Technology Upgrades

Our Life

User Manual

Caution:

- Please read the instruction manual carefully and thoroughly before operating this device.
- Also please keep it available for future reference.

Content

1. For Your Health and Safety

- To avoid any danger or loss caused by inappropriate use, please read this manual carefully.
- The hazards and losses caused by improper use are stated in the safety precaution section, and divided into “Contraindications” and “Warnings and Precautions”.
- Please keep this manual carefully.

List of Symbols

	Type BF equipment
	Warning
	Non-ionizing radiation
	Date of manufacture
	Manufacturer
	Serial Number
	Fragile, handle with care
	Keep upward
	Keep dry
	The product is: 1. Dust-tight 2. Protected against the effects of temporary immersion in water.
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	The number of the notified body (0123)
	Authorized representative in the European Community
	Refer to user manual
	Please dispose of the device/battery/accessory/packing in accordance with the legal obligation in your area
	Medical device
	Single Patient-multiple use
	Consult instructions for use

Contraindications

- Do not use with electronic monitoring equipment, NMR-imaging, pacemaker, defibrillator or high-frequency medical device.
- Do not use near short-wave, microwave. (such as 1m)
- Patients with severe heart disease, severe hypertension and skin disorder are forbidden to use this product.
- Patients with active hemorrhage, acute purulent inflammation, malignant neoplasms, thrombophlebitis, sepsis and cardiopulmonary failure are forbidden to use this product.
- Do not use this product for purpose other than treatment.
- Do not apply this product to unconscious patients.
- Do not disassemble, repair or rebuild this product.
- Do not touch the charging connector/battery and the patient simultaneously when charging/using.

Warnings and Precautions

- The safety of usage during pregnancy or menstruation has not been determined.
- Electrode positioning and stimulation parameters' setting should be conducted by professionals. If you keep feeling pains or rash, please stop using this product.
- Please do not position the electrode in the area of malignant neoplasms, neck arteries (throat) or thrombus.
- Use caution when positioning electrodes in areas of altered sensation.
- Do not apply electrodes to areas with compromised skin integrity.
- Muscle training might cause disorder of rehabilitation of a recent surgery; Electrode positioning areas are not sensitive enough.
- Please use with caution when the arteries of used are a show partial occlusion, when the patient has vascular atrophy because of hemodialysis, or when the vascular system shows instability.
- Please use with caution if the treated areas have structural deformity.
- This product should be conducted by doctors.
- Patients should keep stable and not move the device while using this unit.
- Patients should not move the electrode or be touched while using this unit.
- Please stop using this product if the body shows any physical abnormality.
- Patients with any of the following conditions are forbidden to use this product:
    - Patients with epilepsy
    - Patients that are pregnant
    - Patients with acute dislocations or fractures of the ankle
    - Patients with regional cancer in the lower leg
    - Patients with metal implants
    - Patients with autonomic dysreflexia

2. Overviews

2.1 Indication for Use

The XFT-2001E Foot Drop System is a wearable functional electrical stimulation device for rehabilitation, with an associated smart phone operating system.

Intended Use
XFT-2001E Foot Drop System is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons. During the swing phase of walking, the XFT-2001E electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the individual's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

2.2 Treatment Principle

XFT-2001E Foot Drop System detects and analyzes the patient's gait patterns in real time through the internal tilt and accelerometer sensors, and then simul-taneously delivers comfortable, low frequency, functional electrical stimulation (FES) to the common peroneal nerve. This in turn will evoke muscle contract-ion and enable the patient to actively walk with a more normalized gait. The mo-st common use of FES for a treatment for foot drop where disruptions of the nerve pathways between the legs and brain cause inability of the patient to lift the foot to the correct angle when walking.

2.3 Use Cycle

Adhere to the principle of gradual progress when using the XFT-2001E Foot Drop System.

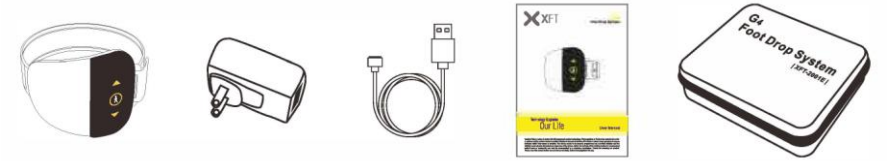
Cycle	Gait mode	Training mode
1st week	Walk for 15-60 minutes a day	Every morning and evening, 15 minutes each time
2nd week	Walk for 1-4 hours a day	Every morning and evening, 20 minutes each time
3rd week& later	Walk for 4-8 hours a day	Every morning and evening, 20 minutes each time

Note: Take off the cuff for 15 minutes after each use.

3. Product Illustration

3.1 Product Parts

XFT-2001E consists of the Stimulator, Power Adapter, charging cable, and app software (optional).



3.1.1 Stimulator

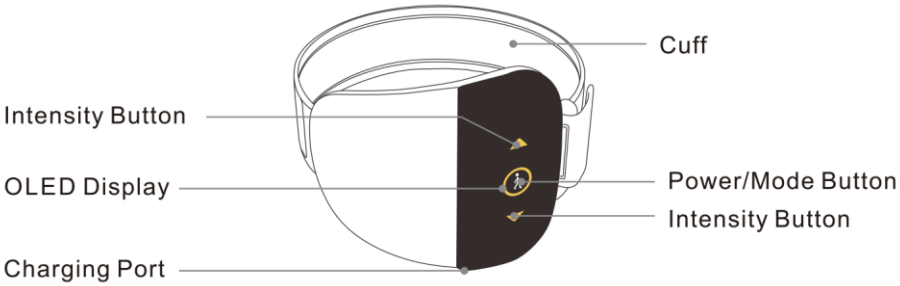
Stimulator

3.1.2 Parts

No.	Parts	Picture	Description
1	Power Adapter		The Power Adapter and Charging Cable are used to charge the device.
2	Charging Cable		

3.2 Operation Panel

3.2.1 Operation Buttons



The stimulator contains 3 buttons (1 Power/Mode Button, 2 Intensity Buttons), and 1 OLEO display.

Power/Mode Button: Press and hold this button for 2 seconds to turn the stimulator on, and the stimulator display shows “XFT” LOGO for 2 seconds; tap this button to switch between Gait mode and Training mode. When the stimulator is turned on, press and hold this button for 2 seconds to turn off the stimulator. In the working state, tap this button to pause the electrical stimulation.

Intensity Buttons: Tap one of the buttons to start electrical stimulation and increase or decrease the electrical stimulation intensity; click the up button to increase the intensity, and click the down button to decrease the intensity.

OLED Display: Display various working states of the stimulator, such as Gait mode, Training mode, electrode loose, low battery icon, electrical stimulation output icon, electrical stimulation intensity, etc.

Charging Port: Users can recharge the stimulator via the charging port.

3.3.2 Indicators

Power-on indication

Press and hold the Power/Mode Button for 2 seconds to turn the stimulator on, and the stimulator display shows “XFT” LOGO for 2 seconds. Tap this button to switch between Gait mode and Training mode.

		
LOGO	Gait Mode	Training Mode

Mode switching

After the stimulator is turned on or it is paused, press  to switch the mode.

	
Gait Mode	Training Mode

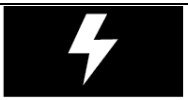
Start/Pause

When the stimulator is in the pause state, press  or  to activate the electrical stimulation intensity; press the up button to increase the intensity, and press the down button to decrease the intensity. The display will show the corresponding intensity value.

	
Stimulation Intensity	Stimulation Intensity

Electrical Stimulation Output Prompt

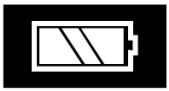
When the stimulator is delivering electrical stimulation, the display will show the lightning symbol. When the Gait mode is activated, there will be a “beep” prompt for each output of the electrical stimulation (the sound can be muted by the app).

	
Lightning Symbol	Stimulation Intensity

Electrode Loose Indication
When the electrodes are in poor contact with skin, the screen will flash the warning icon and “Drop” alternately. The stimulator will have 3 beeps and stop automatically. Please take off the stimulator, wet the skin and wear the stimulator again, and then press the intensity button to continue the mode.

	
Electrode Loose	Electrode Loose

Low Battery / Charging Prompt
When the stimulator is in low battery, there will be a battery icon flashing once per second on the screen. The dynamic charging icon is displayed while charging, and the full battery icon is displayed when charging is completed.

			
Low Battery, flash once per second	Charging	Charging	Full Charge

Automatic Screen Saver
The screen saver will sleep in 30 seconds if no operation on the stimulator; and then screen saver icon will show up in 1 minute and move from left to right.


Screen Saver Icon

3.3 APP Software Description

Operation Buttons
Software Name: Foot Drop Rehab

Operational Environment:
Hardware Requirements:
- iPhone 5s and subsequent release models of the iPhone.
- Mobile phone with Android 6.0 and later.

Software Environment:

iOS:
- System environment: iOS 9.0 or later.

Android:
- Android 6.0 and later.
- Security software: none.
- Network requirements: Bluetooth communication.

Data Transmission
Data is transmitted between app and Stimulator via Bluetooth communication.

Storage Medium
APP software data is stored in the mobile terminals.

User Login
Username and password shall only be set by user.

Detection, response and recovery of network security events
Data transmission between app software and device is carried out through specific Bluetooth service channel, data format and data verification requirements are required at the same time, which can avoid connection and control of other devices or software.

When the connection between app software and device is interrupted during usage, app software will give a reminder of disconnection, and you can control the device by pressing the button on the device.

After the Bluetooth connection between the app software and the device is disconnected, the app will search and connect the device that has been turned on if the device needs to be re-controlled by the app.

Software Update
The latest version of the app can be updated and installed through the app Market. If your phone is iOS system then you can update through App Store, and if is Android system you can update it through Google Play.

4. General Operation Instruction

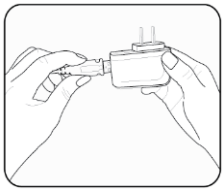
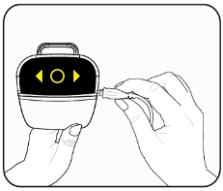
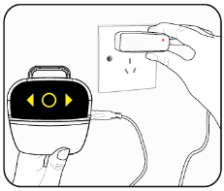
4.1 How to clean the device?

- Use a sponge or a soft cloth to remove dust and dirt from the electrode surface before use, please keep the electrodes clean.
- After cleaning, wipe the electrode with a sponge or a soft cloth dampened with disinfectant (do not rub too much disinfectant liquid on a sponge or a soft cloth to avoid splashing into the inside of the device causing malfunction or danger). The disinfectant is a 75% medical alcohol.
- Wipe the electrode 3 times with a sponge or a soft cloth dampened with disinfectant.

4.2 How to Use XFT-2001E?

XFT-2001E can be used with or without app.

Please check if the stimulator is fully charged before use. If necessary, please charge the stimulator. The display will indicate the battery icons when charging.

		
Connect charging cable to the power adapter.	Connect charging cable to the stimulator.	Connect power adapter to the power outlet.

How to charge the Stimulator
During use, if you find that the intensity is weak or the low battery icon appears on the screen, please charge it in time. It needs about 8 hours to fully charge the stimulator, and it can be used for about 10 hours when fully charged.

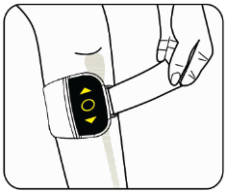
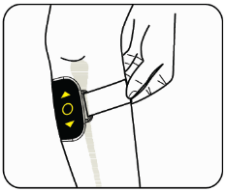
Please shut down the stimulator and store it if it is not in use.

Note: Please use the power adapter supplied by XFT. Do not use the stimulator while charging.

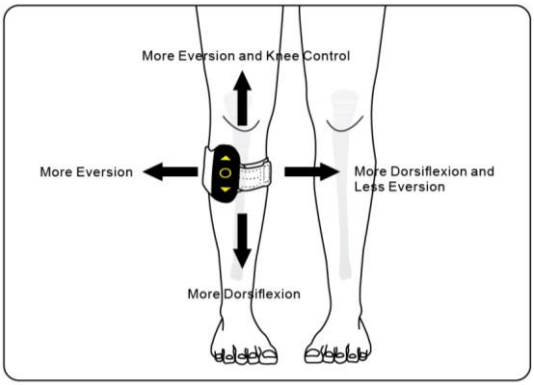
4.3 Use without App

4.3.1 Wear the Stimulator

- Use a wet towel to clean the skin of the leg.
- Sit on a chair, bend and relax the leg.
- Place the stimulator in the correct position under the knee.

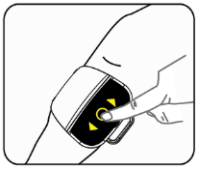
		
Position the cuff on the leg below the knee.	Align the vertical edge of the stimulator with the tibia.	Fasten the cuff, but don't violently pull the cuff.

To optimize individual function, the stimulator position might be adjusted slightly, please consult the fitter.



4.3.2 Power on and Operate

Press and hold the Power/Mode Button for 2 seconds to turn the stimulator on, and the stimulator display shows “XFT” LOGO for 2 seconds. Tap this button to switch between Gait mode and Training mode.



		
LOGO	Gait Mode	Training Mode

When the stimulator is in the pause state, press  or  to activate the electrical stimulation intensity; press the up button to increase the intensity, and press the down button to decrease the intensity. The display will show the corresponding intensity value.

	
Stimulation Intensity	Stimulation Intensity

Note: In order to allow the skin area covered by the stimulator to breath and to prevent skin irritation and redness, stimulation should be suspended, and the stimulator removed at regular intervals. This allows the skin to breathe fully and in the process of using the product.

4.3.3 Power off

When the stimulator is turned on, press and hold the Power/Mode Button for 2 seconds to turn it off.

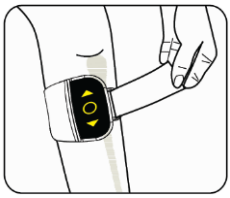
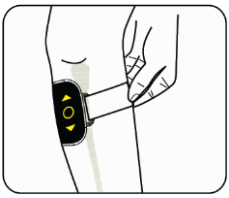
4.4 Use with App

4.4.1 Install App

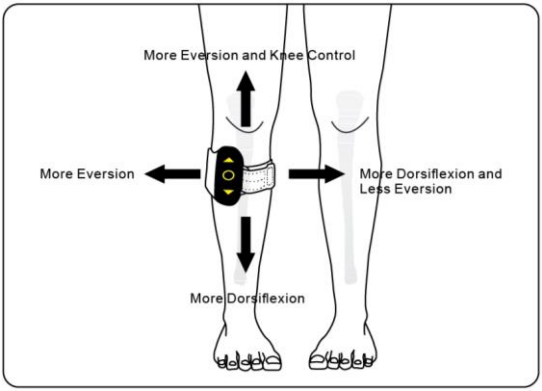
Procedure	Operation Description
Step 1	Go to App Store or Google Play. Search “Foot Drop Rehab” to find the app. Install on your mobile phone.
Step 2	Run the app on your mobile phone and create a user ID for the first time.

4.4.2 Wear the Stimulator

- Use a wet towel to clean the skin of the leg.
- Sit on a chair, bend and relax the leg.
- Place the stimulator to the correct position under the knee.

		
Position the cuff on the leg below the knee.	Align the vertical edge of the stimulator with the tibia.	Fasten the cuff, but don’t violently pull the cuff.

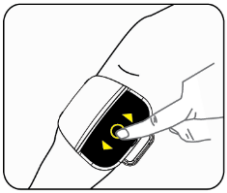
To optimize individual function, the stimulator position might be adjusted slightly, please consult the fitter.



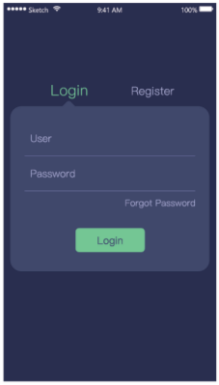
4.4.3 Power On and Operate

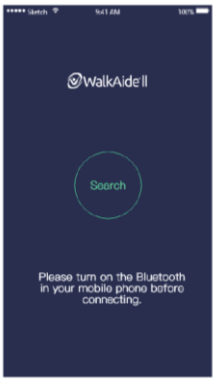
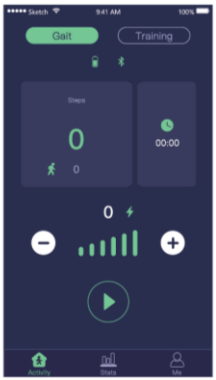
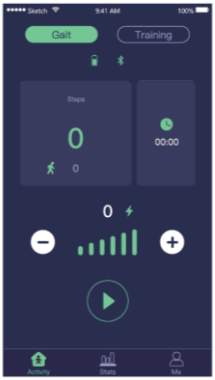
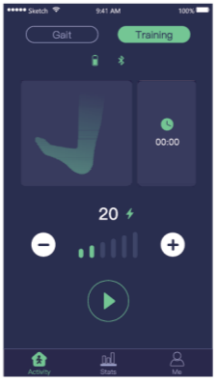
Power On

Press and hold the Power/Mode Button for 2 seconds to turn the stimulator on, and the stimulator display shows “XFT” LOGO for 2 seconds. Tap this button to switch between Gait mode and Training mode.



4.4.3.1 Login the app and connect the Stimulator to the app via Bluetooth.

Procedure	Operation Description	App Interface
Step 1	Open the Bluetooth on your mobile phone and run the app.	
Step 2	Enter your name and Password, and press the Login icon to login.	

Step 3	Press the “search” icon to search for the stimulator.	 
Step 4	Select the stimulator in the Equipment List and enter the home page.	 
Step 5	Select mode between Gait mode or Training mode.	 

Gait Mode

1) Start: The app sends the Gait mode parameters and the mode start command to the stimulator, receives the stimulator's reply, and enters the walking working interface.
2) Pause: The app sends a Gait mode pause (stop) command to the stimulator, receives the stimulator's reply and pauses the walking.
3) Continue: The app sends the Gait mode (start), and you have to adjust the intensity again. After receiving the stimulator's reply, the walking work continues.
4) End: After long press and stop for 1.5 seconds, the Gait mode stop command is sent to the stimulator; the app receives the stimulator's reply, and the Gait mode stops.

Under the Gait mode for Pro Version, user can choose among smart mode, normal mode and manual mode.

1) Smart Mode: The stimulator automatically calculates the tilt angle A to start the electrical stimulation and the tilt angle B to end the electrical stimulation according to the gait data of the first four steps of the patient. The parameters hat can be adjusted are the electrical stimulation intensity, frequency and pulse width in the lower-level interface of the "Parameter Settings."
2) Normal Mode: The stimulator performs electrical stimulation according to the set parameters. The parameters that can be adjusted are the electrical stimulation intensity, and the frequency, pulse width, tilt angle A, tilt angle B, duration, delay time, ramp up and ramp down in the lower-level interface of the "Parameter Settings."
3) Manual Mode: The clinician can manually press the "Start" button to deliver stimulation at certain time by observing the patient's gait when the patient is walking. The parameters that can be adjusted are the electrical stimulation intens-ity, frequency and pulse width in the lower-level interface of the "Parameter Settings."

Training Mode

The stimulator performs electrical stimulation based on a combination of parameters of the selected Training mode. The parameters combine 9 preset mode-s and 1 custom mode. The electrical stimulation can be adjusted after the preset mode starts, and other parameters cannot be adjusted. All parameters can be adjusted in the custom mode.

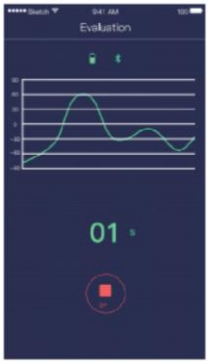
1) Start: The app sends the Training mode parameters and the mode start comma-nd to the stimulator, receives the stimulator's reply and enters the Training work interface.
2) Pause: The app sends a Training mode pause (stop) command to the stimulator, receives the Stimulator's reply, and the Training is suspended.
3) Continue: The app sends the Training mode (start), and you have to adjust the intensity again. After receiving response, and the training work continues.
4) End: After long press and stop for 2 seconds, send the Training mode stop co-mmand to the stimulator, receives the Stimulator's reply and the Training mode stops.

Choose one mode

9 pre-set Training modes with fixed parameters; custom mode with adjustable parameters.

Evaluation Mode for Pro Version

1) Evaluation Mode: Collect the angle data generated by the stimulator during the patient's walking. The collection duration is 60 seconds by default and the maximum is 90 seconds. The acquisition begins to draw an angle waveform and displays the countdown of the acquisition time. You can stop in the middle. The acquisition is completed to display the evaluation results.
2) Start: The App sends an Evaluation mode to start the command to the stimulator, receives the Stimulator reply, and enters the evaluation work interface.
3) End: After long press and stop for 1.5 seconds, send the Evaluation mode stop commando the stimulator; the App receives the stimulator's reply, and the eval-uation mode stops.
4) The evaluation mode stops calculating the reference parameters based on the collected data. The collected data needs to meet certain conditions before the reference parameters can be calculated, otherwise the prompts are re-acquired.

Evaluation Mode	Start Evaluating
	

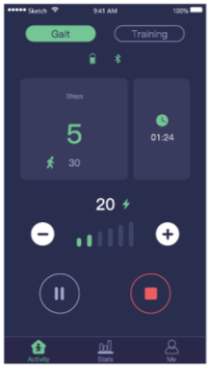
Shut Down

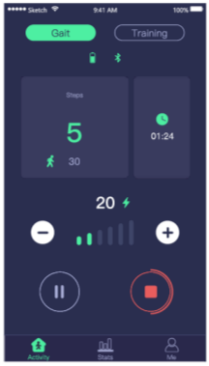
When the stimulator is turned on press and hold the Power/Mode Button for 2 seconds to turn it off.

4.4.3.2 The APP Consists of 3 Sections: Activity, Stats, and Me.

4.4.3.2.1 Activity

Gait mode

Procedure	Operation Description	APP Interface
Step 1	Set the parameters.	
Step 2	Adjust the stimulation intensity.	

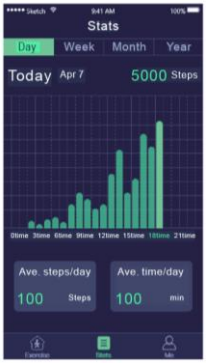
Step 3	Press and hold the button (for 1.5 seconds to end the session.	

Training mode

Procedure	Operation Description	APP Interface
Step 1	Set the session.	
Step 2	Adjust the stimulation intensity.	
Step 3	Press and hold the button (1.5 second to end the session.	

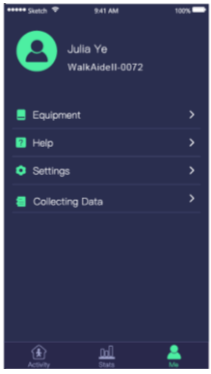
4.3.3.2.2 Stats

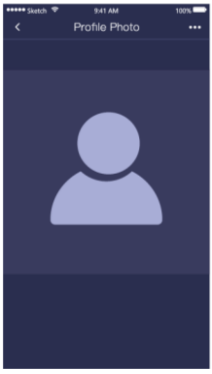
There are 4 types of statistics: Day, Week, Month and Year.

Day	Week	Month	Year
			

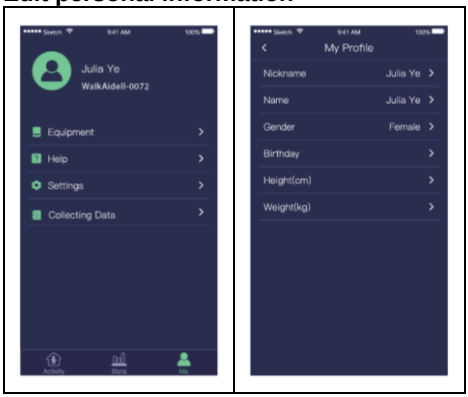
4.3.3.2.3 Me

Change your profile photo.



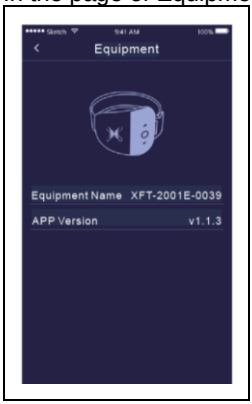


Edit personal information



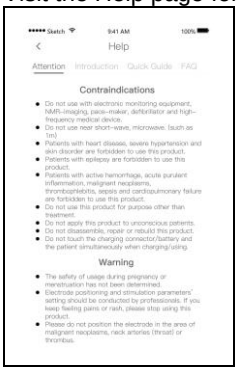
Equipment Information

In the page of Equipment, you can see the name of the stimulator and App version.



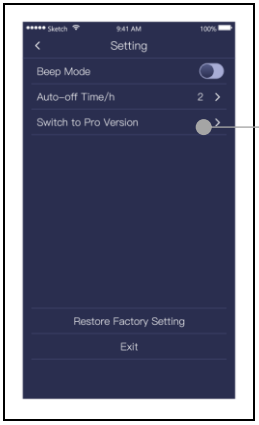
Help

Visit the Help page for Attention, Introduction, Quick Guide, and FAQ.



Setting

From the Setting page, you can turn on or turn off the buzzer on the stimulator, set the auto-off time, switch to Pro version, restore factory setting or Exit.



Please note that it requires the appropriate professional knowledge and should be used by a physician or a qualified clinician for the Use of the Pro version.

5. Attentions

5.1 Troubleshooting

Malfunction indicator will show the following troubles:

5.1.1 Electrodes Loose

The malfunction indicator flashes slowly once per second. When the system detects that the electrode is loose, an indicator will display, and the device will stop running. Please adjust the place of the electrode and press the Power/Mode Button again.

5.1.2 Low Battery

When the stimulator battery is low, the battery icon flashing once per second on the screen.

5.2 Allergy Prevention Advice:

- Do not position on the skin with makeup or oil.
- Remove the hair on the treatment part for better electrical conductivity. Electric razor or a pair of scissors is recommended.
- If any skin irritation or allergy occurs, please stop using the stimulator immediately and follow doctor's instructions.
- Do not position on allergic area.

6. Care and Maintenance

6.1 Maintenance for Stimulator

- Always handle the stimulator carefully.
- Do not expose the stimulator with too much water for long time, excessive heat or vibration.
- Keep it away from children.
- Use a wet cloth with little neutral detergent or alcohol to clean the stimulator surface.
- Avoid dropping the stimulator. Although this device is robustly designed, damage may occur and cause the stimulator to malfunction.
- Do not try to dismantle the stimulator. Please contact the distributor or clinical facility where you purchased the device if there is any problem.

6.2 Maintenance for the Metal Electrodes

- Metal electrodes can be used long term. Please keep them clean.
- Use medical alcohol to clean the electrode surface and a clean towel to wipe or dust it.
- Do not wash with detergent or hot water.
- Electrodes should be kept clean, covered and carefully stored when not in use.

6.3 Skin Care

Please check your skin condition before and after use. Slight redness is normal and it indicates the blood circulation is faster in this area. Always add ample amounts of water to the area of skin that will be in contact with the electrodes.

6.4 Skin Irritation Prevention

- Use water to remove all makeup, unclean areas or oil from the skin.
- Do not position the electrodes over an irritated area of the skin.
- Removing hair may enhance the electrical intensity and enhance the motor response. If necessary, an electric razor or a pair of scissors is recommended to trim the hair where the skin contacts the electrodes. Remove the hair the day before use. Do not shave and then immediately place the electrodes as it could cause discomfort.
- If any skin irritation or allergy occurs, please stop using the stimulator immediately and follow doctor’s instructions.

6.5 Product Service Life

The service life of the XFT-2001E is 5 years. At the end of its life expectancy or when the device ceases to continue working, please dispose of it in accordance with the local and national regulation.

6.6 Battery Safety

Please charge this device only with the original power adapter and do not use the device while charging. The device needs about 8 hours to charge when completely drained of power. The device is designed to work for 10 hours with a full charge.

6.7 Device Storage

- Please do not store the device in a place with direct sunlight, high temperature or moist, dusty, or corrosive gas.
- Please store the device in a place out of reach from children.
- The user does not need to maintain the device, please ask the seller or manufacturer.
- Please do not throw, tread on, or heavy press the device.

7. FAQ & Troubleshooting

Q1. What should I do if the stimulation intensity is weak?

- Adjust the intensity through the stimulator or the app.
- Adjust the position of the electrode.
- If the stimulator battery is low, please charge it in time.
- Wet the skin with some water or the connect gel so as to increase the electrical conductivity between the electrode and the skin.

Q2. I have turned on the stimulator and chosen the Training or Gait mode. The indicator light is on, but there is no reaction for the electrical stimulation, why?

- Check whether the stimulator has been fastened well to the leg and close to the skin.
- Check whether the intensity has been adjusted to the appropriate value.
- Wet the skin with some water or the connect gel so as to increase the conductivity between the electrode and the skin.

Q3. What should I do if the skin in the area covered by the electrode and the cuff is severely red, stinging or allergic?

Stop using it immediately. After observing for a period of time, if no abnormality is found, wait until the skin is completely improved before continuing to use the device. Remember to regularly ventilate the skin covered by the stimulator.

Q4. The stimulator automatically shut down after the battery icon flashes on the screen.

This indicates that the stimulator battery is low and needs to be recharged. It takes about 8 hours for the stimulator to charge. After the battery is fully charged, the stimulator can last for about 10 hours. When the battery is low, please charge it in time.

Q5. What should I do if the screen shows “ ⚠ ” and “ Drop ” icon alternately?

This icons are reminders of electrode loose. Please check whether the stimulator has been fastened well. Or please check whether the skin is wet enough. If not, please wet the skin with some water or the connect gel before using.

Q6. What should I do if there is sporadic strong electrical stimulation?

- Wet the skin with some water or the connect gel so as to increase the conductivity between the electrode and the skin.
- Check whether the skin in the area covered by the electrode is red or has a wound.
- Check whether the stimulator has been fastened well to the leg or the electrode has been placed on the current position.

Q7. Why can’t I feel the stimulation when there should be stimulation output?

Normally it is because the cuff position has been changed or the Gait mode has been changed. Please readjust the stimulator placement or reset the parameters of Gait mode.

Q8. Can I use oil or lotion on my legs?

No, please make sure the skin is clean before using the stimulator and wet the skin with some water or the connect gel so as to increase the conductivity between the electrode and the skin.

8. Product Specifications

8.1 Stimulator Specifications

- Communication method: Bluetooth 4.0
- Communication frequency: 2402MHz-2480MHz

8.2 Stimulator

Stimulator Specifications	
Power Supply	3.7V rechargeable lithium battery
Classification	Type BF applied part,  internally powered equipment
Shutdown Current	≤50μA
Working Current	≤120mA
Wave form	Asymmetric biphasic balanced wave
Frequency	16-50Hz (±10%)
Pulse Width	100-300μs (±10%)
Output Intensity	0-90mA(±10% or ±2mA, whichever is greater, with 500Ω load)
Dimension	(133mm±10mm)*(102.5mm±0.15mm)(13.8mm±5mm)
Weight	155±109

8.3 Power Adapter

The power adapter used with the unit can be purchased from our company, or in the market according to the following requirements:

- The rated output of the power adapter is DC5V, 1.2A. The power adapter shall comply with the requirements of IEC 60601-1.

Dimension	71x41x31.5mm
Input	AC100-240V, 50-60Hz, 0.3A
Output	DC 5V, 1.2A

8.4 Working and Storage Environment

Working Conditions:
- Temperature: 5~40°C (41°F~104°F)
- Relative Humidity: ≤80%(Non-condensing)
- Atmospheric Pressure: 86~106kPa

Transport and Storage Conditions:
- Temperature: -20~55°C (-4°F~131°F)
- Relative Humidity: ≤93%(Non-condensing)
- Atmospheric Pressure: 70~106kPa

Production Date: see the label
Service Life: 5 Years

8.5 Accessories

Stimulator	1 pc
Power Adapter	1 pc
User Manual	1 pc
Charging Cable	1 pc
APP Software	Optional

8.6. Wireless Technology Description

Type of wireless technology	Bluetooth V4.0 BLE
Wireless function	Transmission the device data and the patient data from transmission terminal equipment to receiving terminal equipment, as well as ensuring the integrity and security of data during transmission.
Modulation Type	GFSK
Modulation Signal Type	Digital
RF Band wise	2402MHz~2480MHz
Channel Number	40(CH0-CH39)
Data rate	1Mbps
Occupied band wide	2MHz
Channel separation	2MHz
Maximum transmission distance	10m
Wireless QoS	I/U (intended-to-unintended) Ratio≤1dB Throughput ≥0.3Kbps Latency (one-way delay)≤1s Jitter (latency variation)≤1 s PER (Packet error rate)≤3%

The wireless QoS need
The XFT-2001E Foot Drop System was designed and tested to have a response rate of 10-1 00ms latency depending on system configuration.

Wireless Interference
The XFT-2001E Foot Drop System was designed and tested to not have interference from other RF devices (including other XFT-2001E Foot Drop System, Wi-Fi networks, cellular devices, microwaves and other Bluetooth devices).

The XFT-2001E Foot Drop System is not susceptible to the wide range of expected EM I emit-ters, such as Electronic Article Surveillance Systems (EAS), Radio Frequency Identification Systems (RFID), Tag Deactivators, and Metal Detectors. However, there is no guarantee that int-erference will not occur in a particular situation.

Caution: If performance of the XFT-2001E Foot Drop System is affected by other equipment, the user should turn the XFT-2001E Foot Drop System off, and move away from the interfering equipment.

9. Product Classification

a) Classified by type of electric shock: internal power supply.
b) The application part is classified according to the degree of electric shock: BF type.
c) Classified by degree of protection against incoming liquid: IP67.
d) Classification according to the degree of safety when using flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: no gas cylinder, non-AP and APG type equipment used in this product.
e) Classified by operating mode: continuous operation.
f) Classified by voltage and frequency of the device: DC3. 7V.
g) Whether the equipment has the application part of the protection against defibrillation discharge effect: This product has no application part for the protection of defibrillation discharge effect, and there is a BF type application part (referred to as a syringe, which is provided by the hospital) which is connected with the human body.
h) Whether the device has a signal output or input part: This product has no signal output or input part.
i) Permanent or non-permanent installation: This product is a non-permanent installation.

※Please handle this product in accordance with the national regulations on the handling of electronic products.

10. Electromagnetic Compatibility (EMC)

This equipment generates, uses, and radiates radio frequency energy. The equipment may cause radio frequency interference to other medical or non-medical devices and to radio communications.

If this equipment is found to cause interference, which can be determined by turning on and off the equipment, the operator or qualified service personnel should take following actions:

- Reorient or relocate the affected device;
- Increase the distance between the equipment and the affected device;
- Power the equipment by another source;
- Consult the service engineer for further suggestions.

⚠ **Caution:** it is customer's responsibility to assure that this equipment and vicinity equipment comply with the contents of IEC 60601-1-2 4th Edition.

⚠ **Caution:** do not use any device that might send out RF signals, including cell phone, radio transceiver and radio control products, which might cause operation parameters beyond the standards. Please shutdown these devices when you are near the equipment. Operator has the responsibility to warn user or any others to comply with this rule.

⚠ **Caution:** manufacturer will not responsible for any unauthorized actions that cause interference. The ME EQUIPMENT or ME SYSTEM is suitable for home and healthcare environments.

Warning: Don't go near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM di-sturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specifi-ed or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this eq-uipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer, Otherwise, degradation of the performance of this equipment could result.

Table 1

Guidance and manufacturer's declaration - electromagnetic emission		
This equipment is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic.
RF emissions CISPR 11	Class B	This equipment is suitable for domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions I EC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complied	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
This equipment is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) I EC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, +15kVair	±8kV contact ±2kV, ±4kV, ±8kV, ±15kVair	Floors should be wood, concrete or ceramic tile. Humidity should be at least 30% if it is synthetic materials.
Electrical fast transients/bursts (EFT) IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Main power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	+0.5kV, ±1kV line-to-line ±0.5kV, ±1kV, ±2kV line-to-ground	±0.5kV,+1kV line-to-line ±0.5kV, ±1kV, ±2kV line-to-ground	
Voltage dips IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	Main power quality should be that of a typical commercial or hospital environment.
Voltage interruptions IEC61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
RATED power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the A.C. mains voltage prior to application of the test level.

Table 3

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">This equipment should be used in the electromagnetic environment specified below. User should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3Vrms 150 kHz to 80 MHz</td><td>3Vrms</td><td rowspan="3">Portable and mobile RF communications equipment should be used no closer to any parts than the recommended separation distance that calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance:
d=1.2/P 150 kHz to 80 MHZ
d=1.2/P 80MHz to 800 MHZ
d=2.3/P 800MHz to 2.7GHz
d=6VP/E
at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device).
Where “P” is the maximum output power rating of the transmitter in watts according to transmitter manufacturer and “d” is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (b), should be less than the compliance level in each frequency range (c).
Interfere nee may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td></td><td>6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz (a)</td><td>6Vrms</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>10V/m 80MHz to 2.7GHz</td><td>10Vrms</td></tr>
</table>

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

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.

a) The ISM (industrial, scientific and medical} bands between 0.15 MHz and 80 MHz are 6.765 MHz to6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHZ, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b) Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this is used exceeds the applicable RF compliance level above, this should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating.
c) Field strengths should be less than 3V/m in the frequency range of 150k~80MHz.

Table 4

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM c) ±5kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 85, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3 ,4, 25;UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation[b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m distance is permitted by I EC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Table 5

Recommended separation distances between portable and mobile RF (Radio Frequency) communications equipment and the XFT-2003E Nerve and Muscle Stimulator			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nerve and Muscle Stimulator as recommended below, according to the maximum output power of the communications equipment.			
This device can be used under the environment that radiated RF disturbances are controlled. User should maintain a minimum distance between portable and mobile RF communications equipment to prevent electromagnetic interference. Following recommended distance is calculated according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz -80MHz $d=1.2\sqrt{P}$	80MHz -800MHz $d=1.2\sqrt{P}$	800MHz-2.7GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.79	3.79	7.27
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance “d” in meters can be estimated using the equation applicable to the frequency of transmitter, where “P” is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

Note 1: At 80M and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.

11. After-sales Service

1) The product is provided with a two-year warranty starting from the date of purchasing.
2) XFT will not provide free repair for the malfunctions caused by the following behaviors:
    - Disassemble or modify the product without authorization.
    - Accidentally blow or drop the product during use or transportation.
    - Lack of reasonable maintenance.
    - Operate not according to the instruction.
    - Repaired by unauthorized repair store.
3) When asking for warranty service, please take with the warranty card.
    - It is charged according to the stipulation of the repair service of the warranty.
    - Please contact XFT if you need warranty service.

12. Use Specification

Item	Description
Product name	Nerve and Muscle Stimulator
Product model	XFT-2001E
Intended use/indications for use	During the swing phase of walking, electrically stimulates the appropriate never/muscles that cause ankle dorsiflexion and may thus improve the individual's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.
Intended patient population	Foot drop patient
Intended part of the body or type of tissue applied to or interacted with	The intact skin surface of the lower leg.
Intended user profile	Intended user includes patient, medical persons and/or other operators, they are required to meet below requirement at least: • Ability to read and understand user manual, and follow the instruction to operate device; • Are healthy or use the device under doctor's direction; • No nationality or race limitation; • Can identify parts of body.
Use environment	• Reusable • Hospital use or home use • Use the EMC environment for Class 1 Group B - Work conditions • Work conditions: Temperature 5~40°C, Humidity ≤80%(Non-condensing) Atmospheric pressure 86~106kPa
Operation principle	Place the Stimulator to correct position under the knee. To optimize individual function the stimulator position might be adjusted slightly.
Contraindications	• Do not use with electronic monitoring equipment, NMR-imaging, pace-maker, defibrillator or high-frequency medical device. • Do not use near short-wave, microwave (such as 1m) • Patients with severe heart disease, severe hypertension and skin disorder are forbidden to use this product. • Patients with epilepsy are forbidden to use this product. • Patients with active hemorrhage, acute purulent inflammation, malignant neoplasms, thrombophlebitis, sepsis and cardiopulmonary failure are forbidden to use this product. • Do not use this product for purposes other than treatment. • Do not apply this product to unconscious patients. • Do not disassemble, repair or rebuild this product. • Do not touch the charging connector/battery and the patient simultaneously when charging/using.

Warranty Card

Product Name: _____ Model No.: _____

Purchase Date: _____ Product Serial No.: _____

Buyer's Information: _____

Distributor's Information: _____

Manufacturer: Shenzhen XFT Medical Limited
Add: Room 203, Building 1, Biomedicine Innovations Industrial Park,
#14 Jinhui Road, Pingshan New District, Shenzhen, China
Tel: 86-755-29888818 Web: www.xft-china.com Mail: xft@xft.cn

Distributor Seal:

Product Name: Nerve and Muscle Stimulator
Model No.: XFT-2001E

Shenzhen XFT Medical Limited
Room 203, Building 1, Biomedicine Innovations Industrial Park,
#14 Jinhui Road, Pingshan New District, Shenzhen, China
Tel: 86-755-29888818 Fax:86-755-28312625

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Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Date: Oct. 21, 2022
Doc. No.: ACP-2002E-GB
Version: C3