p>Felix™ NeuroAI™ Wristband</p> <p>a. The Felix™ NeuroAI™ Wristband has an authentication procedure before responding to any commands from the mobile application.</p> <p>b. Once the Felix™ NeuroAI™ Wristband is connected to the mobile application, the application should initiate a handshake with an encrypted nonce. Only after the Felix™ NeuroAI™ Wristband has authenticated the nonce, can it respond to the subsequent commands from the mobile application.</p> <p>c. The encryption key is saved on the Felix™ NeuroAI™ Wristband, the mobile application, and the server.</p> <p>d. Resetting the Felix™ NeuroAI™ Wristband will result in the mobile application generating a new encryption key</p> <p>Mobile Application</p> <p>a. The mobile application will initiate a handshake with an encrypted nonce once the Felix™ NeuroAI™ Wristband is connected to it.</p> <p>b. The mobile application will securely exchange an encryption key with the server upon launch.</p> <p>All sensitive data transmitted between the mobile application and the server will be encrypted.</p>

When a security breach occurs, we will promptly notify patients. A push notification will be sent to the mobile application. If an email address or phone number is available, a message relevant to the incident will also be dispatched to ensure timely awareness of the security event. The message will include a concise description, essential precautions, and our plans along with the timeline.

Product support will be available for at least 5 years from the date of delivery. End-of-support notification will be sent via the mobile application as well as posted on the manufacturer's website.

Software Bill of Materials (SBOM) can be requested by contacting the manufacturer.

# 7 List of Symbols

Symbols	Meaning	Applied Components	
	Type BF Applied Part	Stimulator	
	Keep Dry	Wireless Charger Connector Band Electrode Band	Strap Stimulator
	Temperature Extremes	Wireless Charger Connector Band Electrode Band	Strap Stimulator
	Humidity Limit	Wireless Charger Connector Band Electrode Band	Strap Stimulator
	Single Use	Electrode Band	
	Refer to the IFU	Wireless Charger Connector Band Electrode Band	
	Attention	IFU	
	Non-ionizing Radiation	Stimulator	
	The Number of Stacking Layers Shall not Exceed 5 Layers	Wireless Charger Connector Band Electrode Band	Strap Stimulator
	Atmospheric Pressure Limit	Wireless Charger Connector Band Electrode Band	Strap Stimulator
	Classification of Waterproof	Stimulator	

## 8 Date of Manufacture and Expiration Date

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- Date of Manufacture: see outer packaging.
- Felix™ NeuroAI™ Wristband Expected Service Life: 3 years.
- Connector Band Shelf Life: 3 years; expected service life: 6 months.
- Electrode Band Shelf Life: 2 years; single-use, non-sterile, disposable.
- Contact the supplier to reorder supplies.

## 9 Electrical Safety Classification

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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.

# 10 Electromagnetic Compatibility (EMC)

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## 10.1 General Information

Electromagnetic compatibility was tested in accordance with IEC 60601-1-2:2014+A1:2020, IEC/TS 60601-4-2:2024, and FDA's Electromagnetic Compatibility (EMC) of Medical Devices (2022) guidance. The Felix™ NeuroAI™ Wristband is intended for use in the Home Environment. In accordance with IEC 60601-1, this device was determined to not have Essential Performance. During immunity testing, functionality observed for degradation included charging, wireless communication, stimulation, and movement sensors.

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## 10.2 EMC Testing

### Emissions Testing

Test Standard	Test Name	Compliance Level
CISPR 11	Radiated Emissions	Group 1, Class B and Group 2, Class B
CISPR 11	Conducted Emissions	Group 1, Class B and Group 2, Class B
EN 61000-3-2	Harmonic Disturbances	Home Healthcare Environment
EN 61000-3-3	Voltage Fluctuation	Home Healthcare Environment

## Immunity Testing

Test Standard	Test Name	Compliance Level
IEC 61000-4-2	ESD Immunity	Contact: $\pm 8$ kV Air: $\pm 2$ , $\pm 4$ , $\pm 8$ , $\pm 15$ kV
IEC 61000-4-3	Radiated RF Immunity	Field Strength: 10 V/m Frequency Range: 80 MHz – 2.7 GHz Pulse Modulation: 80% AM at 1 kHz
IEC 61000-4-3	Proximity fields from RF Wireless Communications Equipment	(Test per Table 9 of IEC 60601-1-2:2020) 385MHz: 27 V/m, 18Hz 450MHz: 28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz: 9 V/m, 217 Hz 810, 870, 930MHz: 28 V/m, 18Hz 1720, 1845, 1970MHz: 28 V/m, 217 Hz 2450MHz: 28 V/m, 217 Hz 5240, 5500, 5785MHz: 9 V/m, 217 Hz
IEC 61000-4-4	Electrical Fast Transients Bursts	$\pm 2$ kV, 100 kHz repetition frequency
IEC 61000-4-5	Surges Line-to-line	$\pm 0.5$ , $\pm 1$ kV
IEC 61000-4-6	Conducted disturbances induced by RF Fields	3V rms 0.15 MHz - 80 MHz, 6V rms for ISM frequencies between 0.15MHz-80MHz 80% amplitude modulation at 1 kHz
IEC 61000-4-8	Radiated Magnetic Immunity	30 A/meter, both 50 and 60 Hz
IEC 61000-4-11	Voltage Dips	0% $U_T$ for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% $U_T$ for 1 cycle 70% $U_T$ for 25 cycles
IEC 61000-4-11	Voltage Interruptions	0% $U_T$ for 250 cycles

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IEC 61000-4-39	Magnetic Field Immunity	(Test per Table 11 of IEC 60601-1-2:2020) 30 kHz, CW, 8 A/m 134.2 kHz, PM, 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 Hz, 7.5 A/m
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NOTE:  $U_T$  is the AC mains voltage prior to application of test level

There were no deviations from the EMC test methods. No allowances described in the test methods were used.

Use only system components designated by Fasikl to ensure EMC compliance.

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## 10.3 EMC Precautions

The following precautions related to EMC should be considered for this device:

- The Felix™ NeuroAI™ Wristband is not compatible with MRI and should be removed during an MRI study.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) and other radiofrequency emitting devices should be used no closer than 30 cm (12 inches) to any part of the Felix™ NeuroAI™ Wristband. Otherwise, degradation of the performance of this equipment could result.

# 11 Wireless Radio Frequency Functionality

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## 11.1 General Information

The Felix™ NeuroAI™ Wristband requires a robust and stable wireless connection to ensure safe and effective operation. The device utilizes Bluetooth Low Energy (BLE) 5.2 for communication with its companion smartphone app. This connection is critical

for transmitting real-time data from the integrated IMU sensors (accelerometer and gyroscope) to the app and subsequently to an AI server for processing.

To maintain optimal performance:

- Low Latency: The BLE connection must provide low-latency data transmission to enable real-time adjustments of stimulation parameters.
- High Reliability: Continuous, uninterrupted BLE connectivity is necessary to support the closed-loop system that dynamically optimizes tremor suppression.
- Sufficient Bandwidth: The BLE connection should support the transmission of high-frequency IMU data without packet loss.

If the BLE connection or internet connectivity is interrupted, the device enters a fallback mode, maintaining stimulation with existing parameters until the connection is restored. Upon reconnection, updated stimulation parameters are seamlessly applied without user intervention.

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## 11.2 Wireless Specifications

Characteristic	Specification
Communication Type	Bluetooth Low Energy (BLE)
Frequency Band	2.402 – 2.480 GHz
Modulation	GFSK
Transmission Power	86.0dBuV/m@3m
Security Features	Only authenticated facilities can connect to the Felix™ NeuroAI™ Wristband

Operating Distance	9 Feet
Quality of Service (QoS)	The Smartphone to Server connection latency must be less than 500 ms and the Stimulator to Smartphone transmission rate should be at least 5kbps.

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## 11.3 Wireless Troubleshooting

### 11.3.1 The Felix™ NeuroAI™ Wristband Cannot be Discovered by the Mobile Application.

- a. Ensure that the phone meets the minimum requirements outlined in Section 6 of this manual.
- b. Ensure that Bluetooth is enabled on the phone.
- c. Ensure that the Felix™ NeuroAI™ Wristband is powered on and positioned within 9 feet of the phone.
- d. Ensure that the Felix™ NeuroAI™ Wristband is not connected to another phone. If it is connected to another phone, the blue light will light up. In this case, please move away from the current location and wait for the blue light turns off and attempt to connect.
- e. If the issue persists, please reboot the Felix™ NeuroAI™ Wristband and relaunch the mobile application, then try again.
- f. If the issue persists, please reach out to the manufacturer for assistance.

### 11.3.2 The Felix™ NeuroAI™ Wristband Pairing Fails.

- a. Ensure that the login method used by the mobile application is the same as before.
- b. Ensure that the mobile application is attempting to connect to the correct Felix™ NeuroAI™ Wristband.

- c. Reset the Felix™ NeuroAI™ Wristband and try to connect again.
- d. If the issue persists, please reach out to the manufacturer for assistance.

### **11.3.3 The Felix™ NeuroAI™ Wristband Fails to Connect.**

- a. Ensure that Bluetooth is enabled on the phone.
- b. Ensure the Felix™ NeuroAI™ Wristband is powered on and positioned within 9 feet of the phone.
- c. Disable and re-enable the Bluetooth on the phone, then try again.
- d. Reboot the Felix™ NeuroAI™ Wristband and try again.
- e. If the issue persists, please reach out to the manufacturer for assistance.

### **11.3.4 The Felix™ NeuroAI™ Wristband Disconnects Frequently.**

- a. Ensure that the Felix™ NeuroAI™ Wristband is positioned within 9 feet of the phone.
- b. Ensure that there are no other devices nearby that could interfere with Bluetooth communication.
- c. Follow the instructions in the mobile application to adjust the necessary settings, ensuring that the mobile application remains active and is not terminated by the system while running in the background.
- d. Place the phone on the same side as the Felix™ NeuroAI™ Wristband.
- e. If the issue persists, please reach out to the manufacturer for assistance.

If there are any other issues not listed above, please contact the manufacturer directly for assistance.

## 12 Federal Communications Commission (FCC)

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This device complies with part 15 of the FCC Rules.

NOTE: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

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) 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.